SOUTHERN COLLEGE OF OPTOMETRY

FWA00013872
SCO IRB00006733

SCO IRB Study #: 2025-05-02CL

Project Title: Crossover Comparison of Two Novel Stenfilcon A Contact Lens Designs

Principal Investigator (faculty): Yueren Wang, OD

Start Date: 5/19/2025 Expiration of IRB Approval: 5/18/2026

The chair of the Institutional Review Board (IRB) of Southern College of Optometry (SCO) has reviewed the Human Subjects Protocol for the research named above and has determined the project to qualify for approval. **In addition, no person listed as a participating investigator in this study participated in its IRB review process. The Principal Investigator (PI) must notify the IRB in advance of any proposed major changes in this protocol, such as additional research sites or research instruments.**

In anticipation that this research project may extend beyond the one-year limit, an annual advance request for continuation of the protocol must be submitted to the IRB 1 month before the expiration date.

Informed Consent forms must be signed by all parties in duplicate, and a copy must be provided to the subject. The Principal Investigator must retain all research data and one copy of each signed consent form for at least three (3) years following the completion of the research activity.

All data and informed consent forms must be available for inspection by members of the SCO IRB or by the United States Department of Health and Human Service or its successors for the protection of humans from research risks.

This action is officially recorded in the Minutes of the Committee. SCO's IRB is in compliance with federal regulations (see above).

Level of Risk for this study: ☒Minimal ☐Low ☐Moderate ☐High

☒Non-significant risk medical device: Daily wear contact lenses

The following documents have been approved:

- ☒ Informed consent document, version Click or tap here to enter text. or document for waiver/alteration of IC
- ☒ Recruitment and advertisement materials/scripts
- ☒ References included in protocol summary
- ☒ Signature assurance sheet, signed by Research Chair
- ☒ Data forms, questionnaires, etc. OR a list of data to be collected
- ☐ Explanation of Conflict of Interest, if applicable
- ☐ Clinical Investigator's Brochure (required for FDA studies), version Click or tap here to enter text.
- ☐ Letter of approval from non-SCO study site (if appl.)
- ☒ Complete grant application (if appl.)
- ☐ Sponsor's protocol (if commercially funded), version Click or tap here to enter text.
- ☐ Amendments

HIPAA documentation attached (select appropriate category):

- ☒ SCO HIPAA De-Identification Certification form
- ☐ SCO HIPAA Authorization WAIVER form
- ☐ SCO HIPAA Authorization form (customized for this study) OR Study Sponsor's HIPAA authorization form
- ☐ HIPAA regulations do not apply to this study

Renewal Interval: 1 year

Patricia M Cisarik, OD PhD

05-09-2025

Patricia M. Cisarik, OD, PhD / John B. Campbell, OD
IRB Chair / Vice President for Academic Affairs
Southern College of Optometry

Date Signed

IRB REVIEWER CHECKLIST – EXPEDITED AND FULL IRB APPLICATIONS

Study Title:	Crossover Comparison of Two Novel Stenfilcon A Contact Lens Designs
Principal Investigator:	Lily Wang, OD
Reviewer Name:	Patricia M. Cisarik, OD, PhD
Review Type:	(•) **Expedited** ( ) **Full**
Date review completed or IRB meeting date:	**5/9/2025**

The IRB agrees that the PI's written INFORMED CONSENT document contains the basic elements and the appropriate additional elements required by federal regulations. (Approved protocols cannot begin until this requirement is met. Reviewer, please attach the completed Elements of Consent document.)	**Yes**
Level of Risk to Humans	**Minimal**
Comments	**None**
IRB Decision	**Approved - the research proposal meets all of the applicable criteria for approval listed below**

PM Cisarik, OD PhD — **5/9/2025**

Signature, IRB Reviewer — Date Signed

Criteria for IRB approval: Select all criteria that the above-titled research protocol meets.

A. Risks to Subjects

Risks to subjects are reasonable in relation to anticipated benefits (if any) to subjects and to the importance of the knowledge that may reasonably be expected to result from the research.	**Yes**
The credentials and/or described qualifications of the research staff and investigators are representative of the appropriate expertise needed to perform their responsibilities in the study.	**Yes**
The research setting (location of research, facilities, drug/device controls and accounting) supports adequate safeguards for protection of human subjects.	**Yes**
The importance of the knowledge expected to result is clear.	**Yes**
Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.	**Yes**
When possible, risks to subjects are minimized by using procedures already being performed on the participants for diagnostic or treatment purposes.	**Yes**
The research protocol addresses the likelihood of harm and magnitude of harm (encompassing potential physical, psychological, social, economic, and/or legal risks to subjects).	**Yes**
The research is likely to achieve its proposed aims.	**Yes**

IRB REVIEWER CHECKLIST – EXPEDITED AND FULL IRB APPLICATIONS

B. Is subject selection equitable in relation to the following?

the objectives of the research	**Yes**
the setting in which the research is to take place	**Yes**
the special problems of research involving special populations	**NA**
recruitment methods	**Yes**
inclusion / exclusion criteria	**Yes**

C. Informed Consent: In this section, if any are marked "NA", the PI must fill out a request for waiver / alteration of the informed consent process, and ALL of the criteria for waiver / alteration must be met.

Adequate provisions are in place for seeking informed consent from each prospective subject or from the subject's legally authorized representative.	**Yes**
The proposed consent process meets all of the required Basic Elements and the applicable Additional Elements of Informed Consent.	**Yes**
The proposed consent process provides the subject or the subject's legally authorized representative with sufficient opportunity to consider whether to participate.	**Yes**
The proposed consent process minimizes the possibility of coercion or undue influence.	**Yes**
The information to be given during the consent process is in a language understandable to the subject or to the subject's legally authorized representative.	**Yes**
The information being communicated during the consent process does not include exculpatory language through which the subject or the subject's legally authorized representative waives or appears to waive any of the subject's legal rights.	**Yes**
The information being communicated during the consent process does not include exculpatory language through which the subject or the subject's legally authorized representative releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.	**Yes**

D. Informed Consent Documentation: if "N/A" is marked for the next item, the PI must fill out a request for waiver / alteration of DOCUMENTATION of Informed Consent, and ALL of the criteria for waiver / alteration of informed consent must be met.

The provisions for documenting informed consent are appropriate.	**Yes**

E. Privacy Issues

The research proposal describes adequate provisions for protecting the privacy of subjects and / or informs subjects of circumstances when privacy will not be maintained.	**Yes**
The research proposal describes adequate provisions for maintaining confidentiality of the data and / or informs subjects of circumstances when confidentiality will not be maintained.	**Yes**

IRB REVIEWER CHECKLIST – EXPEDITED AND FULL IRB APPLICATIONS

F. Remaining Issues

Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence (i.e., children, prisoners, decisionally-challenged.	**NA**
If the study is greater than minimal risk, clinical research, or is a NIH-funded / FDA-regulated clinical trial, adequate provisions are in place for monitoring the data collected to insure safety of subjects.	**Yes**
If the proposal is a multi-center study in which the lead PI is an employee of SCO or SCO is the coordinating institution, the plans for communication among sites are adequate to protect the participant (ex. consider communication of protocol modifications, data and safety monitoring reports, and reports of unanticipated problems.)	**NA**
Proposed payment to participants and / or cost to subjects for participation is appropriate.	**Yes**
If a conflict of interest is identified for the PI or research staff, the conflict of interests in relation to human research protections is appropriately minimized or managed (ex. limit who obtains informed consent; add disclosures in the informed consent process).	**NA**
Review and approval by another person or committee (as applicable for medical research) has been conducted to assess the protocol for overall sound research design, as indicated by the SIGNATURE ASSURANCE SHEET signed by the Principal Investigator and his/her department chairperson (or appropriate equivalent).	**Yes**
Approval from external institutions has been obtained from an authorized official.	**NA**

ELEMENTS OF INFORMED CONSENT

Study Title: Crossover Comparison of Two Novel Stenfilcon A Contact Lens Designs

Principal investigator: Lily Wang, OD

IRB Committee Reviewer: Patricia M. Cisarik, OD, PhD

IRB Committee Reviewer's decision regarding the Informed Consent Process for this study:

The informed consent document (or script if documentation of informed consent has been waived) contains all of the basic elements and the additional elements that are appropriate for this study.

Comments: None

Patricia M Cisarik, OD, PhD — 5/9/2025

IRB Reviewer Signature — Date Signed

Basic Elements of Informed Consent (REQUIRED, except where noted)

Yes 1. A statement that the study involves research.

Yes 2. An explanation of the purposes of the research.

Yes 3. An explanation of the expected duration of the subject's participation.

Yes 4. A description of the procedures to be followed.

Yes 5. Identification of procedures that are experimental. (May be omitted if there are none; required for FDA-regulated drug and device studies.)

Yes 6. A description of any reasonably foreseeable risks or discomforts to the subject. (May be omitted if there are none; required for FDA-regulated drug and device studies.)

Yes 7. A description of any benefits to the subject or to others which reasonably may be expected from the research. (May be omitted if there are none; required for FDA-regulated studies.)

Yes 8. A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the subject. (May be omitted if there are none; required for FDA-regulated studies.)

Yes 9. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. (May be omitted if confidentiality will not be maintained; required for FDA-regulated studies.)

Yes 10. A statement that the Food and Drug Administration may inspect the records. (May be omitted for research that is not FDA-regulated.)

Yes 11. An explanation as to whether compensation is available if injury occurs. (May be omitted if the research involves no more than minimal risk.)

NA 12. If compensation is available when injury occurs, the compensation is explained and contact information is given for further information.

Yes 13. An explanation about whether any medical treatments are available if injury occurs. (May be omitted if research involves no more than minimal risk.)

ELEMENTS OF INFORMED CONSENT

Yes 14. If medical treatments are available when injury occurs, the medical treatment available is explained and contact information is given for further information.

Yes 15. Contact information for the research team for answers to questions about the research, concerns, or complaints.

Yes 16. Contact information for someone independent of the research team for problems, concerns.

Yes 17. Contact information for answers to questions about research subjects' rights.

Yes 18. A statement of whom to contact in the event of a research-related injury to the subject. (May NOT be omitted just because the research involves no more than minimal risk.)

Yes 19. A statement that participation is voluntary.

Yes 20. A statement that refusal to participate will not result in penalty or loss of benefits to which the subject is otherwise entitled.

Yes 21. A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional Elements of Informed Consent (if appropriate)

Yes 22. A statement that the particular treatment or procedure may involve risks to the subject that are currently unforeseeable. (Look for when research involves investigational drugs/devices, novel procedures involving risk, or when a goal of research is to define safety.)

Yes 23. A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus that are currently unforeseeable. (Look for when the research involves pregnant women or women of child-bearing potential when the effects of the procedures have not been evaluated in pregnancy, or when a goal of the research is to define safety in pregnancy.)

Yes 24. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. (Look for when the protocol mentions this as a possibility.)

Yes 25. Any additional costs to the subject that may result from participation in the research. (Look for when additional costs are expected.)

Yes 26. The consequences of a subject's decision to withdraw from the research. (Look for when withdrawal from the research will have adverse consequences.)

NA 27. Procedures for orderly termination of participation by the subject. (Look for when such procedures are part of the protocol.)

NA 28. A statement that significant new findings that result during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject. (Look for in long-term clinical trials.)

Yes 29. The approximate number of participants involved in the study.

Yes 30. The amount and schedule of all payments to the participant.

Application for Initial SCO IRB Review: Protocols Involving Human Subjects

Project Title: Crossover Comparison of Two Novel Stenfilcon A Contact Lens Designs

Principal Investigator: Yueren Wang, OD, FAAO

Read before starting application

PI email: ywang@sco.edu

PI phone: 901-252-3691

App Submission Date: 5/1/2025

Start Date: 5/19/2025

End Date: 5/19/2026

Co-PI: Rebekah Tuchscherer ☐Faculty ☒Student ☐Other

Other Personnel: Click or tap here to enter text. ☐Faculty ☐Student ☐Other

Funding Sources: N/A

Examples of Funding Sources

Does this research involve the use of drugs or medical devices that are undergoing FDA investigation or FDA-approved drugs or devices in a non-approved manner? ☐ Yes ☒ No

If yes, please specify and briefly explain:

Click or tap here to enter text.

Describe any equipment to be used on the subjects, calibration procedures, & safety checks.

- **Computer vision syndrome questionnaire (CVS-Q)** is a reliable and valid tool for measuring frequency and intensity of visual symptoms related to computer use in the workplace.
- **Binocular logMar (H/Lo contrast) visual acuity at 6M and 40cm.** The M&S Technologies Smart System II (M&S Technologies, Niles, IL) has been shown to be comparable to ETDRS and Pelli Robson charts. Computer tests have been shown to a reliable, capable way of assessing vision.
- **Binocular range of clear vision.** Use a near card with subject observing an isolated 20/30 target on the phoropter near testing rod. Pull back until subject report blur (repeat 3 times). Puss in until subject report blur (repeat 3 times).
- **Subjective assessment of accommodation** is assessed by plotting a binocular defocus curve over-refraction at 6M (-3.00 to +3.00D in 0.50D steps) in phoropter while wearing contact lenses. Room luminance will be controlled and subjects will view optotypes through a standardized 4 mm aperture to reduce confounding effects on retinal defocus. Lenses will be presented in a randomized order.
- **Objective assessment of accommodation** Multiple studies support quantitative and qualitative changes in accommodation may be associated with asthenopia. The Grand Seiko WR 5500 (AIT, Bensenville, IL) has been shown to be capable of reliably measuring objective accommodation.

Identify all personnel who will be collecting data from subjects or operating equipment and their special skills or qualifications. (Add extra pages if needed.)

Rebekah Tuchscherer

Application for Initial SCO IRB Review: Protocols Involving Human Subjects

Does the project require the use of hazardous materials, such as radioactive substances or biological tissues (human or animal)? ☐Yes ☒No

If yes, what precautions will be taken for handing and storing these materials?

Click or tap here to enter text.

Click here to see a list of items that must be included in the protocol to be turned in with this application.

Application for Initial SCO IRB Review: Protocols Involving Human Subjects

Informed consent containing the basic elements and applicable additional elements as outlined in the SCO IRB document "Elements of Informed Consent" must be obtained from subjects BEFORE participation in any study. However, if ALL of the necessary criteria are met, you may apply for permission to alter some or all of the elements or to have the informed consent requirement waived altogether. Click the button to the left to see the criteria necessary to waive or alter the IC:

Critera for waiver/alteration IC

If you wish to apply for a WAIVER or ALTERATION of the informed consent document and process, specify whether you are requesting a waiver or an alteration and give the rationale below:

Click or tap here to enter text.

If you plan to obtain informed consent, but with to waive DOCUMENTATION of informed consent, give your rationale below:

Click or tap here to enter text.

List the TOTAL number of subjects AT SCO that you wish to enroll: 30

Is this a MULTI-CENTER study? ☐Yes ☒No

If yes, list the TOTAL enrollment at all sites: Click or tap here to enter text.

Will the GENDER or RACE of the subjects be limited? ☐Yes ☒No

If yes, give rationale: Click or tap here to enter text.

Check each of the populations below that will be used in your research:

☐Adults with cognitive impairment	☐Patients	☐SCO or TEC employees
☐Pregnant women or neonates	☒SCO students ☐Other	
☐Prisoners	☐Minors (<18 yrs)	
☐Non English-speaking subjects	☐Anyone likely to need surrogate consent	

Check all of the following subject recruitment methods that will be used. You will also need to ATTACH a copy of all printed ads, text-based messages, scripts of announcements and voice/verbal recruitment messages, etc.

☐Flyers, banners, or other postings	☒Email	☐Telephone
☐Public announcements before groups	☐Text msg	☐US mail
☐Radio or TV ads	☐Social Media	
☒Recruitment by clinicians or staff	☐Other Click or tap here to enter text.	

Application for Initial SCO IRB Review: Protocols Involving Human Subjects

Does the PI, Co-PI, any ancillary staff, or any member of their immediate families:

1. own or control any equity interest in any drug, device, or technology involved in this research study? ☐Yes ☒No
2. have a financial interest in any listed external support? ☐Yes ☒No
3. function as an advisor, employee, officer, director, or consultant for any listed commercial source of external support? ☐Yes ☒No

If YES to <u>any</u> of these 3 questions, please ATTACH detailed information to permit the IRB to determine whether such involvement should be disclosed to potential research subjects.

Click here to save as pdf before signing

PI Signature _____

Please add this form to your Informed Consent document for subjects to read and sign. If Informed Consent is waived for this study, you must still have subjects read and sign this form before participation.

SCO HIPAA DE-IDENTIFICATION CERTIFICATION

De-identified information is health information that cannot be linked to an individual. HIPAA lists 18 specific identifiers that must be removed to qualify as de-identified data.

The following identifiers CAN be recorded:

1. Initial 3 digits of the zip code if the population is greater than 20,000 people.
2. Age, if less than 90 years.
3. Gender
4. Ethnicity

Instructions: If you are de-identifying protected health information (PHI) for your study, complete this de-identification certification form and submit it with your IRB application.

Reidentification: The Privacy Rule permits a researcher to assign and retain a code to allow the re-identification of PHI. The code *cannot* be derived from or related to the information about the subject.

For example, you would not record the subject's initials and last 4 digits of a subject's social security number because the code is derived from the subject.

The researcher may not disclose the re-identification code or its method of re-identifying PHI.

Assurance Statement: The HIPAA Protected Health Information identifiers will NOT be recorded with the data as part of this research study. If applicable, I agree to the Privacy Rule's requirements listed above for re-identification.

PI Name (print or type): Yueren Wang, OD

PI Signature: 

Study Title: Crossover Comparison of Two Novel Stenfilcon A Contact Lens Designs

Print This Form

Signature Assurance Sheet

Study Title: Crossover Comparison of Two Novel Stenfilcon A Contact Lens Designs

Principal Investigator's Assurance Statement: **Instructions**

I understand the Southern College of Optometry's policies concerning research involving human subjects and I agree:

1. to comply with all IRB policies, decisions, conditions, and requirements;
2. to accept responsibility for the scientific and ethical conduct of this research study;
3. to obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent/assent form;
4. to report to the IRB in accord with IRB/IBC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects;
5. to complete, on request by the IRB, the Continuation/Final Review Forms;
6. to notify the Research Department and/or the IRB of the development of any financial interest not already disclosed;
7. that each individual listed as study personnel in this application has received the mandatory human research protections education (e.g., Dunn & Chadwick, CITI);
8. that each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.

Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting the study.

Signature _____ **5/5/2025**

Type PI Name: Yueren Wang, OD PI email: ywang@sco.edu

Click here to print after signing

***Research Director's Assurance Statement:**

I certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study; to the competency of the investigator(s) to conduct the project and their time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate. If the principal investigator assumes a sponsor function, the investigator knows the additional regulatory requirements of the sponsor and can comply with them.

Signature _____ Click or tap to enter a date. 05/05/2025

Research Chair: Chris Lievens, OD, MS, PhD

***If the Principal Investigator is also the Chairperson of the department, VP of Academic Affairs or equivalent should sign the Signature Assurance Sheet.**

****Faculty Advisor's Assurance Statement:** **Click here to see if you need to sign below**

I certify that I have reviewed this research protocol and that I attest to the scientific merit of this study; to the competency of the investigator(s) to conduct the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate.

Signature _____ **5/5/2025**

Type PI Faculty Name: Yueren Wang, OD Type PI Faculty email: ywang@sco.edu

Crossover Comparison of Two Novel Stenfilcon A Contact Lens Designs

Principal Investigator:
Yueren Wang, OD, FAAO

Optometry Student Researcher:
Rebekah Tuchscherer,
O.D. Candidate, Class of 2028

Southern College of Optometry
1245 Madison Ave.
Memphis, TN 38104
ywang@sco.edu

Background and Rationale:

Computers, tablets, smartphones, and other digital devices have become an integral part of daily life. The average daily screen time now exceeds seven hours per day,[1] a number that continues to rise amid growing reliance on remote work, virtual education, and streaming media platforms. As screen time continues to escalate, an increasing number of individuals are reporting symptoms associated with prolonged digital usage. This condition, referred to as Computer Vision Syndrome (CVS) or digital eye strain, encompasses a spectrum of visual and ocular symptoms including eye fatigue, dryness, blurred vision, and headaches.[2,3]

A systematic review found that the prevalence of CVS among digital device users varies widely, from 38.6% to 95.8%, depending on the criteria used and the population studied.[4] The etiology of CVS is multifactorial and can be divided into three broad categories: refractive and accommodative demand, binocular vision stress, and dry eye, often exacerbated by reduced blink rates during screen use.[4] Contact lens wearers, in particular, may face heightened risks as lens wear can amplify dry eye symptoms during digital device use, stressing the importance of tailored lens designs.[5]

In response to these challenges, the contact lens industry has developed new lens technologies aimed at mitigating the visual strain associated with digital screen use. Innovations include designs that incorporate blue light filtering technology,[6] reduce accommodative demand,[7] and promote tear film stability.[8,9] Despite these advances, the current body of evidence evaluating the clinical efficacy of such lenses is limited, and heterogeneity in materials, optical profiles, and individual wearer characteristics presents further challenges to generalizability.

Given the increasing digital dependency and the rising public health impact of CVS, there is a critical need for rigorous, evidence-based research to assess the performance of emerging contact lens technologies. The proposed study will address this gap by comparing the efficacy of two novel *stenfilcon A* contact lens designs in alleviating accommodative burden associated with digital device usage.[10]

Experimental design:

This is a randomized, double-masked, crossover clinical trial. Subjects (N= 30) will be randomly assigned to wear either the MyDay (stenfilcon A, Scottsville, NY) and then the MyDay Energys (stenfilcon A, Scottsville, NY) single vision contact lenses for a period of 5 days. Subjects will then be crossed over to the opposing design after a three-day wash-out period.

Symptoms and visual performance will be assessed at baseline and exit from each design using primary outcomes measures.

- **Computer vision syndrome questionnaire (CVS-Q)** is a reliable and valid tool for measuring frequency and intensity of visual symptoms related to computer use in the workplace.
- **Binocular logMar (H/Lo contrast) visual acuity at 6M and 40cm.** The M&S Technologies Smart System II (M&S Technologies, Niles, IL) has been shown to be comparable to ETDRS and Pelli Robson charts. Computer tests have been shown to a reliable, capable way of assessing vision.
- **Binocular range of clear vision.** Use a near card with subject observing an isolated 20/30 target on the phoropter near testing rod. Pull back until subject report blur (repeat 3 times). Puss in until subject report blur (repeat 3 times).
- **Subjective assessment of accommodation** is assessed by plotting a binocular defocus curve over-refraction at 6M (-3.00 to +3.00D in 0.50D steps) in phoropter while wearing contact lenses. Room luminance will be controlled and subjects will view optotypes through a standardized 4 mm aperture to reduce confounding effects on retinal defocus. Lenses will be presented in a randomized order.
- **Objective assessment of accommodation** Multiple studies support quantitative and qualitative changes in accommodation may be associated with asthenopia. The Grand Seiko WR 5500 (AIT, Bensenville, IL) has been shown to be capable of reliably measuring objective accommodation.

Inclusion criteria:

- Score of >6 on CVS-Q
- Male or female
- Age >18 years to 35 years of age
- Experienced, well-adapted contact lens wearers
- Spherical equivalent refractive error between ±6.00DS with astigmatism < -0.75D
- Normal stereopsis and binocular status

Exclusion criteria:

- Monovision
- History of refractive surgery
- Binocular vision abnormalities
- Current ocular or systemic disease that may affect the eye
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.

- If eyes become red or irritated.
- The patient is unable to follow lens care regimen or unable to obtain assistance to do so

Sample size:

Sample size calculations were based on logMAR visual acuity values from Elliott et al. (1995). Assuming a clinically significant difference of 0.1 logMAR and a standard deviation of 0.06, a two-tailed t-test with α=0.05 and β=0.20 indicates a sample size of <27 subjects. To account for a 10% dropout rate, 30 subjects will be enrolled.

Statistical Analysis:

Descriptive statistics will be provided for the cohort including age, gender, equivalent spherical refraction, hours spent using a smart device per day, and average wearing time per day. Primary outcome measures will be compared using either parametric or non-parametric testing after testing sample distributions for normalcy. Correlations between CVS-Q and outcome measures will be assessed.

This study will comply with the tenets of the Helsinki Declarations and will be approved by the Institutional Review Board.

Schedule of data collection

- At scheduling
    1. Spec & CL Rx within one year.
- Baseline Visit
    1. Screening for eligibility
        - Cover test: no strabismus
        - Steropsis: at least 40" of arc with no suppression
        - Refraction if last eye exam was > one year
    2. Enrollment & random assignment to a lens
    3. Informed consent
    4. CVS-Q
    5. Baseline tests through updated refraction
        - LogMAR Hi/Lo contrast at 40cm and & 6M
        - Range of clear vision
        - Defocus testing
        - Test accommodation
    6. Lens fitting of lens one. Trial lens ordering for both lens 1 and 2 if no power available in Rx.
- Second Visit: Scheduled 1-2 weeks after lens dispense, subject required to wear lens for minimum of 5 days, 10 hours per day. Minimum of 3 day washout from habitual CL.
    1. CVS-Q
    2. Tests through lens 1.
        - LogMAR Hi/Lo contrast at 40cm and & 6M
        - Range of clear vision
        - Defocus testing
        - Test accommodation
    3. Refit into lens 2.
- Second Visit: Scheduled 1-2 weeks after lens dispense, subject required to wear lens for minimum of 5 days, 10 hours per day. Minimum of 3 day washout from Lens 1.
    1. CVS-Q
    2. Tests through Lens 2.
        - LogMAR Hi/Lo contrast at 40cm and & 6M
        - Range of clear vision
        - Defocus testing
        - Test accommodation

Computer Vision Syndrome Questionnaire (CVS-Q)

To be completed by subject

Indicate whether you experience any of the following symptoms during the time you use the computer at work. For each symptom, mark with an **X**:

a. First, the frequency, that is, how often the symptom occurs, considering that:

- NEVER = the symptom does not occur at all
- OCCASIONALLY = sporadic episodes or once a week
- OFTEN OR ALWAYS = 2 or 3 times a week or almost every day

b. Second, the intensity of the symptom:

Remember: if you indicated NEVER for frequency, you should not mark anything for intensity.

	a. Frequency			**b.** Intensity	
	NEVER	**OCCASIONALLY**	**OFTEN OR ALWAYS**	**MODERATE**	**INTENSE**
1 Burning					
2 Itching					
3 Feeling of a foreign body					
4 Tearing					
5 Excessive blinking					
6 Eye redness					
7 Eye pain					
8 Heavy eyelids					
9 Dryness					
10 Blurred vision					
11 Double vision					
12 Difficulty focusing for near vision					
13 Increased sensitivity to light					
14 Coloured halos around objects					
15 Feeling that sight is worsening					
16 Headache					

Apply the following expression: $\text{Score} = \sum_{i=1}^{16} (\text{frequency of symptom occurrence})_i \times (\text{intensity of symptom})_i$

To be completed by investigator

Calculation of **TOTAL SCORE**

Considering that:

Frequency:

- Never=0
- Occasionally=1
- Often or always=2

Intensity:

- Moderate=1
- Intense=2

	Frequency	Intensity	Frequency x Intensity
1 Burning			
2 Itching			
3 Feeling of a foreign body			
4 Tearing			
5 Excessive blinking			
6 Eye redness			
7 Eye pain			
8 Heavy eyelids			
9 Dryness			
10 Blurred vision			
11 Double vision			
12 Difficulty focusing for near vision			
13 Increased sensitivity to light			
14 Coloured halos around objects			
15 Feeling that eyesight is worsening			
16 Headache			
$\text{Score} = \sum_{i=1}^{16} (\text{frequency of symptom occurrence})_i \times (\text{intensity of symptom})_i$ *=			

If the total score is ≥6 points, the worker is considered to suffer Computer Vision Syndrome

* The result of Frequency X Intensity should be recoded as: 0 = 0; 1 or 2 = 1; 4 = 2

References:

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Crossover Comparison of Two Novel Stenfilcon A Contact Lens Designs

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Optometry Student Researcher:
Rebekah Tuchscherer,
O.D. Candidate, Class of 2028

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C. Statement of Research Plan

a. Statement of Problem:

Computer Vision Syndrome (CVS), also referred to as digital eye strain, is a group of vision-related issues arising from prolonged digital screen use. According to the American Optometric Association, many individuals experience discomfort that increases with extended screen exposure. With widespread use of digital devices across all age groups, individuals spend over five hours per day on screens, exacerbating CVS symptoms.

Contact lens manufacturers continue to develop designs aimed at mitigating CVS symptoms by reducing higher-order aberrations, accommodative/convergence demands, and improving tear film stability. However, comparative studies evaluating these claims are limited due to variability in lens properties. This study aims to assess the validity of these claims by comparing symptoms and visual performance of two novel stenfilcon A lens designs.

b. Experimental design:

This is a randomized, double-masked, crossover clinical trial. Subjects (N= 30) will be randomly assigned to wear either the MyDay (stenfilcon A, Scottsville, NY) and then the MyDay Energys (stenfilcon A, Scottsville, NY) single vision contact lenses for a period of 1 month. Subjects will then be crossed over to the opposing design after a three-day wash-out period.

Symptoms and visual performance will be assessed at baseline and exit from each design using primary outcomes measures.

- **Computer vision syndrome questionnaire (CVS-Q)** is a reliable and valid tool for measuring frequency and intensity of visual symptoms related to computer use in the workplace.
- **Binocular logMar (H/Lo contrast) visual acuity at 6M and 40cm.** The M&S Technologies Smart System II (M&S Technologies, Niles, IL) has been shown to be comparable to ETDRS and Pelli Robson charts. Computer tests have been shown to a reliable, capable way of assessing vision.
- **Subjective assessment of accommodation** is assessed by plotting a binocular defocus curve over-refraction at 6M (-3.00 to +3.00D in 0.50D steps) in phoropter while wearing contact lenses. Room luminance will be controlled and subjects will view optotypes through a standardized 4 mm aperture to reduce confounding effects on retinal defocus. Lenses will be presented in a randomized order.
- **Objective assessment of accommodation** Multiple studies support quantitative and qualitative changes in accommodation may be associated with asthenopia. The Grand Seiko WR 5500 (AIT, Bensenville, IL) has been shown to be capable of reliably measuring objective accommodation.

Inclusion criteria:

- Score of >6 on CVS-Q
- Male or female
- Age >18 years to 35 years of age
- Experienced, well-adapted contact lens wearers
- Spherical equivalent refractive error between ±6.00DS with astigmatism < -0.75D
- Normal stereopsis and binocular status

Exclusion criteria:

- Monovision
- History of refractive surgery
- Binocular vision abnormalities
- Ocular or systemic disease
- Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- If eyes become red or irritated.
- The patient is unable to follow lens care regimen or unable to obtain assistance to do so

Sample size:

Sample size calculations were based on logMAR visual acuity values from Elliott et al. (1995). Assuming a clinically significant difference of 0.1 logMAR and a standard deviation of 0.06, a two-tailed t-test with α=0.05 and β=0.20 indicates a sample size of <27 subjects. To account for a 10% dropout rate, 30 subjects will be enrolled.

Statistical Analysis:

Descriptive statistics will be provided for the cohort including age, gender, equivalent spherical refraction, hours spent using a smart device per day, and average wearing time per day. Primary outcome measures will be compared using either parametric or non-parametric testing after testing sample distributions for normalcy. Correlations between CVS-Q and outcome measures will be assessed.

This study will comply with the tenets of the Helsinki Declarations and will be approved by the Institutional Review Board.

c. Institutional and other resources available:

All patient visits will be conducted at the Southern College of Optometry (SCO). The M&S Technologies Smart System II needed for binocular visual acuity testing and subjective assessment of accommodation, in addition to the Grand Seiko WR 5500 needed for objective assessment of accommodation, will also be

provided by the Southern College of Optometry. The study contact lenses will be provided by CooperVision. Funding for student research participation and conference travel is supported by the SCO Summer Research Fellowship Program.

d. **Relevance of Problem to Optometry or Vision Science:** Computers, tablets, e-readers, and cell phones garner an ever-increasing presence in patients' day-to-day lives. Optometrists and vision scientists are likely to be confronted with increasing levels of Computer Vision Syndrome in patient care. Research on the impact of contact lens designs on CVS symptoms is essential for guiding clinical recommendations. This study will contribute valuable data regarding the efficacy of novel lenses like Biofinity Energys and MyDay Energys in alleviating CVS.

e. **Plans for Publication:** An abstract describing the primary outcome will be submitted to Academy 2026 Anaheim, and a manuscript on the same topic will be submitted to Contact Lens & Anterior Eye.

f. **Time Table:**

	2025	2025	2025	2025	2025	2026
	April	May	June	July	Aug	May
Activity						
IRB Preparation						
Data Collection						
Data Analysis						
Final Study Report						

D. **Budget**

Projected Expenses	**Cost per unit**	**Units**	**Total**	**Source of funding**
Research Subject Compensation	$50 (3 visits)	30 subjects	1500	
Statistician ($125/hour)	$125/hour	2 hours	250	
Fluorescein Strips	$80	1 box	80	
Contact lens cases	0.21/each	90	19	
		Total	$1849	BSK grant

Overhead Fees covered by SCO

- Research Coordinator time
- Contact Lens Staff time
- Facility fees
- Student researcher time and fund
- Conference presentation and travel fees
- Manuscript publication fees

E. **Requested Support from Beta Sigma Kappa**

Amount of Funding Requested: $1849

Describe/Itemize the costs comprised in this amount:

- Research subject compensation: Used to reimburse subjects for their time and effort to participate in the research project. The projected time needed is one hour per visit. Subjects (N = 30) would receive $15 via Visa gift card for each of the first two completed visits, and $20 on the last visit upon completion of the study. Subjects completing all three visits would receive a total of $50.
- Statistician: To aid in robust analysis of the final research data. Hiring an independent statistician to perform data analysis will aid in manuscript acceptance and publication.
- Supplies for research study
    - Fluorescein strips: To be used to assess ocular health.
    - Contact lens cases: To be used for subjects to remove and store their contact lenses for the assessment of ocular health.

Justification for equipment, supplies and other expenses: Because this project includes multiple, long visits and extended commitment from research subjects, financial incentive will likely aid in greater recruitment and retention. The prospect of reimbursing subjects for their time is also likely to speed up enrollment, ensuring that the project can stay on track for completion in a timely manner.

Plan for additional funding: In the unlikely event that the expense for their project exceeds the amount of the budget, additional funding will be sought through additional grants or the Southern College of Optometry.

F. **Documentation**

X_____
Yueren Wang, OD, FAAO
Faculty Advisor

X_____ 4/1/2025
J. Bart Campbell, OD, FAAO
Vice President for Academic Affairs
Southern College of Optometry

Scripts for recruitment

Hello SCO family!

We are conducting a study evaluating the efficacy of a new daily contact lens design marketed for digital eye strain.

The study includes *three* visits scheduled 1-2 weeks apart. At the visit, we will fit you in either the MyDay or MyDay Energys lens and ask you to wear each lens for 5 days before switching to the other lens. At each visit, we will measure your VA, range of clear vision, subjective/objective accommodation, and ask you to fill out a questionnaire. Each visit is estimated to take 1 hour to complete.

Inclusion criteria:

- Currently experiences some eye strain when using digital devices.
- Age >18 years to 35 years of age
- Experienced, well-adapted contact lens wearers
- Spherical equivalent refractive error between ±6.00DS with astigmatism < -0.75D
- Normal stereopsis (40" of arc or better) and normal binocular status
- Eye exam within 12 months (we're happy to schedule you an exam if needed).

Exclusion criteria:

- History of refractive surgery
- Binocular vision abnormalities
- Current ocular or systemic disease that may affect the eye

As thank you for your time, a $50 Amazon gift card will be sent to your preferred email address at the conclusion of the study.

If you have any questions or would like to participate, please email Rebekah Tuchscherer at rtuchscherer@sco.edu to schedule your visit.

Thank you for your consideration,

Dr. Wang and Rebekah

Approved by SCO IRB
amc 5/9/2025

Study Title: Crossover Comparison of Two Novel Stenfilcon A Contact Lens Designs

Study number (if applicable):

SCO IRB Study #: 2005-05-02CL

Principal Investigator (PI): Yueren Wang, OD, FAAO

PI's Contact information

Phone: 901-252-3691 Email: ywang@sco.edu

Study sponsor: N/A

Additional Research Team Members: Rebekah Tuchscherer

We are asking you to participate in a research study. The purpose of the study is to:

The study aim to compare the efficacy of two novel *stenfilcon A* contact lens designs in alleviating accommodative burden associated with digital device usage.

The data collection for this research study will take place from 5/19/2025 to 5/19/2026. The amount of time that we will need from you to complete the study is described below:

Three separate visits: 1-2 weeks apart
1. Baseline visit: 1hr
2. Second visit: 1hr
3. Third visit: 1hr

Below is a description of the procedures that will take place during your visit(s):

Computer vision syndrome questionnaire (CVS-Q) is a reliable and valid tool for measuring frequency and intensity of visual symptoms related to computer use in the workplace.
Binocular logMar (H/Lo contrast) visual acuity at 6M and 40cm. The M&S Technologies Smart System II (M&S Technologies, Niles, IL) has been shown to be comparable to ETDRS and Pelli Robson charts. Computer tests have been shown to a reliable, capable way of assessing vision.
Binocular range of clear vision. Use a near card with subject observing an isolated 20/30 target on the phoropter near testing rod. Pull back until subject report blur (repeat 3 times). Push in until subject report blur (repeat 3 times).
Subjective assessment of accommodation is assessed by plotting a binocular defocus curve over-refraction at 6M (-3.00 to +3.00D in 0.50D steps) in phoropter while wearing contact lenses. Room luminance will be controlled and subjects will view optotypes through a standardized 4 mm aperture to reduce confounding effects on retinal defocus. Lenses will be presented in a randomized order.
Objective assessment of accommodation Multiple studies support quantitative and qualitative

changes in accommodation may be associated with asthenopia. The Grand Seiko WR 5500 (AIT, Bensenville, IL) has been shown to be capable of reliably measuring objective accommodation.

1. **Baseline Visit**
    a. Screening for eligibility
        - Cover test: no strabismus
        - Stereopsis: at least 40" of arc with no suppression
        - Refraction if last eye exam was > one year
    b. Enrollment & random assignment to a lens
    c. Informed consent
    d. CVS-Q
    e. Baseline tests through habitual Rx.
        - LogMAR Hi/Lo contrast at 40cm and & 6M
        - Range of clear vision
        - Defocus testing
        - Test accommodation
    f. Lens fitting of lens one. Trial lens ordering for both lens 1 and 2 if no power available in Rx.
2. **Second Visit:** Scheduled 1-2 weeks after lens dispense, subject required to wear lens for minimum of 5 days, 10 hours per day. Minimum of 3 day washout from habitual CL.
    a. CVS-Q
    b. Tests through lens 1.
        - LogMAR Hi/Lo contrast at 40cm and & 6M
        - Range of clear vision
        - Defocus testing
        - Test accommodation
    c. Refit into lens 2.
3. **Third Visit:** Scheduled 1-2 weeks after lens dispense, subject required to wear lens for minimum of 5 days, 10 hours per day. Minimum of 3 day washout from Lens 1.
    a. CVS-Q
    b. Tests through Lens 2.
        - LogMAR Hi/Lo contrast at 40cm and & 6M
        - Range of clear vision
        - Defocus testing
        - Test accommodation

None of these procedures are considered experimental in nature.

Although we will take all necessary precautions to avoid or minimize risks or discomforts to you as part of your participation in this study, risks or discomforts may occur. The risks or discomforts that we think you MAY experience include:

- Potential contact lens complications may include discomfort, dryness, redness, blurred vision or infection.
- Potential solution complications may include stinging, burning, redness or blurred vision.
- There are no known complications associated with any of the procedures though time is required to complete the testing and you may experience some fatigue.

Your participation in this research study may benefit you or other people in the following way(s):

Potential benefits to you or others may include authentication of claims related to the relief of symptoms associated with prolonged use of digital devices.

If you choose not to participate in this research study, the following are alternative treatments or therapies that you may choose to pursue with your regular eye care or medical care practitioner:

Continue with your habitual contact lenses.

All information that we collect during the study will remain confidential. This means that only people who are directly authorized by Yueren Wang, OD will have access to the information. Any publications or presentations that may result from this research study will not use identifiers that can link you to the data or to the research study in general.

The Food and Drug Administration may inspect the records: ☒ Yes ☐ No

Research Related Injury

If an adverse reaction or an injury requiring treatment occurs as a result of your participation in the research study, no funds have been set aside for financial compensation. If treatment is required, contact Yueren Wang, OD who will coordinate the care for the reaction or injury, which will take place at The Eye Center when possible. The cost of care will be billed to you or your insurance company. The care for the reaction or injury will continue until your doctor determines that the reaction or injury has resolved.

Questions, Concerns, Complaints

If you have any questions, concerns, or complaints about the research, you may contact the principal investigator, Yueren Wang, OD, or any other member of the research team listed on the first page of this document. If you believe you have a research-related injury, contact the principal investigator, Yueren Wang, OD.

If you have any other problems or concerns that the principal investigator cannot answer for you, or if you have questions about your rights as a research subject, you may contact the chairperson of the Institutional Review Board of the Southern College of Optometry (Patricia Cisarik, 901-722-3327).

Approved by SCO IRB
amc 5/9/2025

Decision to Participate

Your participation in this research study is voluntary. Your refusal to participate will not result in any penalty or loss of benefits to which you are otherwise entitled. Your treatment at the Southern College of Optometry or The Eye Center will not be affected in any way should you choose not to participate.

If you agree to participate, you may decide to withdraw from the study at any time. Withdrawal from participation in the study will not result in any penalty or loss of benefits to which you are otherwise entitled. Your treatment at the Southern College of Optometry or The Eye Center will not be affected in any way should you choose to withdraw from the study. Any data that has been collected will be destroyed unless prohibited by state or federal law.

This study is a clinical trial? ☒ Yes ☐ No

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Other Risks

One or more of the procedures or treatments in this research study may involve risks to you that we cannot foresee. Should you have any questions or concerns that a symptom you are experiencing may be related to your participation in the study, contact the principal investigator, Yueren Wang, OD.

If you are, or become, pregnant, one or more of the procedures or treatments in this research study may involve risks to the embryo or fetus that are currently unforeseeable. **Please inform the principal investigator**, Yueren Wang, OD **if you are pregnant or may become pregnant** at any time during your participation in the research study.

Your participation in the research study may be terminated by the principal investigator, even if you have signed this informed consent, under the following conditions:

Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
If eyes become red or irritated from the study lenses.
The patient is unable to follow lens care regimen or unable to obtain assistance to do so

Your participation in this research study may result in some additional costs to you. The anticipated additional costs to you include the following:

Traveling to and from the Eye Center for your visits.

Should you decide to withdraw from the research before the end of the study, you may experience the following consequences:

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OMC 5/29/2025

Disqualification for the optional compensations in the form of gift card or extra credit.

The principal investigator,Yueren Wang, OD, will determine when your participation in the research study has been completed. You will be dismissed from the research study in the following manner:

At the conclusion of the third visit, you will be thanked for your participation in the study. We will verify your email for the gift card compensation.

If significant new findings develop during the course of this research that may influence whether you want to continue to participate, we will inform you of these new findings and attempt to explain them to you so that you can make an informed decision about whether to continue.

Approximately 30 subjects are enrolled in this study.

The amount and schedule of reimbursements for your participation in this research study are outlined below:

Upon completion of all three visits, a $50 Amazon gift card will be sent to the participant's email address within 1 week of the last study visit.

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OMC 5/09/2025

Consent / Assent (if under age 18 years) Signatures

Help

I have read the informed consent in its entirety. I acknowledge that Yueren Wang, OD, or another member of the research team, has provided information about the procedure described above, about my rights as a subject, and has answered all questions to my satisfaction. I understand that I may contact Yueren Wang, OD at **ywang@sco.edu** should I have additional questions. I understand the potential risks and will contact Yueren Wang, OD if I experience any adverse reactions. I may also contact Dr. Patricia Cisarik, the IRB chair, at 722-3327 if I have questions or concerns about my rights concerning participation in the study.

I understand that I am being asked to participate in a research study and no guarantee has been given to me concerning this treatment or procedure

I sign this informed consent to participate in the research study entitled **Crossover Comparison of Two Novel Stenfilcon A Contact Lens Designs** freely and voluntarily and have been given a copy.

Date _____ Time _____ AM / PM

Signed_____

Witness(es)_____

Signature of person authorized to consent for subject if required (if subject is under age 18 years or has cognitive impairment)

_____

Relationship to subject: _____

I certify that I have explained the informed consent to the subject and/or the subject's representative and supplied the subject a copy.

Date _____

_____

Signature of PI or other member of the research team

Print this document

Approved by SCO IRB

amc 5/9/2025