Maximizing the Initial Experience of a Neophyte Scleral Lens Wearer

Study Protocol and Statistical Analysis Plan

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INTRODUCTION & RATIONALE

Scleral lens (SL) prescribing has dramatically increased over the past few years likely because of the advent of better SL designs, better materials, and greater awareness of the technology.[1] SL market growth has also likely increased because SLs were once reserved for patients with complex ocular surface diseases, though advances with SL technologies have allowed SL fitting to include patients with dry eye and even patients who have relatively uncomplicated refractive errors.[1, 2] While SLs are maintained and cared for much like soft contact lenses (e.g., they require a contact lens care system), SL wearers also need help with applying their lenses. Patients specifically are advised by their care provider to insert their SLs with their fingers (tripod method), a DMV inserter with an open or closed end (hole potentially aides in vision), or a specialized o-ring that is balanced on a finger. Our clinic also utilizes a tea light candle with a DMV inserter attached to the top of it when patients have mobility issues. While work from this investigator's study group has found that 54% of patients prefer DMV inserters for applying their SLs as compared to the above other options, these preliminary data were obtained through a cross-sectional electronic survey from subjects who completed their SL fitting up to two years ago. Therefore, the goal of this proposal is to conduct a randomized controlled study aimed at learning the best method for applying SLs and factors associated with successfully completing SL application and removal training. These data are needed because it will help practitioners with patient education and because it may increase the likelihood that patients will be successful with SLs.

SPECIFIC AIMS

This study will address the following specific aims and associated hypotheses:

1. **Determine a neophyte SL wearers' preferred scleral lens application method.** *Hypothesis 1: There will be no statistical difference in the SL patient's preference among the five application methods (DMV inserter with an open or closed end, three fingers, o-ring, tea light candle) after the initial training visit.*

2. **Determine factors that influence the amount of time it takes for a neophyte SL wearer to be able to successfully apply and remove their SLs.** *Hypothesis 2: Past contact lens experience, SL diameter, uncorrected visual acuity, and subject age will all influence the total time needed to complete all five application methods successfully.*

STUDY DESIGN

Subjects and Recruitment

This study will be conducted at the UAB School of Optometry (Birmingham, AL, USA). Subjects will be recruited by word of mouth during regular clinical care. Adult (>18 years) subjects will be recruited for this study. Subjects will be excluded if they have past experience or advanced knowledge of SLs, a physical or cognitive condition that may prevent them from successfully wearing SLs (e.g., stroke), or if they are currently participating in another clinical trial. Since there is limited data on this topic and since the literature lacks a method for calculating a sample size for a five-way comparison, a true sample size calculation is not possible for this project. Since this study is preliminary in nature, 25 subjects will be recruited to gain an initial understanding of how subjects prefer to apply SLs. Five additional subjects will be recruited to account for screen failures (total of 30 subjects).

<u>Clinical Protocol</u>

Visit 1: Baseline Visit

1. Subject History, Eligibility, Informed Consent: Subjects will be asked to complete an IRB-approved screening survey to verify that they are still eligible for the study. Eligible subjects will be enrolled, consented, and requested to sign a privacy document. All relevant subject history will be gathered via a questionnaire developed by the investigators that asks about the patient's past contact lens and ocular disease history. Non-eligible subjects will be dismissed at this time.

2. Questionnaires: All subjects will be asked to complete the Standardized Patient Evaluation of Eye Dryness (SPEED) questionnaire because it is a validated dry eye symptoms questionnaire that asks about the most common dry eye symptoms.[3] Subjects will also be asked to complete the Contact Lens Dry Eye Questionnaire (CLDEQ)-8 because it is a validated instrument that asks about contact lens comfort and coping mechanisms. The Orthokeratology and Contact Lens Quality of Life Questionnaire (OCL-QoL) will also be administered because it assesses the patient's visual quality of life.[4]

3. Visual Acuity: Uncorrected and habitually-corrected visual acuity will be measured with a high-contrast Snellen chart. If the patient is unable to read the 20/40 letters, the investigator will pinhole over the patient's unaided or presenting refractive error correction to determine the subject's visual potential.

4. Manifest Refraction: The investigator will determine the subject's refractive error with a phoropter, and binocular balance will be performed if best-corrected visual acuity is equal in between eyes. Visual acuity will be recorded as described above in step 3.

5. Slit-Lamp Biomicroscopy: The investigator will use a slit-lamp biomicroscope to document normal and/or remarkable findings of the anterior eye structures: eyelids, conjunctiva, and cornea.

6. Topography: Topography will be performed with the SMap3D. The device's standard procedure will be followed, and parameters from this measurement will be sent to the manufacture to help determine the patient's first SL.

7: Scleral Lens Fitting: The Europa lens will be fit based upon the manufacturer's guidelines with their fitting set. A slit-lamp biomicroscope evaluation will be performed on the trial lens to estimate the central corneal clearance and overall fit after 30 minutes of settling. SL information will be provided to the manufacturer to help determine the patient's first SL.

Visit 2: Dispense Visit

1. Visual Acuity: Visual acuity with habitual correction will be measured with a high-contrast Snellen chart. If the patient is unable to read the 20/40 letters, the investigator will pinhole over the patient's unaided or presenting refractive error correction to determine the subject's visual potential.

2. Slit-Lamp Biomicroscopy: The investigator will use a slit-lamp biomicroscope to document normal and/or remarkable findings of the anterior eye structures: eyelids, conjunctiva, and cornea.

3. Lens Dispense: The investigator will orient the patient and apply the ordered SLs to each eye. The investigator will use a slit-lamp biomicroscope and OCT to evaluate the SLs after 30 minutes of lens settling. If the lenses fit acceptably, the patient will undergo application and removal training (based on the randomization order

determined during step 4). If the lenses do not fit acceptably, new lenses will be ordered, and the subject will be scheduled for a follow up visit for after the study lenses arrive.

4. Randomization: The investigator will access the online randomization tool (REDCap) and determine the order by which subjects will apply their lenses (*DMV inserter with an open end (A), DMV inserter with a closed end (B), three fingers (C), o-ring (D), tea light candle (E)*). Right eyes will undergo the application protocol; however, if the patient only needs a SL for their left eye, the left eye will undergo the protocol. Hand and eye dominance will be recorded. Subjects will then be instructed via training videos created by the investigators on how to do each application method. Each training video will be shown before starting each application method, and the examiner will answer the subject's questions prior to attempting the application method. The same investigator will teach each subject. Subjects will be timed during each application; however, time recording will not be made obvious. After a subject successfully completes an application method once for the designated eye, they will be asked to do the subsequent method. If a subject is unsuccessful with a method and declines to continue that method after being encouraged, the time will be recorded, and they will be allowed to try the next method. The subject will be allowed up to 15 minutes to complete each method. If the subject is unable to complete the method within that time frame, they will be instructed to do the next method to help avoid fatigue. If a patient stops a procedure before completing an application, this event will be recorded. Patients will be encouraged to try all five methods on the same day; however, subjects will be allowed to come back on a subsequent day if they get tired. Subjects will be asked to rank the ease of application for each method from easiest to most challenging after trying each method. If a subject needs a SL for their contralateral eye, they will be taught how to apply this lens after they have completed the training for their designated eye. If a subject is able to apply the lenses, they will be asked to remove the lenses as well. Only one removal method will be used (small plunger), and the removal time will also be timed for each method (timed separately from application).

5. SL Release: After a subject completes the application and removal process, they will be given everything they need to wear the lenses (non-preserved saline (Adipack), application devices). They will also be given a trial bottle of Boston Simplus (contact lens care system), and they will be allowed to try their lenses for about one week. Subjects will be instructed to use their preferred application method at home.

6. SL Adaptation Form: Subjects will be given a take-home diary to complete during the one-week trial period. This diary will ask the subject about their experience with applying and removing their lenses, their comfort, and their perception of the SLs.

Visit 3: Outcome Visit

1. Visual Acuity: Visual acuity with SLs will be measured with a high-contrast Snellen chart. If the patient is unable to read the 20/40 letters, the investigator will pinhole over the patient's unaided or presenting refractive error correction to determine the subject's visual potential.

2. SL Evaluation: The investigator will use a slit-lamp biomicroscope to evaluate the SLs. The subject will be required to have worn their lenses for at least two hours before the study visit. Anterior segment optical coherence tomography (OCT) will also be performed to obtain an accurate central corneal clearance measurement.

3. Questionnaires: All subjects will be asked to complete the SPEED, CLDEQ-8, and OCL-QoL questionnaires at the final SL fitting visit. They will also be asked to complete an investigator-designed questionnaire to understand the initial SL wearing experience.

4. Study Completion: The subject will be compensated, and the subject will be exited from the study, but they will be encouraged to continue their SL care with their provider.

Data Collection and Analysis

Data collection will be performed with Research Electronic Data Capture (REDCap). Data will be analyzed with STATA 16 (StataCorp LLC; College Station, TX). Means and standard deviations will be used to understand general data trends. ANOVA will be used when comparing application methods. Regression analysis will be used to find associations with the speed of being able to complete the application process. Paired t-tests will be used to compare questionnaire scores at the final visit to the baseline visit. If the assumptions of these tests cannot be met, suitable alternative statistical tests (e.g., Kruskal-Wallis) will be used.

STUDY TIMELINE

	2020	2020	2020	2021	2021	2021	2021	2021
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
Activity								
IRB Review	■	■						
Data Collection			■	■	■	■		
Data Analysis							■	■
Final Study Report								■

PUBLICATION PLANS

An abstract on application methods will be submitted for presentation at Academy 2021 Boston. A summary of this work will be submitted as a manuscript to *Contact Lens & Anterior Eye*.

CONCLUSIONS

This project will be the first to formally evaluate SL application methods in a randomized fashion, work that will help guide patient education and doctor prescribing. It may also lead to more patients becoming successful SL wearers by streamlining the overall SL fitting process.

REFERENCES

1. Harthan J, Nau CB, Barr J, et al. Scleral Lens Prescription and Management Practices: The SCOPE Study. *Eye Contact Lens* 2017.
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3. Ngo W, Situ P, Keir N, Korb D, Blackie C, Simpson T. Psychometric properties and validation of the Standard Patient Evaluation of Eye Dryness questionnaire. *Cornea* 2013;32:1204-1210.
4. McAlinden C, Lipson M. Orthokeratology and Contact Lens Quality of Life Questionnaire (OCL-QoL). *Eye Contact Lens* 2017.