Refitting contact lens dropouts into a modern daily disposable contact lens

Study Protocol & Statistical Analysis Plan

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Andrew Pucker, OD, Associate Professor, Principal Investigator
University of Alabama at Birmingham
Birmingham, AL 35294

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How does DT1 sphere perform in those who previously dropped out of contact lenses due to comfort or dryness?

Principal Investigator:
Chris Lievens, OD, MS, FNAP, FAAO[2]

Additional Support:
Katherine Bickle, OD, MS[3]
Quentin X. Franklin, BS[1]
Michael Christensen, OD, PhD, FAAO[2]
Shane Kannarr, OD[4]
Catherine Hogan, OD, FAAO[2]
Andrew D. Pucker, OD, PhD, FAAO, FSLS, FBCLA[1]

Southern College of Optometry[2]
1245 Madison Ave.
Memphis, TN 38104
clievens@sco.edu

University of Alabama at Birmingham[1]
Birmingham, AL
Memphis, TN

ProCare Vision Center[3]
Granville, OH

Kannarr Eye Care[4]
Pittsburgh, KS

I. INTRODUCTION & RATIONALE

CL discomfort is a complex phenomenon that has been defined by the Tear Film and Ocular Surface Society in their seminal report on contact lens (CL) discomfort as a condition that results in "episodic or persistent adverse ocular sensation related to lens wear, either with or without visual disturbance resulting from reduced compatibility between the CL and the environment, which can lead to decreased wearing time and discontinuation of CL wear."[1] A recent review by Pucker and Tichenor found that CL discomfort was the top reason for established CL wears to cease wearing CLs.[2] This same review alarmingly found that the frequency of CL dropout was about 20% across the many studies aimed at evaluating this condition, which is surprising given the introduction of better soft CL materials and daily disposable CLs over the past 20 plus years.[2]

Dailies Total1 (DT1), which is a relatively new daily disposable CL, is a commonly used trouble shooting CL for patients who have failed with other CLs because DT1 utilizes advanced material technology that is specifically aimed at improving CL comfort. While DT1 is commonly used in these struggling patients, the literature currently lacks a targeted study aimed at understanding the frequency of successfully refitting CL dropouts into this advanced CL. Thus, the purpose of this study is to determine the frequency that past CL wearers who failed because of dryness or CL discomfort who can comfortable wear DT1.

II. SPECIFIC AIM

We plan to accomplish our goal by pursuing the following specific aim and testing the associated hypothesis:

Aim:

Determine the frequency of past CL wearers who failed because dryness or CL discomfort who can comfortably wear DT1. Hypothesis 1: At least 50% of past CL wearers can comfortably wear DT1 at one month (Positive Visual Analog Scale Score (VAS) based upon $^{+}50/^{-}50$ VAS scale with 0 as neutral).

Exploratory Outcomes

A Likert questionnaire will be used to determine the following patient-reported outcomes at 1 and 6 months: 1. Likelihood of continuing to wear DT1, 2. Overall satisfaction while wearing DT1, Overall vision while wearing DT1, 3. End of day comfort while wearing DT1. The SPEED questionaries will also be used to determine the frequency of DT1 wears who can comfortable wear DT1 (scores ≤ 3).[3]

III. STUDY DESIGN

Participants

This 6-month, three-visit clinical study will be conducted at the University of Alabama at Birmingham (Birmingham, AL, USA), the Southern College of Optometry (Memphis, TN), and ProCare Vision Center (Granville, OH). One month will be the primary outcome timepoint because Young et al. found that most participants who dropped out of CLs in their study dropped out by 1 month (23% dropout).[4] Participants will also be called at 6-months like in Young et al.'s study to determine the ultimate CL success frequency. This 6-month survey will be an exploratory outcome that will supported by the investigators (not Alcon). Participants will be recruited via clinic records, email, and fliers. Participants will be prescreened with an IRB approved phone script prior to the study visit to help determine if they qualify for the study. The reason why all potential participants dropped out of CLs will be recorded even if they are not included in the study. Adult, 18-

to 40-year-old, past CL wearers who have best corrected 20/20 visual acuity or better will be recruited. Participants will be required to have worn CLs for at least one year in the past. Participants over the age of 40 years will be excluded to avoid presbyopia-related vision issues. All participants will be required to have dropped out of CLs within the past two years because of discomfort or dryness. This determination will be made by listing Young et al.'s list of reasons for dropping out of CLs and asking the participants to indicate their top reason for dropping out of CLs: 1. Discomfort or Dryness, 2. General Poor Vision, 3. Poor Reading Vision, 4. Difficulty with Handling, 5. Advised by Practitioner, 6. Inconvenient, 7. Eyes were Red, 8. Lost Interest, 9. Too Costly, 10. Reaction to Care Products, 11. Lost Lenses, 12. Other.[4] Participants will be considered a CL dropout if they have not worn CLs in the past 3 months. Participants will be required to have scores of ≤3 on the SPEED questionaries (no significant dry eye symptoms).[3] Participants will be required to be able to wear DT1 Sphere (astigmatism better than 0.75 D OD/OS). Participants will be required to provide a glasses prescription that is less than 3 years old. Participants will be excluded if they are past rigid CL wearers, have a past history of being diagnosed with dry eye or ocular allergies, have known systemic health conditions that are thought to alter tear film physiology, have a history of viral eye disease, have a history of ocular surgery, have a history of severe ocular trauma, have a history of corneal dystrophies or degenerations, have active ocular infection or inflammation, are currently using isotretinoin-derivatives or ocular medications, or if they are pregnant or breast feeding.[5]

Sample Size

This pilot study is proposing a sample of 60 participants (20/site) to estimate the initial frequency that participants can comfortably wear DT1 at 1 month. This sample size was selected because it is a feasible number of participants that can be recruited while also providing enough data to determine if at least 50% of participants can comfortable wear DT1 CLs. These should also be enough participants to evaluate exploratory patient reported outcomes such as the likelihood of continuing DT1 after completing the study. An additional 5 participants per site are being requested in case someone fails the glasses prescription requirements for this study. Additional participants will only be recruited if needed.

Surveys and Clinical Tests

Visit 1: Baseline

1. Participant History, Eligibility, Informed Consent: Participants will be asked to repeat the IRB approved screening survey at the study visit to verify that they are still eligible for the study. All participants will be screened with the SPEED questionnaire to understand their initial eye comfort (scores ≤3 required).[6] The SPEED is being selected because it has been validated in both CL and non-CL wearers. All relevant patient demographics will be collected via a questionnaire developed by the investigators. Non-eligible participants will be dismissed at this time or rescheduled depending upon the reason for ineligibility. Eligible participants will be enrolled, consented, and requested to sign a privacy document.

2. Visual Acuity with Spectacles: Visual acuity will be measured with a Bailey-Lovie high-contrast chart.

3. Manifest Refraction: The investigator will determine the participants' refractive error with a phoropter, and binocular balance will be performed if best-corrected visual acuity is equal in between eyes. No more than 1.00 D of sphere will be added beyond the initial blur balance starting point.

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

5. CL Fitting: Participants will be fit in DT1 sphere CLs. The CLs will be evaluated for centration, movement, coverage, and CL power adjustments will only be made if they improve Snellen visual acuity.

Visit 2: 1 Week

1. Stannard Patient Evaluation of Eye Dryness (SPEED): The SPEED questionnaire will be completed.

2. Visual Acuity with CLs: Visual acuity will be measured with a Bailey-Lovie high-contrast chart.

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

4. CL Evaluation: The CLs will be evaluated for centration, movement, and coverage, and lens power adjustments will only be made if they improve Snellen visual acuity.

Visit 3: 1 Month (Primary Endpoint)

1. Stannard Patient Evaluation of Eye Dryness (SPEED): The SPEED questionnaire will be completed.

2. Visual Analog Scale (VAS): The VAS will be completed.

3. Investigator Survey: An exploratory questionnaire that probes topics such as vision, dryness, comfortable wear time, and willingness to continue wearing the contact lenses will be completed.

4. Visual Acuity with CLs: Visual acuity will be measured with a Bailey-Lovie high-contrast chart.

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

6. CL Evaluation: The CLs will be evaluated for centration, movement, and coverage, and lens power adjustments will only be made if they improve Snellen visual acuity.

7. Study Completion: The participants will be compensated for their time, and they will be released from the clinical segment of the study. If participants like the CLs, they will be given a prescription for the CLs, though they will be required to buy their own CLs. The participants will also be educated that they will be called in 6 months to understand their wearing experience if they decide to continue wearing DT1 CLs.

Data Analysis

All data will be analyzed with Stata/IC 15 (StataCorp LLC; TX, USA). The frequency of participants who have comfortable VAS scores will be calculated at both the 1-month (primary outcome) and 6-month visits (exploratory outcome). The frequency of each Likert question and the SPEED will also be calculated.

Training of Study Personnel

Prior to enrolling any participants all examiners will participate in a training session developed by Andrew D. Pucker, OD, PhD. This full investigator meeting will ensure that all study investigators are performing the

procedures in the same manner. Data from each investigator's first participant will also be monitored for quality control by the study's coordinator before the investigator is allowed to see additional participants.

IV. Study Timeline

	2021	2021	2021	2022	2022	2022	2022	2022	2022	2022
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul
Activity										
Contracting										
IRB Preparation										
Data Collection										
Data Analysis										
Final Study Report										

*****An initial analysis of the 1-month data will be conducted by April 2022 while the 6-month data analysis will not occur until July 2022. The investigator's commitment to Alcon will be completed with the 1-month analysis.

V. Publication Plans

An abstract describing the primary outcome will be submitted in May 2022 to Academy 2022 San Diego, and a manuscript on the same topic will be submitted to *Contact Lens & Anterior Eye* after the Academy 2022 San Diego. The abstract will be submitted to the Academy first because the Academy requires that abstract materials have not been presented/submitted elsewhere.

VI. Conclusions

This project will describe the frequency of past CL wearers who can comfortable wear DT1. These data are important because they could provide credence for fitting struggling soft CL patients into DT1, which could help curb the frequency of CL dropout and help grow the CL market.

VII. References

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4. Young G, Veys J, Pritchard N, Coleman S. A multi-centre study of lapsed contact lens wearers. *Ophthalmic Physiol Opt* 2002;22:516-527.
5. Sullivan BD, Crews LA, Sonmez B, et al. Clinical utility of objective tests for dry eye disease: variability over time and implications for clinical trials and disease management. *Cornea* 2012;31:1000-1008.
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