Total30 Sphere Contact Lenses

Study Protocol and Statistical Analysis Plan

NCT05183022

November 17th, 2022

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CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: Do Total30 Sphere Contact Lenses Provide a Comfortable Wearing Experience All Day?

UAB IRB Protocol #: IRB-300008004

Principal Investigator: Andrew D. Pucker, OD, PhD

Sponsor: ALCON RESEARCH, LTD

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to determine if Total30 sphere contact lenses provide a comfortable wearing experience all day.
Duration & Visits	You will be in this study for about 1 month. This study will have 3 in person visits, which will each last about 1 hour. You will also be asked to complete text surveys outside of your study visits.
Overview of Procedures	This study will include eye tests, surveys, eye comfort logs, and the wearing of Total30 sphere contact lenses. You will be asked to wear Tota30 sphere contact lenses for at least 16 hours per day. You will also be asked to complete several surveys via text message designed to gauge your eye comfort.
Risks	The risks of this study do not exceed that of a normal eye exam. The use of all contact lenses comes with a risk of eye irritation or eye infection; however, eye infections with contact lenses are very rare.
Benefits	You may not benefit directly from this study, but knowledge gained from this study could potentially help future persons who have contact lens discomfort.
Alternatives	The only alternative to this study is to not take part in this study and to continue with your regular eye care.

Purpose of the Research Study

We are asking you to take part in a research study. Although there has been several soft contact lens innovations over the past few decades such as the advent of daily disposable contact lenses, about 20% of all contact lens wearers drop out of contact lenses annually. The top reason for dropping out of contact lenses is eye discomfort, which typically gets worse towards the end of the day. This study plans to determine if Total30 sphere contact lenses can provide a comfortable wearing experience all day and for the one-month life of the contact lens. We plan to enroll a total of 58 subjects at the University of Alabama at Birmingham.

Conflict of Interest Disclosure

Dr. Andrew Pucker, the principal investigator for this study, has received consulting fees from the sponsor and from companies other than the sponsor, which may affect his financial interests. If you would like more information, please ask Dr. Pucker.

Study Participation & Procedures

If you agree to participate, you will be asked to come in for 3 in person visits over the course of 1 month, which will each last about 1 hour. You will be asked to complete surveys used to gauge eye comfort, and you will be asked complete the below procedures. The testing listed below is often included in a typical eye exam.

Study Visit 1: Baseline

- **Subject History, Eligibility, Informed Consent:** You will be asked to complete a screening survey to verify that you are eligible for the study. This screening survey will include the Contact Lens Dry Eye-8 Questionnaire (CLDEQ-8), which is a contact lens comfort survey. We will also fully explain this study to you and let you decide if you would like to participate.
- **Visual Acuity with Glasses:** We will evaluate your ability to read the eye chart.
- **Glasses Prescription:** We will determine your glasses prescription with a machine called a phoropter, and we will determine how well you can read the eye chart with this prescription.
- **Slit-Lamp Biomicroscope:** We will use a lighted biomicroscope to document your anterior eye health.
- **Contact Lens Fitting:** We will fit you in Total30 sphere contact lenses, and we will teach you how to use these contact lenses. We will also give you everything you need to take care of the contact lenses.
- **Compliance & Daily Comfort:** We will send you a test text message to make sure they you can complete our virtual comfort surveys. We would like you to wear your contact lenses at least 16 hours per day, and we would like you to start wearing them between 6:00 AM and 8:00 AM on the days that you will be completing the text messaging surveys. You will need to complete the surveys on days 1, 2, 3, 4, 5, 14, and 1 day before your last study visit. We will call you to remind you about the day 14 end last surveys. On the days we ask you to complete surveys, you will need to complete a survey before CL application, directly after CL application, and at 8 hours, 10 hours 12 hours, 14 hours, and 16 hours post lens application. Each survey should not take more than 5 minutes to complete.

Study Visit 2: 1 Week

- **Questionnaires:** We will ask you to complete the CLDEQ-8 questionnaire as well as an investigator designed survey to judge your contact lens wearing experience, eye symptoms, and vision.
- **Visual Acuity with Contact Lenses:** We will evaluate your ability to read the eye chart.
- **Slit-Lamp Biomicroscope:** We will use a lighted biomicroscope to document your anterior eye health.
- **Contact Lens Evaluation:** We will evaluate the fit of your contact lenses. Contact lens adjustments will only be made if they improve your vision on the eye chart. If a contact lens adjustment is made, you will need to repeat the first week of contact lens wear with a new set of contact lenses.

Study Visit 3: 1 month

- **Questionnaire**: We will ask you to complete the CLDEQ-8 questionnaire as well as an investigator designed survey to judge your contact lens wearing experience, eye symptoms, and vision.
- **Visual Acuity with Contact Lenses:** We will evaluate your ability to read the eye chart.
- **Slit-Lamp Biomicroscope:** We will use a lighted biomicroscope to document your anterior eye health.
- **Completion:** You will be compensated for your time, and you will be released from the study.

Additional Information:

Your research data will be stored in a de-identified manner (private information with all identifiers removed). Your de-identified private information may be used for future research studies or distributed to another researcher for future research studies without additional informed consent. **This is only when there are no identifiers associated with the data.**

Risks and Discomforts

This study does not have any inherent risks greater than a normal contact lens exam or contact lens wear. Contact lens wearers may have mild discomfort while wearing their contact lenses. Contact lens wear may lead to red eyes, uncomfortable eyes, temporarily decreased or permeant vision loss, or even an eye infection; however, these issues are very rare if the contact lenses are worn correctly. Ask the study doctor if you have any questions about wearing contact lenses. You will also need to use a contact lens care system to clean your contact lenses (ClearCare). This solution contains hydrogen peroxide, which can burn your eye if you do not use the solution correctly. ClearCare is only safe if it is naturized for 6 or more hours in the provided contact lens case. If used corrected, ClearCare is one of the safest and most effective contact lens care systems in the market. If you have any questions about using ClearCare, please ask the study doctor.

Benefits

You may not benefit directly from taking part in this study. However, knowledge gained from this research will help the medical community better understand if Total30 sphere contact lenses are able to provide all day comfort for contact lens wearers. You will also get the opportunity to try a new contact lens.

Alternatives

Your alternative is to not participate in this study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
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 any 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; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

Who may use and give out this information?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. “Sponsor” includes any persons or companies

that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, as necessary for their operations; the UAB IRB and its staff of *UAB* and its billing agents
- ALCON RESEARCH, LTD

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

<u>Voluntary Participation and Withdrawal</u>

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. However, you should return to see the study doctor for safety reasons so you can be taken off the study drug and referred for follow-up care. Contact the study doctor if you want to withdraw from the study.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study.

Payment for Participation

You will be paid $200 via a Greenphire Clincard at the completion of this 1-month study to compensate you for the time that you devoted to this study. A $100 dollar bonus is available to those who complete at least 90% of the text message surveys. If you do not meet the study's requirements based upon your baseline study visit numbers, you will be compensated $20 for your time. The contact lenses and care products (contact lens case and contact lens solution) used in this study will be provided at no charge. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

Payment for Research-Related Injuries

UAB and Alcon have 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.

New Findings

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. Andrew D. Pucker at (205) 975-9938 or after hours by emailing him at 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.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Signature of Participant Date

_____

Signature of Person Obtaining Consent Date

Do Total30 Sphere Contact Lenses Provide a Comfortable Wearing Experience All Day?

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I. INTRODUCTION & RATIONALE

Contact lens (CL) discomfort affects most CL wearers with discomfort consistently topping the reasons why established CL wearers drop out of CLs.[1] In fact, studies have consistently found that the frequency of CL dropout is around 20% with this dropout frequency staying relatively stable over the past 20 plus years.[1] This static frequency of CL dropout is surprising since there have been a number of dramatic soft CL innovations during this time frame (e.g., widely available daily disposable CLs, silicone hydrogel CL materials with high oxygen transmissibility, new CL surface coatings).[2]

Another common issues that CL wearers frequently face is that their discomfort symptoms increase towards the end of the wear day.[3] This burdensome discomfort can unfortunately cause patients to remove their CLs before their desired wear time.[4] While comfortable wear times vary from patient to patient, Terry et al. has suggested that patients should be able to comfortably wear their CLs for at least 12 hours per day for at least 6 days per week.[5] Nevertheless, the literature currently lacks sufficient data to comment fully on the full day wear experience, which for many patients may be 16 or more hours per day, especially if they have demanding careers. One CL that has the potential to allow for all day comfort is the Total30 Sphere CLs, which is a new water gradient, monthly CL aimed at delivering all day comfort and visual performance. Therefore, the purpose of this study is to map comfort over the full wear day in established, asymptomatic, soft CL wearers who are refit in Total30 Sphere CLs. These data are not only important for judging the performance of Total30 Sphere CLs, but they will provide some of the first insights into the full day CL wearing experience over one month.

II. SPECIFIC AIM

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

> **Aim 1: Determine if Total30 Sphere CLs provide a comfortable wearing experience all day.**
> Hypothesis 1: Patients who are refit in Total30 Sphere CLs will have a comfortable wearing experience after 16 hours as based on visual analog scale (VAS) scores.

III. STUDY DESIGN

Subjects

This one-month, three-visit study will be conducted at the University of Alabama at Birmingham (Birmingham, AL, USA). Subjects will be recruited via clinic records, email, and fliers. Subjects will be screened prior to the study visit with an IRB approved phone screening survey. Adult, 18- to 45-year-old, CL wearers who have 20/20 visual acuity or better and who are minimally symptomatic will be recruited (Contact Lens Dry Eye Questionnaire [CLDEQ]-8 ≤10).[3, 6] Subjects will be required to be able to wear Total30 Sphere CLs, and they will be required to have a smart phone with text messaging capabilities to be able to answer electronic survey questions. Subjects will be required to have astigmatism better than or equal to -0.50 D in each eye, and they will be required to have regularly worn 2 week or monthly CLs within the past 6 months and be a current CL wearer. Subjects will be required to provide a glasses prescription that is less than 3 years old. Subjects will be required to be willing to start wearing their CLs between 6:00 AM and 8:00 AM and wear their CLs until 11:00 PM each day text messaging data is collected. Subjects will be excluded if they are current or past hard CL wearers, 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 active ocular infection or inflammation, are currently using isotretinoin-derivatives or ocular medications, are currently using rewetting drops or artificial tears, or if they are pregnant or breast feeding.[7]

Sample Size

This will be a pilot study to understand CL comfort throughout the day in monthly soft CL wearers. We estimate that 48 subjects will be enough to gain a general understanding of ocular comfort across the entire day based upon past research (40 subjects + 8 subjects to account for attrition and missing data).[8-10] An additional 10 subjects are being requested to account for screen fails; however, recruitment will stop when 48 subjects fully qualify for this study (max of 58 subjects).

Surveys and Clinical Tests

Visit 1: Baseline

1. Subject History, Eligibility, Informed Consent: Subjects will be asked to repeat the IRB approved phone screening survey at the study visit to verify that they are still eligible for the study. All subjects will be screened with the CLDEQ-8 questionnaire regarding their habitual CLs over the past two weeks to verify that they are asymptomatic CL wearers. While subjects will be asked to report to the visit without their CLs, they will be asked to complete the CLDEQ-8 as if they are wearing their habitual CLs. All relevant patient demographics will be collected via a questionnaire developed by the investigators. Non-eligible subjects will be dismissed at this time or rescheduled depending upon the reason for ineligibility. Eligible subjects 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 subject's refractive error with a phoropter, and binocular balance will be performed if best-corrected visual acuity is equal in between eyes.

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: Subject will be fit in Total30 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. Subjects will be given a 1-month supply of CLEAR CARE® CL solution. Subjects will be educated on how to use CLEAR CARE®.

6. Subject Compliance & Daily Comfort: All subjects will be encouraged to wear their CLs for at least 16 hours per day and to start wearing their CLs between 6:00 AM and 8:00 AM on days that they will be completing text messaging surveys. Subjects will be educated that they will be required to complete Qualtrics surveys on their phone. Subjects will be asked to complete a test survey before they leave the first study visit to make sure that they system is compatible with their phone. These surveys will ask subjects about their eye comfort with a visual analog scale (slider scale with 0 as neutral comfort, -50 extremely uncomfortable, and +50 extremely comfortable) at before CL application, directly after CL application, and at 8 hours, 10 hours 12 hours, 14 hours, and 16 hours post lens application on the first 5 days. This same system will be used to monitor how many hours they wear their CLs each day. Subjects will finally be asked to complete these surveys on day 14 and 1 day prior to their 1-month visit (1 month) to understand comfort over the life of the CLs. Subjects will be called the day before the day 14 and 1-month surveys to remind them about these surveys. Subjects will be allowed to schedule their day 14 and 1-month surveys within 3 days of these time points to allow for better compliance.

Visit 2: 1 Week

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

2. 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.

3. 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. If a refractive error adjustment of more than 0.25 D is made, the patient will be given a new set of lenses and be required to repeat the 1-week visit.

Visit 3: 1 Month

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

2. 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.

3. 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. If interested, the patient will be given a prescription for the CLs upon request.

4. Study Completion: The subject will be compensated for their time, and they will be released from the study.

Data Analysis

All data will be analyzed with Stata/IC 15 (StataCorp LLC; TX, USA). VAS comfort scores will serve as the primary endpoint and be reported as percent of patients who are comfortable at each timepoint. Comfort comparisons across visits or across the wear day will serve as exploratory endpoints, and these outcomes will be measured with paired t-tests or ANOVA.

Training of Study Personnel

Prior to enrolling any subjects 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 subject will also be monitored for quality control by the study's coordinator before the investigator is allowed to see additional subjects.

IV. Study Timeline

	2021	2021	2021	2021	2021	2021
	July	Aug	Sep	Oct	Nov	Dec
Activity						
Contracting	■	■				
IRB Preparation	■	■				
Data Collection			■	■	■	
Data Analysis						■
Final Study Report						■

V. Publication Plans

An abstract describing comfort across the wear day will be submitted to Academy 2022 San Diego (main outcome), and an abstract will be submitted to Heart of America Eye Congress describing how comfort changes over the wear month. A manuscript on the same topics will be submitted to *Contact Lens & Anterior Eye* after the Academy 2022 San Diego abstract is submitted because the Academy requires that abstract materials have not been presented/submitted elsewhere.

VI. Conclusions

This project will be among the first to describe the progression of CL comfort throughout the day for Total30 Sphere CLs. These data are important because they could provide insight into end of day CL discomfort, and they will provide data needed for proper patient education.

VII. References

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4. Nichols JJ, Willcox MD, Bron AJ, et al. The TFOS International Workshop on Contact Lens Discomfort: executive summary. *Invest Ophthalmol Vis Sci* 2013;54:TFOS7-TFOS13.

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