FULL PROTOCOL TITLE: An Evaluation of Tangible Boost Replenishing System on the Continued Efficacy of Tangible HydraPEG Rigid Gas Permeable Contact Lens Coating.

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1.0 Objectives

1.1 Describe the purpose, specific aims, and/or objectives.

The goal of this research is to determine if the Tangible Boost system adequately replenishes the HydraPEG coating on the surface of a rigid contact lens. HydraPEG is a soft and rigid contact lens coating, primarily composed of polyethylene glycol, which is covalently bound to the surface of a contact lens. The HydraPEG coating is intended to improve wettability and comfort with rigid lenses, and is currently FDA approved. HydraPEG can be applied to soft or rigid contact lenses, but the coating naturally diminishes from the surface of the lens over time (due to cleaning, and blinking over the surface of the contact lens). Tangible Science, the company that produces HydraPEG, has recently come out with a new product called Tangible Boost, intended to be used every 30 days and replenish the coating on the surface of the lens.

Tangible Boost (also known as HydraPEG Replenish in some of the FDA documents) is a solution composed on the same components of the HydraPEG coating). Essentially, Tangible Boost solution is the HydraPEG coating, it is just in solution that can be used at home by the subjects after the initial HydraPEG is applied at the lens manufacturing lab. The Tangible Boost kit consists of two unit dose HydraPEG solutions (components A and B), as well as a barrel case, and the lens wearers are instructed to empty the two vials into the case and soak their lenses for 30 minutes every 30 days to replenish the coating. This product configuration has been optimized to facilitate ease of use for the patient.

This is a study to evaluate the efficacy of Tangible boost to replenish the HydraPEG coating on rigid gas permeable (scleral and corneal) contact lenses.

1.2 State the hypotheses to be tested.

We hypothesize that the Tangible Boost replenishing system will re-build the HydraPEG coating that naturally diminished from the contact lens surface over time, and improve the comfort and visual performance of HydraPEG coated rigid gas permeable lenses. We anticipate that this be shown by improved patient symptoms and lens wettability after treatment with Tangible Boost.

2.0 Background

2.1 Describe the relevant prior experience and gaps in current knowledge.

Gas permeable rigid contact lenses are commonly used as refractive treatment, for normal individuals, but also specifically for individuals with irregular ocular surfaces that require the rigid lens material to mask irregularities on the front refracting surface of their eye (the cornea). However, these lenses rely on surface treatments and coatings in order to improve their interactions with the front surface of the eye and the tear film, which are very sensitive tissues that can respond negatively to the rigid materials (for example: discomfort, dryness). Several studies have found that reducing the friction between the lens and the surface of the eye (as well as the eyelid) will improve the comfort of the lens while a patient is wearing them. The primary principle behind HydraPEG coating and Tangible Boost replenishing system is that they reduce friction between the lens and the eye surface and eyelids.

Contact lens manufacturers and distributors are continuously developing new products and technology to make the surface of a contact lens more compatible with the ocular surface. HydraPEG is a newly FDA approved coating that is available in the US and Europe, and the Tangible Boost treatment being evaluated here is an important component of maintaining this treatment of the lens surface.

2.2 Describe any relevant preliminary data. Reference previously approved IRB protocols (by number), if applicable.

Hydra-PEG (Ocular Dynamics, Menlo Park, CA) is a contact lens coating designed to improve the lens/ocular surface interface by mimicking the natural tear film's water content and wettability. A previous study done at UH showed that the coating improved comfort and vision when applied to scleral contact lenses. (ID# 16071-01). The Hydra-PEG coating is FDA approved for use as a contact lens coating.

2.3 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

Knowledge gained by this work will increase our understanding of the surface characteristics of rigid lenses and the interaction of the lens surface with the ocular surface.

3.0 Inclusion and Exclusion Criteria

3.1 Describe the specific criteria that define who will be included or excluded in your final study sample. Make sure to include age.

The participant will be eligible to participate if the following criteria apply: 1. Written Informed Consent has been obtained prior to any study-related procedures taking place; 2. Written documentation has been obtained in accordance with the relevant county and local privacy requirements, where applicable (i.e., Written Authorization for Use and Release of Health and Research Study Information to obtain contact lens prescription and wearing information from their medical record should the subject be a patient at the UH College of Optometry); 3. Male or female,18 years of age and older prior to the initial visit; 4. Is an established scleral or corneal rigid contact lens wearer; 5. In the opinion of the investigator, the subject has the ability to follow study instructions; 6. In the opinion of the investigator, the subject has the ability to complete all study procedures and visits.

The participant would not be eligible to participate if at least one of the following criteria is met: 1. Has never worn either scleral or corneal contact lenses before; 2. Does not possess a usable pair of spectacles; 3. Has any ocular disease or abnormality that would affect the wearing of contact lenses; 4. Is aphakic (i.e., missing their natural lens inside the eye); 5. Is currently participating in any other type of eye-related clinical or research study; 6. Is pregnant or nursing as reported by the subject. 7. Has a condition or is in a situation which, in the investigator's opinion, may put the subject at significant risk, may confound study outcomes, or may significantly interfere with the subject's participation in the study. 8. Has a known and self-reported allergy to the following substances: Dextran, polyethylene glycol, hydroxypropyl methylcellulose, or polyvinyl alcohol, which are components of the Tangible Boost and HydraPEG systems. 9. Has had previous ocular surgery within the past 12 weeks.

3.2 Describe how potential subjects will be screened for eligibility based on these criteria.

Subjects will be screened as either corneal or scleral CL wearers prior to coming in for visit 1 of the study, either in person, over email, or over the phone when they show interest in the study. The screening for ability to wear a rigid lens in the study will occur at visit 1 by the investigator, when the subjects are diagnostically fit with a scleral or corneal lens (whichever modality they habitually wear).

3.3 Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the populations listed below as subjects in your research unless you indicate this in your inclusion criteria.)

The following special populations will be excluded from this study:

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers) -
- Pregnant women
- Prisoners

4.0 Vulnerable Populations

4.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

Students may be recruited for participation in this study (if they wear rigid corneal or scleral lenses habitually), and the investigators on this study are instructors in the clinic at UHCO. These investigators will not be the individuals recruiting or obtaining consent from students in their own clinical student group at the time of the study. There will be no influence on grading of any student based on their participation or non-participation in this study.

5.0 Number of Subjects

LOCAL:

5.1 Indicate the total number of subjects to be accrued locally.

A maximum of 40 subjects will be enrolled in this pilot study.

5.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

We expect about a 20% screen fail/drop out rate, so will expect to recruit approximately 35-40 subjects, and the first 30 to be eligible and complete the study will be used for data analysis.

5.3 If not provided in the "study-wide" section, provide justification for the number of subjects. A power analysis is required for research that is more than minimal risk.

This is a low risk study; there are limited data collected in other studies on rigid lens wear with the HydraPEG coating, so the data collected in this preliminary study will be used for future power calculations for larger studies. We chose 30 subjects to allow for an increased likelihood of reaching significance values with a moderate sample size. Further studies with larger sample sizes will likely be indicated if variability is high among the outcomes.

6.0 Recruitment Methods

LOCAL:

6.1 Describe when, where, and how potential subjects will be recruited.

Recruitment will begin once IRB approval has been received, and will occur through The Ocular Surface Institute at UHCO. Subjects will be recruited through the methods described in 6.3, and if a patient is interested in participating in the study, they will be directed to the principal investigator or the study coordinator who will go over the study and ask the screening questions on the eligibility screening document (see appendix). If they are eligible based on the screening criteria, they will be invited for Visit 1 of the study. If the person calls to learn about the study the investigator or coordinator will use the outline to determine initial eligibility.

6.2 Describe the source of subjects.

Our study will involve established rigid contact lens wearers (corneal or scleral). The subject pool will consist of patients who are actively coming through the CL clinic, or individuals who are affiliated with UHCO and/or the UH community (ie. Faculty, students). All established corneal and scleral lens wearers in the community will be given the opportunity to participate in this study. We anticipate that most of our subjects will be from the patient population in the specialty contact lens service at the University Eye Institute at UHCO, which has a high population of rigid lens wearing patients actively coming through the clinic. We will not be doing a chart review and calling patients who are not coming into the clinic. Patients that do not come into the clinic but hear about it by word-of-mouth or through a UHCO affiliate are welcomed to participate.

6.3 Describe the methods that will be used to identify potential subjects.

A recruitment ad will be printed (see appendix) and will be placed on bulletin boards around the UHCO campus (there are specific boards designated for study announcements on the campus), and at the check-in counter at the cornea and contact lens service at the University Eye Institute. In addition, the study coordinator will email a copy of the recruitment ad to the faculty and staff at UHCO (not the entire university). Clinicians working at the UEI may speak to patients and/or give them a copy of the recruitment advertisement to review.

6.4 Describe materials that will be used to recruit subjects.

See appendix for recruitment advertisements to be posted and emailed, and a phone and in-person eligibility screening outline.

7.0 Multi-Site Research Communication – N/A

8.0 Study Timelines

8.1 Describe:

The total duration of the subjects' participation in the study will be approximately 5 months. It is anticipated that to enroll all study subjects it will take approximately 4-6 months. The estimated date for completion of this study is 11-12 months after the start of recruitment.
Visit 1: The total time commitment required is approximately 100 minutes once informed consent has been commenced until the last test is completed.
Visit 2: The total time commitment required is approximately 45 minutes until the last test is completed.
Visit 3: The total time commitment required is approximately 85 minutes until the last test is completed.
Visit 4: The total time commitment required is approximately 25 minutes until the last test is completed.
Visit 5: The total time commitment required is approximately 25 minutes until the last test is completed.

9.0 Study Endpoints

9.1 The primary endpoints in this study are as follows:

- visual acuity
- contact lens comfort questionnaire
- keratograph surface evaluation (tear break up score)
- ocular surface staining

9.2 The secondary endpoints in this study are as follow:

- contact lens fitting characteristics (apical clearance, limbal clearance, scleral landing evaluation)

10.0 Procedures Involved

10.1 Describe and explain the study design.

Once a subject has been identified, the initial visit will be scheduled. During the experimental day, informed consent will be completed, and the subjects will complete the following tasks: (1) an investigator will conduct visual acuity assessments of both eyes (Snellen). (2) The subjects will be asked to complete a survey (on contact lens satisfaction). (3) After the survey, the subject will sit with their lenses for assessment using the Keratograph topographer. (4) After topography, slit lamp assessment of the rigid lenses, and then of the cornea and conjunctiva (after lens removal) with and without Lissamine Green staining will be done.

At visit one, the following additional task will be performed: (1) The subject will be asked to sit for a corneal or scleral lens fitting visit (based on what they wear habitually), where the investigator will fit the subject with a commercially available scleral or corneal lens. All subjects will be refit into the Advanced Vision Technologies (AVT) brand of rigid lenses, manufactured at AVT Technologies in Colorado. If they already wear the AVT brand, the lens parameters will simply be re-ordered. All lenses will undergo a diagnostic fit with an AVT lens. The parameters available at AVT are similar to those available at all other major labs in the US.

A second visit will be to evaluate the fit of the ordered study lenses (which will have been coated with the HydraPEG coating), and will be for the dispense of the lenses. In addition to evaluating the lenses, the subjects will be asked to complete a short survey on their satisfaction with their current lenses. After this visit, the subjects will then wear the lenses for 30 days, on a daily basis as they habitually would, cleaning the lenses with ClearCare hydrogen peroxide cleaning system, a commonly used commercially available soft and rigid contact lens cleaner. After 30 days of lens wear, they will report for visit 3.

At the third visit, the same testing will be performed from visits 1 and 2, the subject will also be given an additional survey regarding the satisfaction with the HydraPEG lenses, and then the Tangible Boost kit or the placebo kit (consisting of

two vials with Unique pH) solutions will be dispensed (randomized) to store their lenses in for 30 minutes that night.

The solution will be dispensed and the subjects trained on its use, and the subjects will be asked to store their lenses in the given solution for 30 minutes that evening, and then transfer their lenses to Unique pH multipurpose rigid lens solution for overnight storage. For the initial training with the Boost or placebo system, the users will undergo an approximately 60-minute user training in which there will be visual and audio recording and still photographs taken in order for a human factors company (Userwise) to analyze the usability of the product. The investigator at the study visit will act as the monitor for the training session. This recorded training step was specifically designed to allow for proper evaluation of the usability of the product, which they will report to the FDA to ensure usability. At the initial visit, the subject will have indicated on the informed consent form whether they agree to participate in the recorded portion of the training. If they do not participate in the recording, they can still be trained and participate in the study.

The subjects will report to the Ocular Surface Institute the next day for Visit 4, at which time the comfort and visit tests will occur again, and an additional survey to evaluate the boost treatment will be given. After visit 4, the subjects will continue to wear the study lenses daily for an additional 60 days, treating their lenses again in the Boost or placebo solution at the midpoint between visit 4 and 5 (30 days after the first treatment with Boost), otherwise cleaning nightly with ClearCare, and will then report to the clinic again 30 days after the midway treatment (approximately 90 days after the initial HydraPEG dispense). The same visit testing will be done at this final and 5th visit, and a final short survey will be done, and then the lenses will be collected from the subjects and sent back to Tangible Science, Inc. for their internal testing of the lenses (no involvement of the UH research team). At this time the study will conclude.

The following table outlines each of the study visits and tells what procedures will be done at each visit:

Procedure	**Length of Time Required for**	**Frequency of Repetition**
VISIT 1: Initial Evaluation		
Informed consent & HIPAA	35 minutes	Once
General History and medications	5 minutes	Once per visit
Visual Acuity	5 minutes	Once per visit

Questionnaires (CLDEQ8 + VAS)	10 minutes	Once per visit
Keratograph Surface Evaluation	5 minutes	Once per visit
Slit-lamp Examination (with lenses on and after lens removal)	10 minutes	Once per visit
Scleral lens / corneal lens fitting	30 minutes	Once
TOTAL TIME	**100 minutes**	
VISIT 2: HydraPEG dispense		
Visual Acuity	5 minutes	Once per visit
Questionnaires (CLDEQ8 + VAS + Secondary VAS for V2)	10 minutes	Once per visit
Keratograph Surface Evaluation	5 minutes	Once per visit
Slit-lamp Examination	5 minutes	Once per visit
Scleral/corneal lens evaluation & dispense. (handling & care paperwork will be dispensed at this visit)	20 minutes	Once
TOTAL TIME	**45 minutes**	
*additional visits may be required to achieve an adequate contact lens fit if the lenses are not acceptable. It is anticipated that the fitting process will take 1-3 visits total (including Visit 1 and 2). The only tasks done at any additional fitting visits will be to evaluate the fit of the lens and make any necessary changes. Follow-up fitting visits are expected to take 15 minutes – for a slit lamp evaluation of the lenses and necessary parameter changes to be determined. Since these are established wearers, we do not anticipate a long fitting process.		
VISIT 3: Tangible Boost Dispense		
Visual Acuity	5 minutes	Once per visit
Questionnaires (CLDEQ8 + VAS + Secondary VAS for V3)	10 minutes	Once per visit
Keratograph Surface Evaluation	5 minutes	Once per visit
Slit-lamp Examination	5 minutes	Once per visit
Tangible Boost kit dispense & training	60 minutes	Once
TOTAL TIME	**85 minutes**	
VISIT 4: Tangible Boost Follow-Up #1		
Visual Acuity	5 minutes	Once per visit
Questionnaires (CLDEQ8 + VAS + Secondary VAS for V4)	10 minutes	Once per visit
Keratograph Surface Evaluation	5 minutes	Once per visit
Slit-lamp Examination	5 minutes	Once per visit

TOTAL TIME	**25 minutes**	
VISIT 5		
Visual Acuity	5 minutes	Once per visit
Questionnaires (CLDEQ8 + VAS + Secondary VAS for V5)	10 minutes	Once per visit
Keratograph Surface Evaluation	5 minutes	Once per visit
Slit-lamp Examination	5 minutes	Once per visit
TOTAL TIME	**25 minutes**	

10.2 Provide a description of all research procedures being performed and when they are performed.

The testing descriptions are summarized in the table below:

Test	Description	Video/Audio recording
General History and Medications	Participants will be asked questions about their general, ocular and medication use histories along with contact lens use history if applicable.	No
Questionnaires	Subjects will be asked to fill out the following questionnaires: • Contact Lens Dry Eye Questionnaire - 8 (CLDEQ – 8) • Visual analog scale (VAS) 0-100 • Secondary VAS scales at Visits 2-5 (unique to each visit) These questionnaires assess the level of eye and/or contact lens discomfort, and assess the subject perception of their habitual lenses and the coated lenses before and after Boost treatment.	No

Scleral/Corneal lens fitting	The examiner will fit the subjects with scleral or corneal contact lenses using commercially available lens fitting sets (AVT scleral and corneal designs, AVT Technologies, CO). The lenses will be fit using the customary fitting procedure, where a diagnostic lens is applied to the eye, an over-refraction is performed, and then customized lenses are ordered with the over-refraction incorporated and any fitting parameters are altered based on the investigators' expertise. Once the lenses are dispensed, the subjects will be reminded of proper handling and cleaning techniques, and given a handout on lens care. In addition, at the 30-day visit subjects will be given instructions on the tangible boost kit or placebo that they are supplied.	No
Scleral/Corneal Lens Evaluation	The ordered rigid lenses will be applied to the eye of the subject by the investigator, after which the fit and vision will be evaluated. At this time, if the fit of the lens is adequate, the lenses will be dispensed. If there are additional parameter changes needed, they will be ordered at this time.	No
Visual Acuity	The participant's vision in each eye will be measured with a high contrast visual acuity chart for the subjects' habitual lenses and the test lenses. The participant will be asked to cover one eye and read the chart, and this procedure will be repeated for the other eye.	No
Slit-lamp Examination	The participant's front portion of each eye and contact lenses will be examined with a lighted microscope. The participant will be asked to place his/her chin on the chinrest and place his/her forehead against the bar and look straight ahead. The instruments light will be shined onto the eye to visualize the ocular surface for approximately 2-3 minutes per eye.	No
Oculus Keratograph	The OCULUS Keratograph® 5M is an advanced corneal topographer with a built-in real keratometer and a color camera optimized for external imaging. It also has a module called the Non-invasive keratograph break-up time, which allows us to evaluate the wettability of the front surface of the lens. The new infrared illumination is not visible to the human eye. This prevents glare during the examination.	No
Lissamine GreenGlo Strips	Individual paper strips, impregnated with 1.5mg of Lissamine Green dye. The dye is attracted to dead cells and irregularities at the ocular surface. These strips are commonly	No

	used in practice as the gold standard for evaluating compromise to superficial corneal or conjunctival tissue. (for this study we will be not be using sodium fluoroecein, which is also sometimes used to assess the tear film).	
Product usability training	Because this is a new product, the company is interested in evaluating the usability of the product based on the instructions in the kits. The subjects will be asked to read the instructions and use the boost product on a pair of dummy lenses without any interference from the investigator. The investigator will act as the monitor, and they will follow the prompts on the instruction sheet (in the appendix) to lead the subjects through the training. The subjects will be recorded, and still photos may be taken. There are prompted questions that the investigator will ask the subjects about their use of the product (see the questions and prompts in the appendix document called Tangible Boost Datasheet). Subjects will be recognizable through the video and audio footage, because the company needs to evaluate facial expressions to observe usability characteristics. This will allow a human factors team at the company to assess how usable the product is based on the packaging and current instructions. See appendix for the Boost kit instructions, as well as the Userwise instruction and prompt sheet.	Yes

Statisical Analysis: Each individual will act as their own control to measure differences in pre and post contact lens measurements (paired non-parametric statistics), and this baseline data will be compared to normative data available for a soft contact lens wearing population. Descriptive statistics will also be employed to evaluate the overall response of the eye to a rigid lens with and without HydraPEG and with and without Tangible Boost.

10.3 What data will be collected, including long-term follow-up?

The following data will be collected in this study:

- visual acuity
- contact lens comfort questionnaire
- keratograph surface evaluation (tear break up score)
- ocular surface staining
- contact lens fitting characteristics (apical clearance, limbal clearance, scleral landing evaluation)

11.0 Setting

11.1 Describe the sites or locations where your research team will conduct the research.

Subjects will be asked to complete measurements at the study visits, which will be conducted in clinical research facilities associated with the University of Houston College Of Optometry. The study visits will take place in The Ocular Surface Institute's research exam rooms in the Health and Biomedical Sciences Building (HBSB).

12.0 Drugs or Devices

Corneal and Scleral lenses are considered class II medical devices by the FDA. All rigid lens materials are FDA approved for use in a rigid contact lens, they are not investigative devices. All lenses will be stored in room 236 of the HBSB at UHCO until time of dispense to the subjects, and only study investigators will have access to the lenses.

The Tangible Boost Replenishing system is not yet FDA approved but is undergoing approval, and the ingredients are all classified under the GRAS (generally recognized as safe) designation through the FDA. The boost system contains the same ingredients as the Hydra-PEG coating that it is designed to replenish. The HydraPEG coating has received approval for use with rigid contact lenses. Full product information regarding the Tangible Boost system, as well as correspondence with the FDA is in the appendix.

13.0 Risks to Subjects

13.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.

Contact lens subject risks are those that are already associated with wearing a contact lens. These risks include developing an abrasion ('cut' on the eye) during lens application or removal, excessive debris accumulation on or beneath the lenses, ocular stinging, redness, itching, or irritation. All contact lens wearers are at risk for developing inflammatory and/or infectious complications during lens wear, but there is no added risk by participating in this study. There are no unforeseeable risks that the investigators can imagine with any of the procedures in this study.

13.2 Describe procedures being performed to monitor subjects for safety

If a subject experiences an adverse event during the duration of the study, they will be instructed to call the study coordinator who will communicate with the investigators to determine the best course of action. If the subject needs to be seen due to an adverse event, a study investigator will examine them and the customary procedure for management will be followed.

13.3 Describe procedures performed to lessen the probability or magnitude of risks.

The investigators will be instructing subjects on the proper handling and care of their lenses, and will instruct the subjects of symptoms of an adverse event and who to call in that case (the coordinator). If an adverse event such as an abrasion occurs during a study visit, the condition will be treated as it is customarily, and the fees associated with treatment will be covered by the study.

14.0 Potential Benefits to Subjects

14.1 Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits.

There is no direct benefit to the subject in participating in this study.

15.0 Provisions to Monitor Data to Ensure the Safety of Subjects – N/A

16.0 Withdrawal of Subjects

16.1 If applicable, describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

Subjects will be withdrawn from the study if they are unable to complete the tasks in the study protocol. In addition, if they experience an adverse event in which the investigator does not feel that the subjects should continue wearing the scleral lenses, they will be withdrawn.

16.2 Describe any procedures for orderly termination.

If a subject is terminated from the study prior to completion, they will still be compensated with the gift cards at the end of each study visit that they attend. They will not be compensated with gift cards for study visits that they do not attend.

16.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.

The data from a subject that withdraws or is terminated from the study will not be included in the analysis.

17.0 Costs/Payments to Subjects

17.1 Describe any costs that subjects may be responsible for due to their participation in the described research.

The only cost that the subjects may be responsible for in this study is the cost of transportation to and from the UEI.

17.2 Describe the amount and timing of any payments or inducements to subjects.

Participants will receive a $20 Amazon.com gift card as compensation for their time at each scheduled visit that is completed (ie. Not paid for unscheduled visits needed to achieve fit if indicated), for a total compensation of $100 if all five study visits are completed. If the subject comes in for a study visit but is ultimately unable to complete the visit after it has begun, they will still be compensated with a $20 gift card. There will be no additional gift cards or compensation given to subjects for coming in for the potential additional fitting visits that may be required if there is a need for additional modifications of the lens to achieve adequate fit and vision.

18.0 Compensation for Research-Related Injury

If there is an ocular injury in this study directly related to the use of the contact lenses and the cleaning systems, treatment for the injury and any subsequent referrals will be covered by the study. The subject will not receive any direct compensation. If there is an unrelated or non-ocular injury during a subject's enrollment in the study, it will not be covered by the study.

19.0 Confidentiality

19.1 Describe the local procedures for maintenance of confidentiality.

The subject ID worksheet, informed consent, subject surveys, and examiner worksheets will all be kept in a single binder, locked in the data collection office at The Ocular Surface Institute. The informed consent forms and the subject ID worksheet will be kept in a separate binder from the study data. The video and audio information, as well as the questions asked regarding the use of the Tangible Boost system, will be sent to UserWise for analysis. Video and audio data will be uploaded to a secure drop box which has limited access to appointed personnel at Tangible Science and UserWise. This video and audio data will then be

transferred to either a portable hard drive at UserWise or a limited access server that is accessible only to employees who need it for writing the report. Once the report is written, this hard drive is stored in a locked archive that has limited employee access and electronic records are stored in a limited access server.

At UserWise, employees only have access to copies of the subject data on a need to know basis while writing up the report. Datasheets do not have any participant names on them, only participant numbers. Only participant numbers are used for writing the report and describing use errors. Once the report is written, electronic files are stored in a limited access server and any hard drives with video data are stored in a locked archive that has limited employee access.

19.2 Describe what direct identifiers will be obtained and any coding systems that will be used for study data (and specimens, if applicable). Note that:

At the start of participation in the study, the subject will be assigned a non-identifiable subject ID that will be used for identification on all other documents used in the study. This identification document, which will be the only document that decodes the subject, will be kept in a locked filing bin in a locked room within The Ocular Surface Institute, separate from the informed consent and other study documents. Names, email addresses, and telephone numbers will be recorded in this subject ID worksheet, which will be a paper file kept in the locked office of the principal investigator (Dr. Maria Walker, office 236 in HSB1).

All other exam findings (survey, questionnaire, exam findings) will be recorded on the paper forms and stored in a binder. This binder will be kept locked in the principal investigator's office (Room 236) when not being used to add or remove data collection worksheets.

19.3 Will anyone outside the research team have access to the identifiers?

Only the investigators and necessary UserWise employees will have access to the paper and electronic records kept in this study. UserWise employees will only be given the data needed to perform the usability study (audio, video, questions)

19.4 How long will the key to the study code be maintained? If not destroyed following data collection, provide justification for maintaining.

All study data will remain on UH property within The Ocular Surface Institute for a minimum of 3 years following study completion. The link will be maintained to allow pertinent regulatory or government agencies to inspect the data and ensure that subjects participated in the study. In addition, Userwise may keep the recording indefinitely and may use the data for other medical research involving the product or subsequent products by the study sponsor.

The principal investigator will be responsible for maintaining study data security and subject confidentiality.

19.5 If audiotaping is conducted, will the recordings be destroyed upon transcription? If not, provide justification.

N/A

20.0 Provisions to Protect the Privacy Interests of Subjects

20.1 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

We will ensure that all data is maintained with confidentiality and will assure subjects of this when they begin the study. If subjects are not comfortable with disclosing any of the information that is asked in the study, they will not be pressured to disclose, but they may not be able to participate if the withholding prevents us from screening or determining eligibility in the study. All PHI (DOB, name, health information) will be stored in the locked office of the Principal Investigator (Dr. Maria K. Walker, Room 236, HSB1). The videos, audio, and photographs taken for UserWise to evaluate the usability of the product will allow identification of subjects, and they will be informed of this when they sign the IC. However, the UserWise company will receive the data in a secure transmission and the data will be viewed on a need-to-know basis by employees of the company. If subjects are uncomfortable with being identifiable to UserWise employees, they can opt out of the recordings in the training and will still be able to participate.

20.2 Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

Subjects will only be asked questions that are relevant to the study and their ocular health. The investigators, who are all optometrists at the UEI that regularly see patients and communicate about potentially sensitive information, have been trained to develop proper rapport with patients and study subjects. All investigators will make every effort to avoid seeming intrusive when asking the subjects questions.

21.0 Informed Consent Process

Informed consent must be obtained from all subjects, unless a waiver or alteration is approved by the IRB (see below).

21.1 Indicate whether you will you be obtaining consent, and if so describe:

Informed consent will be obtained before any testing is done. The subject will be provided an informed consent document written in non-technical language. The study staff will review the document with the subject and will give the subject adequate time to review the form and ask any questions before deciding whether to participate. After answering any questions, the study staff will invite the subject to participate in the study and will have the subject sign the consent form. The investigators and key personnel associated with the informed consent process are trained to not influence the participant in their decision to participate in the research or not. The individual may choose not to sign the consent form without any coercion from the study personnel. Students will be informed that their participation is voluntary and will not affect their academic standing. Staff and faculty will also be informed that their participation is voluntary and will not affect their employment status. Non-participation in the study from patients will not impact future care. See the Informed Consent document in the appendix. Informed consent is estimated to take approximately 35 minutes for this study.

22.0 Process to Document Consent in Writing

We will be following "SOP: Written Documentation of Consent (HRP-091)."

23.0 HIPAA

The HIPAA AUTHORIZATION form is attached.

24.0 FERPA – N/A

25.0 Data Management

25.1 Describe the data analysis plan, including any statistical procedures.

Data will be stored in a study paper file. Paper files will be kept in a filing cabinet within The Ocular Surface Institute (Health and Biomedical Sciences Building). Electronic data will be stored on a password-protected computer in a locked office in rooms 232, 236 or 250 within The Ocular Surface Institute of the Health Biological Sciences Building (HBSB). All study data will remain on UH property within The Ocular Surface Institute for a minimum of 3 years following study completion. The principal investigator will be

responsible for maintaining study data security and subject confidentiality, and the PI and the study coordinator will be responsible for receipt and transmission of the data. The investigative team, study sponsor and inspectors from regulatory agencies such as the US Food and Drug Administration will have access to the data if requested for study monitoring or an audit.

All collected data will be documented on study documents and analyzed for differences between baseline and test data. Hypothesis testing will be performed using statistical analyses including parametric or nonparametric comparisons (i.e., t-tests, signed-rank tests), analysis of variance, general linear models, correlation, or regression techniques.

The recorded audio and video data will be sent to UserWise for analysis of the usability of the product.

26.0 Specimen Use and Banking – N/A

27.0 Community-Based Participatory Research – N/A

28.0 Sharing of Results with Subjects

28.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others.

Study results will not be shared with subjects, unless the investigator feels that the subject should know something about the ocular health of their eye as a result of the study.

29.0 Resources

29.1 Describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform your/their roles.

All investigators in this study are Optometrists, and are qualified to examine subjects and evaluate the performance of the contact lenses. The investigators all have experience working within The Ocular Surface Institute, and with all the exam rooms, equipment, and data storage rooms. All investigators have completed the necessary training for good clinical practices, and are specialists in corneal and scleral lens fitting and management. The study coordinator is an experienced coordinator at TOSI whose primary role is to coordinate studies such as this one.

She is also trained on IRB practices and is experienced with informed consent processes and confidentiality.

29.2 Describe other resources available to conduct the research: For example, as appropriate:

We do not expect to have difficulty recruiting subjects in this study. Most of our subjects will come from the patients in the clinic at the University Eye Institute at UHCO. We estimate that we have access to about 200 potential subjects that we expect to fit our eligibility criteria.

30.0 Additional Approvals

- N/A

Eligibility Screening /Recruitment Script for the Tangible Boost Study

Once the patient has specified that they are interested in obtaining more information about the study, the investigator will give an overview of the study, including all of the following points:

- The purpose of this study is to compare the vision and comfort differences between rigid lenses that are coated with HydraPEG and treated with Tangible Boost replenishing system, and those that are coated and treated with the placebo system.
- HydraPEG is a new coating that is bonded to regular contact lenses and may improve comfort and vision with rigid contact lenses. HydraPEG is composed of approximately 90% water, and the remaining components are wetting and viscosity agents that are used in several eye drops to improve wettability and tear film surface integrity. This coating is approved by the FDA, but it is known to deplete over time. The new Tangible Boost system is a solution that coated lenses will be stored in overnight every 30 days, in order to replenish the coating.
- We are recruiting patients who are habitual wearers of rigid contact lenses (either scleral or corneal)

After giving a brief overview of the study, the investigator will ask the potential subject:

1. Are you interested in hearing about what your role would be if you qualify for the study?

Yes (move on) No (stop)

- If you decide to be a subject in this study, you will be asked to come in to the University Eye Institute on approximately 5 occasions, over a period of about 5 months.
- The initial visit is so that we can evaluate your current lenses, and have you fit with the study lenses.
- When you arrive that first day, a series of images will be taken of your habitual lenses, and the lenses will be removed so that you can try on the study lenses to be sure they fit properly and offer you good vision.
- At the second visit, the lenses will have been ordered and coated with the HydraPEG coating. At this time, if the lenses are not adequate we will have to re-order the study lenses, so you will not be given them that day. If this is the case, you will be asked to return for an additional visit to evaluate and dispense the re-ordered study lenses.

- After the visit in which the study lenses are deemed dispensable, you will wear the study lenses, cleaning and storing them with Unique pH cleaning system, for 30 days.
- After 30 days, you will be asked to come in for the third visit, similar to the initial Visit. When you arrive for the 3rd visit you will have the same vision and image testing done that was done at the initial visit. You will then be given a solution to store your lenses in overnight – you will be given either the tangible boost replenishing system, or the placebo (unique pH) – which you will be asked to store your lenses in that evening.
- The day after the boost dispense, you will return to the ocular surface institute to go through the same evaluation of the lenses that you underwent at the previous visit. At that point you will be asked to wear your lenses for another 60 days (storing your lenses in the test solution at the midpoint 30 days between).
- You will be asked to come in for the 5th and final visit approximately 90 days after you initially are given the HydraPEG lenses. At this point the same testing will be done, and then you will be asked to return the lenses to the investigators and the study will end.

After giving the potential subject an overview of their role in the study, the investigator will ask:

Q1. Do you wear rigid contact lenses as your primary mode of vision correction? (if yes, continue to Q2)

Yes No

Q2. Do you have any eye conditions that you know of?

Yes No

If yes, name them:

_____

note: patients will probably name the condition that they are being prescribed rigid lenses to treat. These conditions are allowed; exclusions are only if the patient has other ocular disease that could confound the data.

Q3: Do you have any allergies to eye drops that you are aware of? Additionally, do you know of any allergies you have to the following substances: Dextran, polyethylene glycol, hydroxypropyl methylcellulose, or polyvinyl alcohol?

Yes No

If no to both parts, continue to Q4.

Q4: As far as you know, are you allergic to Unique pH multipurpose GP lens cleaner?

Yes No

If no, they qualify for the study.

At this point, if the patient is still interested in participating in the study, the investigator can begin the formal Informed Consent process.

Instructions for Contact lens Handling:

- Clean lenses with **Unique pH**
- Store lenses in **Unique pH**
- Rinse lenses (if needed) with **Purilens or Unique pH**
- **Do not use tap water on lenses**

Patient Survey: Lens Dispense Visit

Patient ID:

Date:

Visit #:

Please rate on the scale below how comfortable your habitual lenses are **upon insertion on an average day**?

extremely uncomfortable — extremely comfortable

Please rate on the scale below how comfortable your habitual lenses are **at the end of the day on an average day**?

extremely uncomfortable — extremely comfortable

Please rate on the scale below what the quality of your vision is on an average day with your habitual lenses?

Poor vision, unable to function — Excellent vision, no awareness of blue

On average, how many hours each day can you comfortably wear your habitual lenses? _____

Comments:

Patient Survey: Boost Dispense Visit

Patient ID:

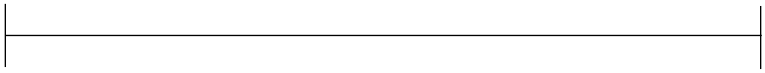
Date:

Visit #:

Please rate on the scale below how comfortable the Hydra-PEG study lenses are **upon insertion on an average day**?

extremely uncomfortable — extremely comfortable

Please rate on the scale below how comfortable the Hydra-PEG study lenses are **at the end of the day on an average day**?



extremely uncomfortable — extremely comfortable

Please rate on the scale below what the quality of your vision is on an average day with the Hydra-PEG study lenses?

Poor vision, unable to function — Excellent vision, no awareness of blue

On average, how many hours each day can you comfortably wear the Hydra-PEG study lenses?

_____

Comments:

Patient Survey: Initial Boost Follow-Up Visit

Patient ID:

Date:

Visit #:

Please rate on the scale below how comfortable the study lenses were **upon insertion today**?

extremely uncomfortable

extremely comfortable

Please rate on the scale below what the quality of your vision **today** with the study lenses?

Poor vision, unable to function

Excellent vision, no awareness of blue

Do you prefer the current Hydra-PEG lenses or your habitual lenses that you wore prior to this study (circle one)?

Hydra-PEG lenses Habitual lenses No preference

Did you prefer the Hydra-PEG lenses before or after the Boost treatment (circle one)?

Hydra-PEG lenses pre-Boost Hydra-PEG lenses post-Boost No preference

Comments:

Patient Survey: Final Boost Follow-Up Visit

Patient ID:

Date:

Visit #:

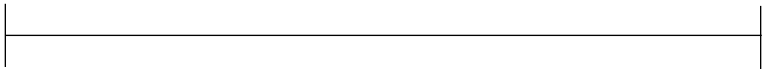
Please rate on the scale below how comfortable the study lenses are **upon insertion on an average day**?

extremely uncomfortable — extremely comfortable

Please rate on the scale below how comfortable the study lenses are **at the end of the day on an average day**?

extremely uncomfortable — extremely comfortable

Please rate on the scale below what the quality of your vision is on an average day with the study lenses?



Poor vision, unable to function — Excellent vision, no awareness of blue

Do you prefer the current Hydra-PEG lenses or your habitual lenses that you wore prior to this study (circle one)?

Hydra-PEG lenses Habitual lenses No preference

Did you prefer the Hydra-PEG lenses before or after the Boost treatment (circle one)?

Hydra-PEG lenses pre-Boost Hydra-PEG lenses post-Boost No preference

On average, how many hours per day can you comfortably wear these lenses? _____

Comments:

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Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

VISIT 1

1. **Time of Day** (military time) : ____:____

2. **Signed informed consent & HIPPA:** ☐$_1$ Yes ☐$_2$ No

3. **Ethnicity**
   ☐$_1$ Hispanic or Latino ☐$_2$ Not Hispanic or Latino

4. **Race**
   ☐$_1$ American Indian or Alaskan Native
   ☐$_2$ Asian
   ☐$_3$ Black or African American
   ☐$_4$ Native Hawaiian or Other Pacific Islander
   ☐$_5$ White
   ☐$_6$ Other, specify _____

5. **Birthdate (mm/dd/yy):** ____/____/____

6. **Gender:** ☐$_1$ Male ☐$_2$ Female

7. **Lens Indication:** _____

8. **Lens Type (circle one):** **Scleral** **Corneal**

9. **Duration of lens wear (months/years):** _____

10. **Average # hours lens wear per week:** _____

11. **Hours of lens wear today:** _____

12. **CLDEQ-8**
    a. CLDEQ-8 completed and verified: ☐$_1$ Yes ☐$_2$ No CLDEQ-8 score: _____

13. **VAS scale**
    a. VAS scale completed and verified: ☐$_1$ Yes ☐$_2$ No VAS score: _____

14. **Medications and Medical History**
    a. Current medications or supplements? ☐$_1$ Yes ☐$_2$ No

Examiner Initials: _____

Evaluation of Tangible Boost Replenishing System

b. Was the concomitant medication log completed? ☐1 Yes ☐2 No
c. Medical or ocular conditions? ☐1 Yes ☐2 No
d. Was the medical and ocular history log completed? ☐1 Yes ☐2 No
e. History of ocular surgeries, ocular injections or laser procedures?
☐1 Yes ☐2 No (If No, skip to question 10)
f. Was the surgery more than 12 weeks ago? ☐1 Yes ☐2 No ☐3 N/A
g. Type of ocular surgery and when it occurred? _____ Date: ____ /____ /____

15. Contact lens history

a. Current lens brand
OD _____
OS _____

b. Current lens parameters (if known)

Base curve: _____

SAG: _____

Diameter: _____

Lens Power: _____

Limbal Profile: _____

Landing Zone Profile: _____

c. Did subject wear their own contact lenses 2 days prior to this appointment? ☐1 Yes ☐2 No

16. Visual Acuity with habitual lenses (logMAR): Record # of letters seen

OD: _____ OS: OD: _____

17. Over refraction (spherical only)

OD ___ ___.___
OS ___ ___.___

Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

18. Slit Lamp Evaluation of Habitual Scleral Lenses

OD		OS
_____	Movement	_____
_____	Centration	_____
_____	Apical Clearance	_____
_____	Limbal Clearance	_____
_____	Scleral Landing Zone	_____
_____	Comments	_____

19. Perform Keratograph NIBUT

OD: NIKf-BUT "until blink" (first break up) _____
NIKavg-BUT "until blink" (average break up)_____
Level: _____

NIKf-BUT "25 seconds" (first break up) _____
NIKavg-BUT "25 seconds" (average break up)_____
Level: _____

OS: NIKf-BUT "until blink" (first break up) _____
NIKavg-BUT "until blink" (average break up)_____
Level: _____

NIKf-BUT "25 seconds" (first break up) _____
NIKavg-BUT "25 seconds" (average break up)_____
Level: _____

20. Slit lamp exam (after lens removal)

OD		OS
_____	Lids and lashes	_____
_____	Conjunctiva	_____
_____	Sclera	_____
_____	Cornea	_____
_____	Iris	_____
_____	Anterior Chamber	_____

Examiner Initials: _____

Subject: _____

Date: _____/_____/_____

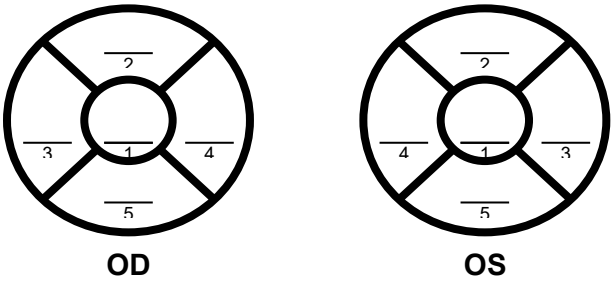
Evaluation of Tangible Boost Replenishing System

_____ Lens _____

21. Eyelid Eversion (GPC grade level: Efron Scale, circle for each eye)

OD:	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
OS:	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4

22. Corneal Fluorescein Staining:
(Efron Scale for each quadrant: 0-4 grading in each quadrant, total score range 0-20)



TOTAL Score: OD _____ OS _____

If subject is wearing scleral lenses, refit with diagnostics, if wearing corneal, order base curve and power based on their habitual lenses and any appreciative OR

23. Diagnostic Fitting with Study Lenses (Scleral Only):

a. Final Diagnostic Lens Parameters

Base curve: _____

Diameter: _____

Lens Power: _____

Limbal Profile: _____

Landing Zone Profile: _____

Examiner Initials: _____

Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

b. Slit Lamp Evaluation of Diagnostic Scleral Lenses

OD		**OS**
_____	Movement	_____
_____	Centration	_____
_____	Apical Clearance	_____
_____	Limbal Clearance	_____
_____	Scleral Landing Zone	_____
_____	Comments	_____

c. Over-refraction of diagnostic scleral lenses

OD: _____ OS: _____

d. Final Visual Acuity with Study Lenses (logMAR): Record # of letters seen

OD: _____ OS: OD: _____

e. Final trial lenses to be ordered:

Base curve: _____

SAG: _____

Diameter: _____

Lens Power: _____

Limbal Profile: _____

Landing Zone Profile: _____

a. **Contact lens order form filled out?** ☐$_1$ Yes ☐$_2$ No

b. **Gift card given?** ☐$_1$ Yes ☐$_2$ No

c. Appointment 2 scheduled? ☐$_1$ Yes ☐$_2$ No

d. Appointment 2 date/time: _____

Examiner Initials: _____

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Subject: ________________

Date: ______/_______/______

Evaluation of Tangible Boost Replenishing System

Concomitant Medication Log (include supplements)

Medication	Dose	Units	Freq	Route	Dates of use	Reason
		☐1 mg ☐2 mcg ☐3 mL ☐4 tab ☐5 other ________	☐1 qd ☐2 bid ☐3 tid ☐4 qid ☐5 prn ☐6 other ________	☐1 po ☐2 SC ☐3 IM ☐4 IV ☐5 topical ☐6 other _______	___/___/___ to ___/___/___ ☐ current	☐1 Dx Med Condition ☐2 Acute Condition ☐3 Prophylaxis ☐4 Supplement ☐5 other: ___________
		☐1 mg ☐2 mcg ☐3 mL ☐4 tab ☐5 other ________	☐1 qd ☐2 bid ☐3 tid ☐4 qid ☐5 prn ☐6 other ________	☐1 po ☐2 SC ☐3 IM ☐4 IV ☐5 topical ☐6 other _______	___/___/___ to ___/___/___ ☐ current	☐1 Dx Med Condition ☐2 Acute Condition ☐3 Prophylaxis ☐4 Supplement ☐5 other: ___________
		☐1 mg ☐2 mcg ☐3 mL ☐4 tab ☐5 other ________	☐1 qd ☐2 bid ☐3 tid ☐4 qid ☐5 prn ☐6 other ________	☐1 po ☐2 SC ☐3 IM ☐4 IV ☐5 topical ☐6 other _______	___/___/___ to ___/___/___ ☐ current	☐1 Dx Med Condition ☐2 Acute Condition ☐3 Prophylaxis ☐4 Supplement ☐5 other: ___________
		☐1 mg ☐2 mcg ☐3 mL ☐4 tab ☐5 other ________	☐1 qd ☐2 bid ☐3 tid ☐4 qid ☐5 prn ☐6 other ________	☐1 po ☐2 SC ☐3 IM ☐4 IV ☐5 topical ☐6 other _______	___/___/___ to ___/___/___ ☐ current	☐1 Dx Med Condition ☐2 Acute Condition ☐3 Prophylaxis ☐4 Supplement ☐5 other: ___________

Examiner Initials: _________

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Subject: ________________

Date: ______/_______/______

Evaluation of Tangible Boost Replenishing System

Medical and Ocular History Log (include Dry Eye and Meibomian Gland Dysfunction)

Condition	Date of diagnosis	Current tx (check all that apply)	State of Condition
	___/___/___ to ___/___/___ ☐ currently being tx	☐1 Medication ☐2 Diet/Exercise ☐3 Monitor ☐4 Therapy (PT, OT, psych) ☐5 surgery/chemo ☐6 behavioral change ☐7 Impending Dx ☐8 other: ___________	☐1 controlled and stable ☐2 currently working with doctor for improvement ☐3 trying new medication ☐4 impending sx/chemo
	___/___/___ to ___/___/___ ☐ currently being tx	☐1 Medication ☐2 Diet/Exercise ☐3 Monitor ☐4 Therapy (PT, OT, psych) ☐5 surgery/chemo ☐6 behavioral change ☐7 Impending Dx ☐8 other: ___________	☐1 controlled and stable ☐2 currently working with doctor for improvement ☐3 trying new medication ☐4 impending sx/chemo
	___/___/___ to ___/___/___ ☐ currently being tx	☐1 Medication ☐2 Diet/Exercise ☐3 Monitor ☐4 Therapy (PT, OT, psych) ☐5 surgery/chemo ☐6 behavioral change ☐7 Impending Dx ☐8 other: ___________	☐1 controlled and stable ☐2 currently working with doctor for improvement ☐3 trying new medication ☐4 impending sx/chemo

Examiner Initials: __________

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Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

VISIT 2

1. **Time of Day** (military time) : ____:____

2. **Hours of lens wear today: _____**

3. **Current Cleaning solution: _____**

4. **CLDEQ-8**
   a. CLDEQ-8 completed and verified: ☐1 Yes ☐2 No CLDEQ-8 score: _____

5. **VAS scale**
   a. VAS scale completed and verified: ☐1 Yes ☐2 No VAS score: _____
   b. VAS supplemental completed and verified: ☐1 Yes ☐2 No

6. **Medications**
   a. Any changes in medications? ☐1 Yes ☐2 No
   b. If yes, please specify:_____

*Note: Habitual lens fit does not need to be re-evaluated at this visit. They may be removed without evaluation.

7. **Slit lamp exam (after lens removal)**

OD		OS
_____	Lids and lashes	_____
_____	Conjunctiva	_____
_____	Sclera	_____
_____	Cornea	_____
_____	Iris	_____
_____	Anterior Chamber	_____
_____	Lens	_____

8. **Corneal Fluorescein Staining**
   (Efron Scale for each quadrant: 0-4 grading in each quadrant, total score range 0-20)

Examiner Initials: _____

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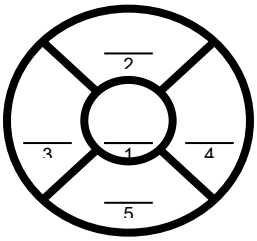
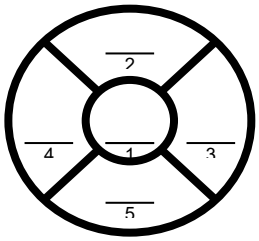
Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System



OD



OS

TOTAL Score: OD _____ OS _____

9. Fitting with Study Lenses:

a. Visual Acuity with Study Lenses (logMAR): Record # of letters seen

OD: _____ OS: OD: _____

b. Over refraction

OD _____
OS _____

c. Slit Lamp Evaluation of Study Lenses

OD		OS
_____	Movement	_____
_____	Centration	_____
_____	Apical Clearance	_____
_____	Limbal Clearance	_____
_____	Scleral Landing Zone	_____
_____	Comments	_____

10. Comments and suggested changes to lens parameters:

11. Need for New Lens order? ☐1 Yes ☐2 No ☐3 Maybe

Examiner Initials: _____

Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

12. New lenses to be ordered (if applicable, if not leave blank):

Base curve: _____

SAG: _____

Diameter: _____

Lens Power: _____

Limbal Profile: _____

Landing Zone Profile: _____

13. Keratograph performed (only if lenses are dispensable)? ☐1 Yes ☐2 No

14. Perform Keratograph NIBUT

OD: NIKf-BUT "until blink" (first break up) _____
NIKavg-BUT "until blink" (average break up)_____
Level: _____

NIKf-BUT "25 seconds" (first break up) _____
NIKavg-BUT "25 seconds" (average break up)_____
Level: _____

OS: NIKf-BUT "until blink" (first break up) _____
NIKavg-BUT "until blink" (average break up)_____
Level: _____

NIKf-BUT "25 seconds" (first break up) _____
NIKavg-BUT "25 seconds" (average break up)_____
Level: _____

15. Contact lens order form filled out? ☐1 Yes ☐2 No ☐3 Not Applicable

16. Gift card given? ☐1 Yes ☐2 No

17. Dispensed Lenses? ☐1 Yes ☐2 No

Examiner Initials: _____

Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

18. Dispensed Unique pH? ☐$_1$ Yes ☐$_2$ No

19. Dispensed DMV? ☐$_1$ Yes ☐$_2$ No

20. Dispensed PuriLens? ☐$_1$ Yes ☐$_2$ No

21. Lens Dispense log filled out? ☐$_1$ Yes ☐$_2$ No

22. Follow up appt made (30 days and +1 day)? ☐$_1$ Yes ☐$_2$ No

23. Follow up appt dates: Appt 4 date: _____

Appt 5 date: _____

Examiner Initials: _____

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Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

VISIT 3

1. **Time of Day** (military time) : ____:____

2. **Hours of Rigid lens wear today: _____**

3. **Current Cleaning solution: _____**

4. **Currently wearing study lenses?** ☐1 Yes ☐2 No

5. **CLDEQ-8**
   a. CLDEQ-8 completed and verified: ☐1 Yes ☐2 No CLDEQ-8 score: _____

6. **VAS scale**
   a. VAS scale completed and verified: ☐1 Yes ☐2 No VAS score: _____

   b. Extended VAS scale completed: ☐1 Yes ☐2 No insertion: _____
   ☐1 Yes ☐2 No removal: _____
   ☐1 Yes ☐2 No vision: _____
   ☐1 Yes ☐2 No Hrs Score: _____

7. **Medications**
   a. Any changes in medications? ☐1 Yes ☐2 No
   b. If yes, please specify:_____

8. **Visual Acuity with Study Lenses (logMAR): Record # of letters seen**

   OD: _____ OS: _____

9. **Over refraction (spherical only)**
   OD _____
   OS _____

10. **Slit Lamp Evaluation of Study Lenses**

OD		**OS**
_____	Movement	_____
_____	Centration	_____
_____	Apical Clearance	_____

Examiner Initials: _____

Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

_____	Limbal Clearance	_____
_____	Scleral Landing Zone	_____
_____	Comments	_____

11. Perform Keratograph NIBUT

OD: NIKf-BUT "until blink" (first break up) _____
NIKavg-BUT "until blink" (average break up)_____
Level: _____

NIKf-BUT "25 seconds" (first break up) _____
NIKavg-BUT "25 seconds" (average break up)_____
Level: _____

OS: NIKf-BUT "until blink" (first break up) _____
NIKavg-BUT "until blink" (average break up)_____
Level: _____

NIKf-BUT "25 seconds" (first break up) _____
NIKavg-BUT "25 seconds" (average break up)_____
Level: _____

12. Are lenses still adequate to be worn? ☐$_1$ Yes ☐$_2$ No

If no, please indicated parameter changes indicated below:

13. Tangible Boost Training and Video recording

a. **Video file name (camera)** _____
b. **Video file name (go-pro)** _____
c. **Videos uploaded to share drive?** ☐$_1$ Yes ☐$_2$ No

Examiner Initials: _____

Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

d. Videos uploaded to Dropbox? ☐1 Yes ☐2 No

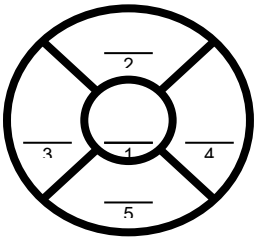
14. Tangible Boost or Placebo Kit Training

a. Boost/Placebo dispensed? ☐1 Yes ☐2 No
b. Boost Log form filled out? ☐1 Yes ☐2 No
c. Boost Lot #: _____

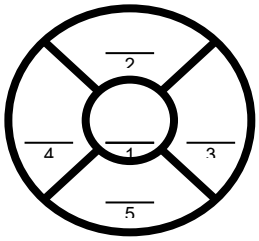
15. Removal of lenses and Slit lamp exam (after lens removal)

OD		OS
_____	Lids and lashes	_____
_____	Conjunctiva	_____
_____	Sclera	_____
_____	Cornea	_____
_____	Iris	_____
_____	Anterior Chamber	_____
_____	Lens	_____

16. Corneal Fluorescein Staining (0-4 grading)



OD



OS

TOTAL Score: OD _____ OS _____

17. Dispensed Unique pH? ☐1 Yes ☐2 No

18. Dispensed DMV? ☐1 Yes ☐2 No

19. Dispensed PuriLens? ☐1 Yes ☐2 No

Examiner Initials: _____

Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

20. **Gift card given?** ☐$_1$ Yes ☐$_2$ No

21. **Follow up appt in 1 day?** ☐$_1$ Yes ☐$_2$ No

22. **Follow up appt date: _____**

Examiner Initials: _____

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Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

VISIT 4

1. **Time of Day** (military time) : ____:____

2. **Hours of lens wear today: _____**

3. **Current Cleaning solution: _____**

4. **Currently wearing study lenses?** ☐$_1$ Yes ☐$_2$ No

5. **CLDEQ-8**
   a. CLDEQ-8 completed and verified: ☐$_1$ Yes ☐$_2$ No CLDEQ-8 score: _____

6. **VAS scale**
   a. VAS scale completed and verified: ☐$_1$ Yes ☐$_2$ No VAS score: _____

   b. Extended VAS scale completed: ☐$_1$ Yes ☐$_2$ No insertion: _____
   ☐$_1$ Yes ☐$_2$ No removal: _____
   ☐$_1$ Yes ☐$_2$ No vision: _____
   ☐$_1$ Yes ☐$_2$ No Hrs Score: _____

7. **Medications**
   a. Any changes in medications? ☐$_1$ Yes ☐$_2$ No
   b. If yes, please specify:_____

8. **Visual Acuity with Study Lenses (logMAR): Record # of letters seen**

   OD: _____ OS: _____

9. **Over refraction (spherical only)**
   OD _____
   OS _____

Examiner Initials: _____

UNIVERSITY of HOUSTON
THE OCULAR SURFACE INSTITUTE

Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

10. Slit Lamp Evaluation of Study Lenses

OD		OS
_____	Movement	_____
_____	Centration	_____
_____	Apical Clearance	_____
_____	Limbal Clearance	_____
_____	Scleral Landing Zone	_____
_____	Comments	_____

11. Perform Keratograph NIBUT

OD: NIKf-BUT "until blink" (first break up) _____
NIKavg-BUT "until blink" (average break up)_____
Level: _____

NIKf-BUT "25 seconds" (first break up) _____
NIKavg-BUT "25 seconds" (average break up)_____
Level: _____

OS: NIKf-BUT "until blink" (first break up) _____
NIKavg-BUT "until blink" (average break up)_____
Level: _____

NIKf-BUT "25 seconds" (first break up) _____
NIKavg-BUT "25 seconds" (average break up)_____
Level: _____

12. Slit lamp exam (after lens removal)

OD		OS
_____	Lids and lashes	_____
_____	Conjunctiva	_____
_____	Sclera	_____
_____	Cornea	_____
_____	Iris	_____
_____	Anterior Chamber	_____
_____	Lens	_____

Examiner Initials: _____

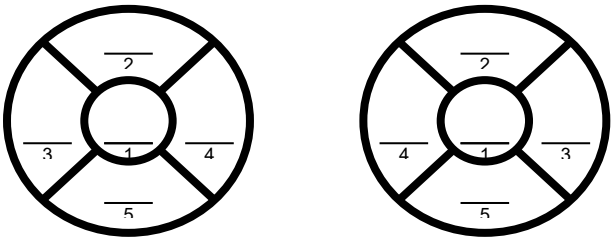
UNIVERSITY of HOUSTON
THE OCULAR SURFACE INSTITUTE

Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

13. Corneal Fluorescein Staining (0-4 grading)



OD **OS**

TOTAL Score: OD _____ OS _____

14. Are lenses still adequate to be worn? ☐1 Yes ☐2 No

If no, please indicated parameter changes indicated below:

15. Gift card given? ☐1 Yes ☐2 No

16. Dispensed Unique pH? ☐1 Yes ☐2 No

17. Dispensed DMV? ☐1 Yes ☐2 No

18. Dispensed PuriLens? ☐1 Yes ☐2 No

19. Follow up appt made (60 days)? ☐1 Yes ☐2 No

20. Call-log filled out for 30 days (reminder)? ☐1 Yes ☐2 No

21. Follow up appt date: _____

Examiner Initials: _____

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THE OCULAR SURFACE INSTITUTE

Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

VISIT 5

1. **Time of Day** (military time) : ____:____

2. **Hours of Rigid lens wear today: _____**

3. **Current Cleaning solution: _____**

4. **Currently wearing study lenses?** ☐$_1$ Yes ☐$_2$ No

5. **CLDEQ-8**
   a. CLDEQ-8 completed and verified: ☐$_1$ Yes ☐$_2$ No CLDEQ-8 score: _____

6. **VAS scale**
   a. VAS scale completed and verified: ☐$_1$ Yes ☐$_2$ No VAS score: _____

   b. Extended VAS scale completed: ☐$_1$ Yes ☐$_2$ No insertion: _____
   ☐$_1$ Yes ☐$_2$ No removal: _____
   ☐$_1$ Yes ☐$_2$ No vision: _____
   ☐$_1$ Yes ☐$_2$ No Hrs Score: _____

7. **Medications**
   a. Any changes in medications? ☐$_1$ Yes ☐$_2$ No
   b. If yes, please specify:_____

8. **Visual Acuity with Study Lenses (logMAR): Record # of letters seen**

   OD: _____ OS: _____

9. **Over refraction (spherical only)**
   OD _____
   OS _____

Examiner Initials: _____

UNIVERSITY of HOUSTON
THE OCULAR SURFACE INSTITUTE

Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

10. Slit Lamp Evaluation of Study Lenses

OD		OS
_____	Movement	_____
_____	Centration	_____
_____	Apical Clearance	_____
_____	Limbal Clearance	_____
_____	Scleral Landing Zone	_____
_____	Comments	_____

11. Perform Keratograph NIBUT

OD: NIKf-BUT "until blink" (first break up) _____
NIKavg-BUT "until blink" (average break up)_____
Level: _____

NIKf-BUT "25 seconds" (first break up) _____
NIKavg-BUT "25 seconds" (average break up)_____
Level: _____

OS: NIKf-BUT "until blink" (first break up) _____
NIKavg-BUT "until blink" (average break up)_____
Level: _____

NIKf-BUT "25 seconds" (first break up) _____
NIKavg-BUT "25 seconds" (average break up)_____
Level: _____

12. Slit lamp exam (after lens removal)

OD		OS
_____	Lids and lashes	_____
_____	Conjunctiva	_____
_____	Sclera	_____
_____	Cornea	_____
_____	Iris	_____
_____	Anterior Chamber	_____
_____	Lens	_____

Examiner Initials: _____

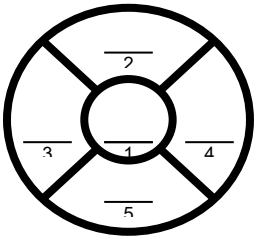
UNIVERSITY of HOUSTON
THE OCULAR SURFACE INSTITUTE

Subject: _____

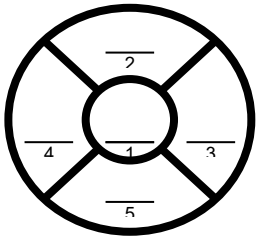
Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

13. **Corneal Fluorescein Staining** (0-4 grading)



OD



OS

TOTAL Score: OD _____ OS _____

14. **Gift card given?** ☐$_1$ Yes ☐$_2$ No

Examiner Initials: _____

UNIVERSITY of HOUSTON
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Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

OPTIONAL VISIT FOR LENS RE-FITTING (TO BE USED IF THERE ARE FOLLOW-UP VISITS NEEDED FOR PROPER LENS FIT)

1. **Time of Day** (military time) : ____:____

2. **Hours of Rigid lens wear today: _____**

3. **Current Cleaning solution: _____**

4. **Currently wearing study lenses?**
   ☐1 Yes (if yes, evaluate lenses and then remove and apply new lenses)
   ☐2 No (if no, apply study lenses)

5. **Slit Lamp Evaluation of Study Lenses (check which lenses are being evaluated)**
   _____ test lenses if dispensed at last visit
   _____ test lenses applied today
   _____ habitual lenses

OD		OS
_____	Movement	_____
_____	Centration	_____
_____	Apical Clearance	_____
_____	Limbal Clearance	_____
_____	Scleral Landing Zone	_____
_____	Comments	_____

6. **(OPTIONAL) Slit Lamp Evaluation of Study Lenses (only to be used if test lenses for dispense were not evaluated above) _____ test lenses applied today**

OD		OS
_____	Movement	_____
_____	Centration	_____
_____	Apical Clearance	_____
_____	Limbal Clearance	_____
_____	Scleral Landing Zone	_____
_____	Comments	_____

Examiner Initials: _____

Subject: _____

Date: _____/_____/_____

Evaluation of Tangible Boost Replenishing System

7. Visual Acuity with study lenses that are being dispensed (logMAR)

OD: _____ OS: _____

8. Perform Keratograph NIBUT (to be performed only if lenses will be dispensed today)

OD: NIKf-BUT "until blink" (first break up) _____
NIKavg-BUT "until blink" (average break up)_____
Level: _____

NIKf-BUT "25 seconds" (first break up) _____
NIKavg-BUT "25 seconds" (average break up)_____
Level: _____

OS: NIKf-BUT "until blink" (first break up) _____
NIKavg-BUT "until blink" (average break up)_____
Level: _____

NIKf-BUT "25 seconds" (first break up) _____
NIKavg-BUT "25 seconds" (average break up)_____
Level: _____

9. Indicate CL design parameter changes needed

10. Gift card given (should be no)? ☐1 Yes ☐2 No

Examiner Initials: _____

Patient/Subject #:_____

Date:__/___/____Time:_____

CONTACT LENS QUESTIONNAIRE-8 (CLDEQ-8)

1. Questions about **EYE DISCOMFORT**:

   a. During a typical day in the past week, **how often** did your eyes feel discomfort while wearing your contact lenses?

   0 Never
   1 Rarely
   2 Sometimes
   3 Frequently
   4 Constantly

   When your eyes felt discomfort with your contact lenses, **how intense was this feeling of discomfort…**

   b. At the end of your wearing time?

Never have it	Not at All Intense				Very Intense
0	**1**	**2**	**3**	**4**	**5**

2. Questions about **EYE DRYNESS**:

   a. During a typical day in the past week while wearing your contact lenses, **how often** did your eyes feel dry?

   0 Never
   1 Rarely
   2 Sometimes
   3 Frequently
   4 Constantly

   When your eyes felt dry, **how intense was this feeling of dryness**…

   b. At the end of your wearing time?

Never have it	Not at All Intense				Very Intense
0	**1**	**2**	**3**	**4**	**5**

3. Questions about **CHANGEABLE, BLURRY VISION:**

   a. During a typical day in the past week, **how often** did your vision change between clear and blurry or foggy while wearing your contact lenses?

   0 Never
   1 Rarely
   2 Sometimes
   3 Frequently
   4 Constantly

   When your vision was blurry, **how noticeable was the changeable, blurry, or foggy vision** …

   b. At the end of your wearing time?

Never have it	Not at All Intense				Very Intense
0	**1**	**2**	**3**	**4**	**5**

4. Question about **CLOSING YOUR EYES:** During a typical day in the past week, **how often** did your **eyes bother you so much that you wanted to close them**?

   0 Never
   1 Rarely
   2 Sometimes
   3 Frequently
   4 Constantly

5. Question about **REMOVING YOUR LENSES:** How often during the past week, did your eyes *bother you so much* that you felt as if you needed to stop whatever you were doing and **take out your contact lenses**?

   1 Never (please skip to question 14)
   2 Less than once a week
   3 Weekly
   4 Several times a week
   5 Daily
   6 Several times a day

Date:

Study:

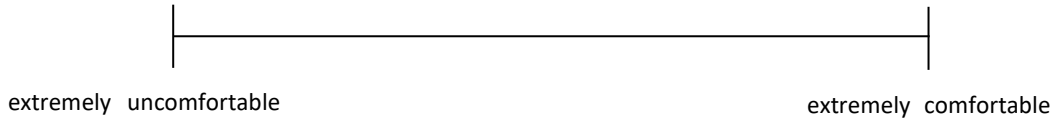
Subject #:

Visit #:

Eye: OD OS

Other Specifications: _____

Please rate on the scale below how comfortable your contact lenses feel at this moment.



Verification Initials: _____

Subject #:

Date:

Visit #:

Eye (circle): OD OS

4M		**4M**		**HI ILLUM/HC**			
131	1.0	D	S	R	K	N	
104	0.9	C	K	Z	O	H	
83	0.8	O	N	R	K	D	
66	0.7	K	Z	V	D	C	
52	0.6	V	S	H	Z	O	
42	0.5	H	D	K	C	R	
33	0.4	C	S	R	H	N	
26	0.3	S	V	Z	D	K	
21	0.2	N	C	V	O	Z	
16.5	0.1	R	H	S	D	V	
13	0.0	S	N	R	O	H	
10.5	-0.1	O	D	H	K	R	
8	-0.2	Z	K	C	S	N	
6.5	-0.3	C	R	H	D	V	

UNIVERSITY of HOUSTON
A CARNEGIE-DESIGNATED TIER ONE PUBLIC RESEARCH UNIVERSITY

Consent to Take Part in a Human Research Study

***Title of research study**:* An Evaluation of Tangible Boost Replenishing System on the Continued Efficacy of Tangible HydraPEG Rigid Gas Permeable Contact Lens Coating.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are a corneal or scleral contact lens wearing member of the population. This research is funded by Tangible Science, LLC (previously known as Ocular Dynamics).

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide, and can ask questions at any time during the study.

Why is this research being done?

This research project is being done to evaluate the effectiveness of a new solution that is designed to replenish the HydraPEG contact lens coating. HydraPEG is a soft and rigid contact lens coating, primarily composed of polyethylene glycol (a safe molecule commonly found in artificial tear solution), which is bound to the surface of a contact lens. The HydraPEG coating is intended to improve wettability and comfort with the lenses, and is currently FDA approved. However, the coating naturally diminishes from the surface of the lens over time (due to cleaning, and blinking over the surface of the contact lens). The Tangible Boost system is used to replenish the coating, and this is a study to evaluate its effectiveness.

How long will the research last?

We expect that you will be in this research study for approximately 5 months once you are enrolled, and there will be a minimum of 5 study visits over the 5-month period. Additional visits may be needed between visit 2 and 3, in order to make any necessary modifications to the way the lenses fit your eye.

Visit 1 will last approximately 1 hour 40 minutes.

The second visit will occur 2-3 weeks after the first visit, and it will last approximately 45 minutes. The 3rd visit, which will be about 1 month after the 2nd visit, and will last about 85 minutes. The 4th visit will be the day after the 3rd visit and will last approximately 25 minutes. The 5th visit will occur approximately 60 days after the 4th visit, and will last approximately 25 minutes.

How many people will be studied?

We expect to enroll about 40 people in this research study.

What happens if I say yes, I want to be in this research?

If you agree to take part in this study, you will first sign this consent form and the HIPAA privacy document before any study-related procedures are performed. You must be at least 18 years of age and be able and willing to follow study instructions. You will not be allowed to participate in the study if you are currently pregnant or nursing. Some exclusion criteria may apply, such as if you use ocular medications (except for artificial tears/rewetting drops), have any ocular infections or any ocular condition that may affect visual performance, have a history of any ocular surgery in the past 12 weeks, participated in another study recently, or had any systemic medication changes recently. Additionally, you must be a habitual rigid contact lens wearer to participate in this study. A study staff member will let you know if you are eligible to participate or not. If you qualify for the study, the following procedures that are in the table below will be performed during the associated study visits. These procedures do not involve treatment for any condition.

If you agree to participate in the usability portion of the study (training), you will be recorded using the tangible boost solution so that the usability of the product can be evaluated. For this portion of the study (occurs during Visit 3), you will watch an instruction video, and then use the boost product on a pair of dummy lenses, after which you will answer some questions about your understanding of the product.

The treatment you get will be chosen by chance, like flipping a coin. You will have an equal chance of being given each treatment. One of these treatments may contain no active treatment (such as standard saline solution), called a placebo. You will not be told which treatment you are getting; however your study doctor will know.

Procedure	**Length of Time Required for Participants**
VISIT 1: Initial Evaluation	
Informed consent & HIPAA	35 minutes
General History and medications	5 minutes

Visual Acuity	5 minutes
Questionnaires (CLDEQ8 + VAS)	10 minutes
Keratograph Surface Evaluation	5 minutes
Slit-lamp Examination (with lenses on and after lens removal)	10 minutes
Contact lens fitting*	30 minutes
*The scleral or corneal lens that you are fitted with is a commercially available rigid lens manufactured by AVT technologies. The lenses will then be coated with the HydraPEG rigid lens coating for increased wettability. These will be the lenses that are dispensed to you at the second visit.	
TOTAL TIME	**100 minutes**
VISIT 2: HydraPEG dispense	
Visual Acuity	5 minutes
Questionnaires (CLDEQ8 + VAS + supplemental VAS)	10 minutes
Keratograph Surface Evaluation	5 minutes
Slit-lamp Examination	5 minutes
Contact lens evaluation & dispense**	20 minutes
**Additional visits may be required to achieve an adequate corneal or scleral lens fit if the lenses are not acceptable. It is anticipated that the fitting process will take 1-3 visits total (including Visit 1 and 2). The only tasks done at any additional fitting visits will be to evaluate the fit of the lens and make any necessary changes. Follow-up fitting visits are expected to take 15 minutes – for a slit lamp evaluation of the lenses and necessary parameter changes to be determined. Since you are an established lens wearer, we do not anticipate a long fitting process.	
TOTAL TIME	**45 minutes**
VISIT 3: Tangible Boost Dispense	
Visual Acuity	5 minutes
Questionnaires (CLDEQ8 + VAS + supplemental VAS)	10 minutes
Keratograph Surface Evaluation	5 minutes
Slit-lamp Examination	5 minutes
Tangible Boost or placebo dispense & training++	60 minutes

++You will be dispensed either a Tangible Boost kit, or the placebo (which is Unique pH, a commonly used overnight storage solution for rigid lenses). These solutions will be stored in two single use vials that will be combined in the supplied case. You will be asked to store your lenses in the solution for 30 minutes that night and then transfer them to Unique pH solution for the rest of the night, and return to the clinic the next day for evaluation wearing your lenses. If you agree, you will be audio and video recorded and photographed during the training session so that we can evaluate how user-friendly the product is. If you do not agree to be recorded during the training session, you will still be trained and can still participate in the study.

This is a randomized study to evaluate the boost solution against a placebo control, so you will not know which of the systems you are being given, and they will not be recognizable from the packaging they are stored in. You will also be asked to use a second dose of the solution (to be given at visit 4) 30 days after visit 4, and 30 days prior to visit 5. You will receive a phone call or email reminding you to use the solution at this mid-visit mark.

TOTAL TIME	**85 minutes**
VISIT 4: Tangible Boost Follow-Up #1	
Visual Acuity	5 minutes
Questionnaires (CLDEQ8 + VAS + supplemental VAS)	10 minutes
Keratograph Surface Evaluation	5 minutes
Slit-lamp Examination	5 minutes
TOTAL TIME	**25 minutes**
VISIT 5: Tangible Boost Follow-Up #2	
Visual Acuity	5 minutes
Questionnaires (CLDEQ8 + VAS + supplemental VAS)	10 minutes
Keratograph Surface Evaluation	5 minutes
Slit-lamp Examination	5 minutes
TOTAL TIME	**25 minutes**

This second table describes the procedures that are included above:

Test	**Description**
General History and Medications	Participants will be asked questions about their general, ocular and medication use histories along with contact lens use history if applicable.
Questionnaires	Subjects will be asked to fill out the following questionnaires: • Contact Lens Dry Eye Questionnaire - 8 (CLDEQ – 8) • Visual analog scale (VAS) 0-100 • An additional VAS survey will be given to evaluate your

	satisfaction and experience with your customary lenses and the coated lenses. These questionnaires assess the level of eye and/or contact lens discomfort.
Scleral / corneal lens fitting	The examiner will fit you with scleral or corneal contact lenses using commercially available lens fitting sets. ~~(from AVT Technologies, CO).~~ Contact lenses will be fit using the customary fitting procedure, where a lens from a fitting set is applied to the eye, the power needed for you is determined, and then customized lenses are ordered with the over-refraction incorporated and any fitting parameters are altered based on the investigators' expertise.
Scleral / corneal Lens Evaluation	The ordered lenses will be applied to your eye by the investigator, after which the fit and vision will be evaluated. At this time, if the fit of the lens is adequate, the lenses will be dispensed. If there are additional parameter changes needed, they will be ordered at this time.
Visual Acuity	Your vision in each eye will be measured with a high contrast visual acuity chart. You will be asked to cover one eye and read the chart, and this procedure will be repeated for your other eye.
Slit-lamp Examination	The front portion of your eye and contact lenses will be examined with a lighted microscope. You will be asked to place your chin on the chinrest and place your forehead against the bar and look straight ahead. The instruments light will be shined onto your eye to visualize the ocular surface for approximately 2-3 minutes per eye.
Oculus Keratograph	The OCULUS Keratograph® 5M is an advanced, non-invasive imaging system that will be used to image the surface of your contact lenses while they are on your eye. These measurements will allow us to evaluate the wettability of the front surface of the lens.
Lissamine GreenGlo Strips	Individual paper strips with 1.5mg of Lissamine Green (a commonly used diagnostic dye for the ocular surface) will be used to put a small amount of green dye on the surface of your eyes. The dye is attracted to dead cells and irregularities at the ocular surface. These strips are commonly used in practice as a gold standard for evaluating compromise to the cells on the front surface of your eye.

Tangible Boost Training	For this portion of the study (occurs during Visit 3), you will begin by watching a 5-minute introduction video about the product and study. You will be presented the Tangible Boost in its packaging which will include material to help you use the product. We will give you some time to familiarize yourself with the materials provided. Once you feel ready to use the product, we will ask you perform a Boost Treatment using the product and other use scenarios with the product, which will take about 60 minutes.

Observations, Video Taping, and Use of Data

This research study includes the following component(s) where we plan to audio record/video record/photograph you as the research subject:

We will record audio and videotape your interaction with the tangible boost replenishing system. In additional still photos may be obtained. We will be observing you and collecting data while you use the product. In addition, we will test certain features and assess the clarity of the instructions and information. You will be asked questions regarding your experience and opinions. By signing this informed consent form, you authorize University of Houston, Tangible Boost and UserWise to take photo and audio/video footage of yourself, your comments, and your interactions with the product. Videos will be used within the companies to make improvements to the Tangible Science product (product development and user experience). These photos and videos may be shared with regulatory agencies; you will be identifiable due to the fact that the company uses facial expressions to evaluate some of the usability characteristics of the product; however, your record will not contain your last name or a medical record number.

If you do not agree to be videotaped and participate in the usability portion of the study, you will still be able to participate in the study.

- ☐ I agree to be [audio recorded/video recorded/photographed] during the research study.
  - ☐ I agree that the [audio recording/video recording)/photographs] can be used in publication/presentations.

☐ I do not agree that the [audio recording/video recording)/photographs] can be used in publication/presentations.

☐ I do not agree to be [audio recorded/video recorded/photographed] during the research study.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for the following, outside of the study visits:

- Applying, remove and cleaning the rigid lenses that you are given in this study, on a daily basis for the study period in which you will be wearing them.
- Storing the lenses in either the Tangible boost solution or the placebo storage solution for 30 minutes at Day 30 and 60 after lens dispense.

What happens if I do not want to be in this research?

You can choose not to take part in the research and it will not be held against you. Choosing not to take part will involve no penalty or loss of benefit to which you are otherwise entitled.

If you are a student, a decision to take part or not, or to withdraw from the research will have no effect on your grades or standing with the University of Houston. If you are receiving clinical care, a decision to take part or not will have no effect on what would be offered to you as part of routine care.

The alternative to this study is continuing wear with your habitual rigid lenses and not receiving the coating or the boost solution.

The important risks and possible benefits of these alternatives include: Possible risks and adverse events are outlined in the section on how this study could be bad for you (two sections below). Possible benefits include experiencing improved comfort during the study while wearing the coated lenses; the coating is available in the US if you chose to have your habitual lenses coated if you like the comfort.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

If you decide to leave the research, there are no adverse consequences. If you decide to leave the research, contact the investigator so that the investigator can follow the proper protocol for exiting a study, and address any concerns or adverse events that you may be having as a result of being in the study (if this is applicable). You have no obligation to inform the investigator of your reasoning for leaving the study, and will not be penalized for exiting the study. However, you will only receive compensation for the study visits that you attend.

If you stop being in the research, already collected data may not be removed from the study database.

Is there any way being in this study could be bad for me?

There are no foreseeable risks related to the procedures conducted as part of this study. There are risks in general that are associated with wearing any type of contact lens. These risks include developing an abrasion ('cut' on the eye) during lens application or removal, the accumulation of debris on or beneath the lenses, ocular stinging redness, itching, or irritation. All contact lens wearers are at risk for developing inflammatory and/or infectious complications during lens wear, but there is no added risk by participating in this study. If you participate in the userwise recorded usability portion of this study, you will not be using the product on yourself during the training session so there is no risk of harm to your lenses from the cleaning products. There is a risk of losing confidentiality/privacy to the employees at UserWise, since they will be viewing the recorded data from the training. The company employees only view the recordings on a need-to-know basis. In the unlikely event of a negative event in this study, please call the study coordinator (Sonia Huerta) or Dr. Maria Walker (contact info at the end of this document), and they will decide if you need to be seen by a professional. If you experience an event such as an abrasion during a study visit, or as a result of wearing the rigid lenses, the condition will be treated as it is customarily, and the fees associated with treatment will be covered by the study. Any necessary and appropriate referrals will be offered by Dr. Maria Walker. If you experience an injury or negative event that is not related to the use of the rigid lens, you will be responsible for any medical treatments through your own medical insurance or as an out-of-pocket expense.

Will I get anything for being in this study?

You will receive a $20 Amazon.com gift card as compensation for your time at each study visit, for a total compensation of $100 if all five study visits are attended. If you come in for a study visit but are ultimately unable to complete the visit after it has begun, you will still be compensated with a $20 gift card. There will be no additional gift cards or compensation given if you need to come in for the potential addition fitting visits that may be required if there is a need for additional modifications of the lens to achieve adequate fit and vision.

There is no additional compensation for participating in the training session (usability study), beyond what you would receive as compensation for participating in a study visit.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include experiencing improved comfort during the study while wearing the coated lenses; the coating is available in the US if you chose to have your habitual lenses coated after the completion of the study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. Each subject's name will be paired with a code number, which will appear on all written study materials. The list pairing the subject's name to the assigned code number will be kept separate from these materials. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the Institutional Review Board (IRB – the organization responsible for overseeing research involving human subjects, in regards to the safety of the subject) and other representatives of this organization, as well as collaborating institutions and federal agencies that oversee human subjects research. In addition, the Food and Drug Administration (FDA) may inspect the records of this study at any time. This research uses or discloses Protected Health Information as defined by the Health Insurance Portability and Accountability Act (HIPAA), and you will be asked to sign an additional document to authorize the use of this information.

The video and audio information, as well as the questions asked regarding the use of the Tangible Boost system, will be securely sent to UserWise for analysis. Userwise may keep the recording indefinitely and may use the data for other medical research, but only research involving the product and subsequent products by the study sponsor.

We may publish the results of this research. However, unless otherwise detailed in this document, we will keep your name and other identifying information confidential.

If the sponsor pays any of your medical expenses, we may be required to give the sponsor (Tangible Science, Inc) your name, date of birth, and Medicare ID or social security number.

Can I be removed from the research without my OK?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include if you are unable to complete the tasks in the study protocol. In addition, if you experience an adverse event in which the investigator does not feel that you should continue wearing the scleral lenses. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you should talk to the research team via Maria K. Walker, mkwalker@central.uh.edu, 713-743-6241, or contact the study coordinator, Sonia Huerta @ 713-743-2736.

This research has been reviewed and approved by the University of Houston Institutional Review Board (IRB). You may also talk to them at (713) 743-9204 or cphs@central.uh.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Consent to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your consent to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

In the future, our research team may be interested in contacting you for other research studies we undertake, or to conduct a follow-up study to this one. ***There is never any obligation to take part in additional research.*** Do we have permission to contact you to provide additional information?

- ☐ Yes
- ☐ No

UNIVERSITY of HOUSTON
A CARNEGIE-DESIGNATED TIER ONE PUBLIC RESEARCH UNIVERSITY

Authorization for Use and Disclosure of Protected Health Information for Research Purposes

State and federal medical privacy laws protect the use and release of your personally identifiable health information ("Protected Health Information"). By signing this document, you authorize the Principal Investigator and research team to access, use and/or release your Protected Health Information for the following research study:

Title of Research Protocol: **An Evaluation of Tangible Boost Replenishing System on the Continued Efficacy of Tangible HydraPEG Rigid Gas Permeable Contact Lens** Coating.**Name of Principal Investigator**: **Maria K. Walker, OD, MS**

This research study is described in full in the associated informed consent document.

The health information that we may use or disclose for this research includes your research record and your complete health care records. This may include, for example, medical history, results of examinations, treatment and outcomes, results of lab tests, or other information contained within your health, billing and/or other records at the:

- University Eye Institute
- The Ocular Surface Institute

Special permission is required to release drug, alcohol, and substance abuse records, HIV/AIDS-related information, genetic information and mental health information. These kinds of records will not be used or disclosed in this study unless a separate section is included below and you specifically allow us to do so by initialing the applicable box(es).

In addition to the UH research team, your Protected Health Information may be used by and/or disclosed to:

- Members and staff of the UH Institutional Review Board (IRB)
- Others with oversight of the study or who are required by law to review the quality and safety of the research, such as the U.S. Food and Drug Administration and/or the Health and Human Services Office of Human Research Protections.

In addition to the purpose of the research described in the consent form, your Protected Health Information may be used to:

- Improve the design of future studies;
- Share with business partners of the sponsor;
- File applications with U.S. or foreign government agencies to get approval for new drugs or health care products; or
- As authorized by federal/state medical privacy laws or as otherwise required or authorized by federal

or state law.

Please note that:

- The research team will use and protect your information as described in this Authorization; however, once your health information is released by the University of Houston, it may not be protected by the privacy laws and might be shared with others. A member of the research team will be happy to respond to any of your questions regarding this.
- Signing this authorization is voluntary. You are not required to agree to the use or disclosure of your Protected Health Information. Signing this authorization is not a condition for treatment (other than treatment related to this research study), payment, or enrollment or eligibility for health plan benefits. However, if you do not sign the document, you cannot participate in this research study and you may not receive research-related treatment.
- The University of Houston will not condition routine clinical treatment, payment, or enrollment of eligibility for benefits based on whether or not you sign this Authorization.
- You may change your mind and revoke (take back) this Authorization at any time. Before doing so, you may want to ask someone on the research team if canceling will affect your research-related medical treatment. If you cancel your permission, you may no longer participate in the research study. Also, if you cancel, your Protected Health Information that has already been collected, used, and/or disclosed in reliance upon this authorization may continue to be used, and to the extent it has already been disclosed may be subject to redisclosure. In addition, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study to the extent authorized/required by law.

☐ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

This Authorization does not have an expiration date. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this authorization, please contact the research team to tell them of this decision. They will give you an address so that you can inform the investigator in writing.

You must also notify the Director of the UH Office of Research Policies, Compliance, and Committees to revoke the authorization.

Director, Office of Research Policies, Compliance, and Committees
University of Houston Division of Research
4302 University Drive, Suite 316
Houston, TX 77204-2015

Signing this form indicates that you have read and/or understand the information in this form, that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed authorization.

Signature of Participant (or Participant's Personal Representative)	Date
Printed Name of Participant (or Participant's Personal Representative)	If applicable, a description of the Personal Representative's authority to sign for the Participant