Title of Project: Tangible Hydra-Peg™: A Promising Solution for Scleral Lens Wearers with Dry Eye

Investigators:

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Abstract:

Dry eye (DE) is a common complaint of millions of people worldwide with a significant impact on quality of life. For decades, this condition has presented a challenge to eye care professionals as conventional therapies are often ineffective. Recently, scleral lenses have demonstrated to be a promising therapeutic and vision rehabilitative option for dry eye sufferers.[1-5] Nonetheless, despite the benefits of scleral lenses for dry eye patients, inadequate wettability of scleral lenses with subsequent diminished comfort and visual clarity remains a concern for scleral lens wearers with dry eye.

Tangible Hydra-PEG ™ (Tangible Science LLC, Menlo Park, CA, USA) is a novel coating technology designed to improve lens wettability, deposit resistance and tear film breakup time, ultimately enhancing contact lens comfort. While studies have shown that Tangible Hydra-Peg technology can improve contact lens discomfort (CLD) in soft contact lens and gas permeable lens wearers, [6-7] to our knowledge, no clinical research investigation has examined the benefits of this new coating on scleral lens wear in dry eye sufferers. As such, the aim of this study is to compare the CLD and DE symptoms of dry eye scleral lens wearers between Tangible Hydra-Peg treated scleral lens wear and untreated scleral lens wear. CLD and DE signs will also be assessed to corroborate our findings.

This will be the first randomized double masked cross-over study to examine CLD and DE symptoms of Tangible Hydra-Peg treated scleral lens wear as compared to untreated scleral lens wear in the dry eye patient population. Tangible Hydra-Peg treated scleral lenses can potentially minimize CLD and DE symptoms, ultimately improving outcomes for patients coping with dry eye disease. This study will provide new information about this innovative technology and help practitioners envisage rehabilitative options which will best optimize the quality of life of this important patient population.

Specific Aims:

1. The primary goal of this study is to compare the CLD and DE symptoms of moderate to severe DE subjects between 30 days of Tangible Hydra-Peg treated scleral lens wear and 30 days of untreated scleral lens wear.
   Hypothesis: CLD and DE symptoms will be significantly better after 30 days of Hydra-Peg treated scleral lens wear as compared to 30 days of untreated scleral lens wear.

2. The secondary goal of this study is compare the CLD and DE signs of moderate to severe DE subjects between 30 days of Tangible Hydra-Peg treated scleral lens wear and 30 days of untreated scleral lens wear in DE subjects. As DE can impact vision quality and Hydra-Peg may impact contact lens wearing times, as a subanalysis, we will also examine contact lens wearing times and quality of vision such as frequency of foggy vision between treated and untreated scleral lens wear.

   Hypothesis: CLD and DE signs will be significantly better after 30 days of Hydra-Peg treated scleral lens wear as compared to 30 days of untreated scleral lens wear. Frequency of foggy vision and contact lens wearing time will be significantly better after 30 days of Hydra-Peg treated scleral lens wear as compared to 30 days of untreated scleral lens wear.

Methods:

Participant Recruitment

In a multi-center randomized double-masked cross-over study, 30 scleral lens wearers with CLD and moderate to severe DE shall be recruited for a non-significant risk 1-month study. Participants will be enrolled at three geographically diverse academic site locations across North America (Fort Lauderdale, FL, Chicago, Illinois, and Sacramento, CA). The participants will be randomly selected from those exhibiting CLD and moderate to severe symptomatic dryness as determined by the validated and commonly used Ocular Surface Disease Index (OSDI) dry eye questionnaire (Appendix A) and the validated Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) (Appendix B). These symptom surveys are recommended to be included in a clinical study assessing DE and CLD by expert researchers of the International Dry Eye Workshop and the International Workshop on Contact Lens Discomfort respectively.[8, 9] The participants will be 18 to 70 years of age and have the presence of reduced tear film break up time (TBUT), a sign of DE and CLD.[8,9]

A participant will be defined as a scleral lens wearer if he or she reports wearing his or her lenses at least 8 hours per day for at least 5 days per week and have had their habitual lenses no longer than 1 year. Due to the widely varying parameters of scleral lenses and lens diameter having an impact on comfort, in this study scleral lens wear will be defined as 15.0 mm to 19.00 mm inclusive. All participants will be required to remain in primarily the same scleral lens

parameters including material throughout the study, except for the change in lens coating. Except for the wash-out periods, all subjects will be required to continue with the same supportive dry eye therapy and use hydrogen peroxide for lens care throughout the study.

Participants with the following will be excluded from this study: disorders that affect sensitivity (herpetic disease, severe diabetes mellitus), anatomic variations of the conjunctiva that can impair proper scleral lens fitting, pregnancy, and significant visual impairment that could confound the results of the study which, for the purposes of this study, will be defined as best corrected Snellen visual acuity worse than 20/30 in either eye or any other ocular pathology (e.g. glaucoma, macular degeneration, keratoconus) other than DE, which may significantly impact visual function.

Experimental Design

30 subjects with symptomatic moderate to severe dry eye and symptoms of CLD will complete a double-masked cross-over study. The participants will be randomly chosen to wear their habitual untreated scleral lenses or Hydra-Peg treated scleral lenses first for 30 days. Half of the participants (15) will be randomly chosen to wear the Hydra-Peg treated scleral lenses first for 30 days, and the other half of the participants (15) will be chosen to wear their habitual untreated scleral lenses for 30 days first. One week wash-out periods with no lens wear will be placed before and between the 30-day test periods. The OSDI, CLDEQ-8, a battery of dry eye diagnostic tests, and tests which will assess the impact of contact lenses on the ocular surface will be administered from 3:00 to 5:00 pm at baseline, after the first test period, and after the cross-over. Contact lens wearing time and questions related to quality of vision will also be collected at baseline, after the first test period, and after the cross-over.

The battery of clinical dry eye sensitive tests will include, TBUT of the ocular surface, and ocular surface staining. TBUT over the surface of the scleral lenses, lid wiper epitheliopathy (LWE), and contact lens-related papillary conjunctivitis we will also be examined as they these factors may change with alteration of a contact lens surface.

The study will be double-masked. Lens pairs will be supplied in identical cases, differing only by code mark unknown to the tester. Only one lens pair during the respective test period (treated or untreated) will be given to each participant. The general study schedule following recruitment is described below.

General Study Schedule

To obtained informed consent

Day 1	**Screening** 1) Informed Consent, HIPAA authorization 2) OSDI and CLDEQ-8 3) Assessment of TBUT
Days 1-8 (1 week)	Wash-out period
Days 9	**Baseline Testing** (1) OSDI, CLEDEQ-8, additional questions (skip questions 3 and 5) (2) Battery of Clinical tests (3) Randomization of lenses
Days 9-39 (30 days)	**Test Period 1** Wear of treated or untreated CL
Day 40	**Post CL Wear Testing** (1) OSDI, CLDEQ-8, additional questions (2) Battery of Clinical Tests
Day 40-47 (1 week)	1 week Wash-out Period
Days 48-78 (30 days)	**Test Period 2** Wear of treated or untreated CL
Day 79	**Post CL Wear Testing** (1) OSDI, CLDEQ-8, additional questions (2) Battery of Clinical Tests

Data Collection:

Data will be kept primarily electronically through REDCap, a secure database application designed to support data capture for research studies. The data will be collected on encrypted and password protected electronic devices. An electronic and hard copy versions of the OSDI and CLDEQ-8 will be available. The hard copy of the questionnaires will be used only if the secure web link or server is not functioning. As soon as the server is functioning, the data from the paper survey will be uploaded to REDCap. The battery of clinical tests will be completed on a form which will be uploaded to REDCap. All data will be de-identified other than by code. The study data will be reviewed by Tangible Science, LLC, and members of this study team only.

Statistical Analysis

The key values used for analysis in this study will be differences in CLD and DE symptoms following scleral lens wear with Tangible Hydra-Peg and that found after untreated scleral lens wear. In addition, we will examine differences in CLD and DE signs between Tangible Hydra-Peg scleral lens wear and untreated scleral lens wear. Preliminary data analyses will include inspection for kurtosis and skewness of each distribution and test for normality, using the Shapiro-Wilk test. Normal distributions will be analyzed using a paired t-test. Non-normal distributions will be analyzed with the Wilcoxon Signed Ranked test.

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