Intracanalicular Dexamethasone used in conjunction with Restasis (cyclosporine ophthalmic emulsion) for the treatment of signs and symptoms of dry eye disease as compared to Restasis with Lotemax (loteprednol etabonate ophthalmic suspension 0.5%) and Restasis monotherapy.

CHESTER STUDY

Compound:	DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg for intracanalicular use
Study Name:	CHESTER STUDY
Protocol Number:	TC-2020-DexRes
Clinical Phase:	Open label prospective
Date of Issue:	01/11/2021
Primary Investigator:	Dr. Tom Chester
Site Name & Location:	Cleveland Eye Clinic 7001 S. Edgerton, Cleveland, OH 44141

CLINICAL STUDY PROTOCOL SYNOPSIS

TITLE	Intracanalicular Dexamethasone used in conjunction with Restasis (cyclosporine ophthalmic emulsion) for the treatment of signs and symptoms of dry eye disease as compared to Restasis with Lotemax (loteprednol etabonate ophthalmic suspension 0.5%) and Restasis monotherapy.
SITE LOCATION(S)	Cleveland Eye Clinic 7001 S. Edgerton Rd, Cleveland, OH 44141
PRINCIPAL INVESTIGATOR	Dr. Tom Chester
OBJECTIVE(S)	To evaluate the benefit of treatment with a physician administered intracanalicular dexamethasone insert in patients with dry eye who are beginning treatment with Restasis (cyclosporine ophthalmic emulsion) to reduce the signs and symptoms of dry eye disease.
STUDY DESIGN	Prospective Open-label Interventional Study
STUDY DURATION	6 months including screening and enrollment
ESTIMATED STUDY COMPLETION DATE	3 months after date of insertion
POPULATION	
Sample Size:	30 patients (60 eyes)
Target Population:	Patients with dry eye who are about to begin treatment with Restasis bilaterally to reduce the signs and symptoms of dry eye disease and who have not been on topical immunomodulation for a minimum of 3 months prior to the start of the study.
TREATMENT(S)	

Study Drug	Sustained Release Dexamethasone, 0.4 mg
Dose/Route/Schedule:	All patients will be prescribed Restasis BID for both eyes who have not been on topical immunomodulation for a minimum of 3 months, and who would benefit from addition of topical pharmacotherapy (immunomodulation). There will be 3 groups. 10 patients will receive Restasis BID and Dextenza in both eyes, 10 patients will receive Restasis BID for 12 weeks and Lotemax BID for one month in both eyes and 10 patients will receive Restasis BID monotherapy. Screening/Prescription 1-week 2-week 1 month 2 month 3 month

ENDPOINT(S)

PRIMARY:

- Mean change in ocular surface staining (sodium fluorescein and lissamine green) from baseline at week 1, week 2, week 4, week 8, and week 12 as measured by the NEI grading scale

Secondary:	• Mean change in MMP-9 from baseline at week 1, week 2, week 4, week 8 and week 12 as measured by InflammaDry • Mean change in tear break-up time (TBUT) from baseline at week 1, week 2, week 4, week 8 and week 12 • Mean change in conjunctival injection from baseline at week 1, week 2, week 4, week 8 and week 12 as measured on a scale of 0-4 and graded by the physician • Change from baseline in meibomian gland scores (expressibility with MGE) at week 1, week 2, week 4, week 8 and week 12. • Mean change in tear osmolarity from baseline at week 1, week 2, week 4, week 8 and week 12 as measured by Tear Lab • Mean change in SPEED scores from baseline at week 1, week 2, week 4, week 8 and week 12 • Mean change in Best-corrected Visual Acuity (BCVA) from baseline at week 1, week 2, week 4, week 8 and week 12 as measured by ETDRS chart Mean change in Schirmer's score from baseline at week 1, week 2, week 4, week 8 and week 12 as measured by Schirmer's test strip

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1. INTRODUCTION AND RATIONALE

1.1. Introduction

Dry eye disease (DED) is a multifactorial disorder of the ocular surface that severely impacts vision and quality of life. Risk factors that contribute to DED include age, gender, hormones, autoimmune disorders, local environment, use of video displays, contact lens wear and exposure to medications/preservatives, all potentially leading to secretory or evaporative DED, or both.[1] The Tear Film and Ocular Surface Society's Dry Eye Workshop II definition recognizes the impact of inflammation, saying, "Dry eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles."[2]

Topical cyclosporine A (Restasis) is indicated to increase tear production in patients whose tear production is presumed to be suppressed because of ocular inflammation associated with DES. A significant number of studies are available concerning the use of cyclosporine as a way to modulate inflammation. Positive effects are consistently seen with the use of this drug for treatment of DES.[3] Topical application exerts a therapeutic effect without causing systemic side effects, because only small amounts can penetrate into the bloodstream after topical application.[4]

After determining the severity of the inflammation in a DED patient, the doctor can then decide if a topical steroid is needed to quickly decrease the overall inflammation along with Restasis.

1.2. Rationale

Although Restasis works as an anti-inflammatory, by preventing T-cells from releasing cytokines and increases tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, we hypothesize that the addition of DEXTENZA® will provide greater symptomatic improvement than pharmacotherapy alone. Additionally, we hypothesize that the addition of DEXTENZA® will show non inferiority in comparison to Restasis in combination with Lotemax.

This study will compare and evaluate the benefit of treatment with a physician administered intracanalicular dexamethasone insert (0.4 mg) bilaterally, compared to Lotemax prescribed BID, in patients that are prescribed Restasis bilaterally to increase tear production in patients with aqueous deficient DED. In addition, the study will evaluate physician assessment of ease of DEXTENZA® insertion.

Drug delivery platforms are an innovative exciting advancement in ophthalmology. They allow patients to eliminate topical medications which are generally associated with lack of compliance, difficulty of use and requiring help from family members. At times, patients may have to take several drops, increasing the likelihood of non-compliance and adding a level of complexity to their drop regimen.

1.2.1. Rationale for Study Design

This prospective study will use a head to head design for 30 participants, 60 eyes. All eyes will receive bilateral Restasis. The study group will consist of 20 eyes receiving DEXTENZA® insertion. The control groups will consist of 20 eyes receiving Lotemax and 20 eyes will have Restasis monotherapy.

2. STUDY OBJECTIVES

2.1. Primary Objective

- Mean change in ocular surface staining (sodium fluorescein and lissamine green) from baseline at week 1, week 2, week 4, week 8 and week 12 as measured by the NEI grading scale

2.2. Secondary Objectives

- Mean change in MMP-9 from baseline at week 1, week 2, week 4, week 8 and week 12 as measured by InflammaDry
- Mean change in tear break-up time (TBUT) from baseline at week 1, week 2, week 4, week 8 and week 12
- Mean change in conjunctival injection from baseline at week 1, week 2, week 4, week 8 and week 12 as measured on a scale of 0-4 and graded by the physician
- Change from baseline in meibomian gland scores (expressibility and quality) at week 1, week 2, week 4, week 8 and week 12.
- Mean change in tear osmolarity from baseline at week 1, week 2, week 4, week 8 and week 12 as measured by Tear Lab
- Mean change in DEQ-5 from baseline at week 1, week 2, week 4, week 8 and week 12
- Mean change in Best-corrected Visual Acuity (BCVA) from baseline at week 1, week 2, week 4, week 8 and week 12 as measured by ETDRS chart
- Mean change in Schirmer's score from baseline at week 1, week 2, week 4, week 8 and week 12 as measured by Schirmer's test strip

3. STUDY DESIGN

3.1. Study Description and Duration

This prospective, open-label, single-center, non-randomized, investigator-sponsored clinical study seeks to investigate the benefit of managing patients with DED with a sustained release intracanalicular dexamethasone (0.4 mg) insert in addition to Restasis compared to Restasis in conjunction with Lotemax and Restasis alone. In addition, this study will evaluate the ease of DEXTENZA® insertion.

After screening a given patient for inclusion and exclusion criteria, and gaining informed consent, both eyes will be prescribed Restasis. Both eyes of 10 patients will be selected to receive DEXTENZA® insertion (study group), while 10 patients will be prescribed Lotemax and 10 patients will be on Restasis monotherapy (control groups). Per patient, the study period will last for approximately 12 weeks after the DEXTENZA® insertion, consisting of one screening/prescription visit and5 post-procedure follow-up visits (week 1, week 2, week 4, week 8 and week 12). At week 1, week 2, week 4, week 8 and week 12, primary and secondary endpoints will be assessed alongside standard-of-care procedures. Adjusting for enrollment period, the study will last a total of approximately 9 months.

4. SELECTION, WITHDRAWAL, AND REPLACEMENT OF PATIENTS

4.1. Study Population

The study aims to enroll 60 eyes of 30 patients who exhibit signs and symptoms of DED, who have not been on topical immunomodulation for a minimum of 3 months, and who would benefit from addition of topical pharmacotherapy (immunomodulation).

4.1.1. Inclusion Criteria

A patient's study eye must meet the following criteria to be eligible for inclusion in the study:

- 18 years of age or older
- Signs and symptoms of DED
- Consent to treat with topical immunomodulator
- Willing and able to comply with clinic visits and study related procedures
- Willing and able to sign the informed consent form

4.1.2. Exclusion Criteria

A patient who meets any of the following criteria will be excluded from the study:

- Patients under the age of 18.
- Pregnancy (must be ruled out in women of child-bearing age with pregnancy test)

- Active infectious systemic disease
- Active infectious ocular or extraocular disease
- Altered nasolacrimal flow of either acquired, induced, or congenital origin
- Hypersensitivity to dexamethasone
- Patients who have been on topical immunomodulating agents in the previous 3 months to their baseline visit
- Patient being treated with either topical, oral, or intravenous immunosuppressive agents, immunomodulating agents, or steroid (including NSAIDS)
- Patients with severe disease that warrants critical attention, deemed unsafe for the study by the investigator

4.2. Treatment Logistics and Accountability

4.2.1. Packaging, Labeling, and Storage

Intracanalicular dexamethasone insert must be stored in a secure area accessible only to the Investigator and their designee(s) and refrigerated and stored between 2° C and 8° C. Intracanalicular dexamethasone insert contains 0.4 mg dexamethasone and is designed to provide a sustained and tapered release of therapeutic levels of dexamethasone to the ocular surface for up to 30 days for the reduction of post-surgical inflammation and pain associated with ocular surgery. Dexamethasone is an anti-inflammatory 9-fluoro-glucocorticoid (also termed a glucocorticoid agonist) and is the active ingredient found in MAXIDEX® 0.1% (dexamethasone ophthalmic suspension), which contains approximately 50 µg of dexamethasone per drop.

Study inserts will be supplied by Ocular Therapeutix in a sealed foil pouch containing one intracanalicular dexamethasone insert in a foam carrier.

Study inserts will be shipped to the site via overnight shipping using cold packs to maintain a temperature of 2° to 8° C. The Investigator, or an approved representative (e.g. pharmacist), will ensure that all study drug inserts are stored in a secured area, under recommended storage conditions and in accordance with applicable regulatory requirements. The shipping box is to be opened and stored immediately at the site in a refrigerator intended for investigational products at a temperature of 2° to 8°C.

When the insert is removed from the refrigerator, it should be visually inspected. Exposure of the insert to temperatures outside these limits it not recommended. Records of actual storage conditions (i.e. temperature log) at the study site must be maintained; and must include a record of the dates, when the refrigerator was checked, the initials of person checking, and the temperature.

4.2.2. Supply and Disposition of Treatments

Study insert will be shipped at a temperature of 2° to 8°C to the investigator as needed during the study.

4.2.3. Treatment Accountability

All study insert accountability records will be kept current.

The investigator will account for all opened and unopened packaging of study inserts. These records will contain the dates, quantity, and study medication

- Inserted in each patient,
- disposed of at the site or returned to Ocular Therapeutix

All accountability records will be made available for inspection by regulatory agency inspectors.

4.3. Concomitant Medications and Procedures

At the discretion of their physician, patients may continue to receive all medications and standard treatments administered for other conditions.

5. Study Schedule of Events and Visit Descriptions

5.1. Schedule of Events

Study assessments and procedures are presented by visit in Table 1.

Table 1 Schedule of Events

Study Procedure	Screening/ Prescription	Week 1	Week 2	Week 4	Week 8	Week 12
Visit	**VISIT 1**	**VISIT 2**	**VISIT 3**	**VISIT 4**	**VISIT 5**	**VISIT 6**
Windows for Visits	**(Day -30 to -1)**	**+/- 1 day**	**+/- 3 days**	**+/- 3 days**	**+/- 3 days**	**+/- 3days**
vInclusion/Exclusion	x					
Informed Consent	x					
Demographics	x					
Medical History and Concurrent Illnesses	x					
Concomitant Medications	x	x	x	x	x	x
UCVA Testing	x	x	x	x	x	x
MR/BCVA (ETDRS at 4m)	x	x	x	x	x	x
Schirmer's Test	x	x	x	x	x	x
Ophthalmic Examination (w/ or w/o dilation)	x	x	x	x	x	x
Meibomian gland assessment (expressibility and quality)	x	x	x	x	x	x
MMP9 with Inflamma Dry	x	x	x	x	x	x
Tear Osmolarity with Tear Lab	x	x	x	x	x	x
Conjunctival Injection Scale 0-4	x	x	x	x	x	x
NaFl Staining	x	x	x	x	x	x
TBUT	x	x	x	x	x	x
Lissamine Green	x	x	x	x	x	x

Intraocular Pressure	x	x	x	x	x	x
Restasis/Lotemax prescription	X					
Intracanalicular dexamethasone insert	X					
Physician ease of insertion questionnaire	X					
Insert Visualization	X	x	x	x	x	x
Subject reported AEs after insertion	x	x	x	x	x	x
DEQ-5	x	x	x	x	x	x

Study Visit Descriptions

5.1.1. Study Procedures

Screening/Prescription

After the patient has provided informed consent, the following information will be collected:

- Inclusion/exclusion
- Demographics
- Medical history and concurrent illnesses
- Concomitant medications
- UCVA and MR/BCVA as measured by ETDRS chart at 4m
- Ophthalmic Examination with dilation
- Intraocular pressure
- Meibomian gland assessment (expressibility and quality)
- DED Assessment
    - Schirmer's
    - MMP9
    - Osmolarity
    - Conjunctival injection
    - TBUT
    - Ocular surface staining (sodium fluorescein and lissamine green)
- Subject reported AE's
- Restasis BID OU prescription
- Lotemax BID OU for 1 month prescription
- DEXTENZA® insertion in one eye

- Insert Visualization
- Physician ease of insertion questionnaire
- DEQ-5

Week 1, Week 2, Week 4 and Week 8

- UCVA and MR/BCVA as measured by ETDRS chart at 4m
- Concomitant Medications
- Ophthalmic Examination without dilation and with IOP
- Insert visualization
- Meibomian gland assessment (expressibility and quality)
- DED Assessment
    - Schirmer's
    - MMP9
    - Osmolarity
    - Conjunctival injection
    - TBUT
    - Ocular surface staining (sodium fluorescein and lissamine green)
- Subject reported AE's
- DEQ-5

Week 12

- UCVA and MR/BCVA as measured by ETDRS chart at 4m
- Concomitant Medications
- Ophthalmic Examination without dilation and with IOP
- Insert visualization
- Meibomian gland assessment (expressibility and quality)
- DED Assessment
    - Schirmer's
    - MMP9
    - Osmolarity
    - Conjunctival injection
    - TBUT
    - Ocular surface staining (sodium fluorescein and lissamine green)
- Subject reported AE's
- DEQ-5

5.1.2. Unscheduled Visits

All attempts should be made to keep patients on the study schedule. Unscheduled visits may be necessary to repeat testing following abnormal laboratory results, for follow-up of AEs, or for any other reason, as warranted.

5.1.3. Adverse Event Information Collection

The investigator (or designee) will record all AEs that occur during the study The definition of an AE and SAE, and information on the determination of severity and relationship to treatment are provided in Section 7.

5.3. Rescue Criteria

Patients will be rescued at any time at the investigator's discretion by removal of DEXTENZA® by manual expression or flushing down the nasolacrimal duct.

6. Safety Definitions, Reporting, and Monitoring

6.1. Definitions

6.1.1. Adverse Event

An AE is any untoward medical occurrence in a patient administered a study drug which may or may not have a causal relationship with the study drug. Therefore, an AE is any unfavorable and unintended sign (including abnormal laboratory finding), symptom, or disease which is temporally associated with the use of a study drug, whether or not considered related to the study drug.

An AE also includes any worsening (i.e. any clinically significant change in frequency and/or intensity) of a pre-existing condition that is temporally associated with the use of the study drug.

6.1.2. Serious Adverse Event

A SAE is any untoward medical occurrence that at any dose:

- Results in **death** – includes all deaths, even those that appear to be completely unrelated to study drug (e.g. a car accident in which a patient is a passenger).
- Is **life-threatening** – in the view of the investigator, the patient is at immediate risk of death at the time of the event. This does not include an AE that had it occurred in a more severe form, might have caused death.
- Requires in-patient **hospitalization** or prolongation of existing hospitalization. In-patient hospitalization is defined as admission to a hospital or an emergency room for longer than 24 hours. Prolongation of existing hospitalization is defined as a hospital stay that is longer than was originally anticipated for the event, or is prolonged due to the development of a new AE as determined by the investigator or treating physician.
- Results in persistent or significant **disability/incapacity** (substantial disruption of one's ability to conduct normal life functions).
- Is a **congenital anomaly/birth defect**
- Is an **important medical event** – Important medical events may not be immediately life-threatening or result in death or hospitalization, but may jeopardize the patient or may require intervention to prevent 1 of the

other serious outcomes listed above (e.g., intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalization; or development of drug dependency or drug abuse). Any malignancy (other than basal cell skin cancers) would be considered a medically important event.

6.2. Recording and Reporting Adverse Events

All AEs and SAEs will be recorded only if they are medically relevant.

All SAEs, regardless of assessment of causal relationship to study insert will be reported to Ocular Therapeutix.

To report an SAE, Ocular Therapeutix will be contacted at the following:

ocutx.pharmacovigilance@propharmagroup.com
SAE hotline: 844-668-3948

The investigator will promptly report to the IRB all unanticipated problems involving risks to patients. This includes death from any cause and all SAEs related to the use of the study insert. All SAEs will be reported to the IRB, regardless of assessed causality.

7. STUDY VARIABLES

7.1. Demographic and Baseline Characteristics

Baseline characteristics will include standard demography (e.g. age, race, weight, height, etc.), disease characteristics including medical history, and medication history for each patient.

8. ETHICAL AND REGULATORY CONSIDERATIONS

8.1. Good Clinical Practice Statement

It is the responsibility of the investigator(s) to ensure that this clinical study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with the ICH guidelines for Good Clinical Practice (GCP) and applicable regulatory requirements.

8.2. Informed Consent

The principles of informed consent are described in ICH Guidelines for GCP.

Ocular Therapeutix will have the right to review and comment on the informed consent form.

It is the responsibility of the investigator or designee (if acceptable by local regulations) to obtain written informed consent from each patient prior to his/her participation in the study and after the aims, methods, objectives, and

potential hazards of the study have been explained to the patient in language that he/she can understand. The ICF will be signed and dated by the patient and by the investigator or authorized designee who reviewed the ICF with the patient.

Patients who can write but cannot read will have the ICF read to them before signing and dating the ICF.
Patients who can understand but who can neither write nor read will have the ICF read to them in presence of an impartial witness, who will sign and date the ICF to confirm that informed consent was given.

The original ICF will be retained by the investigator as part of the patient's study record, and a copy of the signed ICF will be given to the patient.

If new safety information results in significant changes in the risk/benefit assessment, the ICF will be reviewed and updated appropriately. All study patients will be informed of the new information and provide their written consent if they wish to continue in the study. The original signed revised ICF will be maintained in the patient's study record and a copy will be given to the patient.

8.3. Patient Confidentiality and Data Protection

The investigator will take all appropriate measures to ensure that the anonymity of each study patient will be maintained.

The patient's and investigator's personal data will be treated in compliance with all applicable laws and regulations.

8.4. Institutional Review Board

An appropriately constituted IRB, as described in ICH Guidelines for GCP, will review and approve:

- The protocol, ICF, and any other materials to be provided to the patients (e.g. advertising) before any patient may be enrolled in the study
- Any amendment or modification to the study protocol or ICF before implementation, unless the change is necessary to eliminate an immediate hazard to the patients, in which case the IRB will be informed as soon as possible

Ongoing studies will be reviewed by the IRB/EC on an annual basis or at intervals appropriate to the degree of risk.

In addition, the IRB will be informed of any event likely to affect the safety of patients or the continued conduct of the clinical study.

A copy of the IRB approval letter will be sent to Ocular Therapeutix prior to shipment of drug insert supplies to the investigator. The approval letter will include the study title, the documents reviewed, and the date of the review.

Records of the IRB review and approval of all study documents (including approval of ongoing studies) will be kept on file by the investigator.

REFERENCES

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3. Schultz C. Safety and Efficacy of Cyclosporine in the Treatment of Chronic Dry Eye. Ophthalmol Eye Dis. 2014; 6: 37–42. Published online 2014 Jun 24.
4. Yavuz B, Bozdag Pehlivan S, Unlu N. An overview on dry eye treatment: approaches for cyclosporin a delivery. Scientific World J. 2012;2012:194848
5. DEXTENZA (dexamethasone insert) Prescribing Information, Ocular Therapeutix,Inc.2019http://www.dextenza.com/wp-content/uploads/2019/06/NDA-208742-S001-Dextenza-labeling-19Jun19.pdf
6. Tyson, SL, Bafna, S., Gira, J.P. et al. Multicenter randomized phase 3 study of a sustained-release intracanalicular dexamethasone insert for treatment of ocular inflammation and pain after cataract surgery. J Cataract Refract Surg. 2018; 45(2): 204-12
7. Walters TR, et al. Efficacy and Safety of Sustained Release Dexamethasone for the Treatment of Ocular Pain and Inflammation after Cataract Surgery: Results from Two Phase 3 Studies. J Clin Exp Ophthalmol. 2016; 7(4): 572.

APPENDICES

I. The investigator will use the NEI scale to grade the cornea using fluorescein and the conjunctiva using lissamine green at visits 1, 2, 3, 4, 5, 6.

II. The investigator will grade the level of ocular injection on a 0 to 4-point scale at visits 1, 2, 3, 4, 5, 6.

0 = None

1 = Mild – Slightly dilated blood vessels; color of vessels is typically pink; can be quadrantal

2 = Moderate – More apparent dilation of blood vessels; vessel color is more intense (redder); involves the majority of the vessel bed

3 = Severe – Numerous and obvious dilated blood vessels; in the absence of chemosis the color is deep red, may be less red or pink in presence of chemosis, is not quadrantic

4 = Extremely Severe – Large, numerous, dilated blood vessels characterized by unusually severe deep red color, regardless of grade of chemosis, which involves the entire vessel bed

III. The investigator will evaluate the expressibility and quality of the meibomian glands at visits1, 2, 3, 4, 5, 6..

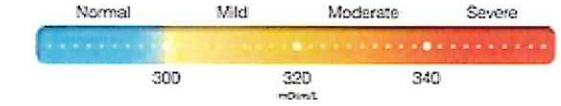
Grade scale for meibomian gland dysfunction

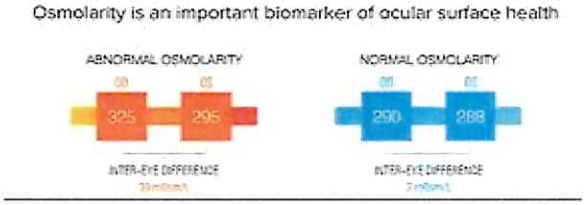
Grade Scale	Percentage of blocked glands	Quality of meibomian secretion
Grade 1	40% - 50%	Clear to mild milky secretion
Grade 2	50% - 70%	Milky to pasty secretion
Grade 3	70% – 85%	Thick, pasty to very little secretion
Grade 4	85% – 90%	Very little to no secretion

Source: J Lee

IV. The investigator will use the InflammaDry to detect levels of MMP9 at visits 1, 2, 3, 4, 5, 6.

V. The investigator will use Tear Lab to assess tear osmolarity at visits 1,2, 3, 4, 5, 6.





VI. The investigator will fill out the following questionnaire on the day of DEXTENZA® **insertion (Screening visit):**

Physician Ease of Insertion Questionnaire

The investigator will grade the level of ease of insertion of the intracanalicular insert on a 0 to 10-point scale.

The Investigator will record ease of insertion procedure on the appropriate Case Report Form.

0	1	2	3	4	5	6	7	8	9	10

Very Easy Very Hard

VII. The investigator will have the patient complete the DEQ-5 questionnaire at visits 1,3,4,5,6,7.