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Slow releasing artificial tears for contact lens wearers with dry eyes

Kelly J. Cochrane
Pacific University

Mark A. Wedekind
Pacific University

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Slow releasing artificial tears for contact lens wearers with dry eyes

Abstract
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Degree Type
Thesis

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Slow Releasing Artificial Tears for Contact Lens Wearers with Dry Eyes

By:
Kelly J. Cochrane
Mark A. Wedekind

Optometry 692
Dr. Alfred Furie, advisor
April 20, 1983
Abstract

Thirteen contact lens patients with an objective and/or subjective diagnosis of dry eye were given a non-medicated (hydroxypropyl cellulose) slow-releasing artificial tear (SR-AT). After two weeks of daily use, a majority of the patients reported positive results, including two patients with giant papillary conjunctivitis (GPC) and one with nocturnal lagophthalmos. It appears that this ocular insert may be beneficial for diagnosing the dry eye problems of contact lens wearers as well as non-contact lens wearers that are due to insufficient hydration and lubrication at the conjunctival/corneal and contact lens interface.

Key Words
slow releasing-artificial tears (SR-AT), giant papillary conjunctivitis (GPC), nocturnal lagophthalmos, dry eye, contact lenses, hydroxypropyl cellulose
Slow Releasing Artificial Tears for Contact Lens Wearers with Dry Eyes

It has been estimated that twenty to twenty-five percent of all persons seen in an eye clinic have subjective complaints of dry eyes.¹ The basic cause of dry eye can usually be attributed to alterations of the preocular tear film, which consists of three basic components:

1. The outer lipid layer is formed by secretions of the meibomian glands of the lids. Its function is to retard evaporation of the underlying aqueous layer and also to help stabilize the tear film against gravity.

2. The middle aqueous layer is secreted by the major and accessory lacrimal glands. It is low in viscosity, and contains the water-soluble components of the tears; salts, glucose, urea, and traces of enzymes, proteins, and glycoproteins.

3. The inner layer consists of mucin, which is spread over the epithelial cell membranes, and is anchored by the microvilli of the surface epithelial cells. This provides a hydrophilic surface for the aqueous tears to spread on, and lowers the surface tension for tear adherence. Mucin is produced by goblet cells of the conjunctiva, and covers the cornea via the spreading action of the eyelids.²,³

Basic causes of dry eye

Tear production tends to decrease with age.⁴ Systemic diseases, physiological damage to the secretory glands, corneal/conjunctival tissue disruption, and mechanical problems can all manifest dry eye.⁵
Dry eye and contact lenses

A contact lens, soft, gas-permeable, or hard, has an immediate thinning effect on the tear film. This is because the contact lens tends to alter the normal spreading of the mucin, diminishes tear circulation with the corneal surface, and mechanical agitation of the secretory glands.

While being worn, most soft contact lenses loose some of their water content and become relatively dehydrated. This increases the need for maintenance of proper integrity of the precocular tear film during the wearing hours.

Corneal sensitivity is usually decreased by contact lens wear. This may cause the contact lens wearer to become a "lazy blinker." Blinking may become incomplete and decrease in frequency. This deviation from the normal four to eight blinks per minute may cause permanent dry spots and epithelial damage.

Until recently, the contact lens wearer with dry eyes has had to instill a liquid re-wetting agent. This constant need for dropping has caused patient inconvenience to the point where some patients give up contact lens wear altogether.

Case history

Subjective symptoms of dry eye frequently arise during the case history. The patient is likely to complain of dry, burning eyes, with accompanying itching and foreign body sensation. Occasionally, the patient will complain of
Case history, continued

photophobia, and/or ropy discharge at the inner canthus. It is important to inquire of current and recurrent illnesses, medications, familial dry eye predilection, vocational and avocational aspects.

Discussion of SR-AT

The slow releasing artificial tear (SR-AT, Lacrisert) is a rod shaped pellet of sterile, inert, water-soluble hydroxypropyl cellulose. It is approximately 3.5 millimeters long, 1.27 millimeters in diameter, and weighs 5 milligrams.\(^{10,11}\) The SR-AT is inserted into the inferior cul-de-sac with a special "L"-shaped plastic applicator (inserts 1,2). Since Lacrisert contains no preservative, the integrity of the lipid layer is unaltered, as contrasted with many preserved rewetting formulations that contain cationic surfactants that disrupt the layer.\(^{12}\)

The insert absorbs available tear fluid and swells many times larger than its original size (pictures 1-4). It gradually dissolves, releasing the hydroxypropyl cellulose, which physiologically resembles the mucin of the inner tear film layer. In some patients with marked tear deficiency, moisture may be insufficient to dissolve the insert. With these patients, sterile saline drops a few times daily may help promote dissolution.\(^{13}\)

Patients in selected studies who demonstrated chronic dry eye symptoms not adequately relieved by the usage of the more conventional liquid tear substitutes have manifested
Discussion, continued

marked relief and fewer objective corneal abnormalities when they used the SR-AT. Some patients find it especially convenient because of the elimination of the need for constant dropping.

Adverse effects of the SR-AT include transient blurring of vision, distorted vision, ocular discomfort or irritation, matting and stickiness of the eyelashes, photophobia, edema of the eyelids, hyperemia, and hypersensitivity reactions. Arthritic or neuromuscularly compromised individuals may have difficulty with installation. Soluble inserts need not be removed, thus limiting patient manipulation to insertion only. Some patients who inserted the Lacrisert at night have complained of very blurred vision the following day, making it difficult to drive or perform usual tasks. Decreases in visual acuity have also been reported.

The literature concerning the effect of hydroxypropyl cellulose on the numerous types of plastic polymers that comprise contact lenses is limited. The approved liquid tear substitutes that commonly contain hydroxypropyl cellulose apparently have not demonstrated any reactions with the contact lens materials. In fact, it would be highly unlikely that a reaction would occur since contact lens wetting and cushioning solutions are actually very similar in chemical composition to the lens polymers.
Methods

Thirteen contact lens patients aged 20 to 27 (four gas-permeable and nine soft lens wearers) were tested with the SR-AT monocularly for a total of two weeks. The left eye was regarded as the control eye, with no insert used in that eye. A patient instruction and information form was given to all patients (insert 3).

An initial exam was performed to determine baseline data and diagnosis. The parameters included:

1. Refractive status. The maximum plus sphere to first readable 20/20 acuity for right and left eyes.

2. Tear break-up time (B.U.T.). A moistened fluorescein strip was first applied to the bulbar conjunctiva. With a biomicroscope (25X), the interval between a complete blink and the appearance of the first dry spot observed in the tear film was determined.

3. Rose bengal staining. A moistened rose bengal impregnated strip was applied to the bulbar conjunctiva. This dye stains devitalized cells and precipitated mucin, both of which tend to be present in chronically dry eyes.

4. Biomicroscope examination. Conjunctival health, corneal integrity (including edema), contact lens movement and cleanliness were recorded.

5. Schirmer I and Schirmer IA Tests. Schirmer I (reflex secretion) was without local anesthesia, and IA (basal secretion) was with the aid of topical proparicaine.21

6. Visual acuity. Visual acuity with and without contact lens correction was recorded.
Each test was done initially, the next day (20 to 24 hours), after one week, and the close out exam after two weeks. The patient was then given a questionnaire for written evaluation of the SR-AT/contact lens system (insert 4).

Results

After the two week trial period, subjective and objective data was analyzed. One of the most significant results was observed in patients eight and nine (table 1). The two patients had histories of chronic giant papillary conjunctivitis (GPC). In the initial exam the papillae size and tarsal involvement areas were quantified. In the close out exam, regression of the GPC was observed. No significant decrease in GPC involvement was noted in patients one and ten.

A t-test of the average breakup times before and with the SR-AT was determined. The increase in the breakup times with the insert was found to be insignificant at the five percent level. However, the SR-AT had an average breakup time of 13.88 seconds as compared to 10.76 seconds for the control eye.

Patient three, diagnosed as having nocturnal lagophthalmos reported increased contact lens comfort. Quantitatively, this patient demonstrated a decrease in breakup time with the SR-AT. However, her breakup time was considered normal before and while using the insert; so this finding is insignificant.

Lens movement observed with the slit lamp in general was increased slightly with the insert. In patients two, eleven, and twelve the movement and centering properties improved dramatically. Magnified inspection of the lens revealed no remarkable residues attributable to the SR-AT. No adverse
effect on the contact lenses was observed.

The range of time tolerance for the insert in the cul-de-sac was six to twelve hours. After this length of time, the pellet expands and dissolves into annoying chunks that tend to float over the lens. Some patients removed the expanded insert when it reached the extreme stage of dissolution.

No significant decrease in visual acuities with Lacrisert was revealed. However, subjective intermittent blurring was reported by all thirteen patients. The degree of blurring usually depended on the length of time the SR-AT had been in the eye; the longer in the eye, the more the blur. Patients four and six reported that they would not continue using the insert because it hindered vision too much.

Nine patients reported increased comfort and felt that the SR-AT would be beneficial in this respect. Patient twelve, who was diagnosed as hypersensitive to thimerosal, found the non-preserved insert to increase his tolerable wearing time.

Discussion

We believe the regression of the GPC involvement in patients eight and nine can be attributed to the increased integrity of the tear film. Since more contact lens and tarsal conjunctiva lubrication was present, less physical abrasion resulted. Since it is believed that GPC is caused either by hypersensitivity to the contact lens materials or to the deposits on the lens, it follows that less contact between the tissue and the plastic may reduce the GPC.

All thirteen patients felt the cost of the SR-AT was prohibitive for daily use (about $20.00 for sixty inserts).
Usage on "bad" days is more of an economic reality.

Ten patients felt that the SR-AT tended to swell to an uncomfortably large mass. Four patients suggested reducing them in size and in fact (to our chagrin) one patient cut the insert in half with a razor blade and had very good success. He noted that this would decrease usage cost in half.

Handling problems in general did not occur. Those patients adept enough to insert and remove contact lenses probably will have no problems handling the SR-AT. Some occurrences of the SR-AT popping out after three or four hours were reported. Patient one who tended to wear her contact lenses up to eighteen hours per day found that insertion of the Lacrisert at noon provided good comfort late into the night.

All thirteen patients had unremarkable case histories with regard to injuries, surgeries, diseases, corneal abnormalities, and systemic diseases. All experienced intermittent or constant contact lens irritation. The SR-AT helped to confirm a diagnosis of dry eye induced contact lens problems since the hydroxypropyl cellulose acts directly to supplement the inner mucin layer of the preocular tear film.
Conclusion
Clinically observed patients may experience dry eye due to conjunctival-corneal-contact lens interface tear component deficiencies. The SR-AT can be used by the eye care specialist as a diagnostic aid for assessment of dry eye manifestations experienced not only by non-contact lens wearers, but contact lens wearers as well.

Kelly J. Cochrane

Mark A. Wedekind

Dr. Alfred Furie

Pacific University College of Optometry
Forest Grove, Oregon
April 1983

The support for this study was provided by the Oregon Optometric Association, and Beta Sigma Kappa (International optometric honor fraternity).
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<tr>
<th>SUBJECT</th>
<th>AGE</th>
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<th>DIAGNOSIS</th>
<th>AVERAGE TEAR BREAKUP TIME</th>
<th>OVERALL IMPRESSION</th>
<th>COMMENTS</th>
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Photos of SR-AT over time

two minutes

2 hours

4 hours

6 hours
Tabulation of Questionnaire Responses

Number of corresponding responses follows each question.

Did you notice any of the following beneficial effects while using Lacrisert:

1. More comfortable contact lens wear? (7)
2. Decreased redness of the eye? (3)
3. Decreased itching and burning of the eye? (2)
4. Decrease in dry eye problems? (9)
5. Do you think that regular use of Lacriserts would increase your contact lens wearing time? (3)
6. Are there any other beneficial effects that you noticed that are not mentioned above? (See Discussion)

Did you notice any of the following adverse effects while using the Lacrisert?

1. Momentary blurring of vision? If so, how often did it happen? (11)
2. Did constant blurring of vision occur until the lens was removed and cleaned? If so, how often did it happen? (7)
3. Eye irritation from the Lacrisert? (3)
4. Foreign body sensation? (9)
5. Matting or stickiness of eyelashes? (7)
6. Difficulty with insertion? (3)
7. Do you think that regular use of Lacriserts would decrease your contact lens wearing time? (3)
8. Are there any other adverse effects that you noticed that are not listed above? (See Discussion)

Do you have any suggestions on how Lacrisert may be improved upon as a product or in its method of use? (See Discussion)

What is your overall impression of Lacrisert?

- 7 subjects had a favorable impression of Lacrisert
- 3 subjects had a negative impression of Lacrisert
- 3 subjects had no strong feelings either favorable or negative of Lacrisert
Bibliography


6. Holly.


23. Ibid.
INSTRUCTIONS FOR USING 'LACRISERT'
(HYDROXYPROPYL CELLULOSE OPHTHALMIC INSERT, MSD)

NOTE: Your physician will demonstrate the proper use of LACRISERT. Please read and follow these instructions carefully for your subsequent use.

Two applicators (one spare) are supplied with each package.

Before opening the package of LACRISERT, wash your hands thoroughly with soap and water.

STEP 1 On a flat surface, open blister pocket slowly and smoothly by peeling back label area. Each blister pocket contains one LACRISERT ophthalmic insert.

STEP 2 Open applicator package with label side up. Avoid touching grooved tip of the applicator. Pick up applicator by the wide end and rinse the tip thoroughly under hot running tap water. Gently shake off excess water.

STEP 3 Hold applicator with tip facing down and with forefinger on top to guide and apply pressure. Press the grooved tip of the applicator onto the center of the LACRISERT ophthalmic insert and it will adhere to the applicator.

STEP 4 Look into a mirror. Starting with the right eye, turn your head to the right so that the colored part of the eye is close to your nose. Use your free hand to grasp the lower lid between the thumb and index finger. Pull the lid away from the eyeball and create a pocket between the white part of the eyeball and the lid.

STEP 5 Place the tip of the applicator containing LACRISERT into the pocket. Avoid touching the colored part of the eye.

Lift applicator, look down, then release lower eyelid. LACRISERT should remain deep in the pocket recess of the eye.

Repeat procedure with left eye, turning head to the left so that the colored part of the eye is close to your nose.

Rinse the applicator thoroughly under hot running tap water after use. Gently shake off visible water droplets and promptly return it to the storage container. Note that the storage container provides space for a strip of two LACRISERT ophthalmic inserts next to the applicator storage compartment.

IMPORTANT

Should the removal of the LACRISERT ophthalmic insert be necessary, follow these instructions.

1. Locate LACRISERT by pulling the lid away from the eyeball while looking for LACRISERT in a mirror.
2. Then close the eyelids.
3. When located, move LACRISERT upward with your fingers through the closed eyelids.
4. Keep the lids against the eyeball and LACRISERT should slip over the lid margin so that you can remove it with a clean facial tissue without touching the colored part of the eye.

CAUTION: Because this product may produce transient blurring of vision, you should exercise caution when operating hazardous machinery or driving a motor vehicle.

Store below 30°C (86°F).
STERILE OPHTHALMIC INSERT

LACRISERT®
(HYDROXYPROPYL CELLULOSE
OPHTHALMIC INSERT, MSD)

DESCRIPTION
LACRISERT® (Hydroxypropyl Cellulose Ophthalmic Insert, MSD) is a rod-shaped, water-soluble, ophthalmic preparation made of hydroxypropyl cellulose, 5 mg. LACRISERT contains no preservatives or other ingredients. It is about 1.27 mm in diameter by about 3.5 mm long.

LACRISERT is supplied in packages of 60 units, together with illustrated instructions and a special applicator for removing LACRISERT from the unit dose blister and inserting it into the eye. A spare applicator is included in each package.

ACTIONS
LACRISERT acts to stabilize and thicken the precorneal tear film and prolong the tear film breakup time which is usually accelerated in patients with dry eye states. LACRISERT also acts to lubricate and protect the eye. LACRISERT usually reduces the signs and symptoms resulting from moderate to severe dry eye syndromes.

INDICATIONS
LACRISERT is indicated in patients with moderate to severe dry eye syndromes, including keratoconjunctivitis sicca. LACRISERT is indicated especially in patients who remain symptomatic after an adequate trial of therapy with artificial tear solutions.

LACRISERT is also indicated for patients with:
- Exposure keratitis
- Decreased corneal sensitivity
- Recurrent corneal erosions

LACRISERT usually reduces the signs and symptoms resulting from moderate to severe dry eye syndromes, such as conjunctival hyperemia, corneal and conjunctival staining with rose bengal, exudation, itching, burning, foreign body sensation, smarting, photophobia, dryness and blurred or cloudy vision. Progressive visual deterioration which occurs in some patients may be retarded, halted, or sometimes reversed.

In a multicenter crossover study the 5 mg LACRISERT® administered once a day was compared to artificial tears used four or more times daily. There was a significant prolongation of tear film breakup time and a significant decrease in foreign body sensation associated with dry eye syndrome in patients during treatment with inserts as compared to artificial tears. Improvement, as measured by amelioration of symptoms, by slit lamp examination and by rose bengal staining of the cornea and conjunctiva, was greater in most patients with moderate to severe symptoms during treatment with LACRISERT. Patient comfort was usually better with LACRISERT than with artificial tears solution, and most patients preferred LACRISERT.

In most patients treated with LACRISERT for over one year, improvement was observed as evidenced by amelioration of symptoms generally associated with keratoconjunctivitis sicca such as burning, tearing, foreign body sensation, itching, photophobia and blurred or cloudy vision.

During studies in healthy volunteers, a thickened precorneal tear film was usually observed through the slit lamp while LACRISERT was present in the conjunctival sac.

CONTRAINDICATIONS
LACRISERT is contraindicated in patients who are hypersensitive to hydroxypropyl cellulose.

WARNINGS
Instructions for inserting and removing LACRISERT should be carefully followed.

PRECAUTIONS
Because this product may produce transient blurring of vision, patients should be instructed to exercise caution when operating hazardous machinery or driving a motor vehicle.

ADVERSE REACTIONS
The following adverse reactions have been reported in patients treated with LACRISERT, but were in most instances mild and transient:
- Transient blurring of vision (See PRECAUTIONS)
- Ocular discomfort or irritation
- Marting or stickiness of eyelashes
- Photophobia
- Hypersensitivity
- Edema of the eyelids
- Hyperemia

DOSAGE AND ADMINISTRATION
One LACRISERT® ophthalmic insert in each eye once daily is usually sufficient to relieve the symptoms associated with moderate to severe dry eye syndromes. Individual patients may require more flexibility in the use of LACRISERT; some patients may require twice daily use for optimal results.

LACRISERT is inserted into the inferior cul-de-sac of the eye beneath the base of the tarsus. Illustrated instructions are included in each package, but initially patients must be instructed in the correct method of insertion. When in the ophthalmologist's office, the patient should read the instructions, then practice insertion and removal of LACRISERT until proficiency is achieved.

NOTE: Occasionally LACRISERT is inadvertently expelled from the eye, especially in patients with shallow conjunctival fornices or when the eye is rubbed. If required, another LACRISERT® ophthalmic insert may be inserted. Experience indicates that transient blurred vision develops in an individual patient; the patient may want to remove LACRISERT a few hours after insertion to avoid this. Another LACRISERT® ophthalmic insert may be inserted if needed.

HOW SUPPLIED
No. 3380—LACRISERT, a rod-shaped, water-soluble, ophthalmic preparation made of hydroxypropyl cellulose, 5 mg, is supplied as follows:
- NDC 006-3380-60 in packages containing 60 unit doses, two reusable applicators and a storage container.
- Store below 30°C (86°F).
- MERCK SHARP & Dohme, Division of Merck & Co., Inc., West Point, Pa. 19486
Subject Release Form

1. Pacific University College of Optometry
   A. Title of Project: The Use of Lacrisert in Conjunction with Soft Contact Lenses.
   B. Principal Investigator: Kelly Cochrane and Mark Wedekind
   C. Advisor: Al Furie OD
   D. Location: Pacific University College of Optometry, Forest Grove, Oregon
   E. Date: 1982

2. Description of Project:
   This project will determine the compatibility of Lacrisert with soft contact lens wearers. The Lacrisert will be placed into the right eye only while contact lenses are worn in both eyes. After two weeks of Lacrisert usage, you will fill out a questionnaire on the effectiveness of the Lacrisert and on any problems encountered during its use.

3. Description of Risks:
   1) Lacrisert may produce momentary blurring of vision.
   2) You may experience initial eye discomfort or irritation from the Lacrisert.
   3) There is a slight chance that you may develop an allergic reaction to the Lacrisert.
   4) From time to time you may experience irritation from bright lights.
   5) The Lacrisert may become contaminated if inserted with uncleaned hands. This could lead to an eye infection.

4. Description of Benefits:
   This experiment will provide valuable information on the use of Lacrisert with soft contact lens patients who have dry eye symptoms. If Lacrisert proves to be compatible with soft contact lens wearers it could provide them with the following benefits: 1) longer wearing time, 2) more comfortable contact lens wear, 3) decreased redness of the eye, 4) decreased itching and burning of the eye, and 5) decreased dryness of the eye.

5. Compensation and Medical Care:
   If you are injured in this experiment it is possible that you will not receive compensation or medical care from Pacific University, the experimenters, or any organization associated with the experiment; however, all reasonable care will be used to prevent injury.

6. Alternatives Advantageous to Subjects:
   Not Applicable.
7. Offer to Answer any Inquiries:
The experimenter will be happy to answer any questions that you may have at any time during the course of the project.

8. Freedom to Withdraw:
You are free to withdraw your consent and to discontinue participation in this project or activity at any time without prejudice to you.

I have read and understand the above. I am 18 years of age or over.

Printed Name ________________________________
Signed _____________________________ Date __________
Address __________________________________________
Phone ______________________

Name and address of a person not living with you who will always know your address
________________________________________
Instruction Handout for the Subject

1) Since Lacrisert may produce momentary blurring of vision you should exercise caution when operating hazardous machinery or driving a motor vehicle.

2) There is a slight chance that you may be allergic to the Lacrisert. If you experience blood-shot eyes, swelling of eyelids with a burning or itching sensation you are to discontinue use of the Lacrisert immediately and notify the experimenters as soon as possible.

Phone: 357-6151 ext. 208 for the optometry clinic
       357-6580 for Mark Wedekind
       357-7412 for Kelly Cochrane

3) Remember to thoroughly wash your hands before inserting the Lacrisert (see instructions next page).

4) Only insert the Lacrisert into the right eye.

5) You must return after the first day of Lacrisert usage and after the first and second week of usage for a progress exam.