

Important Information

Corneal Collagen Cross-linking with Riboflavin (C3-R) Treatment “OFF-LABEL”

GENERAL INFORMATION

The following information is intended to help you make an informed decision about undergoing a Corneal Collagen Cross-linking with Riboflavin (C3-R) treatment.

It is impossible to list all of the possible risks and complications associated with this proposed procedure or any other treatment. Risks and complications that are considered to be unforeseeable, remote, or commonly known are not discussed. In addition, because C3-R treatment is a relatively new treatment, there may be long-term effects not yet known or anticipated at the present time.

The U.S. Food and Drug Administration (FDA) primarily regulates medical devices and drugs. The use of Riboflavin is considered a form of vitamin supplementation and therefore is not regulated by the FDA. Riboflavin is usually administered orally and therefore the use of riboflavin drops in this treatment would be considered “off-label”. The procedure also uses ultraviolet-A (UVA) light in low dose which is considered “off-label” since the device is typically used in dermatology for skin treatments. The UVA device we use has a filter, which reduces the UVA exposure to a level less than a day at the beach. However, the device is labeled that you should use protective eyewear with the device. The use of this device without protective eyewear is considered “off-label”. Your doctor can use “off-label” treatments and procedures if you are in agreement.

AN OVERVIEW OF THE C3-R TREATMENT PROCEDURE

Diagnosis: You have been diagnosed with a weakened cornea condition.

C3-R Treatment Described: The treatment is performed using a topical application of riboflavin (drops in the eye). The procedure involves holding your eyelids open with a lid holder. Riboflavin drops are administered over a 30 minute period while wearing specially designed glasses that deliver ultraviolet-A light directly to the cornea (clear portion of the eye). The application of the riboflavin and ultraviolet-A is intended to encourage collagen crosslinking, a connection between collagen fibers, within the cornea. Collagen is a protein substance of white fibers. Patients with a weakened cornea have a reduced tensile strength of these collagen fibers. Crosslinking therefore theoretically increases the tensile strength of the collagen fibers, thus resulting in an increased rigidity (strength) of the cornea.

Limits of C3-R treatment: Although the goal of C3-R treatment is to stabilize/strengthen the cornea, this result is not guaranteed. This procedure is not designed to reduce your need for glasses or contacts lenses to obtain optimal vision. Additional procedures, spectacles, contact lenses, Intacs, or cornea transplant may be required to achieve adequate vision.

C3-R treatment will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, or retinal degeneration or detachment.

C3-R treatment does not correct the condition known as presbyopia (aging of the eye), which occurs in most people around age 40 and requires them to wear reading glasses for close-up work, sometimes including computer distance.

Risks and Contraindications

Contraindications: The treatment should not be performed on persons:

- with uncontrolled vascular disease
- with uncontrolled autoimmune disease;
- who are immune-compromised or on drugs or therapy that suppress the immune system;
- who are pregnant, nursing, or expecting to become pregnant within the one month following the C3-R treatment;
- with residual, recurrent, or active ocular disease(s) or abnormality except for keratoconus in either eye;
- with active or residual disease(s) likely to affect wound-healing capability;
- with unstable or uncontrolled diabetes;
- with uncontrolled glaucoma
- with uncontrolled blepharitis

If you know that you have any of these conditions, you should inform your physician. In addition, if you have any other concerns or possible conditions that might affect your decision to undertake C3-R treatment, you should discuss them with your physician.

Risks: The risks of C3-R treatment include, but are not limited to:

- **Loss of Vision:** C3-R treatment can possibly cause loss of best-corrected vision. This can be due to infection (internal or external), scarring or other causes. Unless successfully controlled by antibiotics, steroids, or other necessary treatment, it could even cause loss of the infected eye. Vision loss can be due to the cornea healing with an irregular surface, which could cause astigmatism and make wearing glasses or contact lenses necessary. Irregular corneal healing could result in an uneven corneal surface so that distorted vision or “ghosting” occurs. This may or may not be correctable by spectacles or contact lenses.
- **Visual Side Effects:** Other complications and conditions that can occur with C3-R treatment include: epithelial defect (the surface cell of the cornea become detached); anisometropia (difference in power between the two eyes); aniseikonia (difference in imaging size between the two eyes); double vision; hazy vision; induced astigmatism; reduced contrast sensitivity; fluctuating vision during the day and from day to day; increased or decreased sensitivity to light that may be incapacitating for some time and may not completely go away; glare and halos around lights, which may not completely go away.
- **Other Risks:** Other reported complications with other cornea procedures that may also occur with this treatment may include: corneal ulcer formation; clouding or hazing of the cornea; cornea scarring; endothelial cell loss (loss of cell density in the inner layer of the cornea, possibly resulting in corneal swelling); ptosis (droopy eyelid); corneal swelling; contact lens intolerance; increased dry eyes; rosacea (eyelid nodules); retinal detachment; new or increased floaters; hemorrhage; diminished depth perception; corneal epithelial (skin) abrasion or defect. Corneal abrasion can slow the recovery process and may lead to reoccurring corneal erosions with eye discomfort and blurred vision. Complications could also arise requiring further corrective procedures including either a partial (lamellar) or full-thickness corneal transplant using donor cornea. These complications include loss of cornea; damage to the cornea; cornea decentration; progressive corneal thinning (ectasia).

It is also possible that the glasses may not deliver the correct amount of ultraviolet-A; in this case, the treatment may be stopped. There are also potential complications due to administration of the riboflavin such as irritation to the eye or skin surrounding the eye. A contact lens may need to be worn as a bandage until the irritation resolves.

In a rare case a cornea transplant may be needed to restore useful vision after this treatment.

- **Employment Risk:** You should be aware that having this surgery may affect future employment opportunities with certain military or law enforcement agencies. This procedure may impair your ability to perform your job.
- **Later-Discovered Complications:** C3-R treatment is a relatively new technique. You should be aware that other complications might occur that have not yet been reported. Longer-term results may reveal additional risks and complications. After the procedure, you should continue to have routine check-ups to assess the condition of your eyes.
- **Risks of Not Undergoing C3-R treatment:** The risks of not having the surgery are limited to those associated with your current visual condition. These include but are not limited to the dangers that may be associated with losing glasses or contact lenses, or the risks of corneal distortion and/or infection from wearing improperly fitting contact lenses.

Alternatives to C3-R treatment

C3-R treatment is purely an elective procedure, and you may decide not to have this operation at all. Among the alternatives are:

- Eyeglasses/spectacles
- Contact lenses
- Orthokeratology
- Intacs
- Cornea Transplant

You may wish to discuss these options with your physician.

Pre- and Post-Treatment Care

Before the C3-R treatment:

- **Pregnancy:** Pregnancy could adversely affect your treatment; In addition, pregnancy may affect your healing process, and some medications may pose a risk to an unborn or nursing child. If you become pregnant in the one month following treatment, you should notify your eye doctor immediately.
- **Taking medications and allergies:** You should inform your physician of any medications you may be taking in order to account for the risk of allergic reactions, drug reactions, and other potential complications during the C3-R treatment and subsequent treatment.
- **Contact lens wearers:** Patients who wear gas-permeable or hard contact lenses must completely discuss with the physician on returning to their use after the procedure. Typically the patient will be requested to continue use of contacts 2-4 weeks after the procedure.

Post-Treatment Precautions:

- **Eye Protection:** Avoid exposing the eye to tap water in the bath or shower, as such non-sterile water may expose the eye to increased risks of infection. Wear sunglasses during the first day after having surgery. The eye shield should be worn nightly for 1 week. Avoid rubbing the eye. The eye may be more fragile to trauma from impact.
- **Operating Motor Vehicles:** After C3-R treatment, in order to operate motor vehicles, glasses, contact lenses, eye drops, or other measures may be needed. After treatment, you may experience starburst-like images or “halos” around lights, your depth perception may be slightly altered, and image sizes may appear slightly different. Some of these conditions may affect your ability to drive and judge distances. Driving should only be done when you are certain that your vision is adequate. On the day of the treatment as well as the day after, we may request you arrange to have a driver.
- **Pain and Discomfort:** The amount of pain and discomfort that can be expected soon after the C3-R treatment varies with the individual. You should expect that the eye will be sore to some extent after the treatment. Vision may be blurry, and you may experience some redness and/or corneal edema (swelling of the cornea). Some patients report the sensation of a foreign object in the eye, itching, or dryness of the eye.