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Patient Information Guide

Corneal Collagen Cross-Linking (CXL) With Riboflavin



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Disclaimer

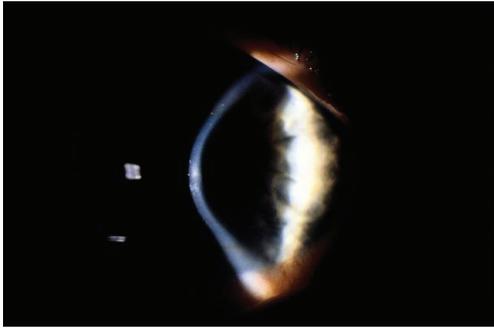
This is general information and is not intended to replace the advice of a qualified healthcare provider.

Please consult your healthcare provider who will be able to determine the appropriateness of the information for your specific situation.

For More Information, Please Contact
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What is Keratoconus?

The cornea is the clear window on the front of the eye. It provides the majority of the eye's focusing power. Keratoconus is a progressive condition in which non-inflammatory processes result in structural changes within the cornea. This causes the cornea to assume a more cone-like shape.



Keratoconus with corneal thinning.

What are the symptoms?

The condition typically starts in adolescence and early adulthood. Patients with Keratoconus often report frequent changes in refraction, substantial distortion of vision, seeing multiple images, streaking and sensitivity to light.

If this condition usually afflicts both eyes, however, one eye may be more affected than the other. The deterioration in vision can affect the patient's ability to drive a car or read normal print.

Initial management is with glasses and/or contact lenses. Corneal transplantation surgery is necessary when vision can no longer be improved with glasses or contact lenses.

Who gets Keratoconus?

It may be inherited in an autosomal dominant fashion. This means that family members may develop Keratoconus. It can also be random with no other family members affected. Both men and women are equally affected with 90% of patients being affected in both eyes.

What are the risk factors for Keratoconus?

Reported risk factors for Keratoconus include eye rubbing, atopy, a family history of Keratoconus, genetic predisposition, and certain conditions such as Down's syndrome, ocular allergy, connective tissue disease, and long-term rigid contact lens wear.

What is corneal Ectasia?

Ectasia is a bulging of the cornea. Ectasia is also called iatrogenic Keratoconus or secondary Keratoconus because it is basically a surgically induced version of the naturally occurring disease Keratoconus. Ectasia is a very serious long-term complication of LASIK.

What causes Ectasia and what surgery is it associated with?

Ectasia is more frequently associated with LASIK because LASIK involves creating a stromal flap in the cornea thereby reducing the strength of the cornea. The thicker the flap and the higher the refractive correction can both promote weakening of the cornea. Since PRK is a surface treatment and does not involve a stromal flap very few cases have occurred following this procedure. It is believed that proper patient selection and the use of the Femtosecond laser to create thin flaps reduces the chance of ectasia occurring post refractive surgery.

Can Ectasia be prevented?

Ectasia results from biomechanical weakening or destabilization of the cornea. This means that many patients developing post refractive surgery ectasia may have gone on to develop Keratoconus naturally in due course of time even if they did not have the surgery. Unfortunately, our current technology does not provide us with a definitive test to identify those patients that may be at risk of developing Keratoconus or post-refractive surgery ectasia.

Young age, changing refractive error with astigmatism, eye rubbing, thin cornea, and abnormal topography are some of the features that may identify patients with very early stage or Forme Fruste Keratoconus - a term used to describe patients that are more likely to progress to Keratoconus. Refractive Surgery in these patients has the potential to speed up the progression of their condition.

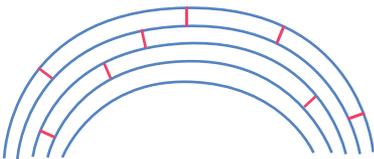
What is Corneal Collagen Cross-linking (CXL)?

A new technique of CXL using the photosensitizer Riboflavin (Vitamin B2) and ultraviolet light (UVA) has been developed in Europe. In extensive experimental studies in animal eyes (including biomechanical stress & strain measurements) researchers have demonstrated a significant increase in corneal rigidity or stiffness after CXL using this Riboflavin/UVA treatment.

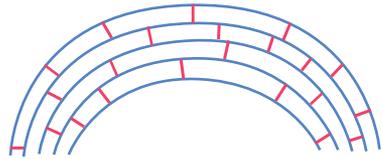
This method works by increasing collagen cross-linking, which is the natural “anchor” within the cornea. This anchor is responsible for preventing the cornea from bulging out and becoming steep and irregular, a consequence of advanced Keratoconus and ectasia.

European clinical studies in humans evaluated the effect of the new CXL method in patients with Keratoconus and showed that, in all treated eyes, progression of the condition was halted. To date there over 100,000 patients have undergone cross-linking.

Before CXL (weaker)



After CXL (stronger)



Corneal layers (blue) and the collagen-cross links (orange)
before and after CXL.

How is the treatment done?

The treatment is performed in our office. Usually, only one cornea is treated at one sitting. The treatment is performed under topical anesthesia (using freezing eye drops). The surgeon removes the surface layer of the cornea (epithelium) and the eye is treated with application of photosensitizing Riboflavin eye drops for 30 minutes. The eye is then exposed to UVA light from a distance of about 5 cm. The total treatment lasts about an hour per eye. After the treatment, antibiotic eye drops are then applied; a bandage contact lens will be inserted that will be removed by the surgeon during a follow-up visit. Protective eyewear, such as sunglasses should be worn for a few days until complete healing takes place.



What is the recovery time after the treatment?

On average, the epithelium of the eye regrows between 4 days to 1 week at which time the surgeon will remove the bandage contact lens. However, in some individuals it may take a little longer. Hence, patients must be available for follow-up visits for the first week after the CXL procedure. Full recovery, meaning stability of the cornea after treatment, is not attained for some months after the treatment.

Post treatment care:

After the treatment, it is expected that one will continue to wear spectacles or contact lenses (although a change in the prescription may be required). One must also continue antibiotic and lubricating eye drops as prescribed by the surgeon.

Will CXL cure my Keratoconus?

It is important to understand that CXL treatment is not a cure for Keratoconus or Ectasia. Rather, it aims to slow or halt the progression of the condition.

A person whose Keratoconus or Ectasia is already so severe that it cannot be corrected by contact lenses is unlikely to gain any benefit from this treatment. In this situation a corneal transplant is usually required.

Am I eligible for this procedure?

To be eligible for CXL treatment you will need to meet two essential criteria:

1. The diagnosis of Keratoconus or ectasia must be confirmed based on clinical examination findings and corneal topography (mapping)
2. There may be evidence of progression of the Keratoconus or ectasia occurring over the last 12 months determined by changes in contact lens prescription, spectacle prescription and measurements of corneal shape (Keratometry or computerized corneal mapping).

You will **NOT** be eligible to undergo CXL treatment if any of the following apply:

- There is a past history of Herpes Simplex Keratitis.
- Your cornea is too thin (less than 400 microns)
- Other corneal disease or scarring is present
- There is a history of chemical burns to the cornea or healing problems.
- There is a known allergy to Riboflavin.
- If you suffer from Nystagmus or other condition which will render it difficult to hold a steady gaze.
- Very advanced Keratoconus or Ectasia.
- Poor best corrected visual activity (BCVA) not improving with contact lenses.
- If you have taken Vitamin C supplements (within 1 week of the procedure).
- If you have recently used Accutane

Patients who have had a corneal transplant in one eye may be able to undergo this treatment in the un-operated eye if it satisfies these requirements. Those who have had transplants in BOTH EYES will not be able undergo this procedure.

What are the potential risks?

There are a number of potential risks associated with CXL treatment although very few complications have been reported to date.

- Ultraviolet light is potentially harmful to the cells and structures of the eye, however with proper application of the Riboflavin drops prior to exposure to the UV light this risk is greatly minimized. Cataracts have not been reported after CXL in European trials.
- The treatment involves the temporary removal of the outer layer (skin or Epithelium) of the cornea. Usually, this surface re-grows within 1 week; however, there is a chance that the surface of the cornea will be slower to heal in some individuals.
- Infection may occur which could lead to the development of corneal scarring. Antibiotics are routinely used to prevent this complication. Corneal scarring might necessitate further surgical procedures (including Corneal Transplantation).
- The increased corneal rigidity induced by exposure to UVA and Riboflavin may decrease over time and further periodic treatments may be required, raising the possibility of other side effects from repeat exposure to treatment conditions.
- Other lesser but more commonly encountered risks include:

Inability to wear contact lenses for several weeks after the treatment.

Changes in the shape of the cornea necessitating a refitting of a contact lens or a change in the spectacle correction.

As is the case with any new treatment, there may also be long-term risks that have not yet been identified.

Will MSP or extended health insurance plans cover the cost of the treatment?

Corneal Collagen Cross-linking (CXL) with riboflavin is a covered benefit from MSP if ectasia is related to or caused by keratoconus.

It is **NOT** a covered benefit if related solely to refractive corneal procedures.

