The Cornea Research Foundation of America is actively involved in evaluating a new corneal strengthening treatment that may help patients with keratoconus.

What is Keratoconus?

Sometimes the cornea, the clear window on the front of the eye, weakens and bulges outwards causing visual distortion. This condition is called keratoconus (cone shaped cornea). The shape of the cornea changes from a smooth, round surface to a cone shape (see drawings to the right).

With keratoconus, your vision changes in two ways. First, the surface of the cornea becomes slightly wavy, which is called irregular astigmatism. Second, as the front of the cornea protrudes outwards and thins, the eye becomes more nearsighted. These changes can dramatically blur your vision, which can be impossible to correct with eyeglasses.

Usually keratoconus occurs in both eyes. In some cases, severe irregular astigmatism and scarring may require a cornea transplant in order to restore useful vision to the eye. We are now doing a treatment which is intended to stop the progression and hopefully prevent the need for transplantation.
Risk Factors of Keratoconus

While the cause is unknown, the following risk factors have been identified:

- **Heredity**—if someone in your family has keratoconus, your chances of developing the condition increase. As a general rule, chances of a blood relative developing keratoconus are approximately 10 percent.

- **Ocular allergy, atopic disease & chronic eye irritation leading to eye rubbing**—weakens the cornea and may accelerate progression of keratoconus.

- **Down’s syndrome and connective tissue disorders**—People with these conditions have a higher incidence of keratoconus.

Symptoms of Keratoconus

There are a number of symptoms including:

- Light sensitivity or streaking
- Blurred, distorted, or double vision
- Poorly fitting contacts
- Frequent changes in your eyeglass prescription
- Seeing multiple images
- Eye strain
- Itching of the eye
- Frequent changes in refraction
- Rapidly increasing or large increases in near-sightedness and astigmatism

Simulation of Vision for Patients with Keratoconus

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Diagnosis of Keratoconus

In many cases, keratoconus is diagnosed as a result of a person noticing a change in their vision and visiting their eye doctor. An eye doctor will measure the curvature of the cornea by doing a corneal topography test.
Treatment of Keratoconus

Due to the progressive nature of keratoconus, there are many stages of treatment.

1. **Eyeglasses**—With early keratoconus, vision can often be adequately corrected with eye glasses, but patients may have crosslinking to prevent further progression.

2. **Contact Lenses**—When irregular astigmatism makes clear vision with eyeglasses impossible, specially fit contact lenses are the next stage of therapy. The rigid lens masks the underlying irregular cornea. However, the steep cone and irregular shape of the cornea makes fitting these lenses challenging, and the experience and expertise of the contact lens fitter is important in determining the success of this treatment. Proper fitting of the lens is crucial to prevent or minimize scarring.

3. **Corneal Collagen Crosslinking**—Crosslinking is designed to impede the progression of keratoconus before surgical intervention is necessary. Some research has shown that the steepness of the cone can be reduced helping to improve vision. This treatment is currently being provided as a research study and involves administering riboflavin eye drops (vitamin B2) while shining a UVA light on the cornea. This procedure strengthens the top layer of the cornea, making it more stiff and less likely to continue progressing into a further conical shape.

4. **Intacs**—If keratoconus progresses to the point where a contact lens cannot be fit or does not adequately correct vision, surgery may be necessary. Small plastic ring segments placed in the cornea can produce a more regular corneal surface in about 2 out of 3 keratoconus patients, making it easier to wear a contact lens.

5. **Cornea Transplant**—Keratoconus progresses to the point where a cornea transplant is needed to restore a more normal shape to the cornea in about 1 in 5 patients. This is usually considered a last resort after all other treatments have failed.

Chronic eye rubbing is associated with keratoconus and may accelerate progression, so don’t rub your eyes!

DON’T RUB YOUR EYES!
What is Crosslinking?

Corneal Collagen Crosslinking is a procedure available as an investigational research study in the United States. The procedure is conducted in an eye doctor’s office and involves the removal of the top layer of skin on the cornea, known as the epithelium, the application of riboflavin solution (vitamin B2) on your eye and shining a UV light on the cornea (see photo to the right). The procedure is completed using carefully selected parameters that strengthen the front layers of the cornea and avoid damaging the back part of the eye. By strengthening the front layers of the cornea, crosslinking is used to help stop the progression of keratoconus. The procedure may not improve your vision; the main objective is to stop your vision from getting worse to the point of needing a cornea transplant. You can view a video of a crosslinking treatment on the Cornea Research Foundation’s YouTube Channel at www.youtube.com/cornearesearch. View directly by clicking here.

About the Study

Prior to receiving the crosslinking procedure, you must be evaluated to see if you qualify to be in the research study. A screening examination will be performed to ensure you are eligible to be in the study. A detailed medical history will be taken and a standard clinical evaluation will be made of your eyes. If it is determined that you are eligible to participate in the study, you will receive treatment and appropriate follow up examinations.

As with any clinical research study, each participant will be required to sign a consent which will provide in-depth information about the study, the risks and benefits and explanation of being a study participant. You will also learn about any costs to you and the number of visits required by you as a study participant during this time.
**How the Treatment Works**

Once in the room where the treatment will take place, you will be positioned so that you are comfortable for the treatment. After the numbing eye drops are put in your eye, your eye will be held open with a special instrument, called a speculum. Riboflavin will be dripped into your eye prior to the light treatment. Next, the light will be positioned over your eye, exposing your cornea to a specific wavelength of light. You will be asked to maintain fixation on a central light as best as you can. After the light goes off, a contact lens will be placed in your eye that will act like a band-aid (which will be removed at your one-week follow-up appointment.)

**Post-Treatment**

After the treatment, you can go home, but someone will need to drive you because the vision in your treated eye will be blurry. Your eye will likely hurt for a few days after the procedure and this is normal. A mild pain reliever may be helpful. You will need to avoid activities that cause eye strain such as reading, watching TV or computer work directly after the treatment. You should try to rest. You will also have some prescription medicines you will need to use after your treatment. One is to help with inflammation and the other is to help prevent infection.

The day after the procedure, you will return for a follow-up exam to ensure everything looks okay. At this time your activity level can start to return to normal but it is imperative to keep your eye safe from dust and debris. You have to use your eye drops as your eye will likely remain blurry and uncomfortable for a few days.

At your one-week appointment, the bandage contact lens will be removed and your vision and eye pressure will be checked. You may still notice that your vision is blurry but this is normal. After this one-week check up, you can return to your normal activities if everything looks good. You will then have a few additional appointments to check your progress in the future.
About the Foundation

The Cornea Research Foundation of America is a globally focused non-profit clinical research and educational organization dedicated to the preservation and restoration of vision with a mission to give people back the use of their eyes.

Disclaimer

The information enclosed in this packet is only general information and is not to be taken as healthcare advice.

If you have questions or would like to see if you qualify:

Please contact Kelly Fairchild, Clinical Research Coordinator at 317-814-2995 or via email at crosslinking@cornea.org.