

Living with Keratoconus

Practice Marketing Kit

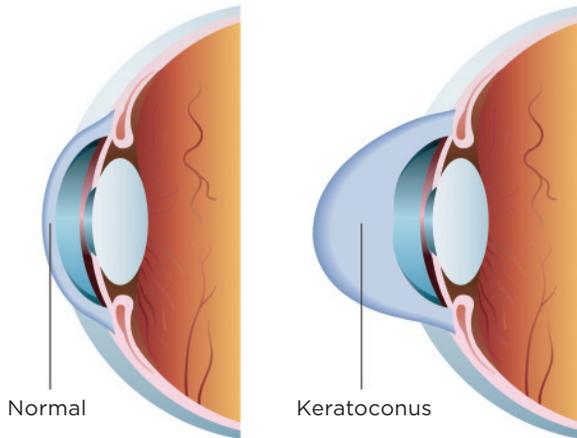


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(844) 528-3376

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What is keratoconus?



Keratoconus, often referred to as 'KC', is an eye condition in which the cornea weakens and thins over time, causing the development of a cone-like bulge and optical irregularity of the cornea.

A rare condition, keratoconus typically first appears in individuals who are in their late teens or early twenties.

Keratoconus:

- Can result in significant visual loss; and
- May lead to corneal transplant in severe cases

You can find more information from the National Keratoconus Foundation at:

www.NKCF.org

Summary of Information About Corneal Cross-Linking

What is corneal cross-linking?

- Corneal cross-linking is a minimally invasive outpatient procedure that combines the use of Photrexa® Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution), Photrexa® (riboflavin 5'-phosphate ophthalmic solution) and the KXL® system for the treatment of progressive keratoconus.
- The safety and effectiveness of corneal cross-linking has not been established in pregnant women, women who are breastfeeding, patients who are less than 14 years of age and patients 65 years of age or older.

What warnings should I know about corneal cross-linking?

- Ulcerative keratitis, a potentially serious eye infection, can occur.
- Your doctor should monitor you for resolution of epithelial defects if they occur.

What are the side effects of corneal cross-linking?

- The most common ocular adverse reactions in any corneal cross-linked eye were haze (corneal opacity), inflammation (punctate keratitis), fine white lines (corneal striae), disruption of surface cells (corneal epithelium defect), eye pain, reduced sharpness of vision (visual acuity) and blurred vision.

The risk information provided here is not comprehensive. To learn more, talk about corneal cross-linking with your healthcare provider.

The FDA-approved product labeling can be found at www.Avedro.com. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch ([/Safety/MedWatch/default.htm](http://Safety/MedWatch/default.htm)) or call 1-800-FDA-1088.

Living with Keratoconus

Learn about the only FDA approved therapeutic treatment for progressive KC



ASK YOUR DOCTOR TODAY

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Photrexa Viscous, Photrexa, and the KXL System are available for sale in the United States. All other Avedro products and procedures are not available in the United States. MA-00545A.

What does corneal cross-linking mean for me?

In April 2016, the FDA approved Photrexa® Viscous (riboflavin 5'-phosphate sodium in 20% dextran ophthalmic solution) and Photrexa® (riboflavin 5'-phosphate sodium ophthalmic solution) and the KXL® System for corneal cross-linking, a minimally invasive outpatient procedure that combines the use of Vitamin B2 eye drops and ultra-violet (UV) light.

Corneal cross-linking stiffens corneas that have been weakened by disease. They are the **first and only** therapeutic products for corneal cross-linking which have been FDA approved to treat progressive keratoconus, and we offer them to patients in our practice.

The approval of Photrexa Viscous, Photrexa and the KXL System offers an effective treatment for patients who, until recently, had no therapeutic options to limit the progression of this sight-threatening disease.



Corneal cross-linking with Photrexa Viscous, Photrexa and the KXL System

What can I expect during the procedure?

- After numbing drops are applied, the epithelium (the thin layer on the surface of the cornea) is gently removed.
- Photrexa Viscous eye drops will be applied to the cornea for at least 30 min;
- Depending on the thickness of your cornea, Photrexa drops may also be required.
- The cornea is then exposed to UV light for 30 minutes while additional Photrexa Viscous drops are applied.

What can I expect after the procedure?

- You should not rub your eyes for the first five days after the procedure.
- You may notice a sensitivity to light and have a foreign body sensation. You may also experience discomfort in the treated eye and sunglasses may help with light sensitivity.
- If you experience severe pain in the eye or any sudden decrease in vision, you should contact your physician immediately.
- If your bandage contact lens from the day of treatment falls out or becomes dislodged, you should not replace it and contact your physician immediately.



Corneal Cross-Linking

Patient FAQ



What is keratoconus?

Keratoconus, often referred to as “KC”, is a non-inflammatory eye condition in which the typically round dome-shaped cornea progressively thins and weakens, causing the development of a cone-like bulge and optical irregularity of the cornea. This causes “static” in your vision and can result in significant vision impairment.

What is cross-linking?

Cross-linking is a minimally invasive, FDA approved, outpatient procedure that combines the use of riboflavin eye drops, *Photrexa® Viscous*, (riboflavin 5'-phosphate in 20% dextran ophthalmic solution), *Photrexa®* (riboflavin 5'-phosphate ophthalmic solution), and ultra-violet A (UVA) light from the *KXL® system* for the treatment of progressive keratoconus.

What is riboflavin?

Riboflavin (vitamin B2) is naturally occurring in the body, including the eye. It is a photosensitizer. Riboflavin is non-toxic and is used as an additive in food and pharmaceuticals.

What is ultra-violet A (UVA) light?

UVA is one of the three types of invisible light rays given off by the sun (together with ultra-violet B and ultra-violet C) and is the weakest of the three.

Does corneal cross-linking require removal of the epithelium?

Yes, your doctor will apply topical anesthesia to numb the eye prior to the removal of the epithelium. This process helps to prepare your eye so that the drug can penetrate the tissue of the cornea to have an effective cross-linking procedure.

Am I awake during the procedure?

Yes, typically you will be awake during the treatment. You'll be given relaxing medication and numbing anesthetic drops.

How long does the treatment take?

The actual procedure takes about an hour, but you will be at the office for approximately two hours to allow sufficient time for preparation and recovery before you return to the comfort of your own home.

What can I expect during the procedure?

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Does it hurt?

There is some discomfort during immediate recovery but usually not during the treatment. Immediately following treatment, a bandage contact lens is placed on the surface of the eye to protect the newly treated area. After the numbing drops wear off, there is some discomfort, often described as a gritty, burning sensation managed with Tylenol and artificial tears. If pain is severe, oral narcotic medications may be used.

Can anyone tell by my appearance that I have had cross-linking?

No. There is no change in the appearance of your eyes following cross-linking.

Is cross-linking right for me?

Patients over the age of 14 who have been diagnosed with progressive keratoconus should ask their doctor whether they may be an appropriate candidate for corneal cross-linking.

Will I need to be out of my contact lenses for this process?

Yes. Typically, doctors ask their patients to stop wearing contact lenses prior to surgery for up to a period of several weeks. Once treated, patients may not be allowed back into contact lenses for 1 month.

How much does corneal cross-linking cost?

Please contact our practice for specific pricing information.

What results can I expect from the procedure?

In two clinical trials, progressive keratoconus patients treated with corneal cross-linking had an average Kmax reduction (which is flattening) of 1.4 diopters in Study 1 and 1.7 diopters in Study 2 at 12-months post-procedure, while untreated patients had an average increase (which is steepening) of 0.5 diopters in Study 1 and 0.6 diopters in Study 2 at 12-months post-procedure. Individual results may vary.

Summary of Information About Corneal Cross-Linking

What is corneal cross-linking?

- Corneal cross-linking is a minimally invasive outpatient procedure that combines the use of Photrexa[®] Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution), Photrexa[®] (riboflavin 5'-phosphate ophthalmic solution) and the KXL[®] system for the treatment of progressive keratoconus.
- The safety and effectiveness of corneal cross-linking has not been established in pregnant women, women who are breastfeeding, patients who are less than 14 years of age and patients 65 years of age or older.

What warnings should I know about cross-linking?

- Ulcerative keratitis, a potentially serious eye infection, can occur.
- Your doctor should monitor your resolution of epithelial defects if they occur.

What are the side effects of corneal cross-linking?

- The most common ocular adverse reactions in any corneal cross-linked eye were haze (corneal opacity), inflammation (punctate keratitis), fine white lines (corneal striae), disruption of surface cells (corneal epithelium defect), eye pain, reduced sharpness of vision (visual acuity) and blurred vision.

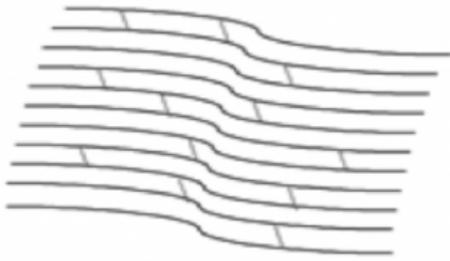
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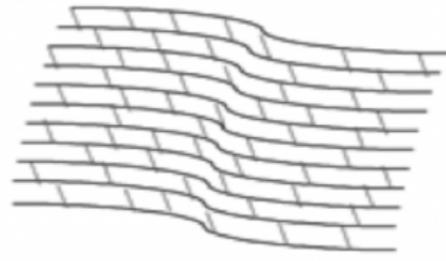
Corneal Cross-Linking³

- Creates new corneal collagen cross-links
- Results in a shortening and thickening of the collagen fibrils
- Leads to the stiffening of the cornea

Less Cross-Linking (Weaker)



More Cross-Linking (Stronger)



Riboflavin

Riboflavin (vitamin B2) is important for body growth, red blood cell production and assists in releasing energy from carbohydrates. Its food sources include dairy products, eggs, green leafy vegetables, lean meats, legumes, and nuts. Breads and cereals are often fortified with riboflavin.

Under the conditions used for corneal collagen cross-linking, riboflavin 5'-phosphate, vitamin B2, functions as a photoenhancer which enables the cross-linking reaction to occur.

Ultra-Violet A (UVA)

UVA is one of the three types of invisible light rays given off by the sun (together with ultra-violet B and ultra-violet C) and is the weakest of the three.

MA-00558A

3. Beshwati IM, O'Donnell C, Radhakrishnan H Biomechanical properties of corneal tissue after ultraviolet-A-riboflavin crosslinking. *J Cataract Refract Surg.* 2013;39(3):451-62. Doi:10.1016/j.jcrs.2013.01.026.

A UV light source is applied to irradiate the cornea after it has been soaked in the photoenhancing riboflavin solution. This cross-linking process stiffens the cornea by increasing the number of molecular bonds, or cross-links, in the collagen.

Is Cross-Linking Right for Me?

Patients over the age of 14 who have been diagnosed with progressive keratoconus or corneal ectasia following refractive surgery should ask their doctor about corneal cross-linking.

Our practice is proud to offer patients in our practice the first and only therapeutic products for corneal cross-linking which have been FDA approved to treat progressive keratoconus. This approval offers an effective treatment for patients who, until recently, had no therapeutic options to limit the progression of this sight-threatening disease.