I Have Kera-What?

"I tried to tell them. I just couldn't see well out of that eye even with new glasses, and the doctor said I just had astigmatism. Then it got worse and started in the other eye. I didn't know how to describe it so they would understand but it was starting to look like this."



The image on the left shows the view from a normal eye. The one on the right shows multiple images as seen by a person with keratoconus. Photo credit: Wikipedia

"At night it looked like a circus. I didn't feel comfortable driving after dark."



Multiple images glare, ghosting glare, and starbursts as seen by patients with keratoconus. Photo Credits: McCain and Spinello and Health and Medicine

"Every time I saw the eye doctor, I said it got worse and the doctor agreed. When I asked what to do about it, the doctor replied, 'We'll watch it.' The next visit went the same way, and I started to think they were going to 'watch' me go blind."

This is the sort of story we have been hearing for decades from thousands of people. It's the story of keratoconus patients worldwide. Once considered a rare disease, keratoconus [ker'-at-o-ko-nus,] is now known to affect millions of Americans.

THE PROBLEM:

In keratoconus, the clear cornea in the front of the eye weakens and bulges forward, becoming less round, thinner, and more cone-shaped, distorting vision even with glasses on. This creates not just astigmatism but **irregular astigmatism**, which can't be corrected with glasses.



A normal cornea compared to a cornea with keratoconus

TREATMENT:

Until recently, little could be done for keratoconus except hoping patients would not get worse and need a risky, invasive, surgical corneal transplant. Often, special contact lenses were tried so patients could function as their condition got worse. Fortunately, this has rapidly changed as new treatments have been developed.

In 2003, in Dresden, Germany, the <u>original form of a procedure</u> called <u>corneal cross-linking (CXL)</u> was reported. Using vitamin B (riboflavin) and UV light, CXL strengthened the cornea and stopped or slowed progression of vision loss from this disease. Unable to get the vitamin into the cornea without surgically scraping off the front surface epithelium, this protective layer is scraped away before the riboflavin drops are applied in the Dresden Procedure. This is why these older procedures are called "epi-off."



For this older form of epithelium-off CXL, the corneal epithelium was scraped off, sometimes with a motorized scrub brush.

Removal of the eye's protective front layer (epithelium) makes the eye <u>susceptible</u> to infection, melting of the cornea, and even development of a hole in the front of the eye.





Corneal infection and perforation (hole in the cornea) can occur after <u>older epi-off CXL</u>.

PLEASE NOTE: Re:Vision <u>NO LONGER PERFORMS</u> THIS OLDER, INVASIVE "EPI-OFF" PROCEDURE.

Over the last fourteen years, Dr. Rubinfeld has invented and patented a unique, non-surgical epithelium-on CXL treatment involving only vitamin eye drops and light <u>without</u> surgical removal of the protective surface epithelium.

A comparison between published results describing what patients experienced after this older "epi-off" procedure and the less invasive, unique epithelium-on technique shows why so much research has been done to find an effective epithelium-on CXL technique.

Epithelium-On CXL-005 data	Epithelium-Off Hersh data
1-2 days	1-2 weeks
1-2 days	3-10 weeks
simultaneous bilateral	3 months
4-6 hours; Tylenol	4-8 days; opioids
1-2 days	weeks to months
1-3 days	1-4 weeks
4 days	2-3 months
	Epithelium-On CXL-005 data1-2 days1-2 dayssimultaneous bilateral4-6 hours; Tylenol1-2 days1-3 days4 days

• <u>Epithelium-on</u> vs. <u>Epithelium-off</u> Recovery <u>Results</u>

ADVANCED TREATMENTS:

As the first surgeon to perform the original epi-off CXL in the Washington, D.C. area in 2009, Dr. Rubinfeld saw first-hand the pain, slow recovery, and risks of this invasive surgical approach. To better treat his patients, he formed and led the world's largest keratoconus research study group. By 2012, he and his teams had developed effective, non-invasive CXL without corneal scraping, as reported in many medical journals and textbooks.





Dr. Rubinfeld in Rome

Seal of Granted U.S. Patent

Dr. Rubinfeld has lectured on his innovations in Rome, Paris, Milan, Lisbon, London, Rome, Amsterdam, Hanoi, and dozens of cities and at U.S. and international conferences worldwide. Over the last decade, his CXL research has resulted in over 20 U.S. and international <u>patents</u> and patent applications and many publications.

One of these <u>publications</u> reported the results of the world's largest keratoconus clinical research study using this patented, less invasive CXL procedure in the prestigious *Journal of Cataract and Refractive Surgery*. Out of the 592 eyes treated with this non-invasive epithelium-on technology, not a single eye lost vision or had their keratoconus progress. This non-invasive treatment was found to be more effective than the more invasive, epithelium-off CXL procedure but without the surgical incisions, pain, long recovery time, and risks of infection, haze, and scarring. Laboratory and other clinical publications have supported this conclusion as well. In 2023, on 2,228 eyes was <u>published</u> showing the same results and safety.

DIFFERENT PATIENTS, DIFFERENT TREATMENTS:

The best treatment of keratoconus occurs when it's caught early and treated with the least invasive CXL treatment available to **prevent vision loss** by stopping progression of the disease. Most of these CXL patients have returned to work or school the day after their CXL. This can be expected to stop their disease and prevent a risky corneal transplant. And that is all that's required.

Because special scanning devices (like the Pentacam) can be needed to detect very early keratoconus, all too often the disease is diagnosed when vision has already been lost. Keratoconus is a dangerously unpredictable condition, often remaining inactive and seemingly stable, then rapidly causing serious vision loss. This is why we strongly recommend that patients **not** wait to be treated. For years, we've seen too many patients tell us that they are "stable" and wanted to "wait" only to see them come back having rapidly losing vision.

For patients with more advanced disease who have already lost vision from keratoconus, the use of an FDA-cleared corneal reshaping technology that's been in worldwide use for decades called <u>Conductive Keratoplasty (CK) in combination with CXL</u> has been shown to restore some of their lost vision.



Conductive Keratoplasty (CK)

This CK device uses radio wave pulses to reshape the cornea **without any incisions or cutting**. In keratoconus, the goal is to flatten and reshape the elevated "cone" that interferes with vision. CK is performed first to flatten the cone, and then the next day, CXL is used to strengthen the cornea and make the effect last. In our studies the results have shown substantial long-term improvement up to 12 years and longer.

EXPECTATIONS:

CXL or CK combined with CXL is <u>not</u> like LASIK or cataract surgery. The objective of these treatments is not to eliminate glasses or provide perfect vision, but to stop progressive loss of vision, and in advanced cases, to restore some of the lost vision.

Remember, these treatments <u>do not eliminate all glare and halos</u>. The goal is to improve your visual functioning once you get your new glasses and/or contacts.

One other concern our patients have is that they are often told that there are "white spots" on their eyes after CK, which trouble other eye doctors.



Yellow arrows show "white spots" where CK was applied. These are normal and fade over time.

Many eye doctors are not familiar with these innovative treatments, so they may be concerned if you're examined outside of our office. Dr. Rubinfeld and our staff would be happy to speak to your doctor if they have any questions.

NEW GLASSES/CONTACTS:

- After **CXL alone**, patients can usually wear their regular glasses the next day and their usual contacts about 3-4 days later with no changes in these lenses.
- Vision after <u>CK combined with CXL</u> takes longer to recover than CXL alone, generally going up and down until your 3 month visit with us to get a new, updated glasses prescription after the procedure. This is **normal** and **expected**, but our patients tell us they feel worried because they thought they were "progressing" and the procedures "didn't work." This is common until they **see for themselves how their new glasses work.**

It is usually best for **our office** to write your new glasses prescription using special techniques about **three months after your procedure**.

Dr. Rubinfeld is personally available at <u>Re:Vision</u> in convenient locations in the D.C. area, Maryland, and Virginia to evaluate patients, discuss the best options to treat these visionthreatening conditions, and answer any questions you may have.

_____ I have read and understood the Kera-What Document

