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Crosslinking Update: Understanding what FDA Approval Means

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Avedro KXL UV Light Source

In the last few months, NKCF has received numerous inquiries about the status of corneal cross-linking (CXL) in the U.S. Some comments on KC-Link and the NKCF Facebook page repeat incorrect or incomplete statements. We'd like to provide some information to consider when making a decision about CXL as a treatment for progressive keratoconus.

What Did the FDA Approve?

In April 2016, Avedro, a company based in Waltham, MA, received FDA approval for a specific piece of equipment (the KXL System: a UV light source), and two riboflavin solutions (Photrexa and Photrexa Viscous) for the treatment of KC. Since then, Avedro has begun shipping the equipment to doctors who purchased the system. If, a few months ago, you were told your doctor was not performing CXL, the procedure may be available beginning in early Fall. (Check [Avedro/find-a-physician](#) for a list of institutions performing the procedure.)

FDA approval was based on results from Phase III clinical trials that enrolled eligible candidates. Patients were either given a protocol that included

epithelium off (epi-off) treatment or a 'sham' treatment where the epithelium was not removed and the UV light was not illuminated. Patients in both groups were followed for at least a year and data was collected on progression of KC. Results from the treated group were found to be superior to the untreated group.

The FDA ruling was based on clinical trial data submitted by Avedro. The FDA did not approve all crosslinking procedures. Very narrowly, the Avedro protocol and equipment are the only FDA approved treatments at this time.

Aren't there other Cross-linking procedures available?

Yes, there are. More than thirty other countries had approved crosslinking before the FDA approval, so there were other advances while the U.S. studies were ongoing. Machines have been developed that offer variable settings and intensities of treatment, and different drug solutions have been tried. There has also been considerable interest in performing crosslinking without removal of the epithelium (epi-on). Crosslinking in conjunction with other vision enhancing surgeries have also been investigated.

- If your ophthalmologist* performs CXL using the Avedro equipment, and follows the protocol that was used in the clinical trials, this is considered an **"FDA-APPROVED TREATMENT"**. (*Since CXL is considered eye surgery, optometrists may not perform cross-linking. If your eyecare is managed by an optometrist, he or she will refer you to an MD for the procedure.)
- If your doctor is performing crosslinking using the Avedro machine and drug solution, but varies the protocol, it is considered an **"OFF LABEL USE"** of an approved procedure. Doctors are given latitude to individualize treatment for their patients. No special permission is required for the surgeon to do this, but they should explain the treatment to you and how it differs from the standard, approved protocol.
- If you doctor performs CXL, but uses another device, protocol or drug solution, he or she may be participating in a clinical trial. These studies are structured so that only certain people are eligible and study participants may be asked to return for post-operative tests in order to

collect data. You should be given information about the study that you are participating in, including who is sponsoring the clinical trial and what will be expected of you. The consent form that you will be asked to sign should indicate the risks and benefits of the treatment, and that this is “**EXPERIMENTAL**” and that there are FDA-approved treatments available.

- Finally, you may find eye doctors who offer CXL using their own devices and their own protocols, who are not part of an organized study. If you learn that your eye doctor ‘invented’ the procedure that you will be receiving and is the only one who performs it, you might ask yourself – if this is such a good procedure, why aren’t other doctors performing it? If your doctor claims to get great results using a secret protocol, ask yourself why have the results not been shared with the medical community and the FDA – the government agency charged with protecting patients against untested treatments?

How can I make my choice?

When contemplating crosslinking, here are two questions to consider:

1. ***Am I a candidate for the procedure?*** Crosslinking is for progressive keratoconus. If your vision is stable, particularly if you are middle-aged or older, you might not need the procedure. Ask your doctor why he or she believes you will benefit from CXL.
2. ***Is this the right procedure for me?*** Learn what protocol the doctor will use and ask about his or her experience. Have the risks and benefits of this particular procedure been fully explained? Are you receiving an FDA-approved treatment or an experimental alternative? If you are enrolling in a clinical trial, are you willing to return for post-operative examinations?

What about payment for crosslinking?

NKCF is regularly contacted by patients looking for a no-cost CXL clinical trial. It is true that in some instances, a manufacturer or investigator will offer medical care associated with a clinical study at a reduced rate (sometimes patients are even given a stipend). This is done when there is no real benefit to

the patient to participate. In the case of crosslinking, the benefit to patients has been demonstrated. Doctors and institutions do not need to offer an incentive for CXL and it is unrealistic to assume you will find a no-cost clinical study to enroll in. Expect to pay a fee that will include the cost of the procedure and the surgeon's time.

Most insurance companies continue to classify CXL as experimental therapy. While there are efforts underway to get the Avedro CXL procedure reclassified as 'standard of care' for progressive keratoconus, it may be some time before CXL becomes a reimbursable or covered procedure by most insurers.

If you are interested in pursuing CXL, assume you will pay for the procedure out of pocket. Your doctor's office staff can explain the total costs and payment options.

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