

Combined Intacs and Corneal Collagen Crosslinking

Corneal collagen crosslinking (CXL) is an experimental procedure which may help decrease the progression of keratoconus. The CXL procedure uses UV light combined with riboflavin (Vitamin B2) to cause corneal collagen molecules to link together. The primary goal of this effect is to strengthen the corneal fibers in order to decrease progression of keratoconus.

CXL is not FDA approved in the U.S. and is available only by participation in the U.S. clinical trial which is available here at the CLEI Center for Keratoconus.

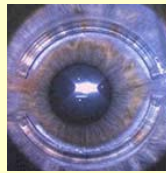
Here at the CLEI Center for Keratoconus, we are participating in a formal study of the effect of combined Intacs and CXL in patients with keratoconus or corneal ectasia after previous LASIK or PRK. This study is being conducted under FDA guidelines. The goal of the clinical trial is to study the benefits and safety of the combined Intacs and CXL as well as to evaluate the timing of the two procedures on clinical outcomes. Two treatment groups will be evaluated:

- (1) Intacs placement followed immediately thereafter by CXL
- (2) Intacs placement initially, followed by CXL after the 3 month follow-up visit

Intacs and CXL Procedures:

Intacs are two small crescents of a contact lens-like material (PMMA). Intacs involves the following steps:

- A channel within the cornea is then prepared. This step is done with a laser called an Intralase[™]
- Two Intacs segments are inserted.
- At the end of the procedure, a stitch is placed over the eye.



Corneal collagen cross-linking involves the following steps:

- Removal of the outer layer of cells of the cornea (clear covering of the eye),
- Applying riboflavin (Vitamin B2 eyedrops) to the eye, and
- Exposing the eye to ultraviolet (UV-A) light.



This will cause a reaction in the eye with the goal to strengthen the fibers that make up the cornea.

At the conclusion of the procedure, a soft contact lens bandage is applied. The lens remains in place for approximately 5 days to aid healing and comfort. The lens is clear and you can see through it.

Eligibility:

- 21 years of age or older
- Diagnosis of keratoconus OR previous vision correction surgery with resulting corneal ectasia
- Vision with contact lenses or glasses is worse than 20/20 in one or both eyes
- If you are female, you cannot be pregnant
- You need to leave your contact lens out for at least 3 months in the eye(s) to be treated
- If you have keratoconus, you cannot have had previous corneal surgery or Intacs



We are currently enrolling patients in this study. Ask the doctor for more information to determine if this is the right procedure for you.