

We are writing to inform you of our new clinical research investigations to study combined corneal collagen cross-linking (CXL) and Intacs in patients with keratoconus or corneal ectasia after LASIK. These studies are the first in the U.S. designed to assess the safety and effectiveness of a combined Intacs/CXL procedure for these conditions.

Corneal collagen cross-linking is a procedure that involves administering riboflavin and ultraviolet light (UVA) to strengthen the front layers of the cornea (the clear front lens of the eye). The riboflavin and UVA light source that is used for CXL are both investigational in the United States and are not approved by FDA. Intacs are intracorneal ring segments which are implanted into the cornea through a corneal tunnel created with a laser. In 2004, Intacs received approval in some situations for the treatment of keratoconus. The goal of Intacs in keratoconus is to decrease the “cone” and make the corneal optical surface smoother.

You may be eligible for the study if you have the following in one or both of your eyes or are:

- 21 years of age or older
- Have been diagnosed with keratoconus or have had previous vision correction surgery and now have corneal ectasia
- Vision with contact lenses or glasses is worse than 20/20
- Corneal thickness greater than 300 microns at the thinnest point
- If you are female, you cannot be pregnant
- Can 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 previous Intacs

If you qualify and decide to participate in the study, you will receive the Intacs, riboflavin, and UVA light at no cost. However, there is a fee for the consultation and surgery. Because of the investigative nature of the procedure, most insurance companies will not cover the surgery and you will be required to pay this fee before the procedure is performed.

If you, or someone you know, may be interested in participating in this CXL/Intacs study, please contact me to learn more about the study or to schedule a consultation examination to see if you qualify for the study. I (or my research staff) may be reached by email at info@vison-institute.com or by phone at 201-883-0505.