

We are writing to inform you of our new clinical research investigation to evaluate any difference between 2 riboflavin preparations during UV administration patients with keratoconus or corneal ectasia after LASIK. The first preparation contains riboflavin in a dextran solution, which may tend to draw water out of the cornea and keep it thinner. The second preparation contains riboflavin in a hypotonic (low salt) solution without dextran, which may tend to keep the cornea more swollen. The primary goal of the study is to see if the use of hypotonic riboflavin (rather than riboflavin with dextran) better maintains consistent corneal thickness during UV administration. The second goal of the study is to determine if better maintenance of corneal thickness potentially could have benefits of better consistency of the procedure, decrease in corneal haze formation, and improved safety of the endothelial cells. These studies are the first in the U.S. designed to assess the safety and effectiveness of a hypotonic 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 yet approved by FDA.

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

- 18 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 1 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 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 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@vision-institute.com or by phone at 201-883-0505.