INFORMED CONSENT FOR CORNEAL COLLAGEN CROSS-LINKING WITH RIVOFLAVIN AND UVA (CXL UVA) FOR PATIENTS WITH KERATOCONUS

INTRODUCTION:

This information is to help you make an informed decision about Corneal Collagen Cross-Linking with Riboflavin and UVA light (CXL-UVA) for the management of your Keratoconus. Take as much time as you wish to make a decision about signing this form. You are encouraged to ask any questions and have them answered to your satisfaction before you give your permission for surgery. Every procedure has risks as well as benefits and each person must evaluate the risk benefit ratio in light of the information that follows. It should be understood that it is impossible to give every piece of information or a complete understanding of the issues that relate to a specific procedure just as it is impossible to convey all information about any complex subject. With this in mind, we have attempted to give you the information needed to make an intelligent and informed decision.

Glasses and contact lenses are the most common method of improving refractive errors. When tolerated, they are likely to be a good alternative to surgery, but they do not halt, prevent or stop the progression of Keratoconus.

Corneal Collagen Cross-Linking will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or retinal detachment. Corneal Collagen Cross-Linking does not correct the condition known as presbyopia (or aging of the eye), which occurs for most people around age 40 and may require reading glasses for close-up work.

KERATOCONUS:

Keratoconus is a corneal disease that occurs when the normally round dome-shaped cornea (the clear outer area of your eye) progressively thins, causing a cone-like bulge to develop.

Keratoconus is typically diagnosed during adolescence and early adulthood with a variable rate of regression. The bulging or "cone-shaped" protrusion is caused by the normal pressure of the eye pushing out on the thinned and structurally weaker areas of the cornea. Since the cornea is responsible for refracting most of the light coming into your eye, an abnormal-shaped cornea can create reduced visual acuity and affect the way you see. This reduced visual acuity can make even simple daily tasks, such as driving, watching television or reading difficult to perform. The actual cause of Keratoconus is not known. There have been studies to suggest a genetic and inherited link to the disease. Other reported risk factors include: eye rubbing, ocular allergy, connective tissue disease, long term rigid contact lens wear and family history of Keratoconus.

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Recent statistics estimate an incidence greater than 1 in 1,000 (based on computerized corneal topography pachymetry and higher-order aberrations). Keratoconus affects males and females in equal proportion and occurs in both eyes in over 90% of patients. Prior to use of Corneal Collagen Cross-Linking, up to 20% of Keratoconus patients eventually required a corneal transplant.

CORNEAL COLLAGEN CROSS-LINKING WITH RIBOFLAVIN & UVA (CXL-UVA):

Currently there is no successful way to stop the progression of Keratoconus. With current methods, using rigid contact lenses or Intra Corneal Ring Segments, only the refractive error can be corrected. These treatments have no effect on the relentless progression of the disease and ultimately a corneal transplant may be required.

A treatment for Keratoconus, which has shown great success, is CXL-UVA. The studies show that when Riboflavin is activated with a UV-A light, the collagen cross-links within the cornea. This allows for some restoration of the cornea's mechanical strength. The procedure is induced by the combination of a photosensitive/photo absorbent agent (Riboflavin) with UV-A light rays. This method works by increasing collagen cross-linking, which are the "anchors" within the cornea.

These "anchors" form links between nearby filaments of collagen, preventing the cornea from bulging out and becoming steep and irregular. The procedure has been performed in Europe since 1998. Clinical studies have demonstrated the safety and effectiveness of CXL-UVA. Many patients have had a lasting effect (no progression) for over 5 years after their initial treatment.

DESCRIPTION OF CXL-UVA:

The procedure is performed under topical anesthetic (numbing eye drops). Dr. Holzman may gently remove the protective layer on the surface of the eye; the epithelium. A special formulation of Riboflavin eye drops are applied to the surface of the eye for a period of time ranging from 5 to 30 minutes or longer. The eye is then exposed to a safe amount of UV-A light for a period of time ranging from 2 to 30 minutes. After the treatment, antibiotics and other eye drops are administered. A protective bandage contact lens is inserted for four to five days. Postoperative instructions are given.

INTENDED BENEFITS:

- Enhanced corneal rigidity
- Increased corneal resistance and biomechanical stability of the cornea
- Prevent disease progression
- May defer the need for a corneal transplant procedure
- May reduce the near-sightedness and astigmatism associated with Keratoconus

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- Enhanced contact lens wear
- Reduced risk of progressive ectasia after excimer laser treatment

ALTERNATIVE TREATMENTS:

- Intra-corneal rings (Intacs)
- Corneal transplant

RISKS, POSSIBLE COMPLICATIONS AND OTHER CONSIDERATIONS:

Corneal Collagen Cross-Linking is a relatively new procedure and there may be some risks which are unknown at this time.

Discomfort: Although many patients experience mild discomfort for a few days following the procedure, patient reactions range from no discomfort to moderate pain. Some patients may experience a burning sensation for a few moments when instilling the eye drops in the first two to three days following the procedure. Most patients who have discomfort describe it as the sensation of have grains of sand or an eyelash in their eye or having a torn contact lens. Sensitivity to light may occur among patients during the period in which the epithelium is healing.

Dry Eyes: After almost any type of eye surgery, this condition may become worse. However, it is usually only slight and temporary. It is possible for Dry Eye to be a problem for a prolonged period of time. The symptoms rarely can be very marked, affecting comfort and clarity of vision even with treatment.

Blurry Vision: During the period in which the protective tissue on the surface of the eye, the epithelium, is healing (generally four to five days), vision is blurry for most patients because of the presence of the protective lens and because the healing edges of the epithelium distort the clarity of light rays entering the eye. This condition clears for most people in a week or two as the surface of the eye heals and again becomes smooth. Complete smoothing of the surface tissue of the treated eye may take as much as six months or longer. During this period, some fluctuation in vision may exist. The healing process is very much individualized and varies from patient to patient. Due to corneal shape changes, new glasses or fitting new contact lenses may be necessary.

Reading Difficulty: Most patients will find it difficult to read the first few days following the procedure.

Sensitivity: Some patients experience increased sensitivity to any contact with the surface of the eye following the procedure. Some patients may not be able to wear contact lenses for several weeks. This condition tends to diminish overtime.

Corneal Haze: If present, is most noticeable in the two-to-four-month period following the procedure. Haze generally has little or no effect on vision and is usually not present after six months. Few patients may experience excessive corneal haze and require treatment. Additional

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treatments with the excimer laser can generally correct problems of excessive haze. Haze has rarely caused permanent vision impairment.

Corneal Edema: The swelling of the cornea after treatment is usually transient, blurring the vision for up to several months.

Raised Eye Pressure: Increased intraocular pressure can occur temporarily in patients who use topical steroid eye drops follow the procedure. Typically, intraocular pressure returns to normal, with no long-term ill effects, once the use of steroid eye drops has been discontinued. If intraocular eye pressure is elevated on a long-term basis, permanent loss of vision can result. Since raised intraocular eye pressure is often painless, periodic evaluation by an eye doctor is imperative. Monitoring intraocular pressure is an important part of your follow-up care.

Slow Healing of the Epithelium: The epithelium is often removed just before the procedure begins. The epithelium usually heals in four to five days, but on occasion, heals at a slower rate than expected. In such cases, there may be increased pain and risk of infection.

Loss of Best-Corrected Visual Acuity: Patients rarely lose the ability to read one, two or more lines on the eye chart in comparison to their previous best-corrected vision. This is usually transient but may be permanent.

Infection: An extremely rare occurrence; To help prevent infection, it is critical that you follow the prescribed postoperative medication regimen and instructions precisely. The infection could be localized to the surface of the corneal or could involve the structures inside of the eye resulting in severe loss of vision.

Corneal Transplant: The CXL-UVA procedure for Keratoconus does not exclude the possibility of a corneal transplant in the future.

Remote Risks: As with any surgical procedure of this type, there is a remote possibility of severe drug reaction, corneal ulcers and scars, endothelial cell loss (loss of cell density in the inner layer of the cornea, possibly resulting in corneal swelling), corneal melting, cataract, iritis, uveitis, retinal changes or other rare complications which could cause partial or complete loss of vision.

Long Term Effects: Because CXL-UVA is a relatively new procedure, the long- term effects and consequences of the procedure have not been fully determined. Longer-term results may reveal additional risks and complications.

Consent to Have Corneal Collagen Cross-Linking with Riboflavin (CXL-UVA)

1. I have read this consent form
2. I have discussed it with Dr. Holzman and have been given the opportunity to ask questions. All other questions which I had have been answered to my satisfaction. I understand how Corneal Collagen Cross-Linking with Riboflavin is performed and acknowledge its possible risks and complications.

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3. I understand that:
    a. The results of Corneal Collagen Cross-Linking with Riboflavin procedure cannot always be predicted. The safety and efficacy of Corneal Collagen Cross-Linking with Riboflavin cannot be guaranteed. My Keratoconus could still progress and I may still need a corneal transplant.
    b. Visual stability or improvement is not guaranteed.
    c. CXL-UVA is not risk free. Complications from the procedure, as described in this consent form are possible. Re-treatments may be necessary but there is no guarantee that retreatments will be successful. As with any procedure of this type, there are risks such as partial loss of best-corrected visual acuity.
    d. Adherence to recommended eye drop regimen and periodic follow-up visits after the procedure are required to reduce the risk of longer-term complications and increase the likelihood that the desired outcome will be achieved.

4. I confirm that I am neither pregnant nor a nursing mother and that I will notify my doctor if I become pregnant in the period following the treatment. I understand that pregnancy may affect my healing response. I also understand that some medications may pose a risk to an unborn or nursing child.
5. My decision to undergo Corneal Collagen Cross-Linking with Riboflavin has been my own and has been made without duress of any kind. I understand that if at any time prior to my procedure, should I decide that I do not want to go forward, I may withdraw my consent.
6. I authorize the eye professionals involved in performing my procedure and in providing my pre and post procedure care to share with one another any medical information relating to my health, my vision or my CXL-UVA procedure, which they deem relevant to providing me with care.
7. I understand that Commercial Insurance does not pay for Corneal Collagen Cross-Linking. I agree to accept personal financial responsibility for the payment of all charges and fees related to my CXL-UVA procedure, including; charges for the procedure itself, medication I may need, pre and post procedure care, Glasses and contact lenses after the procedure and for the expenses connected with my travel to see Dr. Holzman. I understand that if at any time prior to my procedure I decide that I do not want to go forward with CXL-UVA I may withdraw my consent.
8. I understand the risk of undergoing the CXL-UVA procedure and hereby consent to the procedure and to any pre or post procedure care which Dr. Holzman deems necessary or advisable.
9. I understand that should the need for additional CXL-UVA treatment become necessary, the cost of the additional procedure and medications will be my responsibility.

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My decision to undergo Corneal Collagen Cross-Linking with Riboflavin and UVA (CXL-UVA) has been my own and has not been made without duress of any kind.

Eye(s) being treated today (please circle):

Right Eye Left Eye Both Eyes

Patient's Signature: _____ **Patient's Name:** _____

Witness Signature: _____ **Witness Name:** _____

I am a duly licensed eye care professional in good standing. I am knowledgeable about Corneal Collagen Cross-Linking with Riboflavin and UVA and its risks and benefits. I have personally discussed the risks with the patient, have given the patient the opportunity to ask questions and have answered those questions to the best of my ability.

Dr. Holzman's Signature: _____ **Date:** _____

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