INFORMED CONSENT FOR CORNEAL COLLAGEN CROSS-LINKING WITH RIBOFLAVIN (C3-R) FOR PATIENTS WITH KERATOCONUS OR CORNEAL ECTASIA

INTRODUCTION:

This information is to help you make an informed decision about Corneal Collagen Cross-Linking with Riboflavin (C3-R) 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 anyone 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 realization, we have attempted to give you the information you need to make an intelligent, informed decision.

Spectacles and contact lenses are the most common method of improving refractive errors. When tolerated well, they are likely to be a good alternative to surgery, but they do not halt, prevent or stop the progression of keratoconus and corneal ectasia. Another alternative form of treatment of refractive disorders (astigmatism and myopia), secondary to the disease, is Intra Corneal Ring Segments called Intacs.

You should understand that having Corneal Collagen Cross-Linking with Riboflavin would not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or retinal detachment. Also, having Corneal Collagen Cross-Linking with Riboflavin does not correct the condition known as presbyopia (or aging of the eye), which occurs to most people around age 40 and may require them to wear reading glasses for close-up work.

WHAT IS 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. Typically diagnosed during adolescence and early adulthood with a variable rate of progression. The bulging or “cone-shaped” protrusion is caused by the normal pressure of the eye pushing out on the thinned 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 yet known, but 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. Recent statistics estimate an incidence of greater than 1 in 1,000 based on computerized corneal topography, pachymetry, and higher-order aberrations. It affects male and female in equal proportion and occurs in both eyes in 90% of patients. Prior to use of corneal collagen cross-linking 20% of keratoconus patients required a corneal transplant.

WHAT is CORNEAL COLLAGEN CROSS-LINKING WITH RIBOFLAVIN (C3-R)?

So far there has not been one successful way to stop the progression of keratoconus. With current methods using rigid contact lens or Intra Corneal Ring Segments, only the refractive error can be corrected, but it has no effect on the progression of the disease. A new treatment for keratoconus, which has shown great success, is C3-R. The Riboflavin, when activated by approximately 30 minutes with UV-A light, increase the collagen cross-links within the stroma and recovers some of the corneal mechanical strength. The procedure is induced by the combined mechanisms of action of a photosensitive/photoabsorbent agent (Riboflavin) with UV-A light rays. The method works by increasing collagen cross linkings, which are the “anchors” within the cornea. These “anchors” and formation of links between nearby filaments of collagen are responsible for preventing the cornea

from bulging out and becoming steep and irregular. The procedure has been performed in Europe over the past six years. Clinical studies have demonstrated the safety and effectiveness of C3-R.

DESCRIPTION OF C3-R:

The procedure is performed under a topical anesthetic (numbing eye drops). It involves gently removing the protective layer on the surface of the eye, the epithelium. Special type of Riboflavin eye drops are applied to the surface of the eye for approximately 30 minutes. The eye is then exposed to a safe amount of UV-A light for 30 minutes. After the treatment antibiotic and other eye drops are used and protective bandage contact lens is inserted for four to five days. Postoperative instructions are given.

Intended benefits:

- Enhance corneal rigidity.
- Increase the corneal resistance and biomechanical stability of the cornea.
- Prevent disease progression.
- May defer the need for a corneal transplant procedure.
- May reduce the nearsightedness and astigmatism associated with keratoconus.
- Enhance contact lens wear.
- Reduce risk of ectasia with excimer laser treatment.

Alternative treatments:

- Intra-corneal rings, INTACS
- Corneal transplant

RISKS, POSSIBLE COMPLICATIONS AND OTHER CONSIDERATIONS:

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

Discomfort:
Many patients experience mild discomfort for a few days following the procedure, although patient reactions range from no discomfort at all 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 having grains of sand or an eyelash in their eyes or having a torn contact lens. Some sensitivity to light exists 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 but usually only slightly and temporary. However, it is possible for it to be a problem for a long 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. However, complete smoothing of the surface tissue of the treated eye may take as much as six months. 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. The condition tends to diminish over time.

Corneal Haze:
If present, is most noticeable in the period two to four months following the procedure. Haze generally has little or no effect on vision and is usually not present after six months. A few patients, however, do experience excessive corneal haze and require treatment. Additional treatments with the excimer laser can generally correct problems of excessive haze; thus 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 couple of months.

Raised Eye Pressure:
Increased intraocular pressure can occur temporarily in patients who use topical steroid eye drops following the procedure. Typically, intraocular pressure returns to normal, with no long-term ill effects, once the use of steroid eye drops has been discontinued. However, 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 the follow-up care provided by your eye care professional.

Slow Healing of the Epithelium**:**
The epithelium is removed just before the procedure begins. The epithelium usually heals in four to five days, but occasionally, it 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**:**
Rarely patients can 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:
Is an extremely rare occurrence. However, to help prevent infection, it is critical that you follow the Bochner Eye Institute prescribed postoperative medication regimen and instructions precisely. The infection could be localized to the surface of the cornea or could involve the structures inside of the eye resulting in severe visual loss.

Corneal transplant:
The Corneal Collagen Cross-Linking procedure with Riboflavin for keratoconus and corneal ectasia does not exclude the possibility of corneal transplant in the future.

Remote Risks**:**
As with any investigational 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 complication which could cause partial or complete loss of vision.

Long Term Effects:
Because Corneal Collagen Cross-Linking with Riboflavin 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 having Corneal Collagen Cross-Linking with Riboflavin …

1. I have read this consent form.

2. I have discussed it with my eye doctor and have been given the opportunity to ask questions. All of the questions, which I had, have been answered to my satisfaction. I understand how Corneal Collagen Cross-Linking with Riboflavin is performed and acknowledged its possible risks and complications.

3. I understand that:

A. Corneal Collagen Cross-Linking with Riboflavin is a new and investigational procedure in Canada.
B. 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 or ectasia could still progress and I may still need corneal transplant.
C. Visual stability or improvement is not guaranteed.
D. C3-R 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 re-treatments will be successful. As with any procedure of this type, there are remote risks, such as partial loss of best-corrected visual acuity.
E. Adherence to recommended eye drop regimen and periodic follow-up visits with an eye doctor 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, I decide that I do not want to go forward, I may withdraw my consent.

6. I authorize the eye doctors involved in performing my C3-R 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 C3-R procedure, which they deem relevant to providing me with care.

7. I understand that information gathered about my procedure and my post-procedure care may be used to study the C3-R procedure. I give permission for my medical records to be released to persons involved in such studies and for my case to be presented at professional or scientific meetings or published journals, as long as I am not identified by name. I also give permission for my C3-R procedure to be observed and for the procedure to be photographed by a still camera, movie camera, or videotape, and for these photographs, films, or tapes to be shown at professional, scientific, educational, promotional, or similar meetings or published in journals, as long as my name is not revealed.

8. I agree to accept personal financial responsibility for the payment of all charges and fees related to my C3-R procedure, including charges for the procedure itself, for medications I may need, for pre-and post-procedure care, for eyeglasses and contact lenses required after the procedure, and for the expenses connected with my travel to the Bochner Eye Institute. I understand that, if at any time prior to my procedure I decide that I do not want to go forward with C3-R, I may withdraw my consent.

Patient Initials:_____

9. I understand the risk in undergoing C3-R procedure performed and hereby consent to the procedure and to any pre- or post-procedure care, which my eye doctors deem necessary or advisable.

10. I understand that should I need additional C3-R, it will be performed by an ophthalmologist of the Bochner Eye Institute. I also understand that I will be required to return to the center in which the prior procedure was performed and that the cost of the additional procedure, expenses for transportation and lodging will be my responsibility.

I hereby agree that the relationship and the resolution of any and all disputes arising therefrom between myself and Dr. Harold Stein, Dr. Albert Cheskes and Dr. Raymond Stein shall be governed by and construed in accordance with the laws of the Province of Ontario.

I hereby acknowledge that the treatment will be performed in the Province of Ontario and that the Courts of the Province of Ontario shall have jurisdiction to entertain any complaint, demand, claim or cause of action, whether based on alleged breach of contract or alleged negligence arising out of the treatment. I hereby agree that if I commence any such legal proceedings they will be only in the Province of Ontario, and hereby irrevocably submit to the exclusive jurisdiction of the Courts of the Province of Ontario.

I consent to undergo Corneal Collagen Cross-Linking with Riboflavin for:

Eye being treated: Right eye Left eye
(Circle one) Both eyes

Patient's Signature: _____ Date_____

Patient's Name: (Print) _____

Witness Signature: _____

Witness Name: (Print) _____

I am a duly licensed eye care professional in good standing. I am knowledgeable about Corneal Collagen Cross-Linking with Riboflavin 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.

Surgeon's signature:_____ Date_____

Surgeon's Name: (Print)_____