

UPDATES IN KERATOCONUS MANAGEMENT AND THE FDA-APPROVED iLINK CROSS-LINKING PROCEDURE



Optometrists play an integral role in early diagnosis and intervention.

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Early diagnosis of keratoconus is imperative. As the condition progresses, it can result in loss of visual acuity and contact lens intolerance due to corneal changes.

The earlier we diagnose keratoconus, the sooner we can intervene and refer a patient for treatment, which may help slow or halt progression of the disease. Corneal thinning, scarring, and other consequences of progressive keratoconus cannot be reversed.

Fortunately, we now have an FDA-approved epithelium-off cross-linking procedure (iLink performed with Photrex, Photrex Viscous [riboflavin 5'-phosphate in 20% dextran ophthalmic solution] & the XTL System; Glaukos)¹ for patients with progressive keratoconus or corneal ectasia following refractive surgery. The iLink procedure is backed by proven safety and efficacy data via an FDA pivotal trial and many peer-reviewed publications. The iLink procedure is well covered by commercial insurance in the United States. All 50 states have more than six plans that cover the procedure, and 96% of commercial lives are currently covered.

EARLY DETECTION

The reported prevalence of keratoconus varies and may be on the rise largely due to improved diagnosis and increased

disease state awareness. In the United States, prevalence is estimated at 1:2000 (1986).² In certain countries, recent studies have shown prevalence to be much higher. In the Netherlands, for example, prevalence is estimated at 1:375 (2017).³

Despite diagnostic advances, progressive keratoconus is often diagnosed too late with irreversible vision loss that could possibly have been prevented. Researchers in Belgium found that 70% of patients reached Topographical Keratoconus Classification stage 2 disease by the time they were diagnosed.⁴ Although many believe the onset of keratoconus occurs in patients in their late teens, the authors reported only 13% of cases in this study were diagnosed in patients younger than 18 (mean, 25 years).⁴ A meta-analysis reported that keratoconus may progress quickly, particularly in younger patients or those with steeper K readings.⁵

Therefore, we need to screen every patient suspected of having keratoconus by asking about family history and considering imaging. Advanced diagnostic tools, such as topography or tomography, can be incredibly helpful in making a diagnosis of keratoconus, although they are not required. The typical age of onset is during the teen years or early 20s, but may present later as well.⁶ Warning signs of keratoconus include eye rubbing,



Courtesy of Gloria B. Chiu, OD, FAAO, FSLs

Figure 1. Advanced keratoconus with central corneal scarring.

distorted mires on keratometry, error messages on autorefractometry, increased astigmatism, unsatisfactory attempts at vision correction, progressive loss of BCVA, and visual distortion.

Various equipment is helpful in early detection. Using retinoscopy, a scissoring motion may be appreciated as two beams come together and then separate. At the slit lamp, we look for corneal thinning and ectasia. Early signs of keratoconus include central striae or a brown iron ring at the base of the cone, while advanced cases show central scarring (Figure 1). Corneal topography provides a 2D view of the corneal anterior surface, and tomography provides a 3D view, mapping the anterior and posterior surfaces, along with corneal thickness data. The posterior elevation map may show changes even before the anterior surface. Anterior segment optical coherence tomography (OCT) provides a detailed cross-section of the cornea.

MANAGING KERATOCONUS

Optometrists have an integral role in diagnosing and managing keratoconus, as 70% of keratoconus patients present to optometrists.⁷ Early intervention with the FDA-approved iLink cross-linking procedure may halt or slow progression. Reduced progression helps maintain the patient's ability to wear contact lenses or glasses. We may manage post-operative care and fit contact lenses before and after iLink. Comanagement allows us to deliver optimal care to our patients and build relationships with ophthalmologists in the community.

We examine patients with keratoconus at least every 6 to 12 months. Those with potential progression can be seen more frequently. Assessments include

refraction and BCVA with glasses and contact lenses, slit-lamp examination, keratometry, pachymetry, and tomography or topography, comparing current results with previous findings. Contact lenses should be evaluated and also removed prior to examinations because they could mask progression. Depending on contact lens type, accurate corneal curvature imaging may require a contact lens break for a couple days. We also should examine the eyelids. Many patients with keratoconus have allergic conjunctivitis, which should be treated to reduce eye itching and rubbing.

After the exam, we consider whether new contact lenses are needed, educate patients about their ocular health, and treat or refer them out for additional treatment. The website livingwithkeratoconus.com provides helpful information for clinicians and patients about progressive keratoconus, the FDA-approved iLink cross-linking procedure, and the broad insurance coverage for iLink.

CORNEAL CROSS-LINKING

Before the iLink cross-linking procedure is performed, the central 9 mm of the corneal epithelium is removed. Photrex Viscous is applied every 2 minutes for 30 minutes. The anterior chamber is assessed for the presence of riboflavin flare, and additional drops are applied as needed to obtain flare. Once flare is obtained, pachymetry is performed to ensure a minimum intraoperative corneal thickness of 400 μm . If corneal thickness is less than 400 μm , drops of Photrex are instilled until corneal thickness increases to at least 400 μm . The cornea is irradiated for 30 minutes, with continued application of Photrex Viscous during irradiation.

Courtesy of Gloria B. Chiu, OD, FAAO, FSL

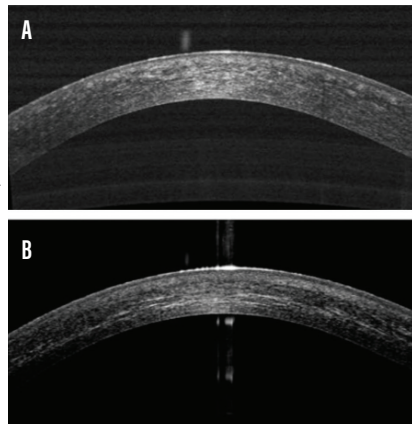


Figure 2. Before iLink (A) and 2 months after iLink (B), demonstrating stromal remodeling.

Activated riboflavin and reactive oxygen interact to stiffen the cornea.⁸

Postoperative treatment includes a topical antibiotic, steroid, sometimes a nonsteroidal anti-inflammatory, lubricants, and placement of a soft bandage lens. Patients are instructed to not rub their eyes. The bandage contact lens is removed after the epithelium is healed. At 1 to 2 months, we assess vision, perform corneal imaging, and consider contact lens fittings. Figure 2 shows before and 2 months after iLink. It may take 1 or 2 months for BCVA to stabilize. We also assess patients every 3 to 6 months after to monitor for stability and good eye health. iLink should not be performed in pregnant women. Complications such as infection, non-healing epithelium, haze, corneal scarring, endothelial cell damage or continued progression can occur.

To set appropriate patient expectations, patients should not be told that the iLink procedure will improve their vision. However, in some cases BCVA may improve. Following iLink, patients should be informed that an important part of continuing care includes the

management of their vision needs after the iLink procedure.

CONCLUSION

Because optometrists provide primary and comprehensive eye care, we can diagnose keratoconus early and ensure appropriate intervention. Advanced diagnostic technologies enable earlier detection, and various contact lens modalities can help optimize vision. The FDA-approved iLink cross-linking procedure can help slow or halt progression of keratoconus to preserve visual function.

When in doubt, refer patients out. Comanaging patients with keratoconus allows for collaboration and an opportunity to build relationships with your ophthalmology peers. ■

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Using Photrex[®] Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution), Photrex[®] (riboflavin 5'-phosphate ophthalmic solution), and the KXL[™] System, the iLink[™] corneal cross-linking procedure from Glaukos is the only FDA-approved therapeutic treatment for patients with progressive keratoconus and corneal ectasia following refractive surgery.¹ [Photrex IFU/p1/col1/para3/lines1-4]

Indications

Photrex[®] Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) and Photrex[®] (riboflavin 5'-phosphate ophthalmic solution) are indicated for use with the KXL System in corneal collagen cross-linking for the treatment of progressive

keratoconus and corneal ectasia following refractive surgery.

Important Safety Information

Corneal collagen cross-linking should not be performed on pregnant women.

Ulcerative keratitis can occur. Patients should be monitored for resolution of epithelial defects. The most common ocular adverse reaction was corneal opacity (haze). Other ocular side effects include punctate keratitis, corneal striae, dry eye, corneal epithelium defect, eye pain, light sensitivity, reduced visual acuity, and blurred vision.

These are not all the side effects of the corneal collagen cross-linking treatment. For more information, go www.livingwithkeratoconus.com to obtain the FDA-approved product labeling. You are encouraged to report all side effects to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

*Photrex[®] Viscous and Photrex[®] are manufactured by Avedro. The KXL[™] System is manufactured by Avedro. Avedro is a wholly owned subsidiary of Glaukos Corporation.

1. Photrex [package insert]. Waltham, MA; Glaukos, Inc. 2016