iLink™ and Scleral Lenses: FAQs

What strategies can help detect keratoconus progression in patients wearing scleral lenses?

Scleral lenses may affect your topography readings and mask keratoconus progression.[1] You may find it necessary to request that a patient remove their scleral lenses. Keep in mind that many patients rely on their scleral lenses for their everyday visual needs and may not be willing to go without them for a period of time.

Provided that the scleral lenses do not have central or limbal bearing on the cornea, your serial topography after lens removal may still yield an adequate representation of the keratoconic disease state. However, if you suspect keratoconus progression, it is highly advisable to recommend lens removal for a period of time to ensure accurate corneal imaging results.

Can scleral lenses affect the corneal topography of my patients with keratoconus?

It is possible for scleral lenses to cause corneal flattening for patients with keratoconus. If your patient is willing, you may consider requesting that they remove their scleral lenses at least 24–48 hours before taking their topography.[1]

Do I need to refit patients for scleral lenses after an iLink™ cross-linking procedure? If so, when?

iLink™ is not a refractive procedure but it may help preserve the level of visual acuity that a patient currently has.[2] Evaluation for visual correction is necessary and essential because patients might experience slight changes in their prescription after cross-linking.[2,3]

Typically, once the epithelium has healed, you can begin assessing patients for scleral lenses. The exact timing for scleral lens evaluation may vary between 1 and 3 months after the procedure, depending on each individual's epithelial healing response.

What impact does iLink™ corneal cross-linking have on the use of scleral lenses?

Some patients with progressive keratoconus may become intolerant to contact lenses over time. Slowing or halting keratoconus progression using iLink™ may reduce the complexity of traditional management techniques, such as frequent contact lens refits, and may improve contact lens tolerance.[4] Overall, iLink™ is intended to complement scleral lenses, not replace them.

How can I help address my patients' visual needs if they are intolerant to scleral lenses?

Scleral lenses are not the only option for your keratoconus patients. Regardless of whether they will be fitted for scleral lenses, it's important to recommend iLink™ corneal cross-linking for them as soon as possible to slow or halt irreversible keratoconus progression. After the procedure, you can evaluate their vision and see how you can address their refractive needs with glasses, soft contact lenses, corneal gas permeable lenses, hybrid contact lenses, other types of specialty contact lenses, or intrastromal corneal ring segments if they are unable to tolerate scleral lenses.

What discussion points are key to setting expectations for scleral lenses?

Patients with progressive keratoconus should consider the importance of slowing or halting their progression. It's important to educate them about the progressive nature of keratoconus and how keratoconus can progress even within 3 months.[5]

Be sure to inform your patients that iLink™ is the only FDA-approved treatment that can slow or halt progression. Additionally, let them know that iLink™ is not a refractive procedure; they can have their visual needs addressed during follow-up appointments, and once disease progression is stabilized, they may be able to get the most out of new scleral lenses.

Are scleral lenses proven safe and effective for patients with keratoconus?

Yes! Studies have demonstrated that more than 90% of keratoconus patients experience improved visual acuity with scleral lenses.[6] Furthermore, in a long-term retrospective study spanning 5 years, scleral lenses were found to be effective with an excellent safety profile in patients with keratoconus.[7]

Keep in mind that only iLink™ can slow or halt the progression of keratoconus, offering stability in scleral lens fittings. Cross-linking may also reduce the need for costly penetrating keratoplasty.[8]

Is it better to fit my patients with scleral lenses before they undergo iLink™ corneal cross-linking, or after?

Every patient's circumstances are different, but it would be better to first treat a progressive keratoconus patient with an iLink™ procedure before fitting with scleral lenses.

It's critical to stress to your patients how important the iLink™ procedure is to preserve as much vision as possible. Waiting will only increase the risk of continued progression and irreversible loss of sight, even within 3 months. Left untreated, 1 in 5 patients with progressive keratoconus may require a corneal transplant.[5,9-12]

What if my patient can't afford iLink™ corneal cross-linking?

Because keratoconus is a progressive disease, early intervention is critical to help preserve vision. Only iLink™ can slow or halt the progression of keratoconus, while management with scleral lenses alone will not. Fortunately, the medical necessity of iLink™ has become widely recognized and commercial insurance coverage for the procedure is now over 95% in the United States for covered lives. Glaukos, the manufacturer of iLink™, also offers patients a copay assistance program that could save patients up to $100 on their copay per eye.

How long can patients wait to get iLink™ corneal cross-linking if they face financial or personal barriers?

Patients with progressive keratoconus should be treated with iLink™ as soon as possible to help preserve their vision. Waiting could increase the risk of continued progression and irreversible vision loss, even within 3 months.[5] If they must wait due to financial or personal barriers, you should stress the importance of having the procedure as early as possible. Make sure that they understand that their keratoconus may progress, and their vision may get worse the longer they wait.[11]

The American Academy of Ophthalmology Corneal Ectasia Preferred Practice Pattern recommends prompt referral of patients who have been diagnosed with progressive keratoconus by their optometrist to a trusted ophthalmologist who can perform corneal cross-linking.[12]

Patients experiencing financial barriers may be directed to **iPath360** from Glaukos—a program providing strategic market access solutions for iLink™ and other Glaukos procedures.

Is it necessary to document failed scleral lenses for reimbursement purposes?

Documenting failed conservative treatment approaches—such as continued progression in a contact lens wearer, inadequate function in glasses or contacts, or contact lens intolerance in patients with progressive keratoconus—is one important criterion in helping payers determine if iLink™ is medically necessary. As you monitor your scleral lens patients, document any continued progression and/or inadequate visual function and promptly refer them to a specialist who can perform iLink™ corneal cross-linking.

Keep in mind that a patient with progressive keratoconus may experience disease progression despite wearing contact lenses of any kind, including scleral lenses. In most cases, this is substantial documentation for reimbursement purposes. However, you can refer to specific payer policies to be sure by visiting **www.glaukos.com/corneal-health/ilink-reimbursement.**

What does a typical cross-linking follow-up schedule look like?

Collaborate with the iLink™ specialist to align on the best time to receive your patient back after cross-linking.

The follow-up schedule for your patients may vary. Generally, it might include:

Between Day 1 and 7

- Topical antibiotics and steroids should be applied
- Frequent use of eye lubricants
- Patients should not rub their eyes
- Remove the bandage contact lens when the epithelium has healed

During Month 1

- View optical coherence tomography imaging
- Continue monitoring tomography and topography
- Assess the patient's vision
- Evaluate the patient for contact lens refitting

Months 3, 6, and 12

- Continue monitoring with tomography and topography
- Assess the patient's vision

What are the possible risks associated with scleral lenses?

Adverse reactions in patients wearing scleral lenses may include microbial keratitis, contact lens–induced acute red eye, corneal infiltrative events, corneal abrasion, pingueculitis, reservoir fogging, poor lens wetting, surface deposits, and corneal hypoxia.[7]

What are the possible risks associated with iLink™ corneal cross-linking?

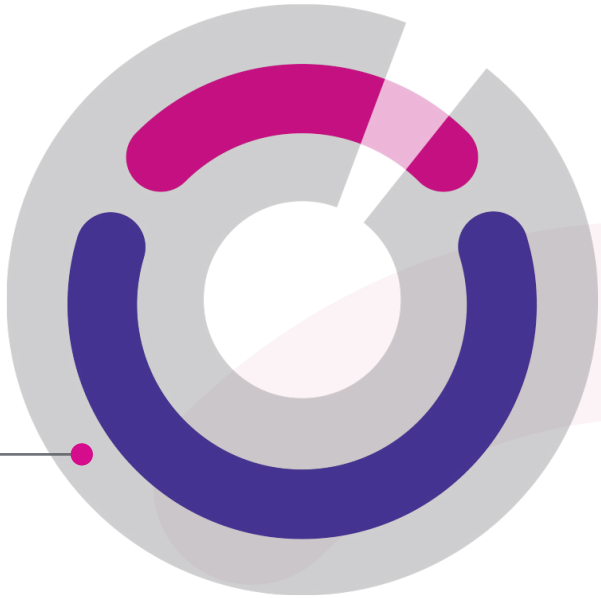
The most common ocular adverse reaction was corneal opacity (haze). Other ocular side effects include punctate keratitis, corneal striae, dry eye, corneal epithelium defect, eye pain, light sensitivity, reduced visual acuity, and blurred vision. These are not all of the side effects of the corneal collagen cross-linking treatment. For more information, go to **www.livingwithkeratoconus.com** to obtain the FDA-approved product labeling.

iLink™ and Scleral Lenses: FAQs (cont.)

Refer patients with confidence

Only iLink™:

- Is an FDA-approved cross-linking procedure
- Is widely covered by insurance
- Slows or halts progressive keratoconus with proven technology, efficacy, and safety



OVER 95%
of commercially insured lives are eligible for insurance coverage for iLink™

Visit iLinkExpert.com to find a trusted iLink™ provider.

REFERENCES

1. Severinsky B, Fadel D, Davelman J, Moulton E. Effect of scleral lenses on corneal topography in keratoconus: a case series of cross-linked versus non–cross-linked eyes. *Cornea.* 2019;38(8):986-991.
2. *How is keratoconus treated?* National Keratoconus Foundation. Accessed April 19, 2021. https://nkcf.org/how-is-keratoconus-treated.
3. Glaukos Data on File. 2021.
4. Ünlü M, Yüksel E, Bilgihan K. Effect of corneal cross-linking on contact lens tolerance in keratoconus. *Clin Exp Optom.* 2017;100(4):369-374.
5. Romano V, Vinciguerra R, Arbabi EM, et al. Progression of keratoconus in patients while awaiting corneal cross-linking: a prospective clinical study. *J Refract Surg.* 2018;34(3):177-180.
6. Schornack MM, Patel SV. Scleral lenses in the management of keratoconus. *Eye Contact Lens.* 2010;36(1):39-44.
7. Fuller DG, Wang Y. Safety and efficacy of scleral lenses for keratoconus. *Optom Vis Sci.* 2020;97(9):741-748.
8. Lindstrom RL, Berdahl JP, Donnenfeld ED, et al. Corneal cross-linking versus conventional management for keratoconus: a lifetime economic model. *J Med Econ.* 2021;24(1):410-420.
9. Pramanik S, Musch DC, Sutphin JE, Farjo AA. Extended long-term outcomes of penetrating keratoplasty for keratoconus. *Ophthalmology.* 2006;113(9):1633-1638.
10. Maharana PK, Agarwal K, Jhanji V, Vajpayee RB. Deep anterior lamellar keratoplasty for keratoconus: a review. *Eye Contact Lens.* 2014;40(6):382-389.
11. Shah H, Pagano L, Vakharia A, et al. Impact of COVID-19 on keratoconus patients waiting for corneal cross linking. *Eur J Ophthalmol.* 2021. doi:10.1177/11206721211001315.
12. Garcia-Ferrer FJ, Akpek EK, Amescua G, et al; American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Corneal Ectasia Preferred Practice Pattern®. *Ophthalmology.* 2019;126(1):P170-P215.

INDICATIONS

Photrexa® Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) and Photrexa® (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 of the side effects of the corneal collagen cross-linking treatment. For more information, go to 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.

iLink™ CROSS-LINKING PROCEDURE

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