Best Practices

in Integrated Care

CRST Cataract & Refractive Surgery Today

AOC Advanced Ocular Care

Volume 2, No. 4

BAUSCH + LOMB

Best Practices in Integrated Care

This ongoing series, now in its second year, is featured in each issue of *AOC* and its sister publication *CRST*. The articles will clarify how eye care providers can best work together to provide patient-centered care of the highest quality possible.

THOUGHTS ON DEFINING UNCONTROLLED OCULAR ALLERGY

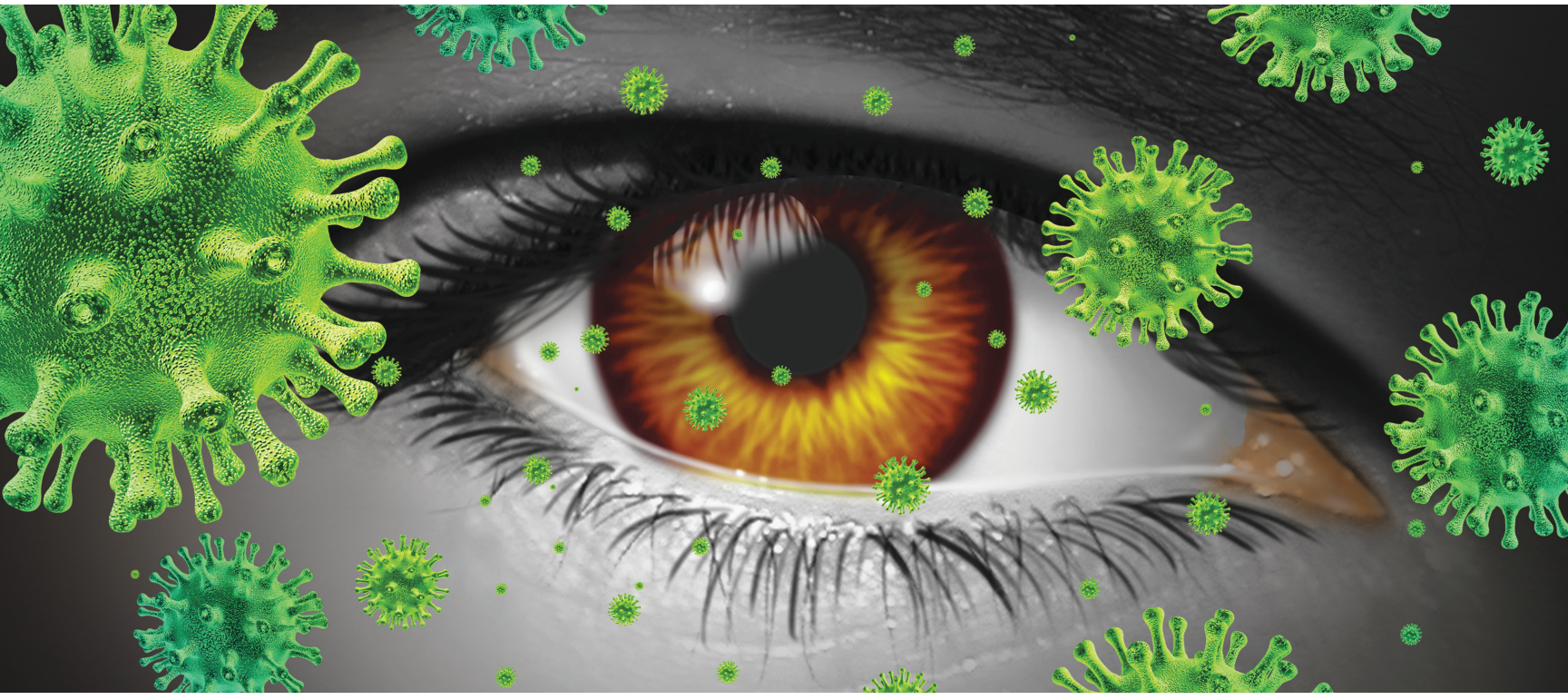
Recalcitrant ocular allergy may be true disease or a different condition altogether.

BY GREGG J. BERDY, MD, FACS

As an ophthalmologist with an interest in allergic conditions, I have the opportunity to examine patients who are referred to our office with severe allergic diseases. Often, by the time patients present to me, they may be on multiple medications, and they already may have seen their primary care provider, or, in some cases, another eye care provider for their initial complaint. The most important aspect of dealing with advanced ocular disease is to confirm the diagnosis. Once that is accomplished, the physician can devise a treatment plan.

CONFIRMING THE DIAGNOSIS

The literature points to a rise in atopic conditions, and data from epidemiologic studies suggest that the prevalence of ocular allergic disease is on the rise.



Previous studies suggest that more than 20% of the US population is affected by ocular allergy,[1] and as many as 30% experience episodes of ocular/nasal symptoms seven or more times throughout the year.[2] The bulk of these patients suffer from seasonal disease, seasonal allergic conjunctivitis, and a smaller, but substantial number of patients manifest a more chronic form of the disease, perennial allergic conjunctivitis.

There is tremendous overlap of the signs and symptoms of ocular allergy with other ocular surface disorders such as dry eye disease, meibomian gland dysfunction, blepharitis, and viral or bacterial infections. Any of these ocular surface conditions may be present concomitantly with ocular allergy. This is why taking a precise history and directing appropriate therapy toward the specific pathophysiology is crucial to successful treatment. Inappropriate therapy can induce toxic medicamentosa conjunctivitis that may mask or worsen the patient's symptoms.

SYMPTOMS AND SIGNS

Itching, the hallmark symptom of ocular allergy, is sometimes difficult for patients to describe. Itching outside of traditional allergy seasons, for example, may really be stinging or burning, indicating other common ocular conditions. Nasal symptoms are present in about 75% of patients.[3] Ocular allergy is usually a bilateral presentation, as allergens affect both eyes.

The pathophysiology of ocular allergy begins when sensitized immunoglobulin E (IgE)-coated mast cells encounter an airborne allergen. When the exogenous allergen binds two separate IgE molecules, it creates a dimer formation,[4,5] thus initiating activation of mast cell-associated enzymes and triggering the biochemical cascade that releases granules into the extracellular space.[6-12] The presentation of disease can be variable and host dependent, thereby compounding the difficulty of identifying true disease.

DIRECTING THERAPY TO THE ETIOLOGY

Dual-acting antihistamine and mast cell stabilizer drugs are very effective for treating ocular allergy; as noted, mast cells play a central role in the allergic cascade, while histamine is one of several important mediators in the etiology.[13,14] Histamine H1 and H2 receptors are present in the conjunctiva.[15,16] The former stimulates the itch response, while the latter initiates vasodilation and redness.[17]

Pharmacologic treatments are quite successful, and it may be tempting for eye care providers to offer topical therapy and bring the patient back if there is an insufficient response. I believe this approach, however, dismisses the importance of ocular allergy. The condition can be severely irritating to the ocular surface and disruptive to patients' daily activities, resulting in potential complications such as keratitis and corneal scarring, which have profound effects on ocular surface health.

Another misunderstood aspect of treatment is the strategy of avoiding, removing, or decreasing the contact time of the inciting allergen to halt the allergic cascade. The belief is that therapy with lubricating eye drops will have a dual benefit, both washing allergens from the eye as well as treating any dry eye disease component of the patient's condition. This approach fails to direct therapy at

the etiology and risks prolonging the patient's suffering and corneal damage. If a thorough history is performed, such guesswork is mitigated.

Strategies directed at treating only the patient's symptoms fail to provide them with a complete treatment. Patients are better served by eye care physicians confirming the diagnosis and directing appropriate therapy at the underlying cause.

When patients self-medicate using over-the-counter medications, there is potential for worsening discomfort and ocular surface problems, especially if the medication contains a preservative. Patients should be educated on the fact that there is a lack of clinical trial evidence confirming the safety and efficacy of over-the-counter agents.

A healthy tear film might ordinarily clear ocular surface irritants such as dust, pollens, or pet dander. In patients with a compromised tear film, however, inflammatory mediators or higher osmolarity may cause irritation that feels similar to an allergic response. This can occur in patients using oral antihistamines, which can dry nasal passages and provide symptomatic relief. However, these oral agents also dry the ocular surface, leading to worsening of symptoms. Therefore, even "appropriate treatment" with oral antihistamines can somewhat mask ocular allergy.

DIAGNOSTICS

Early referral of a patient to an ophthalmologist or eye care specialist trained in ocular allergy will lead to more favorable outcomes. A full workup may be necessary to reassess the diagnosis so that therapy can be directed at the correct underlying cause.

A recent trend in managing ocular allergies is the availability of noninvasive skin testing (Doctors Allergy Formula [Bausch + Lomb] and allMedRx [Allergy Matrix]). Both of these tests can confirm a patient's sensitivity to a panel of common allergens; however, their exact role in the clinic is still being determined. These tests may help practitioners educate patients on avoidance, although they may be unnecessary in the era of dual-acting agents that treat the end result of the allergic cascade regardless of the offending allergen.

Skin testing is also becoming more popular in ophthalmic settings. This diagnostic test can be useful for disproving or proving true allergy, for directing patients' education, and as a lead in to using immunotherapy. A negative skin test result that reveals a positive histamine control and a negative water control in a patient reporting allergy-like symptoms may be a clue that there are other ocular surface concerns. A poor tear film may not clear pollen or dust, which in turn acts as an irritant, even if those proteins are not inciting an IgE reaction with mast cell degranulation.

A positive skin test result can help patients understand the importance of compliance with topical agents. Studies show that topical eye drop therapy is more effective than oral medications for ocular allergies—but, only if patients take them.

Skin testing to determine the specific inciting allergen may be useful in those patients who are only receiving partial benefit from an eyedrop, or if immunotherapy is a consideration. It may take up to 2 years for immunotherapy to have its full effect, as it takes time to prime the immune system and desensitize the immune response. Given that immunotherapy must be directed at the inciting allergen, positively identifying it is of utmost importance.

The size and potential of the ocular allergy market has made it attractive for industry, and several companies are developing diagnostics for the space. Advanced Tear Diagnostics' product Tear Scan measures lactoferrin and IgE levels. This test may have a role in differentiating dry eye disease and ocular allergy: low lactoferrin levels may suggest dry eye caused by aqueous deficiency, and the presence of IgE indicates allergic activity.

CONCLUSIONS

Syndromes that masquerade as ocular allergy can be revealed by a thorough workup, evaluation, and patient history.[18-20] Of these tools, the history is of utmost importance in these patients.

Eye care providers have the tools and training necessary to understand the true cause of a patient's symptoms and, therefore, to direct appropriate therapy. We should encourage our colleagues in other specialties to refer early and often for the sake of our patients. ■

1. Bielroy K, Katelaris CH, Lightman S, et al. Treating the ocular component of allergic conjunctivitis and related eye disorders. *Med Gen Med*. 2007;9(3):35.
2. Nathan RA, Meltzer ET, Selner JC, Storms W. Prevalence of allergic rhinitis in the United States. *J Allergy Clin Immunol*. 1997;99:S808-S814.
3. Bousquet J, Khaltaev N, Cruz AA, et al. Allergic Rhinitis and its Impact on Asthma (ARIA) 2008 update (in collaboration with the World Health Organization, GA(2)LEN and AllerGen). *Allergy*. 2008;63(suppl 86):8-160.
4. Ishizaka T, Ishizaka K. Biology of immunoglobulin E: molecular basis of reaginic hypersensitivity. *Prog Allergy*. 1975;19:60-121.
5. Siraganian RP, Hook WA, Levine BB. Specific in vitro histamine release from basophils by bivalent haptens: evidence for activation by simple bridging of membrane bound antibody. *Immunochemistry*. 1975;12:149.
6. Foreman FC, Hallett MB, Mangar J. The relationship between histamine secretion and ^{45}calcium uptake by mast cells. *J Physiol*. 1977;271:193-214.
7. Irani AM, Butrus SI, Tabbara KF, Schwartz LB. Human conjunctival mast cells; distribution of MCT and MCTC in vernal conjunctivitis and giant papillary conjunctivitis. *J Allergy Clinl Immunol*. 1990;86:34-40.
8. Flowers RJ, Blackwell GJ. The importance of phospholipase A2 in prostaglandin biosynthesis. *Biochem Pharmacol*. 1976;25:285-291.
9. Warner JA, Peters SP, Lichtenstein LM, MacGlashan DW Jr. 3H arachidonic acid incorporation and metabolism in purified human basophils. *Fed Proc*. 1986;45:735.
10. Hanahan DJ, Demopoulos CA, Liehr J, Pinckard RN. Identification of naturally occurring platelet activating factor as acetyl-glyceryl-ether-phosphorylcholine (AGEPC). *J Biol Chem*. 1980;255:5514-5516.
11. Chilton FH, Ellis JM, Olson SC, Wykle RL. 1-O-alkyl- 2-arachidonoyl-sn-glycero-3-phosphocholine: a common source of platelet activating factor and arachidonate inhuman polymorphonuclear leukocytes. *J Biol Chem*. 1984;259:12014-12019.
12. Barnes PJ. New concepts in the pathogenesis of bronchial hyperresponsiveness and asthma. *J Allergy Clin Immunol*. 1989;83:1013.
13. Schwartz LB, Austen KF. Structure and function of the chemical mediators of mast cells. *Prog Allergy*. 1984;34:271-321.
14. Snyder SH, Axelrod J. Tissue metabolism of histamine -C14 in vivo. *Fed Proc*. 1965;24:774-776.
15. Owen DA, Poy E, Woodward DF. Evaluation of the role of histamine H1- and H2-receptors in cutaneous inflammation in the guinea-pig produced by histamine and mast cell degranulation. *Br J Pharmacol*. 1980;69:615-623.
16. Robertson I, Greaves MW: Responses of human skin blood vessels to synthetic histamine analogues. *Br J Clin Pharmacol*. 1978;5:319.
17. Harvey RP, Schocket AL. The effect of H1 and H2 blockade on cutaneous histamine response in man. *J Allergy Clin Immunol*. 1980;65:136-139.
18. Berdy GJ, Berdy SS. Ocular allergic disorders: disease entities and differential diagnoses. *Curr Allergy Asthma Rep*. 2009;9:297-303.
19. Berdy GJ. Treatment stategies for ocular allergy. *Advanced Ocular Care*. 2010;1(2):39-41.
20. Berdy GJ, Leonardi A, Abelson MB. Antihistamines and mast cell stabilizers in allergic ocular disease. In: Albert DM, Miller JW, Azar DT, Blodi BA, eds. Albert & Jakobiec's *Principles and Practice of Ophthalmology*. Philaldelphia, PA: Saunders Elsevier, Inc.

Gregg J. Berdy, MD, FACS

- in practice with Ophthalmology Associates, St Louis, Missouri
- assistant professor of clinical ophthalmology in the Department of Ophthalmology and Visual Science at Washington University School of Medicine, St. Louis, Missouri
- gregg.berdy@youreyedoc.com
- financial interest: none acknowledged

Best Practices in Integrated Care

CORNEAL COLLAGEN CROSS-LINKING: WHAT IT MEANS FOR PATIENTS WITH ECTASIA

The recent FDA approval of a cross-linking procedure is only the beginning.

BY CASEY CLAYPOOL, OD

The recent approval of a corneal collagen cross-linking (CXL) procedure by the US Food and Drug Administration adds an important potential treatment strategy for eyes with ectasia, keratoconus, and other dystrophies that result in irregular astigmatism. CXL has been performed in Europe since the 1980s, so there is a wealth of clinical data demonstrating its safety and efficacy. The procedure has undergone significant refinements, and the technology and techniques used continue to evolve. The currently approved procedure (Avedro) is an epithelium-off (epi-off) technique in which the corneal epithelium is debrided before saturation with riboflavin and exposure with ultraviolet light. Research is ongoing on various epi-on procedures that may add additional options to what can be done to help patients with irregular corneas.

RECOGNIZING ECTASIA

A discussion of CXL should begin with proper recognition and diagnosis. Unfortunately, as disastrous as keratoconus and ectasia can be to patients' vision, it is likely an underdiagnosed disease state. In many cases, it is discovered too late in its natural history for treatment to have a meaningful effect.

Ectasia is a dynamic disease in which the cornea will continue to change in shape in response to a number of factors. Eye rubbing may shift the degree of astigmatism or yield more profound vaulting of the corneal shape. Environmental factors may also play a role. If a misshapen cornea compromises the blink response, dry eye disease can be a result. Dryness can compound the refractive error and further degrade the corneal shape if there is diminished natural ability to restore the tear film.

Ectasia is progressive, and it may result in blindness or a corneal transplant if left untreated or unaddressed. It is crucial to recognize the early signs of the condition so that treatment can be initiated. CXL stabilizes the cornea and halts ectasia's progression, but if it is performed late in the disease state, visual ability may already be permanently compromised.

Eye care providers should consider ordering topography on any patient who presents with more than a 1.00 D unexplained change in refraction, especially if the patient has recently undergone refractive surgery. If the topography shows no ectasia, it may be prudent to follow the patient with repeat topography and examination every 6 to 12 months to rule out potential ectasia or keratoconus.

EPI-ON VERSUS EPI-OFF CXL

As I stated, an epi-off procedure was recently approved for use in the United States. This is a very important and positive step forward for patients with keratoconus. Contact lenses such as

rigid gas permeable or newer scleral contact lenses are excellent for correcting vision but do not stop the disease from progressing. Uncorrected and best-corrected vision will continue to diminish. In addition, these lenses may require a trained specialist to fit, and access to services can be an issue, and, frankly, some patients want another option. Until recently, the only recourse for such patients was intrastromal corneal ring segments or corneal transplants. Even more rare was an opportunity to have off-label CXL or be treated as part of a clinical trial.

There is still discussion in many circles about whether epi-on or epi-off is a better approach. In clinical studies, both epi-on and epi-off approaches have demonstrated over 90% success rates.[1-3] To date, data do not definitively answer which is the better approach or whether one or the other may be more favorable for a particular type of patient when each is done properly. Where I practice, we are involved in an ongoing trial of an epi-on technique. We favor this approach, and I can say from our experience that it works extremely well.

HOW IT IS DONE

During an epi-off procedure, the corneal epithelium is stripped away to allow the riboflavin to soak through the stroma before applying ultraviolet light. Removal of the epithelium can be associated with complications.[4,5] Patients with steep corneas may be difficult to fit into soft or bandage contact lenses, which may delay the healing process. Corneal ulcers are also a risk, as are perforations, both of which elevate the risk of needing a transplant. Some studies have indicated permanent scarring and haze with loss of BCVA following epi-off crosslinking.[4,6,7]

Early attempts at epi-on procedures were not successful because insufficient time was allotted to allow the riboflavin to saturate through the stroma. With newer formulations of riboflavin (it is now possible to achieve penetration in about 17 minutes compared with 45 minutes with older formulations), combined with new understandings of how to detect adequate stromal penetration (ie, checking for flare at the slit lamp), epi-on can be at least as successful as epi-off with less risk of attendant side effects.[3,8] In fact, in some studies, better visual recovery and outcome in comparison to epi-off has been observed because there is not as much trauma to the cornea. These considerations may be critically important in eyes with steeper corneas and in pediatric and older patients.

CONCLUSION

Eye care specialists in the United States have been eagerly awaiting the arrival of CXL for years. Now that we have an approved procedure, there is at least a mechanism to treat keratoconus and ectasia with an on-label procedure. Access to services and insurance issues will still need to be sorted out, but this is a tremendous advance for patients.

CXL, whether properly done epi-on or epi-off, helps to stabilize the cornea to prevent continued progression, and reported success rates are over 90%.[2,3] In some cases, there is an additional refractive benefit in terms of improvement in BCVA.[3] I would advise my peers and colleagues to counsel patients appropriately and educate them on the fact that the goal of CXL is to achieve stabilization, and in some cases, refractive improvement is a bonus. It should soon be standard of care to never see a loss of a line of visual acuity due to corneal ectasia.

I am excited about the continuing research in this field. The Food and Drug Administration approval of one approach by one company is not the end of the journey. Experts are investigating how CXL may be used to treat low amounts of myopia, limit diurnal fluctuations in radial keratotomy patients, and if it can be paired with LASIK to treat hyperopia. Benefits for patients will be ongoing as the research continues. ■

1. Raiskup-Wolf F, Hoyer A, Spoerl E, Pillunat LE. Collagen crosslinking with riboflavin and ultraviolet-A light in keratoconus: long-term results. *J Cataract Refract Surg.* 2008;34:796-801.
2. Soeters N, van der Valk R, Tahzib NG. Corneal cross-linking for treatment of progressive keratoconus in various age groups. *J Refract Surg.* 2014;30(7):454–460.
3. Stulting D. Predicting and treating corneal ectasia after LASIK. Presented at: ASCRS-ASOA Symposium & Congress; May 7, 2016; New Orleans, LA. http://www.ascrs.org/center-for-learning/video/ascrs-opening-general-session-binkhorst-lecture. Accessed May 31, 2016.
4. Raiskup F, Hoyer A, Spoerl E. Permanent corneal haze after riboflavin-UVA-induced cross-linking in keratoconus. *J Refract Surg.* 2009;25:S824-828.
5. Rubinfeld R. Surgical treatments range from cross-linking to keratoplasty when keratoconus progresses. *Ocular Surgery News U.S. Edition*. April 25, 2016. http://bit.ly/102uTjO. Accessed May 31, 2016.
6. Koller T, Mrochen M, Seiler T. Complication and failure rates after corneal crosslinking. *J Cataract Refract Surg.* 2009;35(8):1358-1362
7. Soeters N, Wisse RP, Godefrooij DA, et al. Transepithelial versus epithelium-off corneal cross-linking for the treatment of progressive keratoconus: a randomized controlled trial. *Am J Ophthalmol.* 2015;159:821-828.
8. Rubinfeld R, Talamo J, Stulting D. Is this the end of the epi-on vs. epi-off debate? Presented at: International CXL Congress; December 2015; Washington, DC. http://bit.ly/1sJ5Wjm. Accessed May 31, 2016.

Casey Claypool, OD
■ Empire Eye Physicians, Spokane, Washington
■ (509) 928-8040; casey.claypool@empireeye.com
■ financial interest: none acknowledged

Best Practices in Integrated Care

CORNEAL DYSTROPHY AND REFRACTIVE SURGERY

It is time to rethink the treatment endpoint in the management of corneal dystrophies.

BY ARUN C. GULANI, MD, MS

When it comes to corneal dystrophies, some surgeons become preoccupied with trying to attach a diagnosis to the condition, and then they go about aggressively fixing the pathology—in some cases, perhaps compromising vison. Although the nomenclature used to diagnose conditions is helpful for naming a situation and looking for associated anomalies, surgeons must focus on the patient's desired outcome.

In my practice, I see patients from all over the world who have been treated previously by excellent surgeons using transplant techniques and technically challenging procedures. These individuals come to me utterly frustrated due to their poor visual performance, which in many cases, is simply a correctable refractive error.

TIME FOR A CHANGE

It is time to dramatically rethink how corneal dystrophies are managed. We must move away from the pathologic standpoint and instead think in terms of total holistic visual rehabilitation. The goal of treating a patient with a corneal scar or dystrophy should be to return him or her to unaided emmetropia. In this context, a host of options opens up to the surgeon.

In my view, ophthalmic surgeons should direct their efforts to addressing the features of corneal scars and dystrophies—what I refer to as the 5S system: sight, scar, shape, strength, and site—using the full spectrum of kerato-lenticulo-refractive techniques at their disposal (Figure 1). In some cases, the additional expertise offered by optometrists can also aid in the patient's visual recovery.

At a fundamental level, I propose changing the treatment endpoint. In corneal scars (dystrophies), surgeons should stop thinking about attacking the scars and correcting the pathology alone (or worse still, correcting a diagnostic readout such as a topography map) and start focusing on how to use all of the tools available to correct vision.

CORNEOPLASTIQUE

Every eye with visual potential should be afforded the best possible chance to regain functional vision at a minimum, and to achieve unaided emmetropia if at all possible. With this goal in mind, I have introduced a superspecialty, corneoplastique, which describes the use of brief, topical, aesthetically pleasing, least interventional and visually promising techniques singly or in combination to manipulate the optical system back to emmetropia. Rather than limiting the management approach to one or a few treatment options, my philosophy is to use the full cadre of laser refractive, lens-based, corneal, intraocular, and combination surgeries with the aim of making the patient's visual outcome the most important endpoint.

In the management of corneal scars and dystrophy, I believe too much focus is placed on types of keratoplasties and technological advances to do the same things (Figure 2). Some surgeons can become too fixated on using a laser instead of a knife, or vice

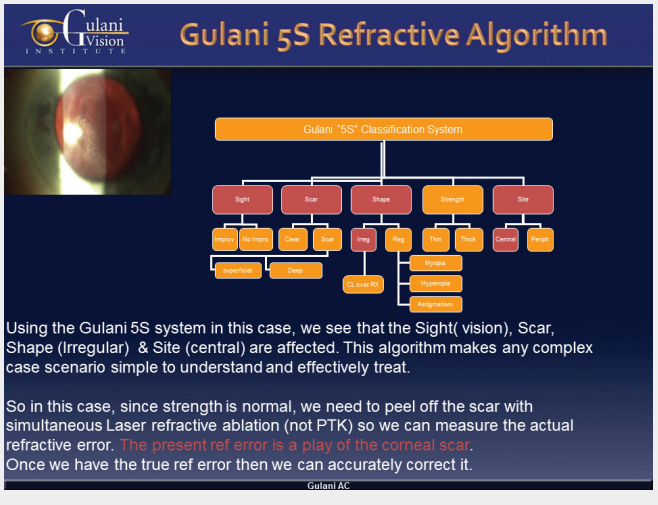


Figure 1. The 5S system: sight, scar, shape, strength, and site.

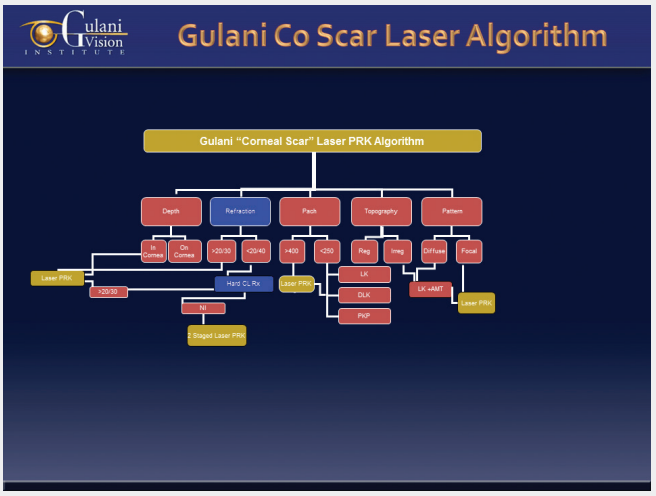


Figure 2. The author's algorithm for corneal scars.

versa, and there is too much debate on the various techniques and surgical acrobatics with less emphasis on the unaided emmetropic visual outcome. How the cornea is cut is not important; what is important is how it is put back together.

For many surgeons, keratoconus is the most commonly seen corneal dystrophy. The current treatment for keratoconus and ectatic conditions is corneal collagen crosslinking. When used in isolation or before correcting the cornea back to emmetropia, CXL "locks" the patient into his or her disability, with a promise that the condition will not get worse. The astigmatism that the patient had before the procedure will still be there; improvements in visual acuity after CXL are a welcome side effect, not the primary treatment endpoint.

Patients deserve better from their surgeons. Consider a hypothetical patient with a corneal thickness of 450 µm and a stable cone, refraction, and topography. The treating optometrist reports a BCVA of 20/25, so there is sight. There is not a scar present, and although the site (corneal center or periphery) is not affected, the patient has a relatively thin cornea (strength) and a high amount of astigmatism (shape). Using my 5S system, I know I must correct for sight and shape.

In this patient, I would perform laser surface ablation because astigmatic treatments remove the least amount of tissue. Correcting the astigmatism brings the patient's visual acuity close to 20/20. INTACS (Addition Technology) could be my backup option if the keratoconus progresses. Because I have already reshaped the optical system close to emmetropia, I can now use CXL to lock in this shape and visual acuity. That is, I will make the shape permanent only after the vision is at or near its greatest potential.

What if a scar were present in this patient? In that case, I would use my "in-cornea" versus "on-cornea" approach and remove the scar simultaneously while using laser surface ablation.

PRK NOT PTK

Much of the current thinking in corneal scar management is to chase the scar using phototherapeutic keratectomy, which deals with the scar but distorts corneal shape. Shape equals vision, therefore in my mind, that is an incorrect approach in terms of the visual acuity endpoint.

During 2 decades, I have taken more than 25 different corneal scar presentations and placed them into two categories:

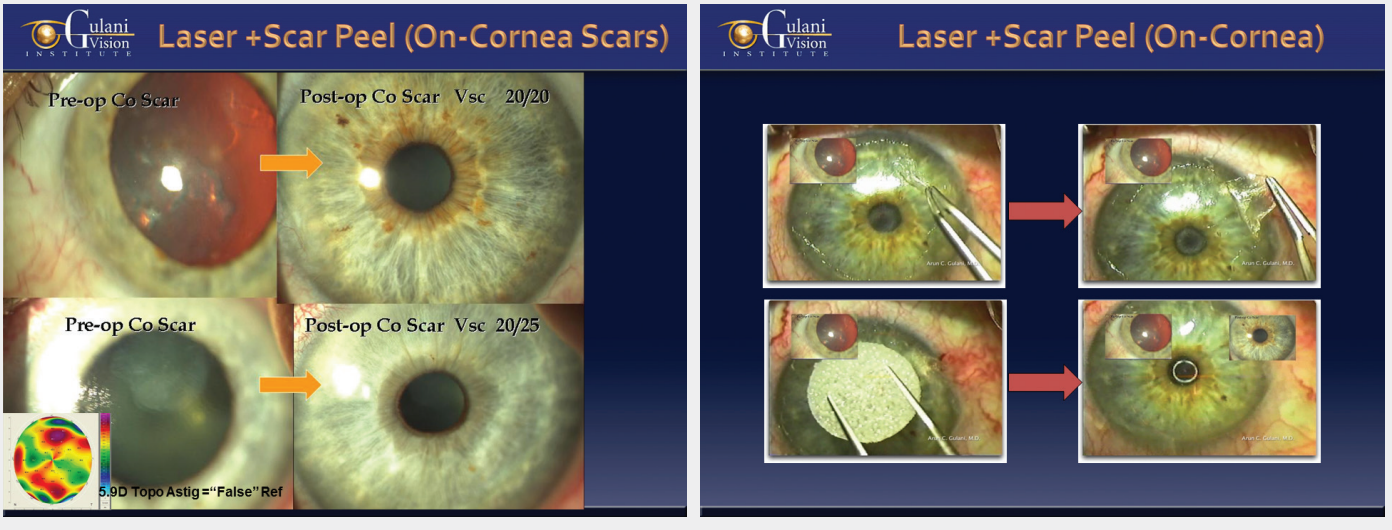


Figure 3. On-cornea scars are those appearing above Bowman layer, leading to camouflaged topography and misleading refractive error.

on-cornea scars and in-cornea scars. On-cornea scars (Figure 3) are those appearing above the Bowman layer, leading to camouflaged topography and misleading refractive error. In-cornea scars, which have become part of the cornea, are directly responsible for the topography, and have a direct correlation to the refractive error. The former can be peeled along with a central PRK application in a single or two-staged procedure. The latter can undergo direct refractive laser PRK straight to unaided 20/20 despite the presence of residual scar (chase the shape not the scar).

Such thinking moves corneal scar management from a hard science to a subtle refractive art, and it also demystifies corneal scars. Practically any etiology, such as those emanating from previous refractive surgery complications, corneal dystrophies, degenerations, infectious keratitis, chemical burns, or posttraumatic opacities can be treated with the same methodology using an excimer laser.

Lamellar Repair/Prepare Techniques

Per the 5S system, consider a cornea with dystrophy and scarring, that is unstable, thin, and weak. I would prepare and repair this cornea by adding strength. Then, I would consider any available directional stabilizing surgeries like INTACS or nondirectional lamellar keratoplasties.

Internal Optical manipulation: Inside-Out Versus Outside-In Techniques

In cases where the cornea is not measurable, I work to first make it measurable. Then I enter the eye for final optical correction for associated refractive errors (outside-in approach). If the cornea is measurable, I would first enter the eye to optically prepare the cornea for future laser PRK to achieve emmetropia (inside-out approach). The internal optical manipulation could be with phakic implants, pseudophakic implants, and even piggyback implants: the permutations are endless.

Posterior Dystrophies (Refractive Surgery)

I apply the same principles to other common dystrophies (ie, Fuchs dystrophy), and those become refractive procedures. I usually perform release incisions on anterior cornea while performing my Descemet-stripping automated endothelial keratoplasy/ Descemet membrane endothelial keratoplasty techniques and use topography to guide my incisions so they serve a dual function of interface fluid release and acting as an astigmatic keratotomy. These cases can undergo premium cataract surgery with toric lens implants, and results can be fine-tuned to emmetropia using laser PRK.

Symbiosis

Technological advances with new-generation contact lenses such as scleral lenses offer an opportunity for optometrists to help every patient achieve his or her vision goals with the least amount of surgical intervention.

LOOKING TO THE FUTURE

If corneal surgeons want patients with corneal scars to achieve the best outcomes possible, then they should focus on what patients want: to recover visual ability and unaided emmetropia. The advent of the integrated care model provides the opportunity for ophthalmology and optometry to work together toward a common goal for patients.

I believe that it is with that spirit of collaboration that we should be managing corneal scars. In some cases, surgery can be avoided altogether through the use of contact and specialty lenses. In other cases, the work of the optometrist can be complementary.

I encourage all my colleagues to change their mindset every time they see a patients with corneal dystrophy and think emmetropia with all the tools of refractive surgery. ■

Suggested reading:

Gulani AC. Corneoplastique: Art of vision surgery. Indian J Ophthalmol. *2014;62:3-11.*

Gulani AC. Using excimer laser PRK—not PTK—for corneal scars: Straight to 20/20 vision. Advanced Ocular Care. *2012(Sept/Oct);1-3.*

Gulani AC. Corneoplastique. Video Journal of Ophthalmology. *2007;22(3).*

Gulani AC. Irregular Astigmatism Management in Unstable Cornea. In: Textbook of Irregular Astigmatism. *Thorofare, NJ: SLACK; 2007:251-61.*

Arun C. Gulani, MD, MS
- founding director and chief surgeon, Gulani Vision Institute, Jacksonville, Florida
- (904) 296-7393; gulanivision@gulani.com
- financial interest: none acknoweldged

Best Practices in Integrated Care

THE ROLE OF SCLERAL LENSES IN CORNEAL SCAR MANAGEMENT

With proper patient selection, scleral lenses offer many benefits.

BY NATHAN SCHRAMM, OD

Although the current thinking among many eye care practitioners is to treat corneal scars as an automatic referral for surgical management, specialty contact lenses may be a viable treatment option in a great number of cases. Because corneal scars are a refractive problem in addition to being an injury to the cornea, successfully placing a patient in scleral contacts may avoid surgical correction as a primary treatment strategy. Also, scleral lenses can serve as an intermediate step before surgical referral, or, in some cases, aid in visual recovery after surgery.

Any discussion about scleral lens use for corneal scar management requires a shift in thinking about how these pathologies affect patients. Ultimately, patients care about their visual function.

INDICATIONS FOR SCLERAL LENSES

For most corneal scars and conditions that do not have an edematous component, scleral lenses are a viable option for avoiding or delaying surgical referral. Eyes with keratoconus (KCN), with or without apical scarring, would fit into the category of corneal conditions that may be correctible with lenses so as to avoid surgery. Patients with KCN may not be able to tolerate—due to comfort or visular acuity—a soft contact lens or small-diameter rigid gas permeable lens (RGP) because of the conical shape of their cornea (see *Scleral Lens in an Eye With Possible Unilateral Keratoconus*). RGPs can cause microtrauma.[1]

RGPs can cause microtrauma. According to a 2010 study, it is important to "reduce oxidative damage" and "minimize corneal microtrauma" to reduce risk of KCN.[1] A properly vaulted scleral lens, on the other hand, sits above and out of contact with the irregularly shaped ectatic cornea. Even in the presence of scarring in these patients, it is likely that the endothelial cell count is sufficient to support scleral lens wear. This way, the patient can benefit from lens wear to correct the irregular astigmatism to improve vision.

> "For most corneal scars and conditions that do not have an edematous component, scleral lenses are a viable option for avoiding or delaying surgery."

Some scleral lenses are classified as a prosthetic; sometimes referred to as a Prosthetic Replacement of the Ocular Surface Environment (PROSE) or EyePrint Prosthetic (EyePrint). Prosthetic lenses are most commonly used for eyes that are disfigured or blind to serve as a protective barrier or cosmesis. The saline fill used with scleral lenses functions to mitigate translucence at the cornea, thereby providing more optimal conditions for focusing light. For patients with certain systemic conditions, including Sjögren syndrome, graft-versus-host disease, and Stevens-Johnson syndrome, who may be experiencing ocular implications that manifest as ocular surface disease, scleral lenses may provide both protection to the anterior surface and a means to address the irregular refraction.

The saline fill of a scleral lens can also be of tremendous benefit to the patient with severe forms of dry eye disease. Although considered an off-label use, many patients with dry eye can gain benefit from both the hydrating and protective qualities of scleral lenses, especially if the natural ability to develop tears has been compromised or lost.

CASE 1: SCLERAL LENS IN AN EYE WITH POSSIBLE UNILATERAL KERATOCONUS

A 44-year-old man was referred for evaluation of keratoconus and consulation for scleral contacts in the left eye because vision could not be improved with glasses, and he could not tolerate soft or small-diameter rigid gas permeable lenses. Previous history was notable for laceration of the left cornea due to trauma 20 years prior. The patient reported visual symptoms of blur, glare, halo, and poor vision even with glasses.

At the time of the examination, unaided visual acuity was 20/20- and 20/200 OD and OS respectively; visual acuity with a pinhole occluder was 20/60+; near visual acuity was 2020/100. Keratometry (K) OS was 46.75 D @ 150° and 47.50 D @ 60°. The refraction was -0.25 -0.50 × 100 (20/20) OD and -3.50 -1.00 × 030 (20/40-). Slit-lamp examination of the left eye revealed a faint vertical opacity. Corneal topography of the right eye showed a fairly spherical cornea and an increase in the inferior Ks due to tearing of the patient during topography. Cone Location and Magnitude Index (CLMI) screening magnitude was 0.61 D with a 0.4% probability of keratoconus. However, in the left eye, the curvature map showed an apex cone, and the CLMI magnitude was 4.94 D with a 98.6% probability of keratoconus.

A central nipple cone was diagnosed, and a decision was made to fit the patient into a scleral lens. Based on a horizontal visible iris diameter of 11.45 mm, Prolate 4500 sag with a 16-mm diameter was selected per the manufacturer's suggested fitting guide. However, that lens did not provide enough central clearance, and so a trial with a greater saggital depth was attempted: Prolate BC 7.00, 16-mm diameter, sag 4800. There was no blanching 360° but there was a little edge lift, slight movement, and lens awareness with blink. A new scleral was ordered with a two-step advanced peripheral system feature to tighten the fit.

At the first follow-up visit with the new sceral, visual acuity was 20/20. The patient then returned the next day, and he reported seeing well, with improved depth perception, less asthenopia, and a comfortable lens fit.

This case demonstrates a possible rare presentation of unilateral keratoconus, which is typically bilateral, although neither eye exhibited Vogt straie or Fleischer rings,[4] retinoscopy of the left eye showed a scissoring reflex which is highly suggestive of keratoconus.[5] Regardless, a scleral lens restored good vision with comfortable wear. The use of the scleral lens likely avoided the need for keratoplasty in an eye that otherwise could not tolerate other refractive correction measures.

POSTOPERATIVE USE

Surgery for corneal scars can be directed at correcting the functional defect, improving the visual defect that is a result of the pathology, or both. Regardless of the approach, postsurgical use of a scleral lens to aid in visual recovery may be additive to the steps the cornea surgeon performed.

Arun Gulani, MD, has pioneered a system of corneal scar management he terms "corneoplastique," which is the use of various refractive techniques to manipulate the optical system back to emmetropia. There are three levels of cases in his classification system. Grade 1 corneal scars are those cases in which a PRK procedure can correct the patient to 20/20; grade 2 corneal scars require a peel, followed by PRK to achieve 20/20 visual acuity; in grade 3 scars, the patient require a peel and PRK, and follow-up care is recommended for additional refractive correction with a specialty contact lens.[2] I have worked on several cases that Dr. Gulani initiated in a follow-up capacity with a high degree of success (see *Scleral Lens Fitting in a Patient After Corneoplastique*).

CONCLUSIONS AND CAVEATS

Scleral lenses can be a challenge to fit, they require special training, and clinicians must educate patients on best practices, which can be time consuming and difficult. Patients may require an inserter device to help place the lens, and others with manual dexterity issues may be unable to use them at all (I have a patient with one arm and others in their 80s who are successful with the lenses, however.) Patients who are unwilling to follow cleaning and removal protocols may also be disqualified as candidates. In my view, however, scleral lenses represent a reasonable approach for patients who wish to avoid surgery for a corneal scar.

When I am working with a patient with a corneal scar, my barrier for referring for surgical consultation usually depends on his or her preference. Some patients will want to try a lens to see if it works, and others may express no interest. I have had several patients who recovered vision using scleral lenses, but then decided to discontinue use because the insertion and removal process was too time consuming. One patient had

CASE 2: SCLERAL LENS FITTING IN A PATIENT AFTER CORNEOPLASTIQUE

A 24-year-old patient was treated for a severe corneal ulcer; after treatment, BCVA was counting fingers at 2 feet due to a dense corneal scar. It was suggested to the patient that a corneal transplant would be necessary. The patient sought a second opinion from Arun Gulani, MD, who subsequently performed laser corneoplastique. Dr. Gulani referred the patient to my clinic for follow-up care after the surgery for a scleral lens fitting.

The case is a grade 3 laser corneoplastique under Dr. Gulani's grading system. In that system, a grade 1 case can be corrected to 20/20 with PRK; a grade 2 scar requires peeling of the scar followed by laser; a grade 3 scar necessitates peeling and laser, followed by specialty contact lens consultation for additional refractive correction.[2]

Seven weeks after the corneoplastique procedure, the refraction in the left eye was -1.25 D -1.25 D 100°; distance visual acuity was 20/150; and pinhole visual acuity was 20/70.

Several trials of scleral lens models were tried before settling on a successful option for the patient. The initial lens was a Prolate 7.80, 17 mm, 4900 sag; however, there was a need to decrease the central zone by 100 µm and the limbal zone by 30 µm; there was blanching inferiorly and superiorly. A second lens with added toric peripheral curves to align the front toric without a dual thin zone, but blanching inferiorly and superiorly persisted. A third trial achieved good clearance in both the central and limbal zones and no blanching. Final BCVA for this patient in glasses was 20/150 and 20/30 with scleral lenses.

This case demonstrates the potential for manipulating the optical system to achieve a good vision outcome in the presence of a dense scar.

never seen 20/20 in her entire life and she felt "everything was too clear." In this case, referral to an appropriate source is in the best interest of the patient and should not be delayed.

Scars that obviously affect all corneal layers and those with edema will cause me to refer the case sooner rather than later. Nocturnal fluctuations naturally cause a 4.5% swelling in the cornea that resolves upon 1 hour of waking. Scleral lenses can indice 3% to 4% edema, but this effect lasts the entire day of wear.[3] This can be problematic in the patients with edematous corneal scarring, low epithelial counts, or Fuchs endothelial dystrophy.

In the right patient, scleral lenses can be of tremendous benefit. The research on this category has exploded over the past few years, and studies point to benefits for a wide range of patients, including those with DED, corneal dystrophy, KCN, graft-versus-host disease, and even patients treated with chemotherapy that lost the ability to naturally create tears. ■

1. Romero-Jiménez M, Santodomingo-Rubido J, Wolffsohn JS. Keratoconus: a review. *Cont Lens Anterior Eye*. 2010;33(4):157-166; quiz 205.
2. Gulani AC. Corneoplastique: art if vision surgery. *Indian J Ophthalmol*. 2014;52(1):3-11.
3. Miller WL Vance K. Johnson L, Bergmanson JP. Scleral contact lens effect on central and peripheral corneal thickness. *Investigative Ophthalmology & Visual Science*. 2015;56:6103.
4. Li X, Rabinowitz YS, Rasheed K, Yang H. Longitudinal study of the normal eyes in unilateral keratoconus patients. *Ophthalmology*. 2004;111(3):440-446.
5. Vazirani J, Basu S. Keratoconus: current perspectives. *Clin Ophthalmol*. 2013;7:2019-2030.

Nathan Schramm, OD
- Natural Eyes of Weston, Florida
- gr8eyedoc@gmail.com
- financial disclosure: has received honoraria from Alden Optical, Fortifeye Vitamins, and Physician Recommended Nutriceuticals