A Good Example

n mid-April, the American-European Congress of Ophthalmic Surgery (ACOS) received word from the FDA that the society may begin its study of corneal collagen cross-linking (CXL). ACOS is sponsoring the study, which will be conducted in cooperation with Avedro, Inc., the manufacturer of the device and supplier of the drug, riboflavin. The investigation is planned

for up to 100 sites. Patients will be treated with the latest technology, only 3 minutes of exposure to ultraviolet light. All patients will receive treatment.

CXL has been established outside the United States as an effective treatment to prevent the progression of ectatic dystrophies such as keratoconus and pellucid marginal degeneration. CXL has also proven useful for treating ectasia after LASIK and PRK. The technique, involving saturating the corneal stroma with riboflavin and then

exposing the tissue to ultraviolet light, was introduced by Theo Seiler, MD, PhD, and his group in Zurich, Switzerland. Surgeons may be seeing only the beginning of how they will use CXL. Already, researchers have proposed using the procedure prophylactically for patients undergoing LASIK or PRK who may be at increased risk of ectasia as well as for the treatment of infections, the prevention of regression after hyperopic LASIK, and the modulation of wound healing after PRK. The series of articles on CXL in this edition of Cataract & Refractive Surgery Today provides an update on the procedure and technology. I am sure that rapid development of both will increase their efficacy and ease of use.

I currently treat patients with CXL under an FDA trial at my clinic in Houston. I consider the procedure to be godsent. Avoid a corneal transplant through the use of vitamin drops and blue light! The concept sounds like something off the back of a comic book. Personally, if I had keratoconus, I would run—not walk—to the nearest clinic that offered CXL (although there really is no

rush, because the disease progresses slowly). I ask my patients to consider that a corneal surgeon who loves to do surgery (ie, myself) is not recommending surgery. That testifies to the soundness of my advice.

I am proud of how well ACOS, the FDA, and Avedro worked together. It was a process, but throughout it, the FDA and Wiley Chambers, MD, were helpful and engaged. Avedro CEO David Muller was committed and dedicated to the idea of a physician group-sponsored investigational device exemption. The leadership

and staff of ACOS—especially Adam Krafczek, the organization's coexecutive director, who reviewed all the documents—made this unique trial happen. I am particularly grateful to John Vukich, MD, who will move it forward as medical monitor. It is hard to think of a better example of industry, the FDA, and physicians' working together to advance a promising treatment for patients. One of my favorite parts of this issue of *CRSToday* is surgeons' essays on what ophthalmologists could learn from Steve Jobs. I would argue that the ACOS CXL trial should be listed as a good lesson on industry's working together with its customers and consumers, and such physician-industry innovation is exactly a stated purpose of ACOS.



Stephen G. Slade, MD Chief Medical Editor

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