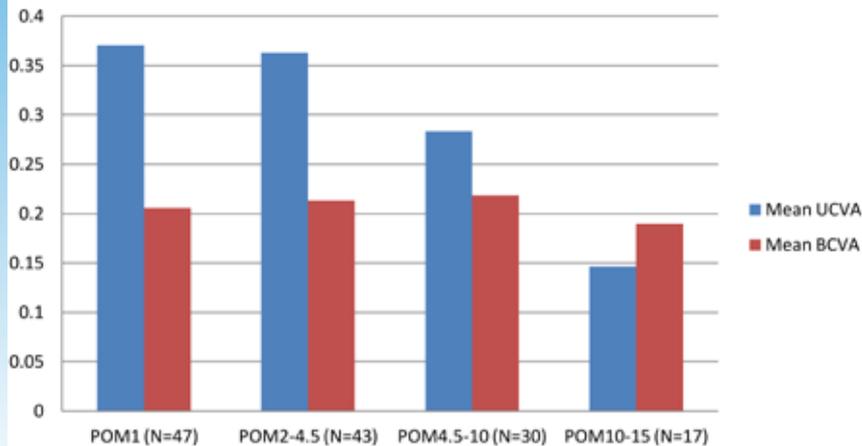


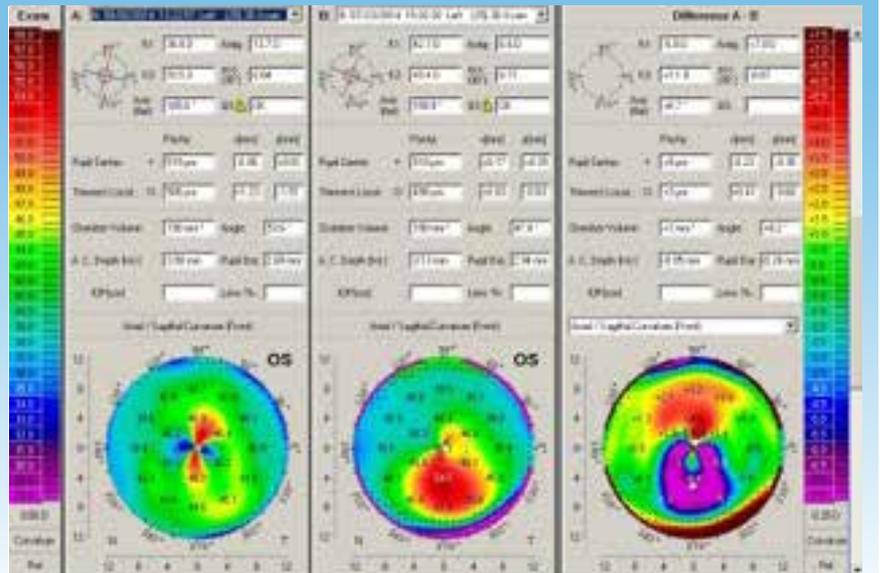
Combining CXL and CK

by Michelle Dalton EyeWorld Contributing Writer

**Eyes with preop BCVA of 20/40 or worse:
Improvement in logMAR VA from preop**



Graph showing long-term improvement from CK plus crosslinking. Visual improvement was found to be greater in patients with worse preoperative best corrected vision.



Preoperative corneal scan of keratoconus patient (middle image) with marked inferior/superior asymmetry. The image on the left is immediately after CK with a new nomogram, and on the right the difference map is visible.

Source (all): Roy Rubinfeld, MD

Corneal collagen cross-linking (CXL) for the treatment of keratoconus and ectasia has been approved throughout the European Union since 2006 but has yet to receive approval in the U.S. In 2009, a group of U.S. corneal specialists formed a non-commercial, physician-sponsored research group, CXLUSA, to investigate and further refine the procedure with the approval of several Investigational Review Boards. **Roy Rubinfeld, MD**, a CXLUSA group member, noted that the Eye Bank Association of America and **Doyle Stulting, MD, PhD**, estimate that more than 40% of the corneal transplants in the U.S. could be avoided if crosslinking were approved in the U.S.

“For patients with keratoconus, the usual objective of CXL is not to get rid of glasses or contacts, but rather to stop [patients] from losing their vision due to progressively worsening irregular astigmatism,” said Dr. Rubinfeld, in practice at Re:Vision – Roy S. Rubinfeld, MD, Rockville, Md., and Fairfax, Va. Dr. Rubinfeld is also a faculty member at Georgetown University Medical Center and Washington Hospital Center, Washington, D.C. “Our most recent developments and protocols now attempt to take people who have poor vision and restore some of the vision that was lost as a result of ectasia or keratoconus.”

Combining procedures

Numerous studies in the literature confirm the ability of CXL to stabilize the cornea and prevent further vision loss in patients with keratoconus. But oftentimes, these patients are displeased they had a procedure but didn’t gain any vision.

“Our patients typically don’t understand that maintaining the same visual acuity is considered a victory,” Dr. Rubinfeld said. Combining CXL with a refractive procedure, however, has been successful in markedly improving vision in some patients, he added. “For example, conductive keratoplasty (CK) is a noninvasive option that does not require any kind of incision and has an excellent safety profile. Combining these 2 non-invasive procedures has yielded very encouraging results and restored the ability to drive and function for many of our patients.”

If a patient presents to one of the study sites with just keratoconus and no vision loss, “CXL alone is the way to go,” Dr. Rubinfeld said. But “if the best corrected vision and/or the quality of vision is not good, we have started offering CK plus crosslinking under one of our approved protocols, and we have been really encouraged by the results.”

Both procedures are noninvasive, involve no epithelial removal or incisions, and have very low risk

profiles, he said, adding **Arthur Cummings, FRCSEd**, had previously found that thermokeratoplasty using another modality subsequently followed by CXL “resulted in patients with longer-lasting results than those where he performed thermokeratoplasty and crosslinking simultaneously.”

As a result of Dr. Cummings’ outcomes and cumulative CXLUSA study results, the procedure of choice for Dr. Rubinfeld for patients with moderate to advanced vision loss from ectasia or keratoconus is CK followed by CXL the next day. To date, there does not seem to be a max K that is too steep to treat, he said.

CK is not without its limits, however. When used as a standalone refractive procedure for the treatment of presbyopia, regression was a common occurrence that led to the procedure becoming less popular as a first-line treatment option for presbyopia.

“CK is a great procedure and even better if you can get the effect to last longer,” Dr. Rubinfeld said. By placing “just a few CK spots in the right places” in patients with keratoconus, he has found a “huge positive effect in regularizing the corneal shape.”

Details of the procedure

Dr. Rubinfeld uses an intraoperative keratometer to ensure he is providing the desired results in real time, and based on serial Pentacam (Oculus, Wetzlar, Germany) images, may take the patient back to the OR for additional spots. He then performs CXL the next day with a proprietary, highly effective epi-on technique.

Although most patients would show regression based on Pentacam images in the first few months after the sequential procedures, the changes remained unnoticed by patients, who still claim good visual acuity, which is borne out in their exams as well, Dr. Rubinfeld said.

The nomogram for treating irregular astigmatism with CK has evolved in the study. Saying he “worked his way up in the protocols” of the CXLUSA group, Dr. Rubinfeld initially made superior CK spots far from the visual axis to steepen the overly flat superior area of the patient’s cornea “to make it more uniform.” Once he realized the superior spots worked, Dr. Rubinfeld added inferior spots “in the hopes that they would flatten the overly steep areas.”

By modifying the number and location of the spots, Dr. Rubinfeld creates more homogenous corneas (in the sense they are less irregular),

and based on positive results with those patients, he started performing apical spots.

"Many of these patients went from 20/800 uncorrected to 20/50 uncorrected in a day," he said.

By the first month, patients have "much better" Snellen acuities, and by month 3 or so, vision has stabilized and spectacles can provide "greatly improved vision in many patients."

Dr. Rubinfeld said surgeons can expect the refractive axis of astigmatism to be around 90 degrees off the topography axis for about the first month postop after the sequential procedures, but then the refractive axis and topo axes begin to align. By 3 to 6 months, "most of the topography changes have regressed, but most of the vision and refractive improvements persist," which reinforces how little science actually knows about the disorder, he said.

With some patients out to 1 year or more post-procedure, "the vision gain improvement has remained," Dr. Rubinfeld said. The group is continuing to refine the

various protocols to determine the best patient parameters likely to benefit from the sequential procedures.

"The results have been promising with both uncorrected and best spectacle corrected visual acuities showing lasting improvements. We found a great potential for improving vision in patients with worse preoperative acuity," said **Sirikishan Shetty, MD**, senior ophthalmology resident at Georgetown University Hospital and Washington Hospital Center.

"We need to constantly reinforce to these patients that this is not LASIK," he said. "It's unlikely these patients will be spectacle-free as a result of these procedures, but the fact that many patients can drive and function again with glasses is very rewarding for the patients and surgeons." **EW**

Editors' note: Dr. Rubinfeld has financial interests with CXLUSA and CXL Ophthalmics (Encinitas, Calif.), as well

as patents related to the proprietary technology used in the procedure. Dr. Shetty has no related financial interests.

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Osmolarity tests confirm majority has elevated levels

The interim results from the U.K.'s National Health Service Dry Eye Disease (DED) Prevalence Study found elevated tear osmolarity levels in 72.3% of the 596 enrolled patients, indicating an abnormal and unstable tear film, TearLab (San Diego) said in a news release.

Three NHS ophthalmology consultants (Hillingdon Hospital, Middlesex; Great Western Hospital, Swindon, Wiltshire; and St. Peter's Hospital, Chertsey, Surrey) compared the efficacy of conventional dry eye tests (tear break-up, OSDI, meibomian gland dysfunction, and DEWS) to determine if osmolarity could improve the identification of DED patients better than conventional tests.

With interim results completed this past June, the researchers found conventional dry eye tests do not correlate well with the presence of DED and that based on these tests, almost half of all cases may not be identified as having DED. Further, osmolarity has the highest agreement (78%) with the DEWS composite score.

An elevated osmolarity measurement (326.8 mOsm/L average) was the only definitive sign in 20.1% of patients (120 individuals) who had significant symptoms but no other sign of dry eye.

The ongoing study hopes to enroll a total of 1,000 patients and will add another site, TearLab said. **EW**



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