



Issue 056

415.922.9500 • www.pacificvision.org

August 2019







Corneal cross-linking on a patient co-managed with Urban Eyes optometry in San Francisco. PVI cross-linking CE dinner for San Francisco Bay Area optometrists at McCormick & Kuleto's in the historic Ghirardelli Building on Fisherman Warf held earlier this summer. More than 60 optometrists attended.

Comanaging Cross-linking Patients:

Practice pearls from the cross-linking CE dinner with Mitch Ibach, OD, FAAO and Ella Faktorovich, MD

In his *Optometry Times* article published earlier this year, Dr. Mitch Ibach - an optometrist in one of the busiest tertiary care surgical centers in the US - said that one of the most rewarding developments in his career has been the opportunity to eliminate the need for corneal transplant in a vast majority of his patients who would have, otherwise, needed it. Historically, as many as 1 in 5 patients with progressive keratoconus have required a corneal transplant, with more than half of those

needing multiple transplants within 20 years. The paradigm shifted with the FDA-approval of cross-linking (CLX) technology (epi off with a suite of CXL products from Avedro). We can now intervene early, halt the disease progression in nearly 100% of patients, and avoid a corneal transplant.

In June, Pacific Vision Institute invited Dr. Ibach to share his CXL experience with the San Francisco Bay Area optometric community. In a fast-paced, case-driven 3-hour CE dinner event, Dr. Ibach detailed his tips and pearls on the crucial role of an optometrist in modern management of patients with keratoconus.

Step 1: diagnosing keratoconus in the OD's office

Optometrist is often the first eye care provider a patient turns to when they "don't see well" or their vision changed. "These patients typically don't

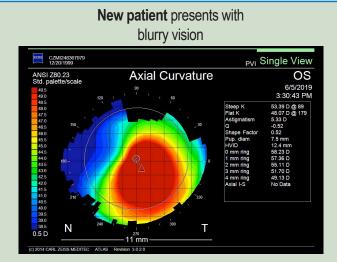
Red flags for possible keratoconus

- Unhappy with glasses
- Frequently changing prescription
- Best corrected Va is not 20/20
- Monocular diplopia despite best correction
- Signs on retinoscopy
- Distorted mires on manual keratometry
- Frequent K changes on autorefractor keratometry
- Slit lamp signs Vogt's striae, stromal thinning, Fleischer ring, Munson's sign, prominent corneal nerves
- Habitual eye rubbing
- Floppy eyelids
- Allergies / Atopic Dermatitis / Asthma

know they have keratoconus," says Dr. Ibach, "They are unlikely to present to a practice that performs CXL; rather, they will visit a primary care optometrist in hopes of improving their refractive corrections."

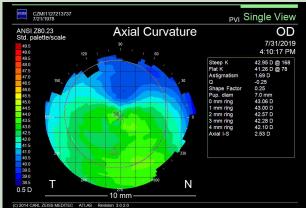


Clinical News & Views



18 y.o. male presented to an OD office for the first time with blurry vision getting worse despite a recent update in prescription. Retinoscopy was suspicious for KCN and OD immediately referred the patient to PVI for a comprehensive corneal eval and **prompt CXL** if KCN was confirmed.

Existing patient presents with vision getting worse



41 y.o. male seen in the OD office for 15 years presented for an annual eye exam and mentioned to his OD that his vision has been getting worse. Increase in cylinder was noted. Patient was referred to PVI for a comprehensive corneal eval and discussion about **possible CXL** if KCN was confirmed

This could be a patient presenting either as a new patient or someone who's been followed in the practice for a long time and who has been noted to have change in their vision. In either case, certain signs and symptoms could be a red flag for keratoconus.

Step 2: referring for a comprehensive corneal evaluation and CXL consult

If KCN is suspected, the patient should be referred for topography, tomography, and epithelial thickness mapping. There are two reasons for this - to confirm the diagnosis and to determine the best course of action to help prevent further corneal changes that may lead to a corneal transplant.

Pacific Vision Institute provides advanced corneal imaging services at the request of primary care optometrists to help determine if their patient has KCN. If KCN is confirmed, the OD is engaged in the collaborative care which may involve cross-linking in appropriate candidates.

A Global Consensus on Keratoconus and Ectatic Diseases project completed several years ago (Gomes, JA, et al. Cornea

2015;34:359-369) pooled opinions of corneal experts worldwide, reaching a consensus regarding keratoconus definition, clinical management, and surgical treatments. In addition to recognizing that the term "collagen cross-linking" should be replaced by "corneal cross-linking," the experts reached a consensus on who should be treated with CXL.

In addition to undergoing advanced corneal imaging, the patient can expect the following during their CXL consult at PVI:

- Chart review from the OD office to determine progression
- Education about their condition
- Explanation of what to expect after CXL
- Meeting with surgical coordinator to review their insurance benefits and coverage, initiate insurance pre-authorization process, discuss cost and financing if not covered, schedule their preop and CXL procedure, and explain postoperative visit schedule at PVI and their OD's office

Global consensus on indications for CXL

- Documented progression, regardless of age
- Risk of progression
 - Young age
 - Mechanical factors eye rubbing, floppy eyelids
 - Ethnic factors Asian and Arabian
 - Allergy/Atopy
 - Connective tissue disorders
 - Hydrops or KCN requiring corneal transplant in the contralateral eye
- KCN eyes that have previously underwent other forms of surgery
 - Intracorneal Ring Segments "Intacs"
 - PRK or LASIK

Step 3: logistics of collaborative care

After their initial consult, the patient will be seen for pre-operative evaluation at PVI. They will review and sign the consent for CXL. Their insurance pre-authorization status will be known at this point and it will be reviewed with them. <u>Very importantly, insurance can be billed ONLY for FDA-approved technology. Currently, Avedro is the only FDA-approved technology for CXL.</u> It is approved for "epi-off" CXL. "Epi-on" is not FDA-approved. It can not be billed to insurance. "Epi-off" CXL with Avedro is a widely covered procedure in the US with major insurances, such as Blue Cross, Blue Shield, Aetna, and others covering some or all of the procedure fee.

The next visit for the patient will be their CXL procedure. The procedure takes about an hour. They may be at PVI for several hours in total. At the end of the procedure, bandage contact lens is placed on the cornea.

Follow up visits will be:

- 1-day (PVI)
- 1-week (PVI or OD, remove BCL, evaluate cornea, address short-term management of visual acuity)
- 1-month (PVI or OD, evaluate ongoing healing)
- 3-month (OD, prescribe longer term vision correction)
- 6 months (OD)
- 12 months (PVI, repeat topography/tomography/ETM to insure stability)

Insurance payers require AT LEAST ONE of the below criteria in order to meet the definition of progressive KCN

- An increase of 1 D in steepest keratometry value
- An increase of 1D in regular astigmatism
- A myopic shift of 0.50 D on subjective manifest
- A decrease of >= 0.1 mm in the back optical zone radius of rigid contact lens wearers where other information was not available
- Failed conservative treatment (e.g. spectacle correction, rigid contact lenses, etc)



- Dr. Faktorovich is interviewed by *Ocular Surgery News* at the American Society of Cataract and Refractive Surgery Annual Meeting in San Diego about the new LASIK screening technology Epithelial Thickness Mapping with Widefield OCT.
- Dr. Faktorovich interviewed by **KRON4 News** on Steph Curry's eye condition keratoconus and corneal cross-linking with the FDA-approved technology



- PVI research "Comparison of Corneal Epithelial Thickness Map (ETM) patterns in normal eyes vs. eyes with mild topographic and tomographic abnormalities" is accepted for presentation at the 2019 Refractive Surgery Subspecialty Day Meeting of the International Society of Refractive Surgery (ISRS) at the American Academy of Ophthalmology Annual Meeting.
- PVI becomes the first and only private practice in San Francisco to perform corneal cross-linking with the FDA-approved technology
- PVI and Dr. Faktorovich interviewed by the *Journal of San Francisco Police Officer's Association* about CONTOURA Vision LASIK
- PVI launches #eyecaseoftheweek on Instagram. Follow @pacificvisioninstitute, see common and uncommon cases, and learn how to manage them. Example swollen optic nerves in a 25-year old presenting for a LASIK consultation. What was the diagnosis and how was she managed? We will discuss it @pacificvisioninstitute



30 Years of LASIK: from patent to patients

Thirty years ago, in the summer of 1989, the US Patent and Trademark Office granted a patent to a retinal surgeon, Dr. Gholam Peyman, for a "Method for Modifying Corneal Curvature." The method came to be known as LASIK. The patent represented a major landmark in evolution of eye care. It was the culmination of more than a century of innovations

in science and technology. It also coincided with the start of a transformative practice model - the collective engagement of optometrists and ophthalmologists in the care of a patient.

We have come a long way since the summer of '89. Correcting sphere and cylinder is no longer enough. We have advanced to treating higher order aberrations we couldn't even detect thirty years ago. We now expect vision outcomes better than 20/20 for the majority of our patients. Today, both optometrists and ophthalmologists are advancing the field of spectacle independence. From prevention to treatment of refractive error, we are united by a common goal to help our patients lead healthy and productive lives.

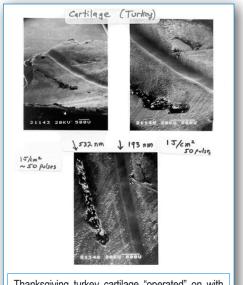
History of innovations in refractive surgery

More than 100 years ago, Hermann Snellen introduced the concept of surgically altering cornea to reduce refractive error.(1) Initially, refractive surgery developed along two paths - radial keratotomy (RK) and lamellar surgery, called keratomileusis.(2) The invention of excimer laser made RK obsolete and transformed keratomileusis into the LASIK of today.

Rapid development of laser technology

In the early 80's, a trio of researchers with diverse expertise were brought together by the International Business Machines (IBM) Corporation at the

company's research facilities in Yorktown Heights, NY. The team consisted of material scientist Samuel Blum, photochemist Rangaswamy Srinivasan, and physicist James J. Wynn. The trio was instructed by IBM to work with excimer lasers, which had just been acquired by the company, to see what type of work they were capable of performing. Srinivasan discovered that the laser can etch polymer materials accurately. He hypothesized that it could also work on biological



Thanksgiving turkey cartilage "operated" on with excimer laser (193 nm wavelength) shows a smooth groove. A longer wavelength YAG laser, 532 nm. on the other hand, coagulates tissue

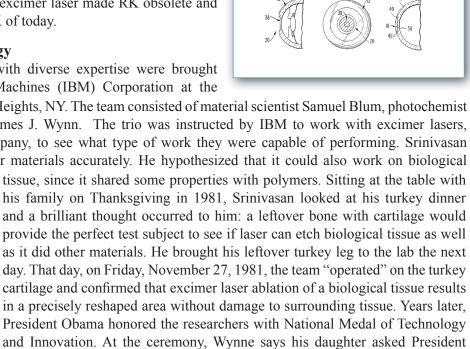


FIG 8

U.S. Patent

FIG 2

FIG. 6.

Ophthalmologist, Dr. Stephen Trokel of Columbia Presbyterian Medical Center in NYC, learned of the work done by the trio of IBM scientists and realized that since cornea is similar to cartilage, the excimer laser could reshape cornea as well. In 1983, Trokel came to IBM's research center to work with Srinivasan on methods of using excimer lasers for corneal refractive procedures.

Obama if he knew anyone who had undergone laser refractive surgery. The president replied, "Yes, my wife Michelle." (https://phys.org/news/2013-11-

Shortly thereafter, Trokel and colleagues at IBM published an iconic paper in

leftover-thanksgiving-dinner-gave-lasik.html).



30 Years of LASIK: from patent to patients



American Journal of Ophthalmology (Trokel et al, Excimer laser surgery of the cornea; *Am J Ophthalmol*. 1983 Dec:96(6):710-5) introducing the idea of using the laser to reshape the cornea in order to correct refractive errors, such as myopia or hyperopia. This paper launched a worldwide program of research to develop excimer laser-based refractive surgery. Thousands of plastic test blocks, cadaver eyes, and animal eyes later, Dr. Marguerite McDonald (Dr. Trokel's colleague) became the first surgeon in the world to perform laser vision correction (PRK) on a sighted eye in 1988.

A year later, at the end of one of the most fast-paced and innovative decades in eye care, Dr. Gholam Peyman patented a procedure that combined excimer laser of the 80's and keratomileusis of the 60's into the procedure that became known as laser in situ keratomileusis. He, too, was honored with National Medal of Technology and Innovation.

LASIK technology has come a long way

The first LASIK was performed in 1990. It was FDA approved in 1999. This year marks a double anniversary of LASIK - 30 years since it was patented and 20 years since it was FDA approved.

In the initial years of LASIK, advancements were focused on fine-tuning the ACCURACY of correcting refractive error -

myopia, astigmatism, and hyperopia. In the early 2000's, attention was turned to improving LASIK SAFETY, with the introduction of the femtosecond laser, which replaced the mechanical microkeratome (the blade) for LASIK flap creation.

All the subsequent work in LASIK vision correction has been directed at improving CUSTOMIZATION of the procedure to achieve correction of both the refractive error and the higher order aberrations, with the goal of improving quality of vision both day and night and achieving vision beyond 20/20 for most patients.

The customization of LASIK began in the mid-2000's with the advent of wavefront-guided ablations. Initially, 200 data points were measured and attempts were made to reduce the aberrations. Over the past 15 years, with the evolution of customization technology, very precise detection and mapping of aberrations has become possible. Three custom LASIK systems are currently available:





- Modern wavefront-guided LASIK (iDesign Advanced Wave Scan, Johnson & Johnson Vision) targets 1,200 aberration data points in the entire optical system.
- Wavefront-optimized LASIK (Wavelight, Alcon) uses laser beam application techniques that optimize corneal asphericity to maintain good quality of vision day and night.
- Topography-guided LASIK (CONTOURA Vision, Wavelight, Alcon) aims at correcting corneal aberrations by mapping 22,000 unique elevation and depression points on the corneal surface.

With these 3 types of custom LASIK, we can now offer our patients better vision than ever. For example, in the recent FDA studies of topography-guided CONTOURA Vision LASIK and wavefront-guided iDesign LASIK, nearly two thirds of patients achieved better than 20/16 uncorrected vision. Today, "better than 20/20" is the new 20/20.

Where are we headed?

Advances in customization are likely to continue with more patients able to achieve vision beyond 20/20. The SMILE procedure is promising, but needs to incorporate treatment of higher order aberrations to achieve the same level of customization as is possible in modern LASIK surgery. The concept of PresbyLASIK may (continued on page 7)



OPTOMETRISTS AND OPTOMETRY STAFF/FAMILY/FRIENDS WHO RECENTLY HAD LASIK AT PVI



Dr. Darwin Tsang (Marin Optometric Group, San Rafael) Procedure: LASIK

Preop Rx: OD: -8.00-2.75x004, OS: -7.75-3.00x002



Jessica Wong (Through the Hayes Optometry, San Francisco)

Procedure: LASIK

Preop Rx: OD: -5.75, OS: -5.75-0.25x178



Gabriella Cao (AccuVision Optometry, San Francisco)

Procedure: LASIK

Preop Rx: OD: -2.75, OS: -3.50



Don Pham (Dr. Krystle Quan, Clear Optometry, San Mateo)

Procedure: LASIK

Preop Rx: OD: -1.75-1.25x163, OS: -2.50-0.50x112



Chrissa Gaines (Dr. Joanne Yee's Optometry, San Francisco)

Procedure: PRK

Preop Rx: OD: -2.00-0.75x172, OS: -2.25-1.25x010

<u>(continued from page 5)</u> continue to be explored to improve both distance and near vision in presbyopic patients while minimizing side effects of a multifocal cornea.

Novel therapeutic approaches to stimulating corneal nerve regeneration and restoring corneal nerve function and sensitivity are being investigated. Nerve growth factor, Cenegermin-containing eye drops (Oxervate, Dompé farmaceutici SpA) have been FDA approved last year for the treatment of neurotrophic keratitis. Further investigation could help determine if such types of medications could enhance healing after LASIK.

We have come a long way in the past 30 years. To quote James J Wynn, the IBM physicist who led the pioneering work in excimer lasers, "Science is an endless frontier and technology is an endless frontier. When you put these two things together and go in the right direction, you can make some really magical things happen."(3)

References

- McAlinden C. Corneal refractive surgery: past to present. Clin Exp Optom 2012:95:386-398
- 2. Reinstein DZ, et al. The history of LASIK. J Refract Surg. 2012;28(4):291-298.
- 3. LASIK Surgery: How IBM's Dr. James Wynne Discovered It. https://www.youtube.com/watch?v=yzavwVLefPw

Some drive from San Francisco to the Silicon Valley and back. Patients may need to temporarily increase font size and contrast on their computer screens. Some may benefit from low Rx readers, i.e. +1.25D or +1.50D. Just as with LASIK, it's recommended patients don't get water in their eyes for one week after PRK, but they can do their usual exercise during this time, other than swimming and surfing. After the first week, the vision continues to improve gradually.

Q: Does pupil size matter in determining LASIK/PRK candidacy?

A: Multiple studies involving thousands of patients found no correlation between pupil size and the quality of vision after laser vision correction. There is a correlation, however, between postoperative corneal shape in the center of the corrected area and the quality of vision. This shape is called corneal asphericity. Ideally, postoperative asphericity should not be very different from the preoperative one. When they are very different, the brain may perceive glare and haloes, for example. When they are similar, perception of glare and haloes is reduced.





Q: How long is the recovery after PRK?

A: During the first several days after procedure, patient is likely to experience eye irritation, tearing, and some burning sensation that should be relieved with medication, such as ibuprofen, for

example. We recommend patient takes 600 mg of Ibuprofen QID for the first 3 days, regardless of how their eyes feel as a baseline to reduce discomfort. They can supplement Ibuprofen with additional medications. At PVI, we developed a treatment plan designed to improve comfort after PRK. Our team are recognized experts in the field of corneal healing, having published studies in the field, including, most recently in the *Journal of Cataract and Refractive Surgery*, a recommendation for the best protocol to enhance patient comfort after the procedure. Many of our co-managed patients can do their usual activities within several days after PRK. During the first week after PRK, vision will be blurry, but functional. Most patients report being able to carry on their usual activities, including driving in familiar areas.



Q: How soon after CXL in one eye, can the other eye be done?

A: We typically recommend CXL in the second eye three months after the procedure in the first eye. During the three months postop, cornea heals and vision recovers. At about 3 months postop, patient can be fit with an updated contact lens to rehabilitate vision in the eye before the other eye is treated.

Q: How can I help my patient get the CXL covered by insurance?

A: Insurance can be billed ONLY for FDA-approved procedure. The only FDA approved CXL is "Epi-off" with Avedro technologies. Performed in this way, CXL is a widely covered procedure in the US with major insurances, such as Blue Cross, Blue Shield, Aetna, and others covering some or all of the procedure fee. We recommend patient's records get e-mailed or faxed to us before their first exam so that we can review them at the patient's initial consult and discuss with them whether it is likely their insurance will cover some or all of their procedure.



