eFocus
Innovation, Leadership, Passion for Perfection

PACIFIC VISION INSTITUTE
Life in Focus

Issue 051 415.922.9500 • www.pacificvision.org March 2018

ADVANCES in REFRACTIVE, CORNEA, and CATARACT SURGERY UPDATE 2018

Eye care has always been at the forefront of innovation. From diagnostics to treatments, every year brings newly approved medications, devices, and procedures. To navigate the ever-expanding field of technologies, we analyze the results of the latest advancements in refractive, corneal, and cataract surgery. We then present evidence-based approach to guiding patients toward the safest, most effective vision care path.

REFRACTIVE SURGERY

The goal of refractive surgery is to correct refractive error safely and accurately and to achieve excellent quality of vision. Over the past decades, LASIK and PRK have evolved to treat myopia up to -12.0D, astigmatism up to 6.00D, and hyperopia up to +6.0D. With the latest generation femtosecond laser, iFS, LASIK flap is created within seconds, safely and accurately, allowing for an ultra smooth corneal bed which is then sculpted by the 5th generation excimer laser with 1.4 diopters/second speed and precision (Wavelight EX500). The latest Pacific Vision Institute results are presented in **Figure 1** comparing 20/20 and 20/15 outcomes in patients treated at Pacific Vision Institute to the results globally in patients treated with the same laser technology.

Based on Criteria Set EX500. Distance: Past 365 Days

	My Results			Global Results		
Click below for Graph	15 to 45 Days	46 to 120 Days	121 to 240 Days	15 to 45 Days	46 to 120 Days	121 to 240 Days
UCVA 20/16 Distance	97%	96%	97%	34%	32%	33%
UCVA 20/20 Distance	100%	100%	100%	87%	88%	87%
UCVA 20/25 Distance	100%	100%	100%	97%	97%	96%
UCVA 20/30 Distance	100%	100%	100%	96%	99%	98%
UCVA 20/40 Distance	100%	100%	100%	99%	99%	99%
MRSE ± 0.25 D	97%	99%	98%	80%	81%	79%
MRSE ± 0.50 D	100%	100%	100%	95%	95%	94%
MRSE ± 1.00 D	100%	100%	100%	99%	99%	99%

Figure 1. PVI LASIK results updated January 2018 (A) Uncorrected Visual Acuity (UCVA) for patients with surgery performed at Pacific Vision Institute (B) UCVA for patients with surgery performed globally with the same laser.

TOPOGRAPHY-GUIDED LASER VISION CORRECTION

Most of the efforts in the past several decades have been directed toward improving the quality of vision and helping patients achieve better vision than glasses and contact lenses. Initial effort toward this goal has been with Wavefront-guided laser vision correction, which treated aberrations in the entire optical system - cornea, lens, and vitreous. Significant corneal thickness was required to achieve such corrections. And most patients only needed to have their corneal aberrations corrected to achieve excellent quality of vision. The focus has, therefore, shifted from Wavefront to Topography-guided correction. After decades of patient treatments, Topography-guided laser vision correction with *Wavelight Topolyzer Vario* and *Wavelight excimer laser* has been FDA approved. Pacific Vision Institute is the first practice in San Francisco to perform Topography-guided laser vision correction.

Patients with normal and symmetric topographies may benefit from a **larger optical zone** achieved with topography-guided correction. 9 mm optical zone treatments are performed to smooth out corneal imperfections. Patients with asymmetric corneas benefit from treatments customized to the shape of their cornea, designed to **even out the asymmetry and normalize corneal surface**. **Figure 2** demonstrates what would happen if a patient with asymmetric corneal astigmatism was treated with non-topography guided correction vs. topography-guided. Symmetric correction of his astigmatism would result in residual corneal irregularity. Topographically-guided correction will normalize his corneal surface and result in a more symmetric cornea with better quality of vision. In the **FDA trials**, a significant percentage of **patients gained lines of best-corrected vision** and achieved **vision better than 20/12.5**.

SUMMARY POINTS:
Topography-guided laser vision correction

- Wide treatment area to smooth out corneal irregularities
- Accurate treatment of asymmetric astigmatism, angle kappa, irregular astigmatism
- More patients achieve 20/12.5 and better than with other LVC corrections

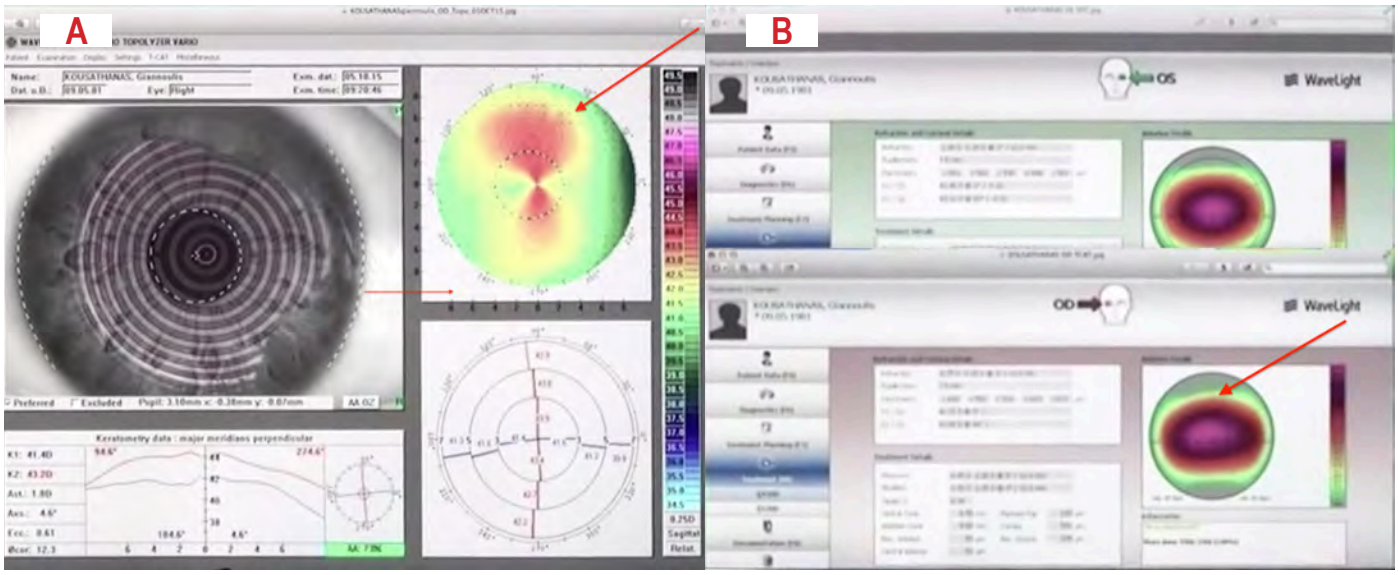

Figure 2. (A) Asymmetric topography (superior steepening) in a 32 year male with MRx -3.00 - 2.00 x 180. (B) Profiles of non-topography guided (upper image) and topography-guided (lower image) ablation of -3.00 - 2.00 x 180. The red arrow indicates topography guided treatment will deliver more treatment to the superior cornea than inferior to create a more symmetric corneal contour

Figure 3 shows *Wavelight Topolizer* corneal maps in a patient with symmetric with-the-rule astigmatism and positive angle kappa. Topography-guided ablation centered on the corneal apex, rather than pupillary center, will result in accurate treatment of the astigmatism. ■

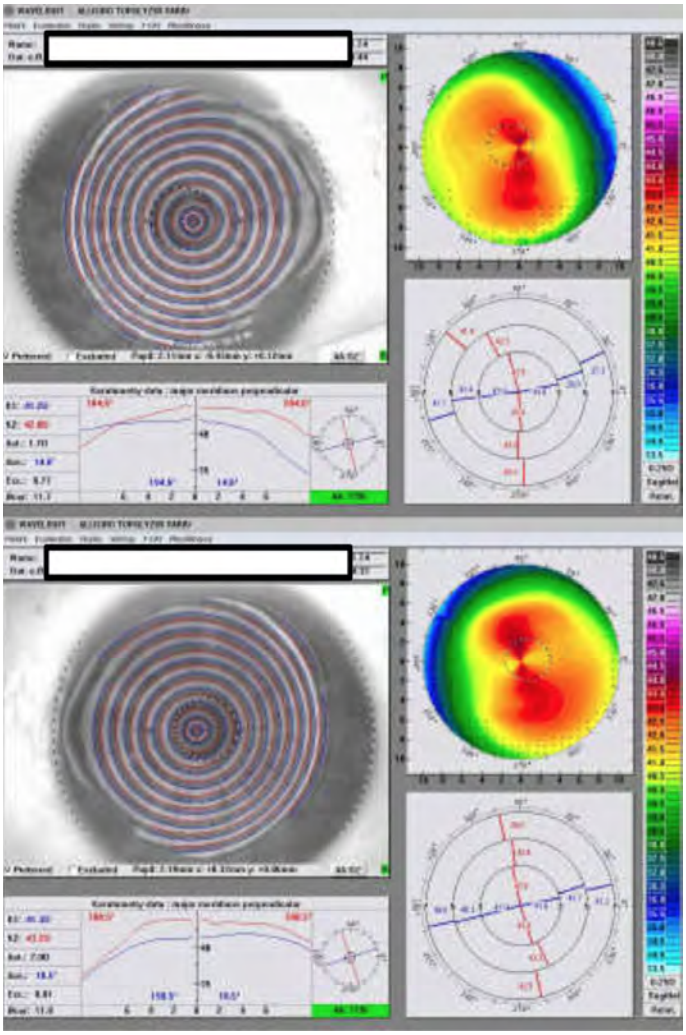

Figure 3. Wavelight Topolyzer corneal maps in a patient with positive angle kappa. The patient will achieve the most accurate correction of his with-the-rule symmetric astigmatism with topography-guided laser vision correction.

SMALL INCISION LENTICULE EXTRACTION (SMILE)

SMILE is a recently-introduced method of correcting mild to moderate myopia that involves a creation of a corneal lenticule between two planes of corneal tissue disrupted with a femtosecond laser. The piece of cornea (lenticule) is then mechanically dissected and removed with forceps. The thickness of the excised corneal piece is determined by the amount of myopia that needs to be corrected. In that sense, SMILE is **reminiscent of Automated Lamellar Keratoplasty (ALK)** - a mechanical procedure performed in the 80's before the advent of excimer laser. Unlike the mature technology of the 5th generation iFS femtosecond laser used to create LASIK flap, the femtosecond laser used in the SMILE procedure is an early generation laser technology from the manufacturer. We described the differences between the two laser systems in *Femtodynamics: A Guide to Laser Settings and Procedure Techniques to Optimize Outcomes with Femtosecond Lasers* (Faktorovich EG. Femtodynamics: A guide to laser settings and procedure techniques to optimize outcomes with femtosecond lasers. SLACK, Inc. Thorofare, NJ. 2009).

Despite the claims of SMILE's advantages compared to LASIK, peer reviewed literature fails to substantiate many of the claims. In the January issue of *Clinical Ophthalmology*, for example, Kanellopoulos AJ demonstrated that SMILE results in more **corneal tensile strength reduction** compared to LASIK (Kanellopoulos AJ. Comparison of corneal biomechanics after myopic small-incision lenticule extraction compared to LASIK: an ex vivo study. *Clin Ophthalmol*. 2018 Jan 25;12:237-245). Vision outcomes in a randomized, prospective, contralateral eye study comparing SMILE with topography-guided LASIK reveal topography-guided LASIK to be superior in all visual performance parameters studied, both subjective and objective (Kanellopoulos AJ. Topography-guided LASIK versus small incision lenticule extraction (SMILE) for myopia and myopic astigmatism: a randomized, prospective, contralateral eye study. *J Refract Surg*. 2017;33(5):306-312). The difference in outcomes between the two techniques was attributed to superior eye tracking, cyclotorsion compensation, and active centration control in LASIK technology compared with SMILE technology.

The inferior SMILE outcomes could also be due to the fact that in LASIK, a single femtosecond laser plane is created during making of the flap. Any irregularities in the femto cut will line up when the flap is returned to its original position following ex-

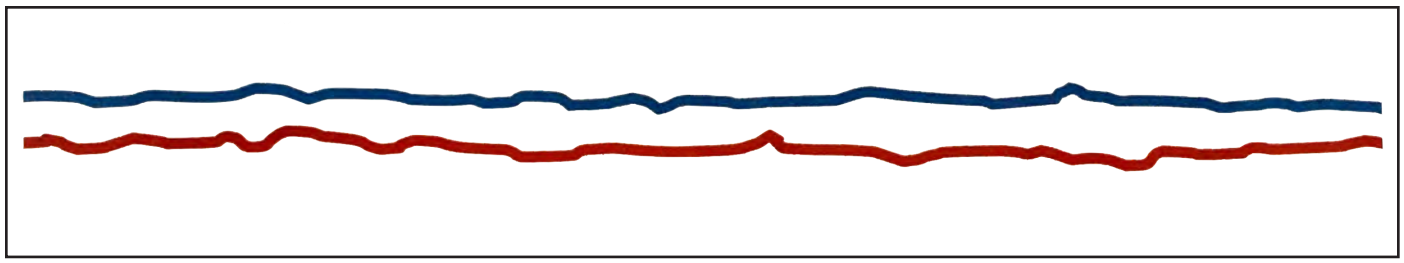

Figure 4. Two femtosecond laser cuts created during SMILE procedure have different patterns of irregularities. After corneal lenticule is extracted, the cuts do not line up precisely, resulting in overall corneal irregularity. (*EyeWorld*, Feb 2018:80)

cimer ablation. During SMILE, **two femtosecond laser cuts** are made. Since no two femto cuts are the same, they **can't line up** after the corneal lenticule is extracted (**Figure 4**). When two surfaces with differing irregularities cannot line up precisely, reports Dr. Steven E. Wilson in February 2018 issue of *EyeWorld*, the resulting irregularities are often transmitted to the anterior surface. The **delayed visual recovery** after SMILE, he reports, could be attributed to the time it takes for the stromal remodeling to reduce the irregularities of the superimposed different surfaces. ■

SUMMARY POINTS: SMILE

- Limited range of correction
- Slower visual recovery vs. LASIK
- Topography-guided LASIK results are superior to SMILE
- Claims of SMILE's advantages over LASIK are not substantiated in peer-reviewed literature

CORNEAL INLAYS FOR PRESBYOPIA CORRECTION

Presbyopia correction remains the target of intense research and development. The latest FDA approved technology is corneal inlays - **Raindrop** (ReVision Optics) and **KAMRA** (AcuFocus, Inc). Earlier this year, ReVision Optics went out of business. Mail-in rebate program for patients who underwent this treatment is no longer being offered. AcuFocus remains operational. In reviewing efficacy results of KAMRA in the published studies, Naroo SA et al state that the studies "report significant improvements in near visual acuity following implantation. However, it should be borne in mind by the reader that all currently published studies are company sponsored (AcuFocus)"(Naroo SA et al. Clinical utility of the KAMRA corneal inlay. *Clin Ophthalmol*. 2016 May 18;10:913-9).

Literature review to assess safety of **KAMRA** implant

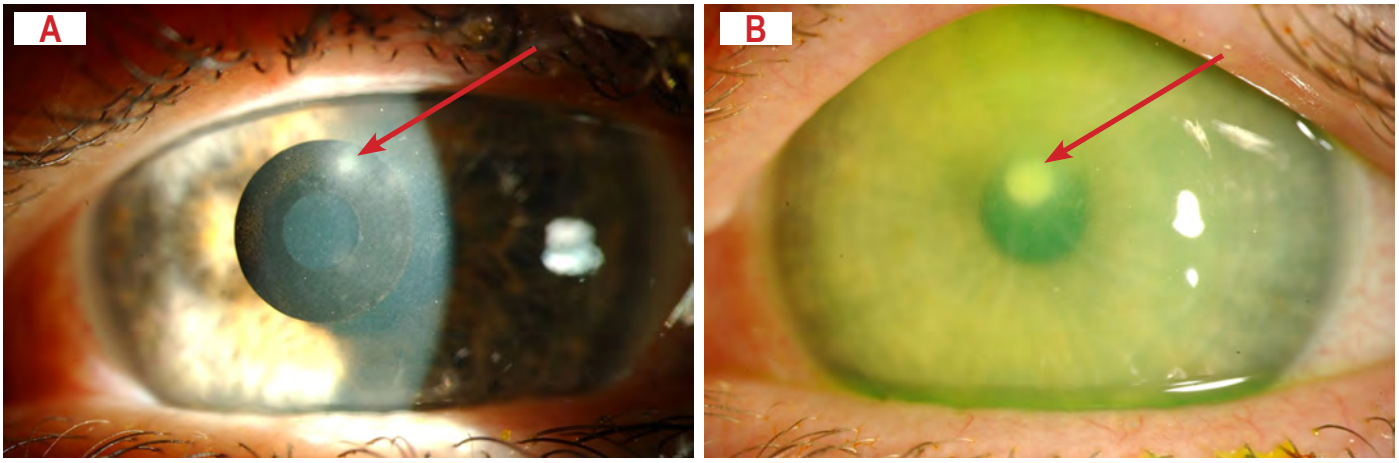

Figure 5. (A) 54 y.o. woman developed a corneal ulcer (red arrow) and corneal haze 3 months after KAMRA inlay implantation. (B) Another 54 y.o. woman developed central corneal abcess (red arrow) and diffuse corneal edema 3 months after KAMRA inlay implantation. KAMRA was explanted.

reveals **14% - 16.7% of eyes losing 1 line of BSCVA** (Tomita M, Kanamori T, Waring GO, Nakamura T, Yukawa S. Small-aperture corneal inlay implantation to treat presbyopia after laser in situ keratomileusis. *J Cataract Refract Surg*. 2013;39(6):898–905; Seyeddain O, Bachernegg A, Riha W, et al. Femtosecond laser-assisted small-aperture corneal inlay implantation for corneal compensation of presbyopia: two-year follow-up. *J Cataract Refract Surg*. 2013;39(2):234–241); corneal **iron deposits** associated with corneal flattening, and **corneal haze** at the outer and/or inner rim of the inlay, near the visual axis.

In July 2017 issue of *Review of Ophthalmology*, Dr. Crewe-Brown reports **inflammation** or aggressive wound healing response in patients after KAMRA implantation into a stromal pocket. This inflammation responds to steroids but sometimes recurs after steroids are discontinued, with patients needing to undergo several cycles of aggressive steroid management.

Infectious keratitis with corneal scarring has also been reported in patients with corneal inlays, including KAMRA (Duignan ES, Farrell S, Treacy MP, et al. Corneal inlay implantation complicated by infectious keratitis. *Br J Ophthalmol* 2016;100:2:269-73). **Figure 5(A)** shows a corneal ulcer and corneal haze overlying the KAMRA inlay in a 54 y.o. woman who presented with a corneal ulcer and a hypopion 3 months after KAMRA implantation. **Figure 5(B)** shows a central corneal abcess in another 54 y.o. woman who underwent KAMRA implantation 3 months earlier at another facility. Due to severity of corneal inflammation, KAMRA was explanted in this patient.

Alio et al reported that the removal of KAMRA has minimal impact on corneal topography and aberrometry during and after recovery if explanted before 6 months (Alió JL, Abbouda A, Huseynli S, Knorz MC, Durrie DS. Removability of a small aperture intracorneal inlay for presbyopia correction. *J Refract Surg*. 2013;29(8):550–556). Thereafter, the changes in corneal topography may remain permanent.

Considering the proximity of KAMRA implant to the visual axis, the risks of the procedure at this time outweigh the benefits. ■

SUMMARY POINTS: Corneal Inlays / KAMRA

- Loss of best-corrected vision
- May result in recurrent inflammation
- Central corneal ulcers have been reported
- Reversible if explanted within 6 months

CORNEAL COLLAGEN CROSSLINKING (CXL)

CXL with **Avedro system is FDA approved** for stabilizing corneas in patients with keratoconus to possibly reduce progression of the disease. Insurance may or may not reimburse some cost of the procedure. As our experience with Intacs for keratoconus taught us, when insurance is involved in reimbursing some cost of the procedure, the most difficult part of the procedure is neither patient selection nor the procedure itself. The most difficult part is helping patients navigate the financial aspects and educating them about how they can receive the best possible outcome.

Avedro is the only FDA approved CXL system in the US. The company charges physicians $2,850 per eye for the riboflavin drops to be used during treatment. There are additional costs for the equipment. Patient's insurance may reimburse a portion of the fee, but typically not the whole amount. Patients need to be aware that when a provider offers to accept a payment lower than what they would have to pay the company for the supplies and equipment, they may not be using an FDA approved system. Such systems have not undergone rigorous testing and may not have technical support available. Patients need to ask if an FDA approved system is used to treat them.

If the physician is using an FDA approved system, the patient needs to understand that **CXL is intended to stabilize progression of keratoconus** and will not, most likely, improve the shape of their cornea significantly. To improve corneal shape, thereby improving vision and contact lens fit, the patient may need to undergo topography-guided PRK after CXL (**Figure 6**). In a long-term follow up study comparing vision after cross-linking plus topography-guided PRK vs. cross-linking alone, uncorrected vision improved by 26.9 letters in the first group and only by 9 letters in the second group (Kontadakis GA, et al.

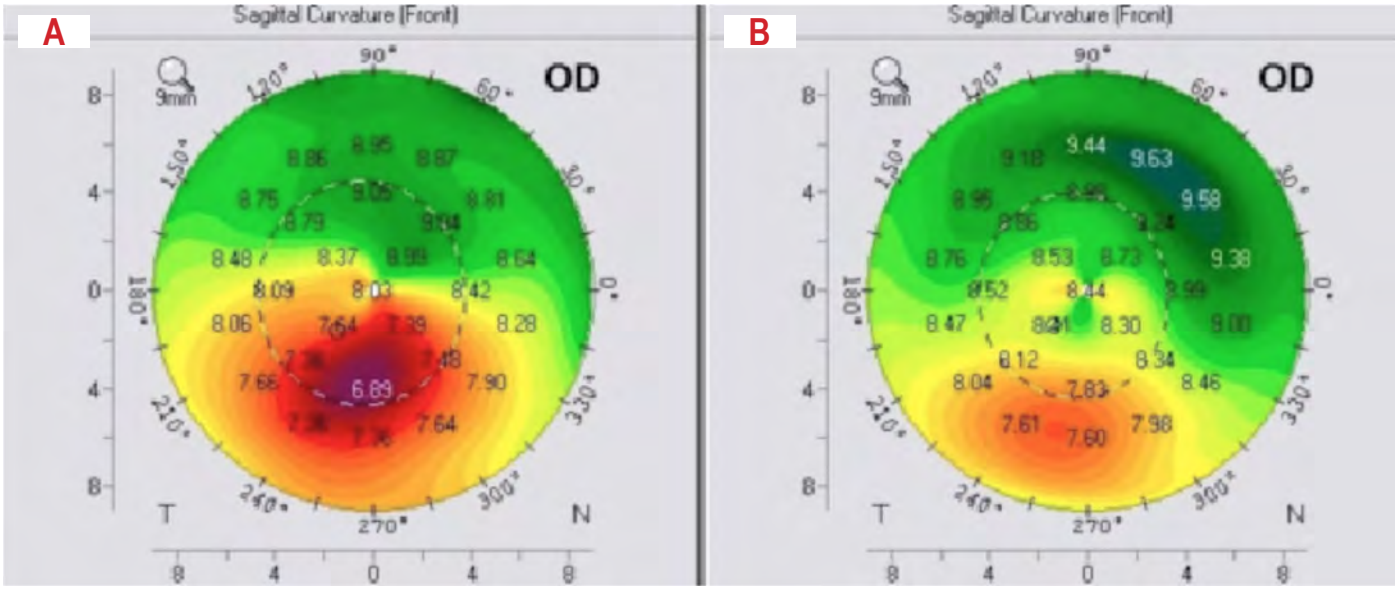

Figure 6. (A) Cornea following CXL. (B) The same cornea following CXL combined with topography-guided PRK

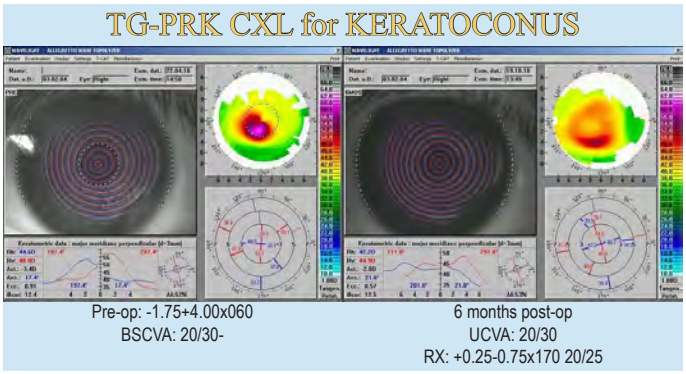

Figure 7. Results of topography-guided PRK combined with CXL

Long-Term Comparison of Simultaneous Topography-Guided Photorefractive Keratectomy Followed by Corneal Cross-linking versus Corneal Cross-linking Alone. *Ophthalmology*. 2016 May;123(5):974-83). 63% of patients in the combined treatment group gained two or more lines of corrected vision vs. 27% of patients in cross-linking only group. The corneas were significantly flatter in the combined treatment group.

Patients need to ask the physician what experience the physician has with topography-guided PRK and whether the fee for cross-linking includes **topography-guided PRK to possibly improve their vision beyond cross-linking alone**. ■

SUMMARY POINTS: Corneal crosslinking (CXL)

- Avedro is the only FDA approved CXL system
- Main treatment goal is to stabilize progression of keratoconus
- Vision improvement is best when CXLis paired with topography-guided laser vision correction

CATARACT SURGERY

As technology advances, many patients expect great distance vision after cataract surgery and some degree of presbyopia correction. Three types of presbyopia-correcting IOLs are currently available: accommodating (Crystalens, Bausch & Lomb), multifocal (+3.0 ReSTOR, ReSTOR ActiveFocus 2.5, Alcon; and Tecnis multifocal 2.5/3.25, Johnson & Johnson Vision), and extended depth of field (Technis Symfony, Johnson & Johnson Vision). Extended depth of field implants provide an elongated focal range rather than two distinct focal points as in a multifocal lens. Although optically it uses a distinct mechanism, functionally the Symfony lens works similarly to a low add multifocal in giving patients distance and intermediate vision (Hovanesian JA, An evidence based approach to choosing presbyopia-correcting implants. *Ocular Surgery News*, 2018 Jan 8)

At Pacific Vision Institute, we use the lens selection guidelines in **Table 1** to satisfy patient's vision needs. ■

IOL	Desired Vision		
	Distance	Intermediate	Near
• Monofocal (+/-toric)	X		
• ReSTOR ActiveFocus 2.5 OU (+/-toric) • Symfony OU • Crystalens OU (+/-toric)	X	X	
• ReSTOR ActiveFocus 2.5 in a dominant eye and +3.0 ReSTOR in non-dominant eye (+/-toric) • ReSTOR ActiveFocus 2.5 OU, targeting -0.5D in a non-dominant eye (+/-toric) • Tecnis 2.5 in a dominant eye and Tecnis 3.25 in a non-dominant eye	X	X	X

Table 1. Types of IOLs

PVI Staff Spotlight

Meet Inna Tolochko. She is a Surgical Assistant at PVI and has been with the practice for 14 years. Inna is in charge of maintaining proper functioning and sterilization of the surgical instruments. She scrubs in and assists PVI surgeons with different types of eye surgeries. Inna also sets up wet labs to assist PVI surgeons with training eye doctors and surgeons in different types of procedures. In her spare time, Inna enjoys running in the Golden Gate Park, reading, visiting her son who is graduating from UC Santa Cruz this year, and growing roses in her garden in the Richmond district of San Francisco where she lives with her family.

PVI co-management program

We welcome the opportnity to help your patients with refractive surgery, cornea, cataract, and lens implant considerations.

Please call us at 415-922-9500 to schedule a surgical consultation for your patients.

Or e-mail us at comanagement@pacificvision.org if you have any questions.

Continuing Education Events

April 2018: Topography-guided laser vision correction (2 hours CE). Patient selection, treatment parameters, indicaitons and contraindications, results, patient counseling, postoperative care, and live surgery observation at our new location 505 Beach Street, San Francisco.

May 2018: New approaches to ocular surface management (2 hours CE). New diagnostic devices, non-prescription, and prescription drugs, and approaches to optimizing ocular surface prior to corneal and cataract surgery

505 Beach St, Ste 110, San Francisco, CA 94133
(415) 922-9500 www.pacificvision.org