eFocus
a PVI publication for the Bay Area Optometric Community

PACIFIC VISION INSTITUTE
Life in Focus

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Experts say... eye care is booming and here is what we need to know to prescribe our patients the very best in 2021

We are inspired by the incredible doctors of the Bay Area optometric community. Our shared enthusiasm for learning and our passion for delivering world class patient care have always been a source of great joy. During a year that threw so many curveballs, we are proud that our work together continued to reflect our passion, our service, and our commitment to the eye care community. Here is to a 2021 full of hope, rewarding work, and more growth and giving. We are stronger, better, and more fired up than ever before. Thank you to the great doctors we work with. We are immensely grateful for your trust and for the opportunity to share in the care of your patients.

In keeping with PVI's annual tradition of bringing experts together to highlight the most significant advances in eye care, our team reached out to key ophthalmic and optometric opinion leaders and asked them "What are the new treatments and diagnostics you believe are important to delivering top-notch patient care in 2021?"

PRESBYOPIA-CORRECTING EYE DROPS

Eyes drops to treat presbyopia are currently the most significant therapeutic advance with enormous potential to treat millions of patients. According to Sheri Rowen, MD, in *Cataract and Refractive Surgery Today*, pupillary miotics will be the first FDA-approved pharmacologic treatments for presbyopia to market. These agents have demonstrated safety, efficacy, and ease of use in early studies. Companies developing miotic drops include Allergan, Presbyopia Therapies, Orasis Pharmaceuticals, and OSRX (an affiliate of Ocular Science).

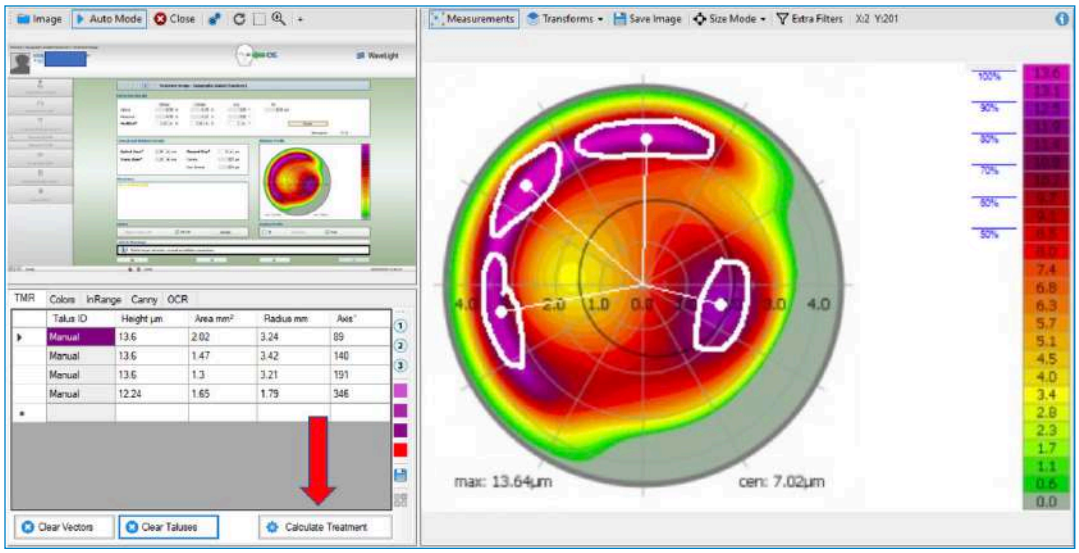
AGN-1883 (Allergan) is a topical drop intended to increase depth of focus. It is instilled once daily in both eyes or in the nondominant eye alone. Phase 2b FDA studies are complete, and phase 3 studies began in late 2018. This drug is reportedly well tolerated and has a fast onset of action. The company says the agent improves the quality of patients' near visual acuity for several hours after instillation, even in mesopic conditions. Allergan received a provisional patent for pilocarpine at a concentration ranging from 1% to 1.5% for the treatment of presbyopia. The company expects to be the first to market with an FDA-approved presbyopia correcting eye drop. It is targeting a US launch date in 2021.

While some novel pharmaceuticals for presbyopia focus on the pupil, others take a different route: the crystalline lens. A topical agent from Novartis, for example, reduces disulfide bonds in the lens, restoring some of its youthful flexibility.

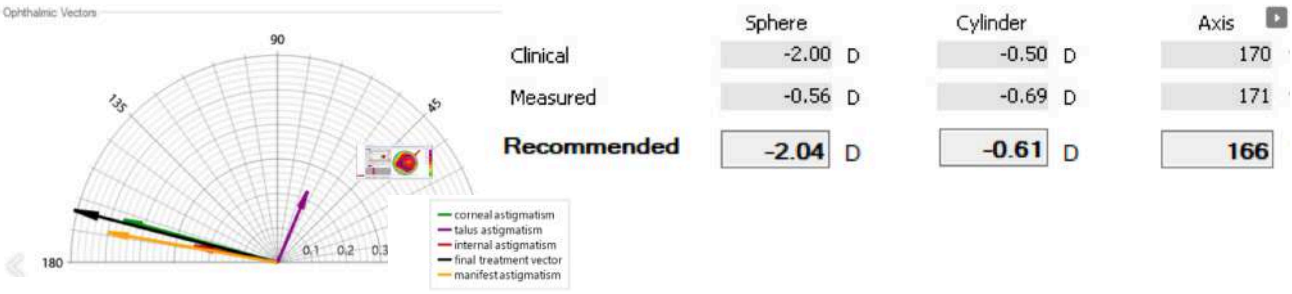
LASIK/PRK

LASIK and PRK remain the gold standard of customized vision correction. 5th generation femtosecond laser flapmakers (iFS) and 6th generation excimer lasers (EX500) are, hands down, the essential tools for any surgeon striving to achieve hyper-accurate vision outcomes for patients. At Pacific Vision Institute, we believe that the stakes are especially high for patients who are "perfect candidates." These patients are used to outstanding visual acuity with glasses and contacts. They will not tolerate anything less than that after LASIK/PRK.

Phorcides Analytic Engine software has been introduced to advance the accuracy of CONTOURA Vision topography-guided Custom LASIK and PRK. It is the first of its kind nomogram enhancing software that calculates the effect of corneal higher order aberrations on refractive error. The sphere and cylinder treated are first modified based on each patient's unique pattern of corneal higher order aberrations. Multiple articles published last year in peer-reviewed journals reveal superior accuracy of this method vs. other methods of planning the laser treatment.



Step 1 of the Phorcides Analytic Engine software analysis identifies a unique pattern of each patient's corneal higher order aberrations (circled). The software then calculates dimensions, including height, of each area and identifies their vector location on the cornea. The areas are added and the total vector is calculated. The ability to calculate total vector of corneal higher order aberrations is unique to Phorcides software.



Step 2 involves vector summation of each patient's different types of astigmatism: corneal + higher order aberrations + internal. The total vector astigmatism is compared to the manifest astigmatism and decision is made on the magnitude and axis of astigmatism programmed for laser treatment.

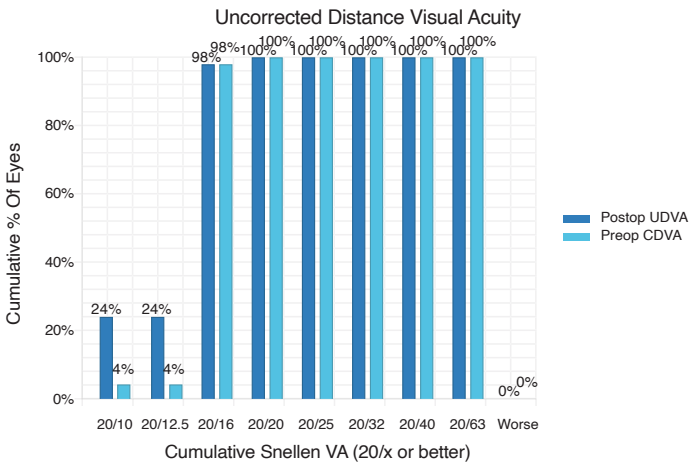
Hyper-accurate outcomes is the new normal in laser vision correction. They can be achieved through integration of evolved technology, advanced treatment planning software, meticulous surgery, and diligent outcomes analysis. Most patients presenting for laser vision correction today, especially if they are perfect candidates, can achieve 20/15 and even 20/10 best corrected vision. They are used to seeing clearly and their expectations for outstanding outcomes are high. Our focus needs to be on delivering this vision to them UNCORRECTED after their LASIK.

The table below presents Pacific Vision Institute Refractive Outcomes and Uncorrected Visual Acuity in patients who underwent Myopic LASIK (M/Procedure LASIK = Wavefront Optimized; M/Procedure LASIK-Topo Guided = CONTOURA Vision), Hyperopic LASIK (H/Procedure LASIK), and Mixed Astigmatism LASIK (X/Procedure LASIK). Average uncorrected vision after Myopic LASIK was 20/14.5 +/- 0.8. It was 20/13.5 +/- 1.2 after CONTOURA Vision LASIK.

Treatment Profile Status

Procedure Comparison Report: Eyes Operated between Wed Feb 5, 2020 to Fri Feb 5, 2021. Compiled on 2/5/2021 9:22:45 AM Show Details

	Postop (Uses the Last Qualified Postop for Each Eye)			
	Refractive Outcomes Compared to Targeted (All Eyes)		Uncorrected Dist Visual Acuity Eyes with Targets (no Monovision). Preop CDVA 20/20(1.0)	
	S.E. (Avg ± SD)	Cyl. (Avg ± SD)	Distance (Avg ± SD)	20/20 Rate
H / Procedure LASIK	0.04±0.22	0.18±0.24	20/16.4±0.5 Lines	100%
M / Procedure LASIK - Topo Guided	0.02±0.08	0.03±0.09	20/13.5±1.2 Lines	100%
M / Procedure LASIK	0.01±0.12	0.05±0.13	20/14.0±0.8 Lines	100%
X / Procedure LASIK	0.09±0.17	0.22±0.18	20/15.0±1.1 Lines	100%



Our data shows that more patients achieved 20/10 *uncorrected* visual acuity postop (24%) than patients who could achieve such vision best corrected preop (4%). The majority of patients had at least 20/16 uncorrected visual acuity.

Factors that correlated most with achieving the best vision postop were (1) patient's age and (2) their refractive error. Younger patients and patients with low-average myopia had the best prognosis. Exceptional care needs to be taken in treating patients who are "perfect" candidates because they expect perfect vision.

TEAR FILM THERAPEUTICS

Exciting advances have been made in adapting existing ocular pharmacologics to deliver fast results to treat conditions where existing treatments take a long time to work.

Eysuvis (loteprednol etabonate ophthalmic suspension 0.25%, Kala Pharmaceuticals) has become the first and remains the only topical steroid to receive FDA approval for short-term treatment (up to 2 weeks) for the signs and symptoms of dry eye disease. The LE 0.25% suspension is formulated with a proprietary mucus-penetrating particle drug delivery technology (AMPPLIFY) that improves bioavailability of the active ingredient at the target site.

"Although cyclosporine ophthalmic emulsion 0.05% (Restasis; Allergan) and lifitegrast ophthalmic solution 5% (Xiidra; Novartis) are good chronic anti-inflammatory medications," said Edward Holland, MD, director of Cornea Services at Cincinnati Eye Institute and a professor of ophthalmology at the Univeristy of Cincinnati in a recent interview, "the difference is that reaching peak benefit often takes weeks to months. With Eysuvis, patients will get immediate relief from the signs and symptoms of dry eye because of the rapid action of corticosteroids against inflammation. The clinical trials of the drug showed that symptomatic improvement began within 1 or 2 days of instillation of the drop. Having an approved corticosteroid is going to change how we manage dry eye." Most of the patient population experiences flares, on average, 4 to 6 times a year, according to Dr. Holland. Moreover, the majority of the 17 million patients with DED say they experience flares vs continuous symptoms. For patients who treat flares when they occur, a short-term treatment is often enough. There are patients who have more severe symptoms and are on chronic medications who will have flares as well and need additional treatments.

TEAR FILM TECHNOLOGIES

Cost-effective solutions to address tear film stability have been studied extensively to analyze their efficacy vs. the costly LipiFlow® Thermal Pulsation System.

TearCare treatment (Sight Sciences) was evaluated in the OLYMPIA dry eye study. The OLYMPIA study, a prospective, randomized multicenter trial, enrolled 235 dry eye patients at ten (10) U.S. sites. The trial was designed to compare safety and effectiveness of a single TearCare procedure to a single LipiFlow® Thermal Pulsation System procedure in treating the signs and symptoms of dry eye disease.

TearCare

- External heating device + manual expression with forceps
- Applicator is applied to the upper and lower eyelids externally
  - Patients can blink/open eyes
- 15-minute cycle of heating followed by manual forceps expression

Results from the study found that a single TearCare treatment safely and effectively achieved clinically meaningful improvements in all signs and all symptoms of dry eye disease (i.e., all p values <0.01). Improvement in signs include: tear break-up time, meibomian gland secretion score, and corneal and conjunctival staining. Improvement in symptoms include: ocular surface disease index score (OSDI), symptom assessment in dry eye score (SANDE) and eye dryness score (EDS). The non-inferiority objectives for the primary endpoints, tear break-up time and meibomian gland secretion scores, were met. Markedly, a significantly greater proportion of TearCare patients showed clinically meaningful symptomatic relief compared to LipiFlow patients, with 72% of TearCare vs. 59% of LipiFlow subjects improving by at least one OSDI category. As a result of their significant symptomatic improvement, TearCare subjects required 22% less lubricant drops than LipiFlow subjects throughout the study.

Who is a perfect LASIK candidate?

A recent analysis of LASIK outcomes at PVI revealed that patients who were the most likely to achieve 20/10 vision postop, were *low to moderate myopes in their 20's.* Increasingly, this is the patient demographic that we are seeing more and more from our co-managing doctors. These young patients typically have healthy corneas, great tear film, and outstanding retinal resolution. Most even wear contact lenses comfortably. Their interest in LASIK is often sparked by their parents' procedures in the past, their friends and coworkers, and, of course, social media. They feel comfortable with scheduling their treatments quickly, especially now that many work from home and their time is flexible. These patients are active, they can't wait to start traveling again, and are not dissuaded by needing reading glasses in their 40's. They believe presbyopia solutions will be discovered by the time they need reading glasses (drops!). Once they make up their mind to have LASIK, they will pursue it.

In counseling these patients for LASIK, we believe, it is essential to educate them that, if everything is done perfectly, they will have the greatest chance of achieving better than 20/20 vision. These patients are especially great candidates for CONTOURA Vision topography-guided custom LASIK. Treating even a small amount of corneal higher order aberrations can make a difference between 20/15 and 20/10 vision in low myopes.

Treatment Ranges for LASIK/PRK vs ICL vs RLE

In counseling patients for their procedures, we also believe in educating them that even though LASIK and PRK are FDA-approved for a wide range of refractive error, patients at the upper limits of approved correction and higher, may do better with procedures such as Implantable Contact Lens (ICL) or Refractive Lens Exchange (RLE). LASIK is FDA-approved for myopia up to -12D; hyperopia up to +6.0D; and astigmatism up to 6D in myopes and 5D in hyperopes. In clinical practice, however, patients who are at the higher end of the approved range, have to be carefully counseled to make sure they have appropriate expectations. Their possibility of regression, for example, is higher than patients who are in the lower to mid-range.

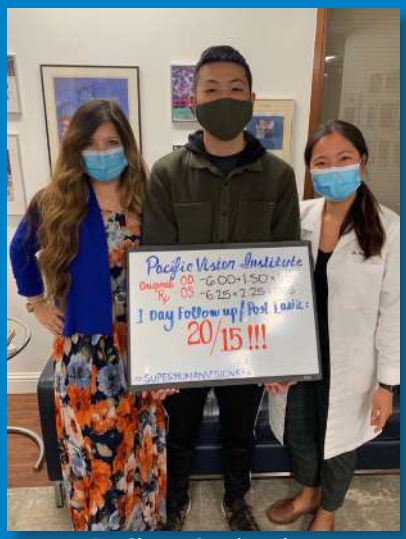
In the table below, we've summarized patient candidacy criteria for different refractive surgery procedures to help counsel patients

	LASIK /PRK candidate	ICL Candidate	RLE Candidate
Myopia	**-0.5D to -12D**	**-3D to -15D**	**>-5D presbyopes**
Hyperopia	**+0.5D to +5D**	**none**	**> +1D presbyopes**
Astigmatism	**0.25D to 5D**	**1D to 4D**	**> 0.5D**
Age	**18 y.o. and older (no upper age limit)**	**21 to 39 y.o.**	**40 y.o. and older (no upper age limit)**

Eye doctors and their family who had LASIK/PRK at PVI

Dr Tiffany La just before her LASIK with Dr. Faktorovich

- Dr. Tiffany La - LASIK
- Dr. Lita Wu's brother - LASIK
- Dr. Lita Wu = Non-candidate
- Dr. Khanh Dao's wife - LASIK
- Dr. Veronica Lam's sister in law - LASIK
- Dr. Rosanna Chen's niece - PRK
- Dr. Chester Quan's nephew - LASIK
- Dr. Jamie Totsubo nephew - LASIK



Dr. Chester Quan's nephew

- Dr. Faktorovich has been chosen by her peers and Castle Connolly Medical to receive **2021 America's Top Doctor and America's Best Physicians 2021** awards representing the top 1% of medical specialists and sub-specialists nationwide

- **Eye On Vision Radio** Vance Durbin interviews Dr. Ella Faktorovich on eye and COVID.

- **Ocular Surgery News** interviews Dr. Ella Faktorovich of Pacific Vision Institute about the surge of LASIK patients during the COVID-19 pandemic.

- **Eyeworld** interviews Dr. Ella Faktorovich of Pacific Vision Institute about the surge of LASIK patients during the COVID-19 pandemic.

- **KCBS** Jim Taylor interviews Dr. Ella Faktorovich of Pacific Vision Institute on quarantine myopia

- **KTVU Channel 2** Frank Mallicoat interviews Dr. Ella Faktorovich of Pacific Vision Institute on myopia in children

- **Edge Pediatrics** interviews Dr. Faktorovich about excessive screen time resulting in Quarantine Myopia

- PVI research on Screening Refractive Surgery Candidates is selected for presentation at this year's **American Society of Cataract and Refractive Surgery** 2021.

- Dr. Faktorovich is an invited guest speaker and section chair at **Neurotalk 2021** in Lisbon, Portugal

- **VisionPlus** publishes Pacific Vision Institute review article "Five Essential Corneal Tests for Accurate Screening of Refractive Surgery Candidates." VisionPlus is an international consumer eye magazine that provides information about new eye products and trends. It is distributed in over 20 countries around the world.

- **Medium.com** interviews Pacific Vision Institute physicians for an article "Excessive Screen Time During Covid-19 Can Harm a Child's Eyesight."

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: My patient is going for a consultation to multiple surgeons. How do I advise my patient where they should have their vision corrected?

A: The patient should be counseled to undergo surgery with the surgeon who achieves the best documented results for patients with similar prescriptions and similar age. The surgeon-specific results should be generated by an unbiased, independent third party data analysis. The patient should ask for the surgeon's better than 20/20 results during their consultation. They then need to compare such results and select the surgeon who achieves the best results in the highest percentage of patients. The surgeon's techniques, technology, experience, and their team all contribute to their results. But, by themselves, they mean nothing unless they result in the documented highest percentage of patients achieving better than 20/20 vision. If a patient says they are going to have their vision corrected where their friend went and had a good result, the patient needs to be counseled that their friend's prescription may have been different and the friend may have different vision demands. The only way to make an educated decision in healthcare is to statistically compare post-treatment results.

Q: What is the recovery like after PRK?

A: During the first several days after PRK, patients may experience eye irritation, tearing, and some burning sensation that should be relieved with medication, such as ibuprofen, for example. Dr. Faktorovich has developed a treatment plan to improve comfort after PRK and has published many studies in the field. After 2-3 days, discomfort will be gone. Vision will be somewhat blurry but functional so that most patients can carry on their usual activities. For computer work, many patients find it helpful to increase font size and contrast during the first several weeks after the procedure. Taking frequent breaks and instilling preservative-free artificial tear drops is also essential to speedy recovery after PRK. Patients can typically drive in familiar areas. With Work From Home programs for most patients, the driving is typically minimal and patients generally have more flexible schedule so that they can recover comfortably after PRK. Just as with LASIK, we recommend for patients not to get water in their eyes for one week after PRK. They can typically do their usual excercise.

OPTOMETRIC CONTINUING EDUCATION

April 28th, 2021:

San Mateo Optometric Society Meeting -

"Crosslinking 2.0: who are the patients today and how are we diagnosing and treating them now." Lecture by Dr. Ella Faktorovich (2 hours CE)

- How young is too young for CXL?
- When should patient be referred for CXL?
- What are new diagnostic methods?
- Which eye is treated first?
- Options for visual rehabilitation during healing?
- What are the outcomes with current methods?
- Who is a candidate for laser vision correction?

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