
CME ACTIVITY

Latest Innovations in Laser Vision Correction: Diagnostics, Techniques, and Current Market

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CONTENT SOURCE

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STATEMENT OF NEED

For nearly 2 decades, LASIK has been considered a safe and effective option for the surgical correction of vision, helping millions of achieve excellent vision without glasses. However, no surgery is completely risk-free, and related and unrelated events have created an ongoing decline in the number of LASIK surgeries since 2008. Unrelated influences included the economic downturn, leaving many individuals without the resources to pay for an elective surgery at that same time that Generation X, a significantly smaller population than baby boomers, entered the age range that is most likely to benefit from LASIK.

In addition to the general economic climate, the Ophthalmic Devices Panel of the US Food and Drug Administration held a meeting in April of 2008 to discuss patient reported outcomes (PROs). Accusations of gross negligence, connections between LASIK patients and increased suicide rates, and high failure rates were all used to request that a moratorium be placed on LASIK devices. The result has been stagnant interest in LASIK among refractive surgeons, and the need to educate both surgeons and patients on the results of the Patient Reported Outcomes with LASIK (PROWL) studies, new developments in technology, and actualized LASIK outcomes.

Following the negative panel discussion in 2008, the PROWL questionnaire was developed to obtain measurable pre and post surgery data on patient reports of expectations, satisfaction, and visual outcomes. Following the completion of PROWL-1, which included military personnel at the US Naval Base in San Diego, Calif, and PROWL-2, which included civilian data, the preliminary findings confirm high patient satisfaction rates following LASIK. In addition, they increase understanding of visual symptoms reported such as halos, glare, starburst, ghosting, and dry eye.

The PROWL studies provided compelling data, showing that overall, less than 1% of subjects experience significant or debilitating difficulties doing usual activities due to vision symptoms, irrespective of correction. In fact, far more patients have the visual symptoms listed above prior to LASIK surgery than do 6 months post-LASIK. In addition, LASIK outcomes are only getting better. In a comparison of preoperative best corrected visual acuity (BCVA) versus postoperative binocular uncorrected visual acuity, 34% of patients had 20/12 BCVA preoperatively compared with 76% achieving 20/12 or better uncorrected visual acuity (UCVA) at 6 months after surgery; 100% of patients achieved 20/25 or better UCVA postoperatively, with 99% achieving 20/16 or better UCVA.

Along with penetration of the LASIK market by the femtosecond laser, improvements in wavefront aberrometry have expanded the range of treatable patients, as well as improved outcomes across all groups of patients. The same high-resolution wavefront aberrometry imaging used by NASA has been adapted to map large refractive ranges with full gradient

topography, capturing images of the eye with a level of detail heretofore unavailable.

Placido disk topographers and Fourier reconstruction algorithms have been the industry standard. However, these devices are limited by their inability to directly capture skew rays and their sensitivity to the radial component of the gradient. Full gradient topography fills in these gaps, potentially increasing accuracy by providing central corneal coverage, capturing both x and y slopes for each spot, reconstructing the corneal elevation much like previous Hartmann-Shack sensor methods.

WAVEFRONT-GUIDED VERSUS WAVEFRONT-OPTIMIZED

Conventional LASIK relies on refraction results and the preferences of the patient when asked to compare corrective lens options during an exam. Wavefront-optimized uses the sphere and cylinder prescription from the patient's exam, and administers additional extra pulses in the periphery of the laser ablation area to manage the LASIK induced spherical aberration so that the patient is left with zero spherical aberration.¹ However, by applying the same number of pulses to every patient with the same prescription, wavefront-optimized LASIK does not optimally treat patients with severe spherical aberration preoperatively and can actually make their night vision worse. Two problems wavefront-optimized cannot address include asymmetrical higher order aberrations, such as coma or trefoil, and worsening the vision of a patient with negative spherical aberration.²

Wavefront-guided, on the other hand, reduces all higher order aberrations. Relying on a very precise method of optic measurement, wavefront-guided technology shines an infrared laser light into the eye and measures how the eye's optical system affects the distorted light wave produced on its way back out. The software then divides the surface of the eye into a grid of 1,000 squares and calculates the number of laser pulses to apply to each individual square to create a focused light ray that penetrates through each part of the cornea and pupil to focus perfectly on the fovea. The new high-definition Hartmann-Shack wavefront sensor provides five times higher spatial resolution, a higher dynamic range, and eight times higher local slope range than its predecessor system.³

Initial published studies are demonstrating that the improved accuracy of the wavefront-guided profile is positively impacting LASIK outcomes. One published report of the new Hartmann-Shack aberrometer demonstrated a reduced mean manifest spherical equivalent from -3.28 ± 1.79 D at baseline to -0.03 ± 0.29 D 1 month after surgery, bringing it within 0.50 D of target in 93.0% of eyes.⁴ Uncorrected distance visual acuity of 20/16 or better was attained in 79% of eyes, 20/20 or better in 93.4% and 20/25 or better in 96.7%. Mean manifest astigmatism decreased from -0.72 D to -0.14 D.

The increase in sampling points and the application of Fourier algorithms that use all valid data within the pupil aperture, even for noncircular shaped pupils, allows this enhanced aberrometer to effectively measure irregular corneas⁵ and induces a minimal amount of higher order aberrations,

regardless of the level of myopic correction achieved or the preoperative magnitude of aberrations.⁶ In addition, the new aberrometer was found to be safe, effective and predictable in patients with simple or compound myopic astigmatism and refractive cylinder >2.00 D.⁷

New educational materials are necessary to help refractive surgeons understand this new technology and how it differs from previous wavefront-guided aberrometers. This CME program will also help them appreciate the exceptional outcomes that can be generated with a much wider range of patients, and learn how to grow the market with the next generation of LASIK patients.

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TARGET AUDIENCE

This certified CME activity is designed for ophthalmologists.

LEARNING OBJECTIVES

Upon completion of this activity participants should be able to:

- Understand the differences between wavefront-guided and wavefront-optimized topography
- Apply evidence-based medicine to achieving the best LASIK outcomes
- Differentiate between patient reported and clinical outcomes, and know how to get the greatest patient satisfaction
- Know how to use new technology for therapeutic treatments in complex corneas
- Evaluate where the LASIK market is headed next

METHOD OF INSTRUCTION

Participants should read the CME activity in its entirety. After reviewing the material, please complete the self-assessment test, which consists of a series of multiple choice questions. To answer these questions online and receive real-time results, please visit evolvemed.com and click "Online Courses." Upon completing the activity and achieving a passing score of higher than 70% on the self-assessment test, you may print out a CME credit letter awarding 1 *AMA PRA Category 1 Credit*.™ The estimated time to complete this activity is 1 hour.

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Latest Innovations in Laser Vision Correction: Diagnostics, Techniques, and Current Market

What prevents people from having LASIK is the classic trio: awareness, fear, and cost. There is a lack of awareness of modern technology in refractive surgery and the truly outstanding outcomes that we can now offer to our patients. While the LASIK of 20 years ago was successful, it is quantitatively different now. It is a challenge to make sure the public is aware of what modern LASIK can offer, which is very different than the standard US Food and Drug Administration labeling for the procedure. The second roadblock is fear. Overcoming patient fear can still be a very big challenge, but the Patient Reported Outcomes with LASIK (PROWL) Study conducted by the FDA is a great tool to show true patient outcomes, the quality of their vision that is attained, and the incredible satisfaction rate that LASIK patients overwhelmingly achieve. Finally, cost is a matter of value. As surgeons, we know the incredible value this can bring to our patients, but we may have trouble conveying that to our patients. Overall, as an eye care community, we need to really understand the latest innovations that are improving refractive surgery, the outstanding outcomes and safety profile that this field attains. Finally, we need to spread the word that no elective procedure has a satisfaction rate that even comes close to LASIK.

—Steven C. Schallhorn, MD

LASER VISION CORRECTION IN 2015

Julian D. Stevens, MD: We have been performing laser vision correction at my hospital for 25 years. During that time period, we have had an incremental improvement in predictability with each technological advance. The result is a dramatic difference between the original treatments and current practice. There is now a very tight scatter of refractive outcomes. The passage of the last two and a half decades have brought an incredible increase in predictability to laser refractive surgery, and it is something we are confident in offering to our patients (Table 1).

Eric D. Donnenfeld, MD: Femtosecond laser technology has dramatically changed LASIK surgery for the better. Not only did it eliminate free flaps, it also made possible thin flaps with reverse side cuts that significantly reduce the loss of corneal sensation. When we first started doing LASIK, we offered courses on management of striae and dealing with small optical zones. Now we have better optical zones and blended prolate zones. Many of the initial complications have virtually disappeared. Although improvements in safety have mirrored the improvements we have seen in predictability, I think safety remains the number one limiting factor for most patients right now. Dry eye disease (DED) remains a challenge, but we have worked very effectively to manage it with improved therapies. There are also neurotrophic medications to support corneal sensation that are being developed.

Steven J. Dell, MD: I agree that cost is not really the driving factor in preventing people from having LASIK. The value proposition for the procedure is quite compelling,

even when compared with the cost of spectacles or contact lenses. The value of the freedom from the need for corrective devices is significant. Patients routinely tell us that LASIK was the very best money they ever spent. It is supremely ironic that at a time when we are achieving the very best outcomes ever seen with LASIK, demand remains sluggish.

TABLE 1. IMPROVEMENTS IN LASIK OUTCOMES AT MOORFIELDS EYE HOSPITAL IN LONDON

| Year | Laser | Standard Deviation of Refractive Predictability for a -4.0 D treatment |
|------|---|--|
| 1990 | Summit Laser | 1.0 D |
| 1992 | VISX 2020B | 0.6 D |
| 1995 | VISX Star Laser | 0.6 D |
| 1998 | B&L Hansatome Microkeratome LASIK | 0.45 D |
| 2001 | VISX WaveScan Wavefront guided LASIK | 0.32 D |
| 2005 | Wavefront-Guided IntraLase Femtosecond LASIK | 0.28 D |
| 2014 | iDesignWavefront-Guided IntraLase Femtosecond LASIK | 0.26 D |

Edward E. Manche, MD: One of the causes of the down turn in the LASIK market was the Ophthalmic Devices Panel of the US Food and Drug Administration (FDA) meeting in 2008 that aired accusations of gross negligence and negative patient-reported outcomes. Following the negative panel discussion, the Patient Reported Outcomes with LASIK (PROWL) questionnaire was developed to obtain measurable pre- and postsurgery data on patient reports of expectations, satisfaction, and

visual outcomes. I had the opportunity to participate in the PROWL study, and it was an incredibly well designed, completely objective study run by the National Eye Institute and the FDA. The objective was to determine the prevalence of post-LASIK patient-reported outcomes in a select population and make an initial validation of a questionnaire in a military population (PROWL-1), and then further validate the questionnaire in the general population (PROWL-2). The quality of the data is unquestionable.

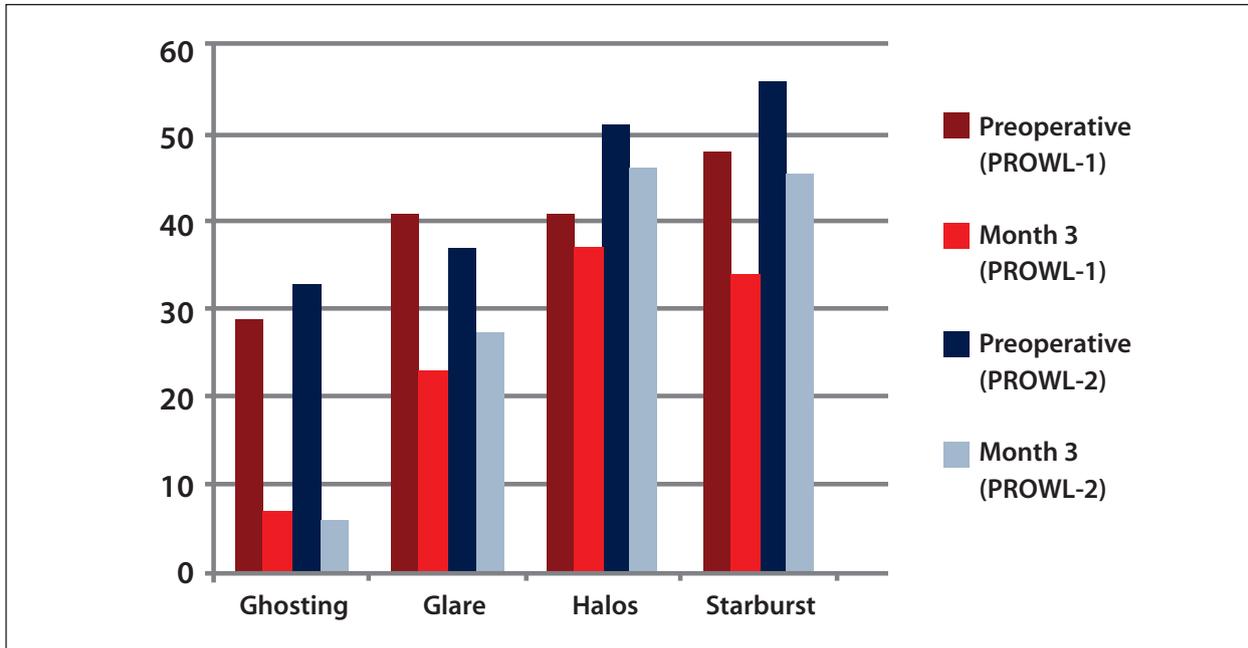


Figure 1. Prevalence of symptoms: preoperative vs. month 3. The prevalence of visual symptoms did not increase postoperatively.¹

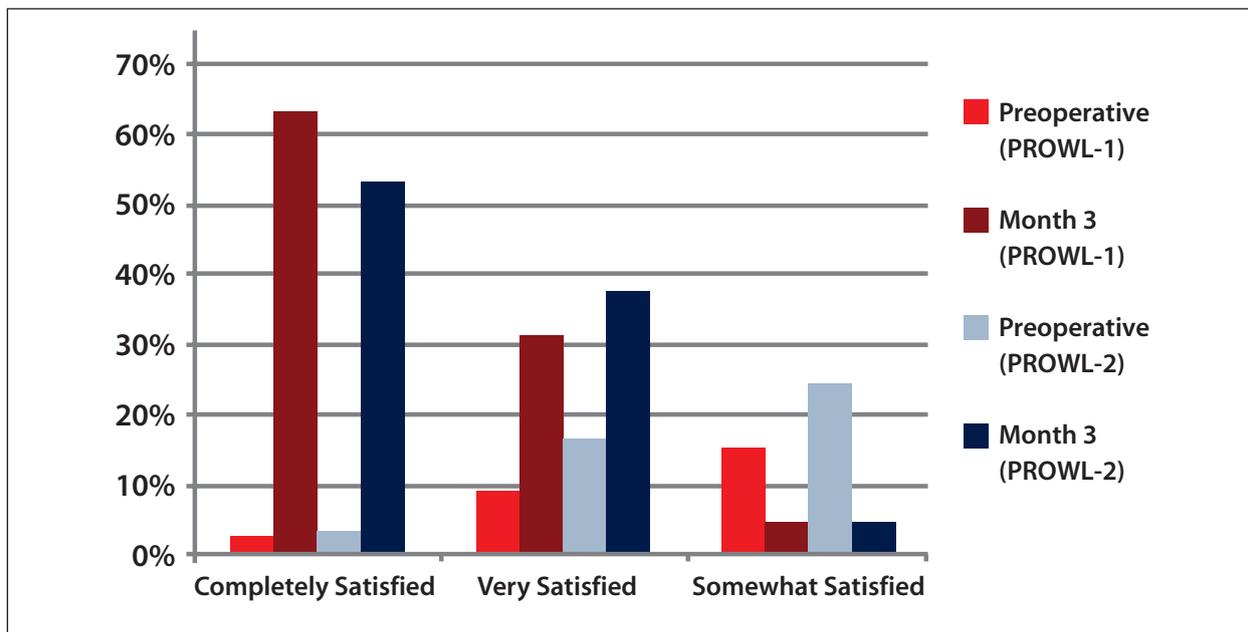


Figure 2. Overall satisfaction with vision. Greater than 96% of subjects were satisfied with their vision at month 3.¹

“What I learned from PROWL is that LASIK actually reduces the severity and incidence of glare and halos.”

—Eric D. Donnenfeld, MD

Both for the US and internationally, these reports will be very helpful in laying to rest some of the misconceptions about LASIK and making surgeons and patients alike more comfortable about LASIK.

Dr. Donnenfeld: The PROWL study was extraordinarily important. In every aspect that was evaluated, patients had less symptomology after surgery with no glasses than they did with their best-corrected vision before surgery, and that was without the ability to do enhancements.¹ We have all had patients who say they have glare and halo with their glasses, and they do not want LASIK because they fear those symptoms will worsen. What I learned from PROWL is that LASIK actually reduces the severity and incidence of glare and halos. It behooves anyone who has an interest or verbalizes an opinion about LASIK surgery to review the results of the PROWL study, particularly anyone in ophthalmology and optometry (Figures 1 and 2).

NEW REFRACTIVE INNOVATIONS

Dr. Schallhorn: For nearly a decade, we have been using ablation profiles guided by a wavefront aberrometer that were intended to correct preexisting aberrations and reduce surgically induced aberrations such as halos, glare, and poor vision in low lighting. While we continue to achieve 20/20 or better visual acuity (VA) and have improved visual quality, there remains a significant amount of surgically induced aberrations.² These surgically

induced aberrations have been linked to the limited precision of the preoperative wavefront measurements, among other things.³ Let us discuss some of the new technology for capturing a more efficacious profile.

Dr. Stevens: We now have higher density wavefront sensors and better rejection algorithms that are making our outcomes very consistent and predictable. In addition, we have further improvements with surface treatment and we are about to see the introduction of the Brillouin laser scattering scanners to measure true corneal strength and biomechanics. This will allow us to truly assess a thin cornea for its strength. Normal collagen strength will be easily differentiated from thin and weak corneas with potential ectasia, so instead of making rough judgments, we will have specific information on individual eyes.

Dr. Schallhorn: Can you review the concept of Brillouin Scatter?

Dr. Stevens: Yes, Brillouin microscopy is the marriage of a confocal microscope to an interrogating laser to enable three-dimensional mechanical imaging. The confocal microscope images the cornea at specific point and individual depths and layers. This allows you to measure the corneal strength via noncontact imaging. The scanners measure the various parameters such as strain and effective strength. This can be built up on a map that looks very much like a topography scan. You can see if some corneas are weak in particular areas or others which are weak overall. You can also see the difference following corneal cross-linking. This technique has been shown to effectively assess the biomechanical properties of the cornea in situ with high spatial resolution.⁴

Dr. Schallhorn: We have also seen new studies that compare wavefront-optimized with wavefront-guided laser treatments. Conventional LASIK relies of refraction results and the preferences of the patient when asked to compare corrective lens options during an exam.

| TABLE 2. WAVEFRONT-GUIDED VS. WAVEFRONT-OPTIMIZED | | |
|---|---------------------------------------|------------------------------------|
| | Wavefront-optimized Treatment (n=150) | Wavefront-Guided Treatment (n=152) |
| Mean Preoperative MR | -4.55+2.35 D | -4.53+2.35 D |
| Cyclotorsion registration enabled | 68.4% | 100% |
| MRSE within 0.5 D 6 months postoperative | 74% | 94% |
| Efficacy indexes (P=.013) | 0.94+0.12 | 0.99+0.14 |
| Statistically better performance in | | |
| -correction of astigmatism | | (0.0071) |
| -induction of spherical aberration | | (P=.0001) |
| - HOAs | | (P=.0287) |

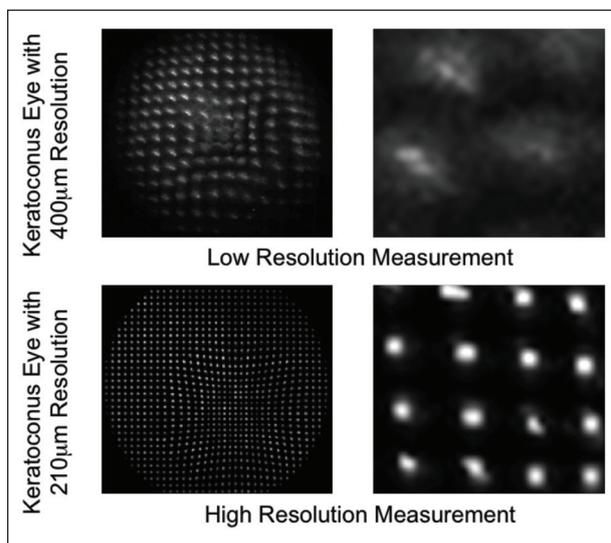


Figure 3. WaveScan vs. iDesign system comparison.

Wavefront-optimized uses the sphere and cylinder prescription from the patient's exam, and administers additional extra pulses in the periphery of the laser ablation area to manage the LASIK induced spherical aberration so that the patient is left with zero spherical aberration.⁵ However, by applying the same number of pulses to every patient with the same prescription, wavefront-optimized LASIK does not optimally treat patients with severe spherical aberration preoperatively and can actually make their night vision worse. Two problems wavefront-optimized cannot address include asymmetrical higher order aberrations, such as coma or trefoil, and worsening the vision of a patient with negative spherical aberration.⁶

Wavefront-guided technology, on the other hand, measures the eye's optical system by shining an infrared laser light into the eye and then analyzing the distorted light wave produced as it exits the eye. This is then used to create a grid pattern over the eye's surface and a specific number of laser pulses are calculated for each individual square. Wavefront-guided technology intends to reduce all higher order aberrations, both pre-existing and surgically induced.

Previous studies showed both systems to be effective, with no significant difference in visual acuity or refractive outcomes in the majority of the population. Only patients with a magnitude of preoperative root-mean-square higher order aberrations of 0.35 μm or greater were positively impacted by wavefront-guided LASIK.

Dr. Manche: We have looked closely at differences between wavefront-guided and wavefront-optimized LASIK outcomes in a number of randomized eye-to-eye clinical trials.^{7,8} While both wavefront-guided and wavefront-optimized LASIK ablations provide outstanding outcomes with excellent safety, there are some small advantages when using wavefront-guided LASIK. These benefits were

“With the iDesign, we are shifting our thinking so that the iDesign wavefront refraction is really the new gold standard.”

—Steven J. Dell, MD

demonstrated with superior best corrected low-contrast VA at 5% and 25% contrast,⁸ as well as a greater percentage of eyes achieving UCVA of 20/16 or better⁷ in the eyes receiving wavefront-guided LASIK surgery.

Dr. Donnenfeld: This is a very exciting time for refractive surgery in the United States, as we recently gained a high-resolution second-generation wavefront aberrometer and that has been available in Europe for some time. This technology has shown to be superior to both wavefront-optimized as well as previous wavefront-guided systems. It truly allows us to customize treatment to individual patient optics.

Dr. Manche: This is true. A new generation Hartmann-Shack aberrometer has been created that captures more than 1,200 data points, as opposed to 240 data points in previous systems. A prospective, comparative masked study compared 302 myopic eyes with or without astigmatism randomly assigned to receive either wavefront-guided ablation using the iDesign Advanced WaveScan Studio System (Abbott Medical Optics) or wavefront-optimized ablation using an excimer laser with cyclotorsion.⁹ The study found that while both systems were effective, safe, and predictable in treating myopia with or without astigmatism, use of the iDesign to plan treatment allowed for improved handling of higher order aberrations, better cylinder correction and better axial and torsional alignment (Figure 3). This results in overall greater efficacy, predictability, safety, and better visual outcomes (Table 2).

Gustavo E. Tamayo, MD: This new high-definition aberrometer is a great improvement over wavefront-optimized treatments. A recent study of 149 myopic eyes showed that use of the iDesign with LASIK and photorefractive keratectomy (PRK) resulted in safe, effective, and predictable outcomes.¹⁰ At 3 months postoperative, 100% of LASIK eyes and 95.5% of PRK eyes were within 0.5 D of emetropia. In addition, postoperative MRSE was -0.16 ± 0.45 D and UCVA of 20/20 or better was achieved in 94.4% of the LASIK group. Similarly, postoperative MRSE was -0.04 ± 0.2 D and UCVA of 20/20 or better was achieved in 95.5% of the PRK group.

Dr. Schallhorn: The improvements in predictability of laser refractive surgery have been significant, and they have impacted patient satisfaction and many other areas. Along with this, we can now offer these excellent, highly predictable results to high myopes and astigmatic patients. I have been very impressed with the iDesign's ability to treat high levels of astigmatism with great predictability. I directed a study that was published this year that specifically looked at patients with moderate-to-high astigmatism. It was a retrospective analysis of 611 eyes with preoperative refractive cylinder from -2.00 D to -6.00 D, and sphere from 0.00 D to -9.75 D. Three months after LASIK guided by the iDesign, 83.8% of eyes had UCDDVA of 20/20 or better, 90.3% had manifest spherical equivalent within + 0.50 D, and 79.1% had residual refractive cylinder within +0.50 D of intended correction.¹

Dr. Manche: I participated in the FDA trials for the iDesign, and the outcomes we have seen are excellent. It allows us to treat up to 5.0 D of astigmatism, whereas previously in the US we could only treat to around 3.0 D of astigmatism. I have been especially impressed at the refractive outcomes in highly astigmatic eyes. This significantly expands the number of patients that can be treated with this technology.

Dr. Schallhorn: In addition to the significant accomplishment of being able to treat a wider variety of patients, there are other "comfort" factors that I really enjoy about the iDesign as well. First, the faster capture rates and excellent ergonomics have made patient throughput more streamlined in every regard. Second, the measurement of cylinder is extraordinary, creating a very good place to start a refraction. I recommend using it at the beginning of a consultation as the basis for a refined manifest refraction. It then considers the corneal curvature and auto-populates the patient profile. Finally, there is better iris registration, which results in an improved capture rate under the Laser.

You can give patients the best possible vision when you treat all ocular aberrations. That requires accurately measuring all of them. In addition, corneal curvature plays an important role in creating an ablation profile. The iDesign has a built in corneal topographer, which is coaxial to the wavefront measurements. This enables the ablation profile and spot pattern to be adjusted according to the corneal curvature. While there is still a lot of room for growth with this platform, larger series comparisons between the WaveScan and the iDesign show that out of the box, the iDesign provides incremental, but significant improvements in results.

Dr. Dell: Incorporating the iDesign into our practice has resulted in a bit of a shift in our thinking regarding the patient's true refractive error and how we should treat it. In the past, we would obtain a manifest refraction and tai-

lor the so-called wavefront refraction so that it essentially agreed with the manifest refraction. The operating hypothesis was that the manifest refraction was the gold standard. With the iDesign, we are shifting our thinking so that the iDesign wavefront refraction is really the new gold standard. While the manifest is still quite important, if there is a disagreement between the two, we place more faith in the iDesign reading than previous wavefront analyzers.

Dr. Donnenfeld: I would like to elaborate on treating all aberrations. In the past, we have not taken into account the full contribution of the posterior cornea to refractive error. Recently, Douglas Koch, MD, did some wonderful work with cataract surgery that shows that the average patient has about -0.3 D of posterior corneal cylinder.¹² Now that I am adjusting for that cylinder when I treat astigmatism, I am seeing better results. That same cylinder applies to excimer laser corneal ablations. As it is impossible to take that corneal cylinder into account with topographical ablation, the optimal results cannot be achieved. By capturing the posterior corneal curvature I anticipate significantly improved results with LASIK, akin to what we have seen in cataract surgery.

Dr. Tamayo: Highly irregular eyes are very difficult to capture, making it nearly impossible to operate on them. However, the dramatic increase in sampling points with the iDesign, together with the more robust system of applying Fourier algorithms, procures ablation patterns even for noncircular pupil apertures. Studies show that use of the high-resolution aberrometer in irregular corneas is associated with a reduction in spherical equivalent that correlates to an improvement in UCDDVA and CDVA.¹³ This has enabled me to treat ectasias, irregular astigmatism after refractive surgery, cataract, radiant keratotomy, and poorly done previous refractive surgery. In addition, it is able to effectively measure highly aberrated eyes following a corneal collagen crosslinking procedure in keratoconic eyes, allowing for further improvement of visual function in these patients.¹⁴

Dr. Donnenfeld. Too often ophthalmologists have cataract patients with irregular corneas that they try to fit into a toric IOL. It is like putting a round peg into a square hole. The idea of being able to perform an ablation to improve the corneal surface, and later perform cataract surgery is going to enable far superior results.

INTERNATIONAL EXPERIENCE

Dr. Schallhorn: When this high-definition aberrometer first became available, I did not believe that the results would be significantly better than what we were getting with our current WaveScan (Abbott Medical Optics), and I was concerned about the added expense and how it would impact patient flow. We had honed our expertise

“There are so many different levels of DED and techniques for treating it, but it should always be tested prior to surgery.”
 —Gustavo E. Tamayo, MD

over the years with that particular wavefront aberrometer and were achieving excellent results. We evaluated the iDesign in a very large series LASIK analysis, comparing approximately 10,000 iDesign treatments to a matched set of approximately 20,000 WaveScan procedures. We found that not only were we able to achieve better UCVA, but that the cylinder outcomes were superior and most importantly, that patient-reported outcomes were improved (Figure 4). We achieved the trifecta of better clinical outcomes, better patient-reported outcomes, and better patient satisfaction. That is when Optical Express went all in and now we exclusively use this high-definition aberrometry.

Dr. Stevens: Initially I thought this very high-resolution wavefront sensor would be most useful for therapeutic eyes due to the extra data density and extra fidelity in the wavefront shaped reconstructions. I was surprised that the primary treatments also improved significantly. It appears that the extra data density is directly impacting final outcomes. Like Dr. Schallhorn, I also noted improvements in

cylinder treatment. Patients that have high cylinders have differential power across the cornea, and the cylinder is not constant throughout the optical zone being treated. The extra data density detects the correct local cylinder and translates it into a treatment table that gives the patient better outcomes.

Dr. Tamayo: The high resolutions make a very clear diagnosis of irregularity, allowing us to treat even very difficult eyes. Although there are very few people with 8.0 D of astigmatism, we are able to treat that high, which is just incredible.

Dr. Donnenfeld: We are just starting our commercial experience here in the United States, but have already noticed some very important features of the iDesign that differentiate it from technologies used in the past. First, it is a much more precise device that takes into account issues such as the distance between the patient and the refracting mirrors and incorporates it into the nomogram. Also, the nomogram is extremely precise, to the point that thus far it does not appear to need any adjustment. The software on this latest version has been adjusted to eliminate the 5% undercorrection that was found on the previous version used in Europe and other countries.

We are also able to treat up to 5.0 D of cylinder. This combines with the advantages of pupil centroid shift and cyclotorsion that are part of the femtosecond laser we use. Compensating for all of these factors is what allows for great refractive cylinder outcomes, which is essential. Finally, I am looking forward to treating mildly and moderately aberrated eyes. This new wavefront will go way beyond previous generations to an 8.3-mm zone, which allows treatment

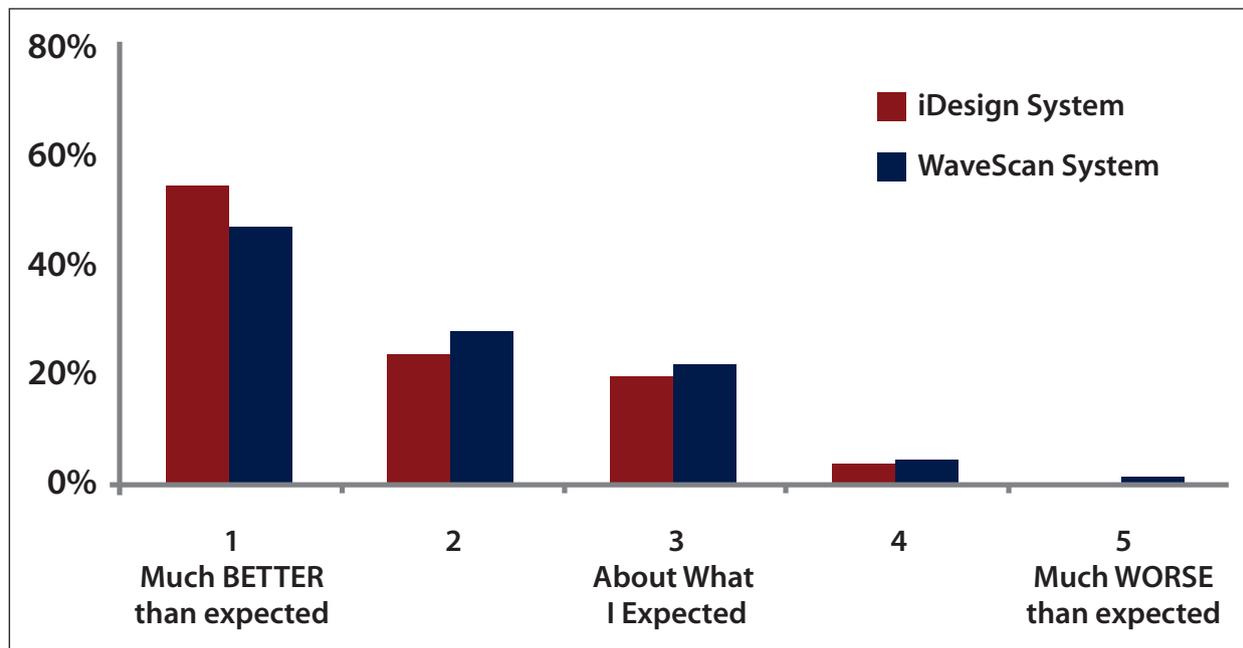


Figure 4. Patient report of overall vision following LASIK with two different systems.¹⁵

“I believe that eye rubbing is
a very important risk factor
for corneal ectasia after
keratorefractive surgery.”

—Edward E. Manche, MD

of the peripheral cornea with customized ablations. Previously, we used nomogram regressions to take our best guess of what we were treating in the periphery. Now we can actually treat the peripheral cornea, which we know is very important for quality of vision, glare, and halo.

Dr. Manche: In the US FDA clinical trials for the iDesign, we found that there was a systemic undercorrection of myopia, just like there was in Europe. For the commercial launch, Abbott Medical Optics has addressed the undercorrection issue with a software update. Using the latest software, undercorrections have been eliminated. I have now been using it commercially for about 2 months and found that it is spot on. Individual surgeons will always have nomogram adjustments, so it is important to treat 20 to 30 eyes, carefully analyze your outcomes and then figure out your personal nomogram.

Dr. Dell: I can also verify that the commercial software release in the US is right on the money. This is one of the rare advantages of practicing in the US, where we typically receive technology after the rest of the world. Refinements to the nomogram have already been completed. Our results truly have been excellent. In fact, the individual who analyzes our refractive data asked if I had gotten a new laser. It feels like I have.

QUALITY OF VISION

Dr. Schallhorn: One of the biggest remaining challenges with LASIK surgery is DED. Multiple studies have shown that 1 year after LASIK, there is no difference in prevalence of dry eye among LASIK patients compared with a matched population. However, there is a difference in the immediate postoperative period that needs to be addressed. I stress to my patients that there is a healing process, and they may very well have symptoms that will get worse for a while. But on average, symptoms return to their presurgical level by 6 months.

Dr. Manche: We completed a study with patients who had LASIK in one eye and PRK in their fellow eye.¹⁶ We evaluated self-reported DED symptoms following surgery. We found that both LASIK and PRK produce an

increase in symptoms of grittiness, foreign body sensation, and visual fluctuation in the early postoperative period. However, all symptoms return to baseline by 12 months. I have patients with DED whose previous optometrist or ophthalmologist suggested they have PRK because it will induce less dry eye issues. However, this study confirmed my clinical impression that there is no difference in postoperative DED symptoms between LASIK and PRK.

Dr. Tamayo: Overall, DED is underdiagnosed. If it was not evaluated before surgery, it is impossible to know if it is the result of the surgery or a pre-existing condition. There are so many different levels of DED and techniques for treating it, but it should always be tested prior to surgery.

Dr. Stevens: There can be patients who do not have symptomatic DED in normal circumstances, but occasionally use drops, and there are some underlying factors present. LASIK, like any ophthalmic surgery, including cataract surgery, can induce episodes of discomfort and unhappiness. From the patient's perspective, LASIK caused the DED. That is why it should be diagnosed before surgery.

Dr. Donnenfeld: I have participated in many published papers on DED and flap architecture, and we have arrived at the same conclusions stated here: that the symptoms almost always return to baseline. However, there are outliers, so there are lessons to be learned. Evaluating and treating DED prior to surgery is very important. We have also changed our surgical technique significantly to create thin flaps with a reverse side cut, which creates better apposition of the flap to the bed. In addition, I personally have changed my surgical technique with myopic LASIK very dramatically. I originally made all my flaps 9.5 mm using keratomes. I now create an 8.3-mm flap, which is close to half of the surface area of my previous treatments. When I am performing LASIK following cataract surgery, pupils are often 3 mm to 4 mm, allowing me to make 7.5 mm flaps. By reducing the size of the flaps, enlarging the hinges, making the flaps thinner, and using reverse side cuts, I have found it greatly reduces the immediate post-operative symptoms of DED.

Dr. Dell: It is clear that DED tends to revert to baseline following laser vision correction in the great majority of patients. I believe it is also important to point out that many of our patients have been habitual users of contact lenses, which may mask some of the symptoms of DED in certain patients, while exacerbating it in others. Additionally, patients who wear rigid gas permeable (RGP) lenses are overtly neurotrophic while in lenses, and when LASIK renders them RGP-free, their neurotrophobia eventually reverses. At that point, they are able to feel every puff of a breeze on their corneas again. This is not the new onset of DED, but rather the newly gained ability to sense it.

There is a lot of potential for growth in the number of LASIK procedures performed, but it is a slow growth.

—Daniel S. Durrie, MD

Dr. Schallhorn: We tend to intensely scrutinize LASIK outcomes in every regard, sometimes beating ourselves over the head with issues like DED or quality of vision. However, we are neglecting to consider the alternatives for the patient. We did a study looking at 5-year outcomes of LASIK compared with a matched population in contact lenses, and we found that the quality of vision is very similar. We also found that the UCVA for the LASIK patients is better than the habitual acuity for the contact lens wearers. When we stratified the data, we found that one of the reasons is that spherical contact lenses are often prescribed in patients with low to moderate amounts of astigmatism. The reason for this is the difficulty fitting and higher expense of toric lenses. Whereas with LASIK, we routinely treat even low levels of astigmatism very effectively, especially with the latest technology.

Dr. Donnenfeld: Contact lens wearers are a very important part of our community, and we certainly advocate the use of contact lenses. But when you compare contact lenses to LASIK over the course of a lifetime, there is no doubt that LASIK is safer. The risk of corneal ulceration and vision loss from contact lens wear, over a lifetime, is much greater than LASIK. Another misconception is that PRK is safer than LASIK. The ASCRS Corneal Committee analyzed the risk of infection following various refractive surgeries, and the risk with PRK was six times greater than with femtosecond laser LASIK. I have to say that the safest way of correcting vision in 2015 is with LASIK performed with a femtosecond laser.

Dr. Tamayo: Fear of ectasia still drives many surgeons' decisions. But current literature places the risk of ectasia complication at 0.1% at the most, so it really is not an issue. In addition to being very rare, it is now imminently treatable with corneal crosslinking. In a review of a series of around 25,000 LASIK cases in my office, I found the only common factor in ectasia was eye rubbing. When I reviewed the literature, I am not the only one who has discovered this.

Dr. Manche: I agree with Dr. Tamayo. I believe that eye rubbing is a very important risk factor for corneal ectasia

after keratorefractive surgery. I now ask my patients if they rub their eyes and have them show me how they rub their eyes. In many instances, the patients will vigorously rub their eyes using their knuckles. I emphasize to patients that it is important not to rub their eyes. I believe we have to educate our patients about this issue.

Dr. Dell: We have been impressed with the incidence of undiagnosed allergy in patients presenting to our clinic for participation in clinical trials for corneal crosslinking. The work-up of all corneal ectasia patients in our clinic now includes cutaneous allergy testing.

REINVIGORATING YOUR LASIK MARKET

Dr. Schallhorn: We know that the results possible with LASIK are exceptional. Let us talk about how to generate appreciation for this technology and capture patients among the millennials.

Dr. Donnenfeld: I am optimistic about the coming demand for LASIK for two reasons. The first is simple demographics. Generation X was not as large as the baby boomer population, slowing down growth in the industry. However, the upcoming millennial population is an even larger group than the baby boomer population. If we can match the level of penetration that we did with the earlier generation, we should see a great increase in the number of LASIK procedures performed. Second, what is really going to drive LASIK is the improved quality of vision that can be achieved. LASIK is unusual, in that there has never been a procedure as accurate or as able to improve a patient's quality of life. Good surgeons and good technology add up to outstanding results, and I think word of mouth is really going to drive LASIK volume forward.

Daniel S. Durrie, MD: Our practice has had great success with the millennial generation, but we have had to adjust everything from how we advertise to how we practice to be able to communicate with them effectively. This is a generation that has grown-up skeptical of being sold something, so they will do a lot of research on their own. Before you see them in your office, they know what the procedure is, what has been the experience of their friends and social media connections, and who are the prominent providers in their area. When they come in, they are looking to decide why they chose you to be their physician and why should they get the procedure done now.

Dr. Schallhorn: Many practices have successfully created comanagement relationships for the purpose of educating the patients, is this what you have done?

Dr. Durrie: Our practice is a little unique in that we do not have any referral of comanagement relationship. We think personal contact with the surgeon is key and the

first time we meet with a patient, we spend an average of 20 minutes speaking with them about the procedure, answering their questions, and forming a relationship with them. We also see them for their postoperative visits. We changed the way we worked because we wanted to be able to talk to our patients at different stages of their vision development. We inform them that their eyes are going to change again when they are in their 40s to 50s, and when they report that a parent has now started wearing reading glasses, it is an opportunity to invite their parents into the office to discuss presbyopia options.

Dr. Dell: Dr. Durrie raises an important point. Many patients tell us their LASIK from 15 years ago “wore off,” when in fact they are experiencing presbyopia. This represents an educational challenge, because it implies that the benefit of LASIK is fleeting. We need to do a better job describing the difficult concept of presbyopia and its interplay with LASIK.

Dr. Schallhorn: Millennials may not trust advertising, yet we all know that we have to work hard to reach out to our future patients. What are you doing to maintain a strong local presence?

Dr. Durrie: There is a lot of potential for growth in the number of LASIK procedures performed, but it is a slow growth, around 5% to 10% per year. Our first priority is providing a superior experience for our patients in every interaction so that they will be happy with their experience and recommend us to others. Second is to have a very strong online presence. We pay a lot of attention to key words and links so that we are one of the top three Google search results when someone searches “modern laser surgery” in our area. We have invested recently to make sure that our website is mobile compatible. Millennials want to be able to see your page, make appointments, and everything else from their phone. We are also very active on a variety of social media channels, most notably Facebook. When someone comments that they are thinking about LASIK, we want our patients to easily be able to say “Hey, I got it at a great place, and I loved it,” and link directly to us.

Dr. Manche: Word of mouth has always been an essential marketing tool for LASIK surgeons. Now with social media, this is electronic, and patients can post their experiences and pictures and far more people will hear about their positive outcomes with LASIK and PRK surgery. This should increase the adoption rate.

Dr. Tamayo: I am optimistic about the future of LASIK vision correction and think the increasing concern about health and exercise will continue to move people toward getting rid of corrective lenses. However, social media is a

blessing and a curse, and the potential for bad publicity is something that we have to face. We do need to develop a strategy to get above any bad publicity that may come.

Dr. Durrie: Review sites have gotten very sophisticated, making it impossible to stack them in your favor. Nor can you delete a negative review. However, there are ways to manage it. First, someone in our office monitors all of the review sites so we know what is being said and can respond to any negative reviews. Second, the only way to minimize a negative review is to have overflowing positive reviews and push it down the page. We actively encourage all of our satisfied patients to review us. Thankfully, we have high rankings on all of the review sites.

We also engage in external marketing, but we have a two-tiered strategy that specifically targets different ads to two groups. First is the 20- to 30-year-old demographic who is wearing contact lenses, and second is the 45- to 60-year-old group who is using readers or bifocals. For the younger group, we focus on benefits they will have with better vision. They may have better performance in their sports or better ability to watch their kids in the swimming pool. We do not directly mention the technology, we focus on how better quality of vision will aid their active lifestyles.

Our most successful advertising to date has been endorsement radio. We have been able to capture most of the key radio celebrities in the city as patients, and then they make unscripted endorsements that are very refreshing for patients.

THE FUTURE OF LASIK

Dr. Schallhorn: Let us talk about the future. Where are we going with laser vision correction, in general? What does the future hold?

Dr. Stevens: I think we are going to see more sophisticated shapes being applied to change the overall asphericity of the cornea. In addition I see the blending of biomechanics into the shape planning. It is not just optimum quality, also involved are regulation of the growth of the eye and overall change. Eventually, we will have a complete understanding of the development of myopia and change in ocular aberrations, so that we can consider treating children to prevent or reduce myopic development. I believe that will be a huge shift in our field.

Dr. Donnfeld: I agree with that completely. The future is going to be objective, evidence-based treatments of disease, and much less subjective opinion. We will rely more upon information generated by high-quality machinery that will enable us to provide expert treatments without having to adjust based on nomograms. We will be using point-of-service testing for ocular surface disease to define DED and address it before surgery. We

will be using biomechanical evaluation before surgery to customize our therapies and eliminate patients that will not achieve optimal outcomes. And we will have objective evidence for refractive outcomes that will allow us to create tighter nomogram adjustments and achieve better vision. These improvements will be incremental, as I believe we have already seen vast improvements with technology. We are at a place right now where I am very proud of what we can achieve and how we can improve patients' lives in a safe and effective way. And I believe that refractive surgery is going to have explosive acceptance over the next few years as the next generation of patients realizes that their quality of life and quality of vision have been dramatically improved. ■

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LATEST INNOVATIONS IN LASER VISION CORRECTION: DIAGNOSTICS, TECHNIQUES, AND CURRENT MARKET

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1. **The PROWL study showed that patient outcomes in terms of ghosting, glare, halos, and starburst were:**
 - a. Worse postoperative compared to preoperative
 - b. The same postoperative as preoperative
 - c. Better postoperative compared to pre-operative
2. **Evaluation of corneal strength is best measured with:**
 - a. Zernicke Polynomials
 - b. Brillouin Scatter
 - c. Fourier Waves
 - d. Topographical Scan
3. **According to work by Doug Koch, MD, the average patient has how many diopters of posterior corneal cylinder:**
 - a. -0.2 D
 - b. -0.3 D
 - c. -0.5 D
 - d. 0.3 D
4. **According to the text, in the past, the _____ was considered the gold standard. Now the _____ should be the new gold standard.**
 - a. Manifest refraction, wavefront refraction
 - b. Wavefront refraction, manifest refraction
 - c. PRK, LASIK
 - d. LASIK, PRK
5. **According to the text, patients with dry eye:**
 - a. Should never have any kind of refractive surgery
 - b. Should have PRK because LASIK induces more dry eye issues
 - c. Can have either PRK or LASIK if the dry eye is first treated appropriately
 - d. Should have LASIK because PRK induces more dry eye issues
6. **The millennial generation is:**
 - a. Skeptical of traditional advertising
 - b. Generally familiar with LASIK before they come into your clinic
 - c. Heavily influenced by reviews found online
 - d. All of the above

ACTIVITY EVALUATION

Did the program meet the following educational objectives?

Agree Neutral Disagree

Understand the differences between wavefront-guided and wavefront-optimized topography.

Apply evidence-based medicine to achieving the best LASIK outcomes.

Differentiate between patient reported and clinical outcomes,
and know how to get the greatest patient satisfaction.

Know how to use new technology for therapeutic treatments in complex corneas.

Evaluate where the LASIK market is headed next.

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Name and email _____

Do you feel the program was educationally sound and commercially balanced? Yes No

Comments regarding commercial bias:

Rate your knowledge/skill level prior to participating in this course: 5 = High, 1 = Low _____

Rate your knowledge/skill level after participating in this course: 5 = High, 1 = Low _____

Would you recommend this program to a colleague? Yes No

Do you feel the information presented will change your patient care? Yes No

If yes, please specify. We will contact you by email in 1 to 2 months to see if you have made this change.

If no, please identify the barriers to change.

Please list any additional topics you would like to have covered in future Evolve Medical Education LLC CME activities or other suggestions or comments.
