



ADVANCED
WAVEFRONT-GUIDED LASIK
DRIVEN BY
THE *iDESIGN*[®] SYSTEM

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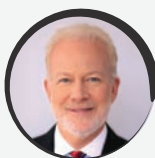
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Dear Reader,

As technology evolves and vision correction options expand, patients inevitably lean more heavily on both optometrists and surgeons to guide them to appropriate procedures that can be executed with precision. Patients of all ages with all types of clinical presentations seek our advice on refractive correction, and optometrists, in particular, are tasked with educating patients about all of their options. Indeed, the primary care providers' narrative has changed significantly over the last several years, as patients' expectations and lifestyles have changed alongside the vastly broadened refractive surgery landscape. Navigating this terrain is what makes the optometrist uniquely equipped to guide each patient as they make this journey.

While it is incumbent upon the surgeon to deliver excellent outcomes, it often is up to the optometrist to help educate and advise the patient to such possibilities. Friends, advertising and the Internet may all be motivators, but they should not play too great a role in decision-making. This important responsibility lies with the primary eye care doctor. As such, optometrists should have in-depth knowledge about the technology that is used by the surgeons to whom they refer.

In this unique roundtable supplement, optometrists and ophthalmologists join together to share their knowledge and experience on advanced wavefront-guided LASIK and how the iDESIGN® System, in particular, has shaped their recommendations.

Sondra Black, OD

Marc Bloomenstein, OD, FAAO

TODAY'S LASIK MARKET AND PATIENT

DR. BLOOMENSTEIN: Based on what you're seeing in your own practices today, what do you think the future holds for LASIK?

DR. BLANTON: Since 2009, we have been hovering at around a half million procedures annually in the U.S. However, we have noticed an upswing in the last couple of years. There is movement in the right direction and we are climbing back up.

DR. CARLSON: One big area of growth that we are witnessing in our practice is the use of refractive surgery to enhance vision in patients later down the road. The volume shift in this category over the past three years is remarkable.

DR. LODEN: We are doing much better with millennials too. Many candidates under age 40 now have the income to afford LASIK and are often prime candidates.

DR. BLACK: In our practice, the LASIK demographic seems to have gotten younger, with an average patient age in the mid 20's as opposed to mid 30's in years past.

DR. ASSIL: It appears the target LASIK audience age range has widened on both ends. Patients as young as 18 years old come in with their parents who've also had the procedure. In addition, we now also routinely see patients above 65 years of age seeking LASIK surgery.

DR. BLOOMENSTEIN: Do you have a target age group or a particular bracket where you focus your marketing?

DR. CARLSON: My target group is everyone who wants to see better. Patients arrive with an abundance of knowledge and a greater degree of confidence, likely due to their research and the recognition that options and procedures have evolved tremendously over the past few decades.

DR. BLACK: There is opportunity with millennials, but we have staff from all age groups working on our social media to engage with and relate to patients across generations. There is also a huge presbyopic population of patients that comes into the clinic seeking a reading glass solution. In a lot of cases, especially with corneal inlays, the laser is the first step before implanting the inlay.

THE EVOLUTION OF LASER VISION CORRECTION TECHNOLOGY

By Sondra Black, OD, and Marc Bloomenstein, OD, FAAO

Once upon a time, LASIK was performed using a standard laser pattern that was based on a single measurement. This method relied on refraction results and the same type of patient preference methodology that we use to compare corrective lens options. The prescription, as generated from a phoropter, was then entered into the laser for the treatment. From there, a theoretical curve, similar to that of glasses, determined the spot pattern that was applied to the eye. Every patient with the same prescription received the same laser treatment, akin to picking out clothes off the rack. But, because the eye's curvature varies and the compensation for the steepness of the curvature is based on averages, some spherical aberration and other aberrations were often induced.

When wavefront-optimized LASIK was introduced, surgeons could use special software to reduce LASIK-induced spherical aberration. Using wavefront modeling and theory, surgeons can administer extra pulses in the periphery of the laser ablation area to manage the induced spherical aberration. However, as with conventional LASIK, the same number of laser pulses are used for every patient with the same prescription. In other words, the procedure is customized to be prescription-specific, but it is not specific to the individual aberrations of each eye. Furthermore, "optimized" simply implies that adjustments have been made to treatments to minimize induction of spherical aberration—it does not mean you can correct ones that exist already. In some patients, depending on their unique curvature, it can actually make the aberrations worse. That is where wavefront guided excels.

With wavefront-guided LASIK, the goal is to reduce all higher order aberrations. This is achieved by introducing a grid of an infrared laser light into the eye. The wavefront technology captures and measures each ray of light as it reflects off the retina and determines the aberrations of the entire eye based upon the deflection of the light from its ideal path. This technique can measure hundreds of individualized light rays that go beyond the ability of the phoropter.

From there, the treatment software calculates the number and diameter of laser pulses to reshape the cornea so that the light from viewed objects will focus perfectly on the fovea.

MAKING TIME FOR PATIENT EDUCATION

By Sondra Black, OD, and Marc Bloomenstein, OD, FFAO

Most patients who say they want LASIK already have some preconceived ideas about what the procedure entails. But beyond what they hear on the radio, few of these patients have a meaningful understanding of their actual choices. This is where we optometrists need to advocate for our patients. In this day and age, LASIK has become synonymous with all refractive surgeries, regardless of the actual procedure or method of treatment. It is our responsibility to guide our patients to a surgeon who is skilled in using the advanced technology that many patients need in order to achieve the desired outcome. Even in the most simple cases, we owe it to our patients to direct them to a surgeon who we would select for ourselves, rather than allow them to assume that the latest and greatest is available at every laser center that's featured on a highway billboard or in the newspaper advertisements.

LASIK can be performed using many different technologies and techniques, and we don't want to confuse patients, but we do need to re-educate them so that they recognize value versus cost. By framing the conversation properly, we can match the patient with a surgeon who can deliver the result that may go beyond expectations.

So how do you find the time to discuss the minutia of LASIK when you have a waiting room full of patients seeking glasses and contact lenses? And, is it even worth it? If your practice has an organized approach, it absolutely is. If your patient enters and exits your practice with no meaningful refractive surgery touch points, it is very likely that the patient will bypass you completely if and when they start to think about it. Consider how you educate your patients about contact lenses; you ask if they are interested in learning more. This same approach can be applied to surgical options.

The good news is you don't have to spend a ton of time getting into specifics. For starters, make sure LASIK has a presence in your waiting room. You could have posters, videos and brochures describing the procedure. Next, include a question about interest on your intake form. It's also helpful to train staff on the LASIK conversation. You can have the initial conversation if you think the patient is an interested candidate, and then your staff can take over from there.

DR. BLOOMENSTEIN: How has the Internet and social media affected your approach to marketing?

DR. BLACK: This is a bigger factor than age since people of all generations are using smart devices in particular. Patients are more likely to look at reviews and Facebook posts than ever before to make a decision before arriving at the clinic. They also turn to email as a mode of reaching out to us.

DR. HOFFMAN: The patient journey is definitely much more computer driven. Our patients are also more likely to schedule their appointments and communicate with us online than in years past.

DR. LODEN: It's true—marketing is totally different. In the past, you just answered the phone and that's where it began. But now, patients know (or think they know) quite a bit about you before you've even met. You can't just do radio and print ads anymore. You need Instagram, Facebook, YouTube, and more. Social media also allows patients to share their results instantly with a huge population, making good results more important than ever.

DR. HARDTEN: Another challenge is that patients often arrive confused, yet ready to make decisions based on marketing or price point. For this reason, you have to stay in front of the patient as much as possible.

WHY WAVEFRONT-GUIDED?

DR. BLOOMENSTEIN: What is your "go to" procedure for correcting refractive error?

DR. BLANTON: We prefer a femtosecond-based flap and an aberrometry-based wavefront-guided LASIK procedure. I firmly believe this state-of-the-art approach allows me to achieve great results.

DR. PEPOSE: I agree. An *iDESIGN*[®] System wavefront-guided treatment with an *IFS*[®] Laser customized flap is my "go to" refractive procedure because, in my clinical experience, it provides excellent safety and reliable outcomes.

DR. HARDTEN: In my experience, especially with newer high-resolution aberrometry, wavefront-guided LASIK offers a high degree of accuracy, safety, and quick recovery.

INDICATIONS: The STAR S4 IR[®] Excimer Laser and the iDESIGN[®] System is indicated for wavefront guided LASIK in patients with myopia as measured by the iDESIGN[®] System up to -11.00 D SE, with up to -5.00 D cylinder; in patients with hyperopia with or without astigmatism as measured by the iDESIGN[®] System up to +4.00 D SE, with up to +2.00 D cylinder; and in patients with mixed astigmatism as measured by the iDESIGN[®] System where the magnitude of the cylinder (1.0 D to 5.0 D) is greater than the magnitude of the sphere, and the cylinder and sphere have opposite signs; with agreement between manifest refraction (adjusted for optical infinity) and the iDESIGN[®] System refraction of 1) SE: magnitude of the difference is 0.625 D, and 2) cylinder: magnitude of the difference is ≤ 0.5 D; with patients 18 years of age and older, and with refractive stability (a change of ≤ 1.0 D in sphere or cylinder for a minimum of 12 months prior to surgery). See important safety information on page 8.

DR. BLACK: We believe so strongly in wavefront-guided LASIK that we don't offer other options. We explain that we only offer what we believe to be the best and patients never have to make the choice whether to pay more for advanced technology.

DR. BLOOMENSTEIN: Why do you offer a wavefront-guided procedure, in particular?

DR. LODEN: In our practice, 98.6% of the patients who we treat see 20/20 after surgery with the **iDESIGN**® System and our nomogram. Our patients also see well postop, which results in little post-operative chair time for our practice.



In our practice,
98.6%
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iDESIGN® System
and our own
nomogram

James C. Loden, MD

HOAs in patients with larger degrees of refractive error.

DR. HOFFMAN: In addition to an overall improvement in visual outcomes, we've experienced a reduction in our enhancement rate with WFG procedures.

DR. CARLSON: Our enhancements have dropped too. In fact, in the last seven months, none of our patients who have had wavefront-guided ablations has returned needing an enhancement.

DR. BLOOMENSTEIN: What are the arguments against wavefront-guided treatments?

DR. HARDTEN: One common reason that I've heard for not performing wavefront-guided treatments is that some of the aberrations in the wavefront come

“ALTHOUGH THE RESULTS FOR BOTH WFG AND WFO ARE QUITE GOOD, QUALITY OF VISION—AND ESPECIALLY NIGHT VISION—IS BETTER WITH WFG IN OUR EXPERIENCE.” - CAROL J. HOFFMAN, MD

from the lens. Yet, in younger patients that don't have incipient nuclear sclerosis, the lens is quite stable. Over time, individuals may develop some lenticular myopia, hyperopia, astigmatism, or other aberrations. Therefore, the wavefront-guided treatments in the typical LASIK-age patient perform quite well, and will provide the patient with higher quality of vision for many years to come. It handles the majority of the higher order aberrations, adapts well to the changing pupil size from dim to bright light, and is very accurate in the level of correction for these patients.

DR. CARLSON: Do you think offering WFG treatments is a differentiating factor in your market?

DR. ASSIL: Yes, if it's communicated properly.

DR. HARDTEN: In our relatively mature market, if a practice isn't offering some type of customized LASIK, they are at a significant disadvantage.

DR. LODEN: I agree. No matter how well we explain customization on our websites, patients don't totally understand it until they come in, or unless one of the more advanced optometric practices educate them.

DR. BLACK: Indeed, we need to help patients understand the process. If we don't discuss technology,

PREOPERATIVE OCULAR SURFACE OPTIMIZATION

By Sondra Black, OD, and Marc Bloomenstein, OD, FFAO

It's not the optometrist's job to perform surgery but it is an optometrist's job to treat dry eyes before referring patients for refractive surgery. If your patient is interested in LASIK, get the process rolling and prepare the ocular surface before making the referral. A healthy ocular surface is essential for proper measurements, and good outcomes, healing and stability.

Depending on the presentation, this can take weeks or months, but it is an important first step that falls squarely on optometrists' shoulders.

CAUTION: Effectiveness and safety have not been established in re-treatment with advanced customvue LASIK or patients with prior LASIK or refractive surgery. See important safety information on page 8.

patients will think it's all the same. They will view LASIK as a commodity and it is our job to educate them on the technology differences.

DR. CARLSON: How do you differentiate between WFO and WFG?

NONE
of our patients who have had wavefront-guided ablations has returned needing an enhancement in the last 7 months.

Alan N. Carlson, MD

laser is better when what a patient really cares about are results. So instead, we say, if you don't see 20/20, we refund your money. The LASIK of 10 to 15 years ago is not today's LASIK.

DR. CARLSON: How has WFG technology impacted your practice?

DR. ASSIL: Our referral network is very interested in it.

DR. HARDTEN: The ability to treat a wider range of patients has attracted the interest of many potential candidates. For example, it's surprising how many patients are just now starting to understand that we can

treat astigmatism.

DR. BLOOMENSTEIN: Why have you stayed with WFG technology while some of your colleagues use WFO?

DR. HARDTEN: The ability to more accurately treat coma is one of many reasons I've chosen wavefront guided over wavefront optimized.

DR. ASSIL: I want to preserve as much corneal tissue as I possibly can. That's why I prefer WFG treatment because it allows me to deliver meaningful improvement in higher order aberrations of high magnitude.

DR. PEPOSE: Indeed, studies have shown that WFG treatments with the *iDESIGN*® System produce excellent refractive outcomes, uncorrected vision, and mesopic contrast sensitivity than WFO treatment in aggregate—and particularly in patients who have a higher level of pre-existing higher order aberrations. In addition, WFG produced excellent outcomes with regard to magnitude and standard deviation of manifest refractive spherical equivalent and residual cylinder.²

DR. HOFFMAN: It's also important to highlight that there is more to our patients' satisfaction than just the Snellen acuity. Although our results with both WFG and WFO have been quite good, we've been impressed with the quality of vision—and especially night vision—with WFG in our experience.

DR. BLANTON: There are several reasons why I have stayed with wavefront-guided technology. Fundamentally, I believe in the science and physics of wavefront-guided technology. The measurement of the

MILLENNIALS

By Christopher Blanton, MD

The millennial generation is huge. In fact, the U.S. millennial population (born between 1982 and 2000) now exceeds the baby boomer population (83.1 million vs. 75.4 million, respectively).¹ Seeing this group of patients roll in the door is a harbinger of good things to come. This very large group is tech savvy and they understand how LASIK surgery works. It is a very precise, technologically oriented procedure that fits right into their mindset.

We have spent a lot of time investigating the kinds of things that appeal to millennials in particular and, as a result, have switched our marketing targets and approach.

We have discovered that Internet-based marketing is clearly the way to go, and we are doing less and less traditional marketing. We are now mostly focused on Internet and search engine optimization because it fits very well into the millennial demographic.

83.1
million
Millennials

VS.

75.4
million
Baby Boomers

optical system of the human eye has reached a level of sophistication unlike we have ever had before. I see it every day in the results I get with the surgical patients. I think much of the movement toward wavefront optimized is primarily driven by price, which I think is unwise. I want to give the best possible surgery to my patients.

THE iDESIGN® SYSTEM DIFFERENCE

DR. BLOOMENSTEIN: What do you like most about the iDESIGN® System?

DR. HOFFMAN: Being able to capture and treat patients with smaller pupil size (4mm with the iDESIGN® System), has improved our ability to treat this subset of patients. In addition, we like the expansion of the astigmatism treatment from -3.00D to -5.00D and the improved accuracy of these treatments.

DR. BLACK: The iDESIGN® Technology allows our surgeons to treat patients who were previously ineligible and provides great outcomes on postoperative day 1.³ It's very rare that we can't do a custom treatment with the iDESIGN® System at our center. The technology enables us to image eyes that could not be captured with older technology, such as small pupils.⁴ It measures

A MAJOR ADVANCE IN WAVEFRONT-GUIDED TREATMENTS

By Jay S. Pepose, MD, PhD

The iDESIGN System provides a number of important advances to wavefront-guided treatments. First, the increased number of lenslets provides 1,257 microrefractions across a 7-mm pupil, thereby obtaining a more precise wavefront profile of the higher and lower order aberrations of the eye. Second, the power of iris registration in further enhancing wavefront-guided treatments is that it provides a static reference point for centration (i.e., the limbus) rather than the pupil center, which can shift with varying degrees of illumination. The impact of more precise resolution of the eye's wavefront (with data reconstruction the equivalent of a 20th order Zernike analysis) plus faster and reliable iris registration is improved outcomes, negligible rates of enhancement, highly accurate correction of astigmatism and extremely high levels of patient satisfaction.

REACHING A STRUGGLING POPULATION

By David R. Hardten, MD

Mixed astigmatism has traditionally been very difficult to manage. Often these patients have become accustomed to their aberrations and may not wear glasses as much as one would think based on their vision, because of the distortions in their vision. Many of these patients also struggle with contact lens fit issues and contact lens rotation.

Now that the iDESIGN System is approved for mixed astigmatism, patients that before were not candidates can enjoy the benefits of wavefront-guided LASIK treatments. Our ability to now treat patients with up to 5.00D of astigmatism gives high-resolution treatment accessibility to a population that can benefit significantly from it.

data over a 7-mm pupil (vs. 6-mm pupil with previous technology), achieving significantly greater capture.^{5,6,7}

DR. CARLSON: I appreciate that we have yet to retreat a single patient who has had laser vision correction using this technology.

DR. BLOOMENSTEIN: What clinical advantages are you seeing with the adoption of the iDESIGN® System?

DR. ASSIL: We're achieving great visual results in patients with larger refractive errors (sphere, cylinder and HOA).

DR. HOFFMAN: We have always had a high percentage of patients with 20/20 vision after WFG treatments, but the number of better than 20/20 has improved. ♦

1. Millennials Outnumber Baby Boomers and Are Far More Diverse, Census Bureau Reports. United States Census, release number CB15-113, June 25, 2015.
2. Sarah Moussa, Alois Drexl, Eva Maria Krall, Marie Dietrich, Eva-Maria Arlt, Günther Grabner, Josef Ruckhofer. Comparison of short-term refractive surgery outcomes after wavefront-guided versus non-wavefront-guided LASIK. Eur J Ophthalmol. 2016; 26 (6): 529-535.
3. Stulting RD, et al. Results of topography-guided laser in situ keratomileusis custom ablation treatment with a refractive excimer laser. J Cataract Refract Surg. 2016;42:11-18.
4. Neal DR, et al. Combined wavefront aberrometer and new advanced corneal topographer. ASCRS 2008; MP392.
5. Schallhorn SC, et al. Wavefront-guided photorefractive keratectomy with the use of a new Hartmann-Shack aberrometer in patients with myopia and compound myopic astigmatism. J Ophthalmol. 2015;2015:514837.
6. Schallhorn S, et al. Early clinical outcomes of wavefront-guided myopic LASIK treatments using a new-generation Hartmann-Shack aberrometer. J Refract Surg. 2014;30:14-21.
7. Prakash G, et al. Femtosecond laser-assisted wavefront-guided LASIK using a newer generation aberrometer: 1-year results. J Refract Surg. 2015;31:600-606.

iDESIGN® Advanced WaveScan Studio System
Healthcare Professional Indications and Important Safety Information

CAUTION: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. **ATTENTION:** Reference the Operator's Manual for a complete listing of Indications and Important Safety Information. **CONTRAINDICATIONS:** Laser refractive surgery is contraindicated for: patients with collagen vascular, autoimmune, or immunodeficiency diseases, pregnant or nursing women, patients with signs of corneal abnormalities including signs of keratoconus, abnormal corneal topography, epithelial basement membrane disease (EBMD) and degenerations of the structure of the cornea, patients with symptoms of significant dry eyes, patients whose corneal thickness would cause the anticipated treatment to violate the posterior 250 microns (μm) of corneal stroma, and in patients with advanced glaucoma, and uncontrolled diabetes. If the patients have severely dry eyes, LASIK may increase the dryness; this may or may not go away. Severe eye dryness may delay healing of the flap or interfere with the surface of the eye after surgery; it may result in poor vision after LASIK. **WARNINGS AND PRECAUTIONS:** LASIK is not recommended in patients who: have systemic diseases likely to affect wound healing, such as autoimmune connective tissue disease, diabetes or an immunocompromised status, have a history of Herpes simplex or Herpes zoster keratitis, have severe allergies or tendency rub their eyes often, have glaucoma, elevated IOP, ocular hypertension or being followed for possible glaucoma (glaucoma suspect), are taking the medication Isotretinoin (Accutane®), are taking antimetabolites for any medical conditions. The safety and effectiveness of this laser for LASIK correction have NOT been established in patients: with progressive refractive errors, ocular disease, corneal abnormality, previous corneal or intraocular surgery, or trauma in the ablation zone, who are taking the medication Sumatriptan (Imitrex®), or Amiodarone hydrochloride (Cordarone®), with corneal neovascularization within 1.0 mm of the ablation zone, over the long term (more than 1 year after surgery for myopia and more than 2 years for mixed astigmatism), for patients who engage in activities that could endanger or damage the LASIK flap, for patients who have a family history of degenerative corneal disease, history of inflammation of the eye, for patients who have a history of crossed eyes (strabismus) or who have undergone strabismus surgery, prior LASIK or Refractive Surgery, with history of any eye diseases or abnormalities such as corneal scars or active disease, and whose BSCVA is worse than 20/20. To reduce the risk of corneal ectasia, the posterior 250 microns (μm) of corneal stroma should not be violated. The treatment of highly myopic eyes necessitates the removal of significant amounts of corneal tissue. The **iDESIGN®** System calculates the estimated residual bed depth using the pachymetry and intended flap thickness entered by the user. Actual flap thicknesses may vary. If the estimated residual stromal bed is ≤ 320 microns, an in-the-bed pachymetric measurement should be performed. **ADVERSE EVENTS:** Possible adverse events include loss of best spectacle corrected visual acuity (BSCVA), serious Transient Light Sensitivity Syndrome, serious primary open angle glaucoma, miscreated flap, melting of the flap, severe glare, and severe dry eyes. Complications can include corneal edema, epithelial ingrowth, diffuse lamellar keratitis, foreign body sensation, and pain.



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