



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

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SPEAKERS:



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TODAY'S LASIK MARKET AND PATIENT

Moderated by Kerry K. Assil, MD

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

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.

Patients as young as 18 YEARS OLD come in with their parents who've also had the procedure.



We now also routinely see patients above 65 YEARS OLD.

Kerry K. Assil, MD

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. ASSIL: 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,

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

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 come 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.

DR. ASSIL: 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 phones 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?

Moderated by Alan N. Carlson, MD

DR. CARLSON: 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.

BETTER DAYS AHEAD

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

INDICATIONS: The STAR S4 IR[®] Excimer Laser System and iDESIGN[®] Advanced WaveScan Studio (iDESIGN[®]) System is indicated for wavefront guided LASIK in patients with myopia as measured by iDESIGN[®] System up to -11.00 D SE, with up to -5.00 D cylinder and in patients with mixed astigmatism as measured by iDESIGN[®] 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 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. HARDTEN: In my experience, especially with newer high-resolution aberrometry, wavefront-guided LASIK offers a high degree of accuracy, safety, and quick recovery.

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



In our practice,
98.6%
of the patients
who we treat
see **20/20** after
surgery with
iDESIGN® System
and our own
nomogram

James C. Loden, MD

sensitivity and patient satisfaction are all consistently high with this treatment.

DR. ASSIL: I particularly appreciate that WFG allows me to treat pre-existing higher order aberrations (HOAs), or irregular astigmatism, and it helps me avoid creating 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. With that in mind, 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 from the lens. Yet, in younger patients that don't have incipient nuclear sclerosis, the lens is quite stable until around age 55-60 when they may have 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 location 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. However, patients are often confused, so most of our efforts on differentiation are focused on the referral doctors.

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.

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.

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

DR. HOFFMAN: We highlight the customization that WFG treatments offer as opposed to treating the patient's refraction alone with WFO.

DR. LODEN: We do this in house, not via external marketing. We believe in marketing outcomes and we stand behind them. We won't brag that our 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. Patient satisfaction is how we power the re-launch of LASIK.

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

DR. HOFFMAN: By embracing the latest advances in custom technology, we are viewed as the premium provider of laser technology in our area.

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

NONE

of our patients who have had wavefront-guided ablations



has returned needing an enhancement in the last 7 months.

Alan N. Carlson, MD

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. PEPOSE: Using a platform that helps me to achieve a high level of 20/16 vision or better, high contrast sensitivity and patient

satisfaction, and very low rate of enhancement all work together to ensure success and continued LASIK growth in my practice.

DR. CARLSON: 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.

“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

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 better 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 better 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 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.

DR. LODEN: Wavefront guided is not the cheapest or the fastest, but it allows us to achieve the outcomes we want, which makes our patients very happy. In the end, this is worth more to us than reduced click rates.

THE *iDESIGN*® SYSTEM DIFFERENCE

Moderated by David R. Hardten, MD

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

DR. ASSIL: I love the reliability of accurate data capture.

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, previously treated eyes and eyes with irregular astigmatism. It measures 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. PEPOSE: The *iDESIGN*® System has 5X resolution of its predecessor, providing up to 1257 microrefractions across a 7mm

pupil. This provides astonishing accuracy, which I noticed immediately in the attempted versus achieved astigmatism correction (treating up to 5.00D of cylinder). The aberrometer integrates seamlessly with the laser and iris registration occurs quicker and with higher regularity than my previous system. This gives me great confidence in treating patients with higher degrees of myopic refractive error and high cylinder, as well as mixed astigmatism.

DR. LODEN: The thing I like most about the *iDESIGN*® System is what it's done for my Saturday mornings. You get the "wow factor" that everyone hopes for at a Saturday morning post-op.

DR. HARDTEN: 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. Our enhancement rate thus far is exceedingly low, and it is much lower for patients with higher astigmatism.

DR. HARDTEN: What would your technicians say

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 1257 microrefractions across a 7 mm pupil, thereby obtaining a more accurate 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 more reliable iris registration is improved outcomes, negligible rates of enhancement, highly accurate correction of astigmatism and extremely high levels of patient satisfaction. This leads to the most powerful, credible (and least expensive) form of marketing and practice growth—word of mouth referrals.

about the *iDESIGN*® System?

DR. ASSIL: They notice the reliability (reproducibility), when capturing multiple images on the same eye, as well as the correlation between manifest and the *iDESIGN*® System cylindrical magnitude and axis.

DR. CARLSON: All six of my technicians would say the transition has been very “Technician Friendly.”

DR. HOFFMAN: My technicians love the ease of use and being able to design treatments for both eyes on the same screen at the same time. They particularly like that a treatment is picked, so they don't have to wait for me to pick it. They also appreciate that it is easier and faster to enter a physician adjustment if needed.

DR. HARDTEN: What advice would you give to surgeons who are adopting the *iDESIGN*® System?

DR. BLANTON: Accommodation is a very critical part of getting a good map, so you have to pay attention to when the patient is accommodating or not accommodating. Train your technicians to avoid stimulating accommodation. It helps to get the measurement right away rather than letting the patient stimulate accommodation by reading in the waiting room. It also helps to describe how patients need to look through the target and not at the target. I would also discourage comparing *WaveScan* System maps to the *iDESIGN*® System maps. These are two totally different devices, so comparisons are not relevant or helpful.

DR. LODEN: Don't think of it as point and shoot. Implement your own nomogram and refract to 20/15.

DR. HOFFMAN: It's always difficult to make a change in technology when you're comfortable with what you're currently using, but the *iDESIGN*® System is worth the learning curve in terms of patient outcomes and patient satisfaction.

DR. HARDTEN: How do you communicate the benefits of the *iDESIGN*® System to your patients?

DR. HOFFMAN: I educate my patients that the *iDESIGN*® System is an advancement of the already quite good wavefront technology. I highlight the

“MY TECHNICIANS LOVE THE **EASE OF USE AND BEING ABLE TO DESIGN TREATMENTS FOR BOTH EYES ON THE SAME SCREEN AT THE SAME TIME.**” - CAROL J. HOFFMAN, MD

improvements that we have seen with outcomes, reduced enhancement rate, and overall excellent quality of vision.

DR. BLANTON: We show patients their *iDESIGN*® System maps, explain that a percentage of their optical problems are a result of higher order aberrations, and talk about how the device enables us to capture multiple micro refractions across the pupil.

DR. PEPOSE: I explain that this is the most accurate fingerprint that we can take of the optical system and it will allow the most accurate correction we can achieve.

DR. LODEN: We wait until the patient is in the door to differentiate ourselves. And, even then, we make it a patient-centric message. We focus the conversation on outcomes. If a patient is particularly inquisitive, we will talk about how *WaveScan* captures 241 data points and now with the *iDESIGN*® System we have over 1,200 data points. We also talk about how this technology minimizes the risk of glare and halo. Above all, we're not going to fall into old traps—we don't bash our competitors. Price wars and actively disparaging competing technology is not good for anyone. We simply focus on what we offer and the outcomes we achieve, then we rest assured that the rise in tide will raise all ships. ♦

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 Dexl, 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.

6. J Ophthalmol. 2015;2015:514837. 2. 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. **INDICATIONS:** The **STAR S4 IR®** Excimer Laser System and **iDESIGN® Advanced WaveScan Studio (iDESIGN®) System** is indicated for wavefront guided LASIK in patients with myopia as measured by **iDESIGN®** System up to -11.00 D SE, with up to -5.00 D cylinder and in patients with mixed astigmatism as measured by **iDESIGN®** 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 **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). **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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