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THE LATEST IN LASIK:

Updates in Technology and Clinical Outcomes

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CONTENT SOURCE

This continuing medical education (CME) activity captures content from a roundtable discussion.

ACTIVITY DESCRIPTION

This activity focuses on the recent innovations and associated developments in LASIK, including modern ablation profiles and modern diagnostics technologies, that can help to increase the level of visual outcomes patients can achieve postoperatively and can also help to further reduce LASIK complication rates. Such educational efforts are also necessary to ensure that surgeons and other eye care practitioners understand the tools available to them to offer patients the most customizable LASIK treatments possible.

TARGET AUDIENCE

This certified CME activity is designed for ophthalmologists interested in surgical vision correction.

LEARNING OBJECTIVES

Upon completion of this activity, the participant should be able to:

- **Identify** the latest clinical studies and the most recent data on postoperative visual acuity after LASIK and the safety of LASIK
- **Differentiate** the latest ablation patterns, including wavefront-guided, topography-guided, and wavefront-optimized
- **Recognize** the benefits of integrating corneal topography measurements into a wavefront-guided excimer laser treatment
- **Use** expanded diagnostics features to plan and customize LASIK treatments based on the individual needs of patients
- **Apply** the various features of excimer laser technologies to deliver a custom LASIK treatment for a wider range of patients

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PRETEST QUESTIONS

PLEASE COMPLETE PRIOR TO ACCESSING THE MATERIAL AND SUBMIT WITH POSTTEST/ACTIVITY EVALUATION/SATISFACTION MEASURES INSTRUCTIONS FOR CME CREDIT.

1. PLEASE RATE YOUR CONFIDENCE IN YOUR ABILITY TO DIFFERENTIATE THE LATEST ABLATION PATTERNS (BASED ON A SCALE OF 1 TO 5, WITH 1 BEING NOT AT ALL CONFIDENT AND 5 BEING EXTREMELY CONFIDENT).

a. 1
b. 2
c. 3
d. 4
e. 5

2. PLEASE RATE YOUR CONFIDENCE IN YOUR ABILITY TO APPLY FEATURES OF EXCIMER LASER TECHNOLOGIES TO DELIVER A CUSTOM LASIK TREATMENT (BASED ON A SCALE OF 1 TO 5, WITH 1 BEING NOT AT ALL CONFIDENT AND 5 BEING EXTREMELY CONFIDENT).

a. 1
b. 2
c. 3
d. 4
e. 5

3. WHICH COMMERCIALLY APPROVED DEVICE HAS THE WIDEST RANGE OF APPROVED INDICATIONS FOR MYOPIA, HYPEROPIA, AND MIXED ASTIGMATISM.

a. Topography-guided LASIK using Contoura
b. Small incision lenticule extraction using Visumax
c. Wavefront-guided LASIK using iDesign
d. All have comparable approval ranges

4. WHICH TECHNIQUE COMPENSATES FOR THE ENTIRE EYE OPTICAL ABERRATIONS INCLUDING PERIPHERAL CORNEAL CURVATURE?

a. Topography-guided LASIK using Contoura
b. Small incision lenticule extraction using Visumax
c. Wavefront-guided LASIK using iDesign
d. Wavefront-optimized LASIK using the Allegretto

5. iDESIGN REFRACTIVE STUDIO HAS SEVERAL SIGNIFICANT IMPROVEMENTS ON iDESIGN ADVANCED WAVESCAN STUDIO. CHOOSE ALL THAT ARE CORRECT.

a. More efficient workflow
b. Wider treatment range
c. Better treatment planning
d. Improved diagnostic capabilities
e. Five times more wavefront data points

6. iDESIGN REFRACTIVE STUDIO ALLOWS CORRECTION OF THE COSINE EFFECT BY?

a. Using measured topography data
b. Using 1,257 wavefront points
c. Averaging the accurately measured K's value
d. Measuring the average manifest prescription more accurately

7. ALL OF THE FOLLOWING TREATMENTS ARE DERIVED FROM A PHOROPTER REFRACTION EXCEPT:

a. Wavefront-optimized
b. Conventional
c. Wavefront-guided
d. Topography-guided

8. iDESIGN IS APPROVED FOR ALL THE FOLLOWING REFRACTIONS EXCEPT:

a. -6.00 -4.00 x 133°
b. +3.00 -4.00 x 092°
c. +5.00 D of sphere
d. Plano -1.75 x 022°

9. STAFF TRAINING ON EFFICIENT WAVEFRONT ABERROMETRY CAN HELP MINIMIZE ACCOMMODATION DURING WAVEFRONT CAPTURE.

a. True
b. False

10. SURGEONS SHOULD CAREFULLY ACCOUNT FOR ACCOMMODATION WHEN SELECTING A SURGICAL TREATMENT PLAN.

a. True
b. False

The Latest in LASIK:
Updates in Technology and Clinical Outcomes

As we enter 2020, the options for laser vision correction are continually advancing, including updated technologies for wavefront-guided, wavefront-optimized, and topography-guided LASIK. The following roundtable discusses the current state-of-the-art LASIK technologies, helps practitioners to identify strong candidates for LASIK, and looks ahead to further market growth.

—Christopher Blanton, MD

Q | CHRISTOPHER BLANTON, MD: Let us start by discussing when and how we got started with LASIK. Dr. Teenan, what platforms have you used?

DAVID TEENAN, MBCHB, FRCS, FRCOPHTH: I've been a refractive surgeon for 12 years, and I started with the VISX excimer laser (Johnson & Johnson Vision). In my earliest cases, I was using aberrometry-driven surgery. Over the years, I have continued to use the VISX platform, and I now have experience with the latest innovation, which is the iDesign (Johnson & Johnson Vision).

ANTONIO UCEDA-MONTAÑÉS, MD, CERT LRS RCOPHTH: I started doing corneal refractive surgery in 2001. My first excimer laser platform was the Mel 60 (Carl Zeiss Meditec), if I remember correctly. Soon afterward, however, I switched to the VISX family of excimer lasers. Over the years, I have used the VISX 20/20, VISX S2, VISX S4 IR, and Star S4 IR with Wavescan, iDesign, and iDesign 2.0. Throughout my professional life, I have also used the Mel 80 and Schwind's excimer laser platforms.

EDWARD E. MANCHE, MD: I've been performing LASIK surgery commercially since the original US FDA approval of the excimer laser in 1995. I was one of the original Summit Technology investigators, and in 1997, I started using the VISX platform. We have currently have two excimer laser platforms at our institution—the iDesign with CustomVue and the WaveLight Allegretto (Alcon) as well as two femtosecond laser platforms, the Intralase iFS150 and the Visumax 500—to be technologically neutral. I also have experience with the Technolas 217 (Bausch + Lomb) having used it for approximately 10 years. I perform wavefront-guided, wavefront-optimized, and topography-guided treatments. I've always been a big advocate of wavefront-guided LASIK, and this technique has gotten better over the years with the continuous advancements and refinements in the technology.

DR. BLANTON: I have a similar VISX/Summit story. I was in the Navy when I first performed conventional PRK with the Summit laser. When I entered private practice, I began with the VISX laser, and when CustomVue was introduced in the early 2000s, we started doing wavefront-guided LASIK. At first, we were not impressed with the early results, until we figured out that we had to make the wavescan match the manifest. Back then, the software tended to underestimate the myopes based on a phenomenon known as chromatic aberration. Once we dialed in our numbers, we had fantastic results with the waverfront-guided surgery, and we have never looked back. I have not done wavefront-optimized, but I'm interested to hear others' experiences.

GEORGE O. WARING IV, MD, FACS: I was fortunate to have access to multiple excimer laser platforms during my training, which was when wavefront-guided and then wavefront-optimized platforms were coming onto the scene. Through the years, we used multiple wavefront-guided platforms, such as the Ladarwave (Alcon) and the VISX systems, including consecutive iterations of the iDesign 1.0 and 2.0. In addition, we have used the Technolas systems, and WaveLight Allegretto wavefront-optimized systems, including the 200-Hz, 400-Hz, and we introduced the first 500-Hz to the United States in 2008. Through the years, the majority of our cases were wavefront-optimized, and we reserved wavefront-guided for highly aberrated eyes. Historically, we found wavefront-optimized to have a more streamlined workflow. With new high-definition wavefront-guided aberrometers, such as the iDesign 2.0, however, we have found these to actually streamline our refractive workflow due to the robust refractive data provided. A recent prospective randomized study demonstrated that a statistically significant higher number of patients were 20/15 or better with the iDesign than with wavefront-optimized systems.[1] At that point, I was compelled to change my practice patterns, and I ended up moving to the iDesign and then to the iDesign 2.0 most recently.

DR. BLANTON: Did you do anything differently when you moved to wavefront-guided LASIK to improve workflow?

DR. WARING: Staff training has helped, as has paying particular attention to efficiency with wavefront captures to minimize accommodation. Other pearls include doing wavefront analysis

as the first diagnostic; to trust the wavefront-assisted manifest to optimize workflow; to control for accommodation with expert dry and cycloplegic refractions; and to optimize one's physician adjustment, which is important for each system, and for tracking and fine-tuning your outcomes.

DR. UCEDA-MONTAÑES: I think the main issue when you start using iDesign is the change in mentality that it requires. Standard treatments are based in phoropter-acquired manifest refractions, while iDesign wavefront relies on wavefront-derived refraction, which might be different and somewhat difficult to understand. It is very important to train staff how to correlate manifest refraction with manifest refraction at infinite lane and how to correlate the latter with wavefront refraction in terms of difference in spherical equivalent between the two. In my experience, once we understood that, the number of patients who required physician adjustments were reduced and outcomes improved.

DR. MANCHE: In my initial experience using the iDesign, as part of the multicenter FDA PMA trial, we experienced significant under-corrections when treating myopia. There was an undercorrection of approximately 0.40 D seen across the board in the iDesign FDA trial for myopic treatments. Based on the results of the FDA trial, the company incorporated a nomogram adjustment for their commercial launch of the iDesign system. When I began using the commercially available iDesign 1.0 system, I noted that we were overcorrecting a significant percentage of the myopic eyes. I was able to develop a personalized nomogram to address the overcorrections. Once the nomogram adjustment was made, the results were spot on with excellent outcomes and predictability. One of the biggest benefits of the iDesign is that the measurement of astigmatism is very accurate in terms of both magnitude and axis. The iDesign 1.0 was very accurate in correcting astigmatism, but the iDesign 2.0 is even more accurate.

DR. BLANTON: The other thing to remember is that the iDesign aberrometer takes into account higher-order aberrations (HOAs), whereas the phoropter doesn't. I've learned to trust the iDesign cylinder implicitly, and I don't play with it. Dr. Teenan, how did you transition from your Wavescan to your iDesign?

DR. TEENAN: I discussed with our staff the issues with the slight undercorrection and made sure that everyone was paying close attention to the wavescans. With each version of the iDesign software, we noticed the accuracy improved and it became easier to get patients to 20/20 and beyond. And you know, the results speak for themselves.

ADVANCES IN LASER VISION CORRECTION

Q | **DR. BLANTON:** The study by Schallhorn et al,[2] which included thousands and thousands of eyes showed that the iDesign was statistically significantly better than Wavescan. The biggest difference with the iDesign is that it fixed the chromatic aberration problem of the Wavescan, and that instantly made the treatments hotter. Another key difference is that the iDesign incorporates a new concept, which is optical infinity. Optical infinity is a term used to describe the fact that, at the typical eye lane length, the eye chart is not really at infinity and, therefore, there is some underestimation of the myopic refractive error. Because our patients, in general, desire to see further than 20 feet away, we need to compensate for that underestimation. A good rule of thumb is that our patients need about an extra 0.25 D of myopic correction to achieve excellent distance vision. The third concept is one that physicians must learn, and that is how to determine a patient's true refractive error based on cycloplegic refraction. Once that is mastered, it is easy to dial in the iDesign and then you start to get these phenomenally good results.

DR. WARING: You bring up some great points. We're able to treat not just sphere and cylinder, but more than a thousand other data points—all the microrefractions that allow us to get to another level of correction. What's really interesting is subjective feedback that we get: People are almost, and I say this as a positive comment, unsettled with what they're seeing because they just don't think that they should be seeing that well. It's a new level of vision correction.

DR. BLANTON: Absolutely totally new. Does anybody have any other reasons they think we might be getting such great vision with the iDesign 2.0?

DR. UCEDA-MONTAÑÉS: I was fortunate enough to be one of the first few surgeons in Europe who started using the iDesign 2.0, back in 2018. Now I have just completed a phase 4 postmarket clinical trial for low to moderate myopia with the iDesign 2.0 Refractive Studio. We had excellent clinical results, which will be published shortly. Throughout the trial, we were able to observe a great degree of refractive correlation between wavefront refractions and manifest refractions at infinite lane length. I believe this is due to two different factors. First, the iDesign 2.0 provides better compensation of chromatic aberration, and second, the device has an improved strategy for the compensation of excessive accommodation. It is a great advantage to use refractions at infinite lane length because it is the only way that we can compare manifest and wavefront refractions using the same language (not manifest taken at 4 or 6 m lanes), which allows us to better understand how the system works and to prevent us from wrongly using physician nomogram adjustments. Further, the iDesign 2.0 maintains the iris registration system of previous platforms, allowing very accurate treatment of astigmatism. Another great advantage of the technology is that it incorporates topographic information into the wavefront-guided ablation calculation, allowing it to read highly aberrated corneas. This also provides a more accurate compensation of the cosine effect as keratometry (K) readings are directly taken from wavefront-derived topography maps, not just using manual K readings. Using the same source of information for wavefront and topography also improves results, as it eliminates the risk of misaligned measurements.

DR. MANCHE: With the iDesign 2.0, you're measuring the whole eye wavefront and you're compensating for the shape of the peripheral cornea. It is a wavefront-guided, topography-integrated system. It is more than just entering the central K readings. You are compensating for the peripheral curvature based on actual corneal topography. It is significantly more precise than typical wavefront-optimized systems that are based on central K readings.

DR. BLANTON: It's a level of precision that we didn't have before. It actually measures the slope of the corneal curvature at multiple data points instead of using two K measurements. Go do a treatment plan on the iDesign 2.0 and then back it off and put your own Ks into the system, or even the same Ks that you got on the topography—this will take it out of the topography-integrated mode. You'll see it changes the pulse pattern of the treatment plan. The iDesign 2.0 really changes the way we put the pulses down in the peripheral cornea.

DR. WARING: My understanding is that there is a topographic registration for the wavefront treatment. It's almost like registering and treating the wavefront more accurately.

DR. BLANTON: Because it's coaxial with the topography. It puts the two data sets together. And you're also getting some other features, including dynamic pupillometry, which is another reason I think we're getting better results. My iris registration rates went from mid-80s to mid-90s when I went from the previous iDesign software to the iDesign 2.0. The other thing I've noticed is that, with the Wavescan, outer iris boundary misidentification occurred about 6% of the time. But on the iDesign 2.0, in the thousands of eyes I have done, I have 0% of misidentified outer iris boundary. So, we can attempt iris registration on every patient at the get-go.

DR. WARING: I agree, in addition, it captures iris registration during treatment much more reliably, and this significantly improves the treatment efficiencies and workflow.

DR. BLANTON: Given the recent FDA approvals for the iDesign, we can now perform LASIK on a larger population of patients. For instance, LASIK is now approved for myopic cylinder as high as -5.00 D and for hyperopia with 4.00 D spherical equivalence and 2.00 D of astigmatism. It is also approved for mixed astigmatism up to 5.00 D. So there are very few people who can't have LASIK at this point on the iDesign.

DR. WARING: The expanded available offset has been an important addition.

DR. BLANTON: Let's talk about that. So, the iDesign 2.0 only allows you to go in one direction. For monovision LASIK, we can add up to 2.75 D with the iDesign. Prior to the approvals, we had a 0.75 D limit.

DR. MANCHE: Occasionally you will have a patient who can't relax their accommodation. For example, assume patient is a -2.25 D myope and the lowest iDesign measurement obtained is -3.25 D. The iDesign 2.0 software allows us to reduce the planned treatment in this case so we can treat the patient using wavefront-guided technology. I performed surgery on a similar case like this last week. I had a patient in her early twenties who had significant accommodation. We were able to reduce the treatment by 1.00 D and, on postoperative day 1, the patient was perfect with no overcorrection. The iDesign 2.0 software has made it possible for you to compensate for patients who overaccommodate as well as treat patients for monovision. This adjustment is a welcome addition to our surgical armamentarium and allows us to treat a greater percentage of patients using wavefront-guided ablations.

DR. WARING: Exactly. And those are the cases where, in the past, you would do conventional LASIK because you simply could not get a good wavefront measurement. The iDesign circumnavigates that and gives us the flexibility to still perform a wavefront-guided procedure. You do have to be careful, however. You'd like the maps all to match, but sometimes they just don't.

DR. BLANTON: Right. With the iDesign, the issue is not undercorrection. Being able to put more plus in is really helpful in those cases. We still can't individually adjust the cylinder, so you either can adjust the sphere or use your own nomogram adjustment.

DR. WARING: However, for the plano presbyope or slight hyperope, with a blended vision plan,we may still perform a standard treatment in the near eye, depending on the offset needed.

DR. BLANTON: Dr. Waring, what are some other examples of when you would do conventional LASIK?

DR. WARING: We use it for enhancements after cataract surgery and refractive lens exchange with diffractive presbyopia correcting IOL technologies. With these IOLs, the chromatic aberration compensation and correction tends to throw off the aberrometry readings to some degree and it also provides a somewhat myopic result, so a conventional procedure works more predictably in this situation. I will say that we have done high-definition wavefront-optimized treatments in these patients, and where the diagnostics and preoperative data makes sense, they tend to do very well.

DR. UCEDA-MONTAÑÉS: I do very few standard treatments; it accounts for less than 5% of my patients. I do most of my cases with wavefront-guided technology, including primary cases; enhancement surgery; and patients with complex cases such as corneal ectasia after CXL, postcorneal trauma, and small optical zones. However, I will choose standard over wavefront-guided treatments only as an enhancement for multifocal IOLs and in patients with very small pupils (< 4 mm) that do not allow a wavefront diameter that is large enough for the customized treatment.

DR. BLANTON: There's a big distinction between a multifocal and a monofocal IOL. With multifocals, an aberrometry-driven surgery will override the purposeful aberrations that are in the IOL. So, that's certainly one example of when conventional LASIK is better. Another instance is hyperopes who want monovision correction; an aberrometry-driven platform cannot make such a correction.

DR. WARING: If you can't get a reliable wavefront, then conventional LASIK will be our back-up plan.

DR. MANCHE: You also have to be cautious about respecting the amount of corneal tissue being removed when performing wavefront-guided enhancements. I use wavefront guided ablations for all of my enhancement surgeries, but I shrink the optical zone to preserve corneal tissue. We find excellent outcomes using this technique and have presented this data at the ASCRS meeting in the past.[3] You get the benefit of the wavefront-guided ablation while removing the same amount of tissue as you would by performing a conventional treatment. In addition, we have found that eyes with the lowest amount of postoperative higher order aberrations have had an initial wavefront guided treatment followed by a wavefront guided retreatment.

DR. BLANTON: Even in conventional LASIK done on the STAR S4 platform, if you go above -6.00 D it automatically uses a 5.5-mm optical zone and if you go above 12.00 D it uses a 5-mm optical zone. So it's automatically doing those multizonal treatments for you, for the same logic that you just presented, Dr. Manche. Let's go on to wavefront-optimized LASIK. What is wavefront-optimized, exactly?

DR. WARING: Wavefront optimization is based on the concept of radial ablation efficiency. In simple terms, the apex of the cornea is more likely to receive more energy due to its proximity to the origin of the laser. Likewise, as you move more to the periphery, you're going to lose energy if it's delivered in the same manner. This is the cosine effect. Based on a normative population, this can be optimized to create a more natural curvature after the treatment, which will reduce induced spherical aberration by delivering more energy to the mid-periphery and the periphery in a transitional fashion.

DR. BLANTON: One topic we have not talked about yet is topography-guided corneal refractive surgery. Anybody doing that?

DR. UCEDA-MONTAÑÉS: I do not perform traditional topography-guided treatments, as the technology I currently use does not have that feature. I do topography-integrated wavefront guided ablations with iDesign 2.0. This system uses a wealth of topographic and keratometric information within the wavefront-guided ablation protocol, allowing us to treat highly aberrated corneas that, in the past, were only addressed with the conventional topography-guided treatments. I believe this system is superior because not only does it improve, or at least not degrade, the global aberrometric profile of the patient, but it also treats corneal aberrations better than its predecessors. It is a way to bridge the gap between purely topography-guided versus wavefront-guided ablations in a simple and user-friendly process. Besides the topography-integrated wavefront-guided ablations, the iDesign 2.0 ensures that only one treatment is needed, while topography-guided ablations usually require a second intervention to adjust the postoperative refractive error of the first surgery in complex cases such as decentrations or small optical zones.

DR. MANCHE: I also perform topography-guided refractive surgery. We use Alcon Contoura on the WaveLight laser. Based on the FDA clinical trial results, nearly 16% of patients achieved an uncorrected visual acuity of 20/10 postoperatively at 1 year.[4] I was curious to see whether I could replicate those clinical outcome using the commercially available technology. I have found the system difficult to use and very time-intensive for both me and my staff. My initial clinical outcomes were not as good as I expected or what was achieved in the FDA PMA study. Initially, I had a number of eyes that had their axes flipped when performing astigmatic corrections. With more experience, the system has become easier to use with more reliable clinical outcomes. I developed my own nomogram which has greatly improved the predictability and efficacy of the treatments. In addition, Alcon has recently released new treatment software (Phorcides) that analyzes and designs the topography –guided treatment ablations. Early results using the Phorcides, treatment software have shown promise with excellent results while simplifying the planning process when using the Contoura topography-guided system.

DR. BLANTON: It's phoropter-based, right?

DR. MANCHE: That's correct. It is phoropter-derived.

DR. BLANTON: So now you're going to reduce some irregularities in the cornea that are topographic, and that will affect your refractive error. How do you figure out how much that is changing the manifest refraction?

DR. MANCHE: I have my own personalized nomogram, which is working well now, but the Phorcides software is designed to assist with the Contoura calculations.

PERSONALIZED NOMOGRAMS

Q | **DR. BLANTON:** Let's talk more about nomograms. How frequently do you use your nomogram adjustments? How do you do them?

DR. MANCHE: It's always evolving. With the initial iDesign system, there was a standard adjustment that was made during the FDA clinical trials. When the iDesign 1.0 was commercially released,

we were told to trust the system as long as it was within 0.67 D of the spherical equivalent. I treated maybe 20 or 30 patients and found a systemic overcorrection in just about every one of those patients. If you're treating a 20- or 30-year-old, generally you get away with a small amount of consecutive hyperopia. But if you're treating a 40- to 50-year-old, you can't. Based on my initial experience, I figured out that you have to back off on the sphere when treating myopic patients. I perform both manifest and cycloplegic refractions as well as pre- and postcycloplegic iDesign measurements. Here is an example of how I plan a treatment for a patient with compound myopic astigmatism. Manifest and cycloplegic refraction is -6.25 D of sphere and +1.50 D of cylinder and the iDesign measures -6.60 D of cylinder and +1.63 D of sphere. The cylinder is not adjustable in the United States, so no adjustment is needed or possible. In this case, I would reduce the sphere closer to what the manifest refraction is.

This approach has given us outstanding accuracy and clinical outcomes. The one area that we are careful is in low myopia and in patients older than 40 years. In these cases, we tend to back off a little bit more on the sphere, because overcorrection is problematic in those patients.

DR. BLANTON: On what percentage of patients do you do a nomogram adjustment?

DR. MANCHE: Almost all of them, even if it is 0.10 D.

DR. BLANTON: I did some training in Japan, and they did it to the 0.01 D, and their results the next day were phenomenally good. I probably do nomogram adjustments on about 30% or 40% of my patients. It's typically 0.30 or 0.40 D, because if I'm down to 0.10 D level, I trust the aberrometer more than I trust my 0.10 D adjustment.

DR. TEENAN: I probably use a nomogram adjustment in 50% of the patients I treat, and it is typically in the 0.40 to 0.50 D range.

DR. UCEDA-MONTAÑÉS: For treatments with the iDesign 2.0, I do not use any adjustment other than the platform's built-in nomogram. I only use a mild undercorrection in myopic patients who are older than 50 years in order to reduce the chances of overcorrection, as this group will not tolerate mild hyperopic shifts. For previous versions of the iDesign, I normally adjusted the myopic sphere according the magnitude of the cylinder using the nomogram provided by the manufacturer. Again, I induced a mild undercorrection in older myopic patients.

DR. WARING: I use a physician adjustment almost uniformly. But we're doing it to match our refraction. But we're doing it to match our refraction. Like Dr. Manche, we do a cycloplegic and a manifest refraction. We have an adjustment on for myopia, where we actually back off our treatment before the physician adjustment.

DR. BLANTON: And this is for your ambient surgical environment?

DR. WARING: Yes. From there, I do the nomogram adjustment to the manifest. This system seems to work well for us.

DR. BLANTON: There is something to be said for that level of precision. How frequently do you need to use more than a 0.75 D adjustment? For me, it's about 1% or 2%.

DR. MANCHE: Very infrequently.

POTENTIAL MARKET GROWTH

Q | DR. BLANTON: Where is the marketplace now for your practices? Are you growing? Are you staying the same? And how might the newer laser vision correction technologies enhance market growth?

DR. MANCHE: We're growing, and our LASIK volume is up. There was a dip in 2015, but right now, our LASIK numbers are up.

DR. UCEDA-MONTAÑÉS: In Europe, we saw an increase in LASIK volumes after the financial crash, particularly in countries such as Ireland and Spain where the economic turmoil was greatly felt. I still believe that LASIK, especially wavefront-guided femtosecond LASIK, is and will remain the main player in the corneal refractive market, even though we might not see the numbers we saw in the past. This is mostly because refractive surgery has evolved in other directions, including multifocal IOLs, phakic IOLs, and SMILE. Obviously this has taken a toll in the market share.

DR. WARING: We're experiencing growth in our LASIK volume as well. And, to answer your question, it's these types of outcomes and these *wow* factors that really have the power to create a buzz. I think technology really does matter.

DR. BLANTON: The biggest obstacle for people is fear, not cost. Patients spend money on contact lenses and solutions and glasses. After LASIK, suddenly all or most of that cost goes away. And then that doesn't include the value of not being dependent upon some device to correct your vision. So, clearly fear is something that is keeping people from having LASIK. The best way that we can alleviate the fear factor is to have stupendous outcomes. I feel very confident that these new platforms give us those outcomes and minimize the chance for serious complications.

DR. MANCHE: I agree. The technology has gotten so much better. Now we have femtosecond lasers, better software, and better ablation patterns on our lasers, and we are also better at screening patients for potential risk of ectasia.

DR. BLANTON: It's a work in progress. We must continue to learn how we can translate our level of confidence, and our knowledge of

these excellent outcomes, to the general public and to the patients who are thinking about having LASIK.

DR. TEENAN: Social media has a lot to do with these things. But negative commentary is out there, too.

DR. MANCHE: You're right. I think it's the old axiom, a happy patient tells 10 people, but an unhappy patient tells 1,000.

DR. BLANTON: Results of the PROWL studies[5,6] have helped, but it hasn't triggered the influx of LASIK patients that we'd hoped to see.

DR. WARING: Companies like Johnson & Johnson Vision and STAAR Surgical are proactively rethinking direct-to-consumer marketing. We are advocates for that. When done responsibly, it can be appropriate to partner with industry to help support that initiative.

DR. BLANTON: I agree.

DR. MANCHE: Ophthalmologists can be our own worst enemy when we promote one technology or procedure over another, whether it's iDesign, Contoura, or SMILE surgery. Ophthalmologists tend to be fairly competitive by nature. There is a temptation to promote technologies that yield excellent outcomes in your hands. Often, surgeons are tempted to downplay or criticize technologies that they don't use or are unfamiliar with. I teach all of my fellows, residents, and staff to never bad-mouth any procedure or any technology. It is important to convey to our patients that all modern keratorefractive procedures are safe and effective. Emphasizing this fact removes a lot of the fear that patients have.

DR. WARING: It is human nature to try to promote your technology as a differentiator, but it is not what's best for the growth of the market. The better thing is to tell patients, "You are in good hands. We have a lot of great tools in our toolbox, and we will select the procedure that is best for you and for your eyes."

DR. BLANTON: Exactly. And the continuing advancement in technologies will give us better outcomes. From there, you can create an universal marketing message for the general public.

DR. MANCHE: It is not uncommon for me to be a patient's third or fourth consult and they ask, "Why should I come here?" My response is something like this, "As long as your procedure is performed using a modern excimer laser, a flap created with a femtosecond laser, and a well-trained surgeon, you're going to get a great outcome." I give the analogy that, if they are thinking of buying either a BMW or a Mercedes, both car companies try to market their cars as the best—but, in reality, they're both excellent cars.

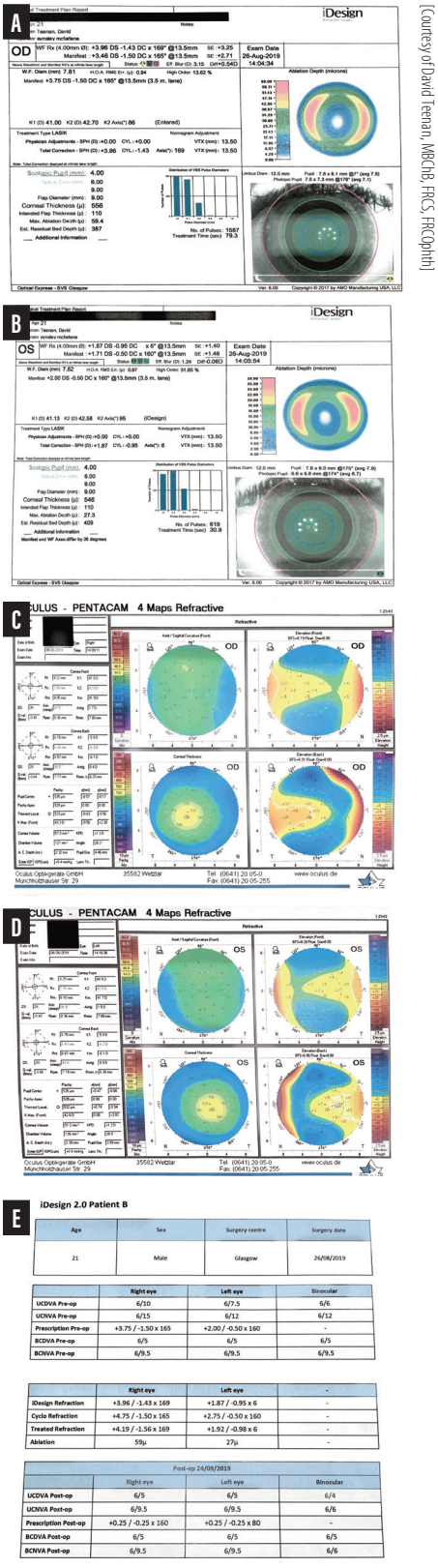
CASE STUDIES

Q | **DR. BLANTON:** Some of the indications for the iDesign 2.0 include mixed astigmatism, which is when the cylinder exceeds the sphere and is of opposite sign; up to 4.00 D of hyperopia with up to 2.00 D of astigmatism; and, for myopic LASIK, up to -5.00 D of cylinder. The other nice thing is that our stability definition has changed: We can now perform LASIK in patients who have experienced a change of less than 1.00 D in sphere or cylinder for a minimum of 12 months prior to surgery. It used to be 0.50 D or less of change in the past 12 months. Dr. Teenan, would you like to share a recent case with us?

DR. TEENAN: Absolutely. I recently performed hyperopic LASIK on a 21-year-old man with mixed astigmatism. Preoperatively, he was +3.75 -1.50 x 165° OD and 2.00 -0.50 x 160° OS. I performed the treatment with the iDesign 2.0, and the patient had an excellent result (0.25 -0.25 x 160° OD and 0.25-0.25 x 80° OS). I think it just shows how good the results are for iDesign 2.0, even in a complex case (Figure 1).

DR. WARING: We've also had a great experience with patients with mixed astigmatism. I have a lot of confidence in patients with mixed astigmatism and myopia, too.

DR. UCEDA-MONTAÑÉS: In my experience with previous



[Courtesy of David Teenan, MBChB, FRCS, FRCOphth]

Figure 1. Preoperative assessment (A) and wavefront maps (B, C), treatment plan (D), and postoperative outcome (E) in a 21-year-old man with mixed astigmatism.

[Courtesy of Christopher Blanton, MD]

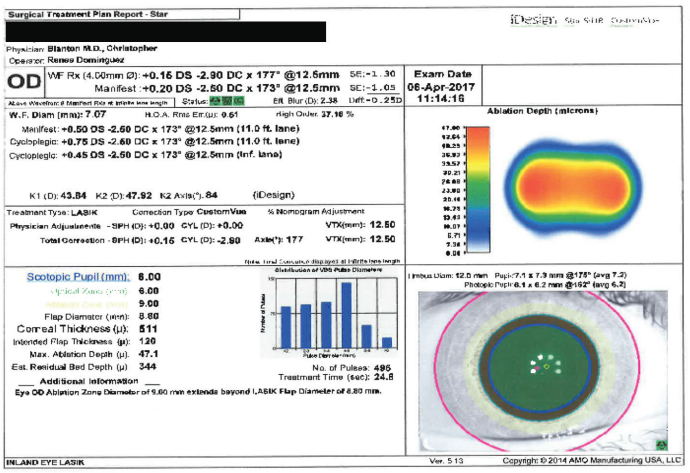


Figure 2. Preoperative maps from a 23-year-old man with mixed astigmatism who underwent customized LASIK with the iDesign 2.0.

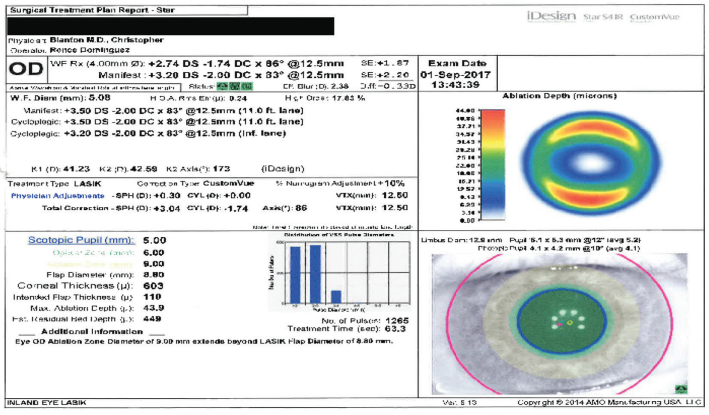
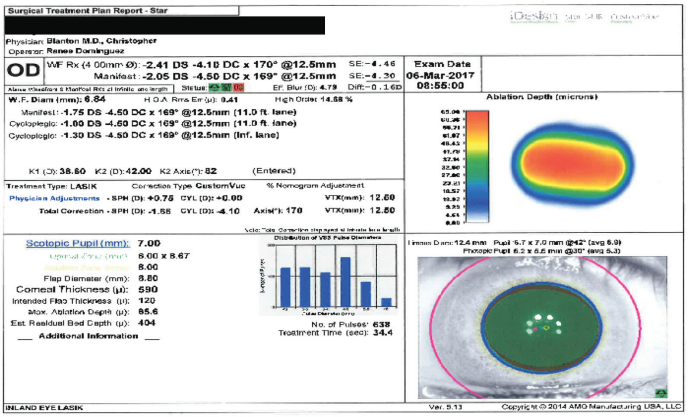


Figure 3. Preoperative maps from a 49-year-old man with hyperopia and amblyopia in his right eye who underwent customized LASIK with the iDesign 2.0.

wavefront-guided platforms, highly aberrated corneas were very difficult to read, and obtaining useful wavefront refractions was always challenging. With the new generation of the iDesign, which incorporates topography and keratometry derived from wavefront measurements, this seems to have improved. In one of my visits to the Middle East to train and assist surgeons with this technology, I remember the case of a mechanic who had a corneal perforation a few years back. The patient developed an irregular astigmatism with loss of BCVA due to increased corneal HOAs. The patient demanded a refractive solution, as he could not tolerate glasses or contact lenses. When the patient was scanned with the iDesign 2.0, the refraction was almost exactly the same as the manifest (-1.50 D of sphere and -6.50 D of cylinder). This encouraged the treating surgeon and myself to go ahead with wavefront-guided surface ablation. From the information that I have from the surgeon, the patient's UCVA and BCVA improved significantly postoperatively. This has also been the case in my patients with post-LASIK ectasia after CXL, whereas with other previous versions we never obtained the same degree of refractive accuracy in highly aberrated corneas.



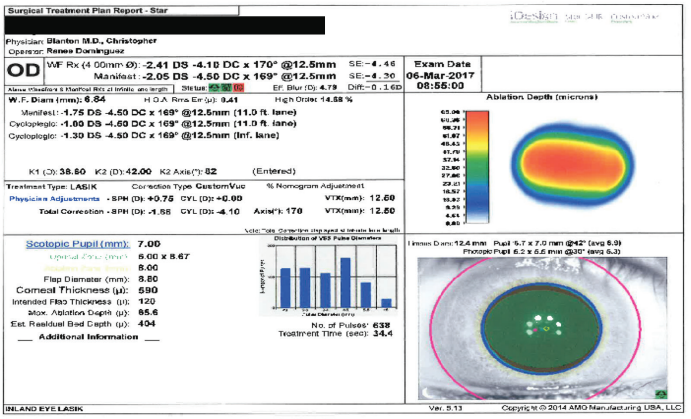


Figure 4. Preoperative maps in a 31-year-old woman with high astigmatism who underwent customized LASIK with the iDesign 2.0.

DR. BLANTON: The diversity of the patient population that we can treat with this platform is excellent, and I have had very few patients with residual refractive errors. My first case is a 23-year-old man who was uncorrected 20/60 OD and 20/30 OS. He had a mixed astigmatism refractive error in the right eye and myopic astigmatism in the left (+0.50 -2.50 x 173° OD, Plano -1.00 x 179° OS; Figure 2). Postoperatively, his UCVA was 20/15 on day 1. I'd say 90% of our patients see 20/15 or 20/20 the next day.

DR. WARING: We frequently see patients who are 20/20 off the table. It is so fun for them and often they are so emotional and happy. If you ever have the opportunity, capture a patient reading their way down the vision chart. We had a great opportunity with a radio personality, and she literally was crying her way down the chart because she could see so clearly, straight down right off the table.

DR. BLANTON: And she was probably a high myope who had an instantaneous improvement in vision. My next case is a hyperope. He's a 49-year-old man who, preoperatively, was 20/30 OD and 20/70 OS. Refraction in his right eye (Figure 3) was +3.50 -2.00 x 083° @ 20/15 and +4.00 -2.25 x 111° @ 20/30+. And he had some amblyopia in his left eye. Now this is one we could argue that a lens-based procedure could have been another option, but he had an excellent outcome after iDesign LASIK. In my amblyopes I never

[Courtesy of Christopher Blanton, MD]

Age Specific Nomogram Adjustment

- 20's
  - Aim for +0.3 D
- 30's
  - Aim for +0.2 D
- Early 40's
  - Aim for +0.1 D
- 45+
  - Aim for plano

Figure 5. Dr. Blanton's personal age-specific nomogram adjustments.

want to overpromise and underdeliver, but I have found that, with LASIK, they get better vision than they've ever had. Nine months postoperatively, this patient was 20/20+ in the right eye and 20/25 in the left. His BCVA preoperatively was 20/30, so he was super happy after surgery.

The next case is a 31-year-old woman with high astigmatism, 4.00 D in her right eye and almost 5.00 D in her left eye (-1.75 -4.00 x 169° @ 20/20+ OD, +0.25 -4.75 x 019° @ 20/40+ OS). Preoperatively, she had a UCVA of 20/70 OD and 20/80 OS. It's a little unusual to see amblyopia in the myopic population, but if the patient has a high level of cylinder, it certainly can induce cylinder-based amblyopia, which she had. This patient did not have any kind of ectatic disease, but I had to do a significant adjustment on her because of accommodation (Figure 4).

One month postoperatively, her UCVA was 20/20+1 OD and 20/25+1 OS. Going from 20/40 BCVA to 20/25+1 UCVA was a super result for this patient. Unfortunately she didn't come back for follow-up after 1 month because she was doing so well. Although as my mentor Peter Laibson, MD, from Wills Eye Hospital says, there are two reasons why patients don't come back: The first is that they are doing really well, and the second is they are doing poorly. But in this case, it was because she had an excellent outcome.

The three cases I presented, and the case that Dr. Teenan presented, help to highlight all of the different patient populations that we can treat now with the iDesign, including patients with high cylinder, those with hyperopia, and those with mixed astigmatism. In all of these patients, I like to aim for optical infinity. In other words, we aim to make them a little hot, which is to say 0.25 D. If you aim for plano, you're going to get a lot of planos. But in a typical bell curve, you're also going to get a few -0.25 D patients. The patients who end up -0.25 D postoperatively are not going to be very happy. If you aim for +0.25 D, you're going to get very few patients with residual myopia, and most of them are young enough and can accommodate well enough that they are very, very happy. Figure 5 shows the age-specific nomogram adjustments that I use with the iDesign 2.0.

DR. MANCHE: I have a couple of cases to share, too. The first is a patient who underwent a custom iDesign procedure in her right eye for a refraction of -4.22 +2.00 x 90° @ 12.5 mm. If you look at just postoperative day 1, her refraction improved to -0.02 +0.06 x 72° @ 12.5 mm (Figure 6).

DR. BLANTON: That's remarkable.

DR. MANCHE: Absolutely. I also have another similar case. This patient had 4.50 D of cylinder preoperatively and postoperatively was practically plano.

DR. WARING: That was the data postoperative day 1?

[Courtesy of Edward E. Manche, MD]

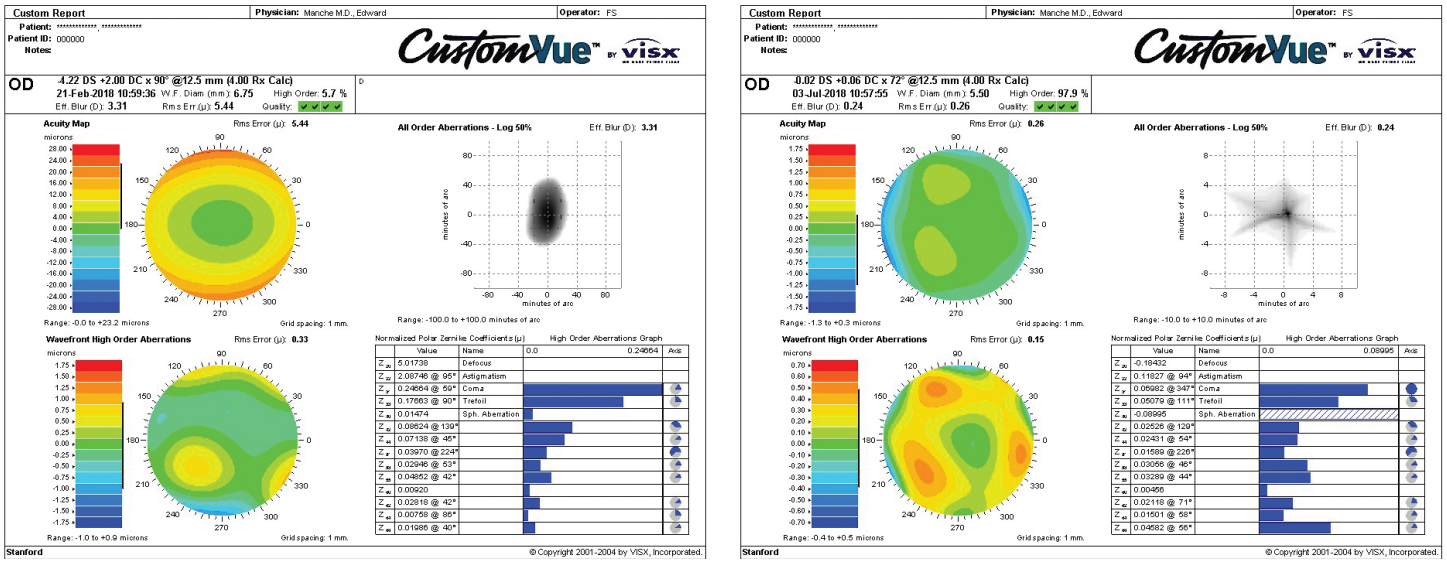


Figure 6. Preoperative (A) and 1-day postoperative (B) wavefronts from a patient who underwent customized LASIK with the iDesign 2.0.

DR. MANCHE: Yes.

DR. WARING: Wonderful!

DR. BLANTON: The level of precision you see in comparing their preoperative numbers to your manifest is phenomenal. I've seen patients who were literally within 0.01 D of my manifest. Of course, you can only get so much on a phoropter, but the data is impressive.

DR. MANCHE: As I told my office staff, the day we get 0.00 D of sphere and 0.00 D of cylinder on the iDesign, we'll have a party.

DR. BLANTON: Your cases were pretty close right there. That's also an important part of what I discuss with my patients. They say, "I have astigmatism?" And I explain that everyone has astigmatism—because we can measure such tiny amounts of it, even as low as 0.01 D of astigmatism. Now, for most people it's not clinically relevant, but everyone has some. Dr. Manche, you don't routinely see numbers that tight, do you?

DR. MANCHE: In my office, we routinely get them.

DR. BLANTON: On day 1?

DR. MANCHE: Yes. We published a paper a couple of years ago that looked at predictability of postoperative day 1 Wavescan aberrometries to final refractive error at postoperative year 1.[7] What we found is that for patients with under -3.00 D of myopia, it is very predictive of the final refraction 12 months postoperatively.

DR. BLANTON: What valuable information!

DR. WARING: Plus, you can celebrate that victory with your patients.

DR. MANCHE: One of the reasons I decided to perform postoperative day 1 aberrometry measurements was to identify over- and undercorrections as soon as possible. This helps me monitor outcomes in real time and allow for early nomogram development and adjustment. With the introduction of new devices and technologies, I want to know right away what I am getting rather than waiting for a month. And also the high cylinders are really accurate. I recently treated a patient with 4.50 D of astigmatism preoperatively, and on postoperative day one, he had 0.60 D of cylinder and at 1 month he was spherical.

DR. BLANTON: I've had some cases that I have presented at meetings and symposia, and I didn't even realize until I looked at the data how close it was to 0, or how close the refraction matched the aberrometry refraction. Your results, Dr. Manche, and the results that I and others on this panel have had, they all reiterate that we are on the right track. The technology that we have available to us today—whether it is wavefront-guided, wavefront-optimized, or topography-guided—the technology is so advanced that it allows us to treat a larger population of patients, including those with myopia, hyperopia, mixed astigmatism, and even presbyopia; and it has improved their chances of achieving not only spectacle independence but also vision that they've never even known was possible. It also provides us with greater confidence in our ability to customize LASIK treatments to new levels. Thank you, Drs. Manche, Teenan, Uceda-Montañés, and Waring, for participating in this roundtable discussion and for sharing with us your insights on modern laser vision correction. ■

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Full Name_____ ❑ MD/DO participant ❑ OD ❑ non-MD participant

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License Number _____ OE Tracker Number _____

DEMOGRAPHIC INFORMATION

Profession
___ MD/DO
___ OD
___ NP
___ Nurse/APN
___ PA
___ Other

Years in Practice
___ >20
___ 11-20
___ 6-10
___ 1-5
___ <1

Patients Seen Per Week (with the disease targeted in this activity)
___ 0
___ 1-15
___ 16-30
___ 31-50
___ 51+

Region
___ Northeast
___ Northwest
___ Midwest
___ Southeast
___ Southwest

Setting
___ Solo Practice
___ Community Hospital
___ Government or VA
___ Group Practice
___ Other
___ I do not actively practice

Models of Care
___ Fee for Service
___ ACO
___ Patient-Centered Medical Home
___ Capitation
___ Bundled Payments
___ Other

LEARNING OBJECTIVES

DID THE PROGRAM MEET THE FOLLOWING EDUCATIONAL OBJECTIVES?	AGREE	NEUTRAL	DISAGREE
Identify the latest clinical studies and the most recent data on postoperative visual acuity after LASIK and the safety of LASIK	_____	_____	_____
Differentiate the latest ablation patterns, including wavefront-guided, topography-guided, and wavefront-optimized	_____	_____	_____
Recognize the benefits of integrating corneal topography measurements into a wavefront-guided excimer laser treatment	_____	_____	_____
Use expanded diagnostics features to plan and customize LASIK treatments based on the individual needs of patients	_____	_____	_____
Apply the various features of excimer laser technologies to deliver a custom LASIK treatment for a wider range of patients	_____	_____	_____

POSTTEST QUESTIONS. PLEASE COMPLETE AT THE CONCLUSION OF THE PROGRAM.

1. BASED ON THIS ACTIVITY, PLEASE RATE YOUR CONFIDENCE IN YOUR ABILITY TO DIFFERENTIATE THE LATEST ABLATION PATTERNS (BASED ON A SCALE OF 1 TO 5, WITH 1 BEING NOT AT ALL CONFIDENT AND 5 BEING EXTREMELY CONFIDENT).

a. 1
b. 2
c. 3
d. 4
e. 5

2. BASED ON THIS ACTIVITY, PLEASE RATE YOUR CONFIDENCE IN YOUR ABILITY TO APPLY FEATURES OF EXCIMER LASER TECHNOLOGIES TO DELIVER A CUSTOM LASIK TREATMENT (BASED ON A SCALE OF 1 TO 5, WITH 1 BEING NOT AT ALL CONFIDENT AND 5 BEING EXTREMELY CONFIDENT).

a. 1
b. 2
c. 3
d. 4
e. 5

3. WHICH COMMERCIALLY APPROVED DEVICE HAS THE WIDEST RANGE OF APPROVED INDICATIONS FOR MYOPIA, HYPEROPIA, AND MIXED ASTIGMATISM.

a. Topography-guided LASIK using Contoura
b. Small incision lenticule extraction using Visumax
c. Wavefront-guided LASIK using iDesign
d. All have comparable approval ranges

4. WHICH TECHNIQUE COMPENSATES FOR THE ENTIRE EYE OPTICAL ABERRATIONS INCLUDING PERIPHERAL CORNEAL CURVATURE?

a. Topography-guided LASIK using Contoura
b. Small incision lenticule extraction using Visumax
c. Wavefront-guided LASIK using iDesign
d. Wavefront-optimized LASIK using the Allegretto

5. iDESIGN REFRACTIVE STUDIO HAS SEVERAL SIGNIFICANT IMPROVEMENTS ON iDESIGN ADVANCED WAVESCAN STUDIO. CHOOSE ALL THAT ARE CORRECT.

a. More efficient workflow
b. Wider treatment range
c. Better treatment planning
d. Improved diagnostic capabilities
e. Five times more wavefront data points

6. IDESIGN REFRACTIVE STUDIO ALLOWS CORRECTION OF THE COSINE EFFECT BY?

a. Using measured topography data
b. Using 1,257 wavefront points
c. Averaging the accurately measured K's value
d. Measuring the average manifest prescription more accurately

7. ALL OF THE FOLLOWING TREATMENTS ARE DERIVED FROM A PHOROPTER REFRACTION EXCEPT:

a. Wavefront-optimized
b. Conventional
c. Wavefront-guided
d. Topography-guided

8. iDESIGN IS APPROVED FOR ALL THE FOLLOWING REFRACTIONS EXCEPT:

a. -6.00 -4.00 x 133°
b. +3.00 -4.00 x 092°
c. +5.00 D of sphere
d. Plano -1.75 x 022°

9. STAFF TRAINING ON EFFICIENT WAVEFRONT ABERROMETRY CAN HELP MINIMIZE ACCOMMODATION DURING WAVEFRONT CAPTURE.

a. True
b. False

10. SURGEONS SHOULD CAREFULLY ACCOUNT FOR ACCOMMODATION WHEN SELECTING A SURGICAL TREATMENT.

a. True
b. False

ACTIVITY EVALUATION/SATISFACTION MEASURES

Your responses to the questions below will help us evaluate this CME activity. They will provide us with evidence that improvements were made in patient care as a result of this activity.

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 _____

This activity improved my competence in managing patients with this disease/condition/symptom ____ Yes ____ No

I plan to make changes to my practice based on this activity? _____ Yes _____ No

Please identify any barriers to change (check all that apply):

____ Cost
____ Lack of consensus or professional guidelines
____ Lack of administrative support
____ Lack of experience
____ Lack of time to assess/counsel patients
____ Lack of opportunity (patients)
____ Reimbursement/insurance issues
____ Lack of resources (equipment)
____ Patient compliance issues
____ No barriers
____ Other. Please specify: _____

The design of the program was effective for the content conveyed. ___ Yes ___ No

The content supported the identified learning objectives. ___ Yes ___ No

The content was free of commercial bias. ___ Yes ___ No

The content was relative to your practice. ___ Yes ___ No

The faculty was effective. ___ Yes ___ No

You were satisfied overall with the activity. ___ Yes ___ No

Would you recommend this program to your colleagues? ___ Yes ___ No

Please check the Core Competencies (as defined by the Accreditation Council for Graduate Medical Education) that were enhanced through your participation in this activity:

____ Patient Care
____ Practice-Based Learning and Improvement
____ Professionalism
____ Medical Knowledge
____ Interpersonal and Communication Skills
____ System-Based Practice

Additional comments:

_____

____ I certify that I have participated in this entire activity.

This information will help evaluate this CME activity; may we contact you by email in 3 months to see if you have made this change? If so, please provide your email address below.

_____