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UNDERSTANDING TECHNOLOGY ADVANCES IN LASER VISION CORRECTION TECHNIQUES

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Understanding Technology Advances in Laser Vision Correction Techniques

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CONTENT SOURCE

This continuing medical education (CME) activity captures content from a roundtable activity held in October 2017.

ACTIVITY DESCRIPTION

Ophthalmologists, optometrists, and other eye care professionals face increasing pressure to remain current in their clinical knowledge, diagnostic skills, and treatment selection due to shifting demographics and increasing numbers of aging patients. These changes are of particular significance in the areas of refractive surgery, where there has been waning consumer interest in elective procedures. In the recent past, the introduction of software improvements on refractive lasers and small-incision lenticule extraction (SMILE) has the possibility of reigniting consumer interest. It is essential that both ophthalmologists and optometrists be up-to-date on the newest technologies to advise patients and to ensure good communication between the patient and other health care providers.

TARGET AUDIENCE

This certified CME activity is designed for anterior segment specialists and general ophthalmologists involved in the management of ocular disorders and diseases.

LEARNING OBJECTIVES

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

- Summarize advantages of laser vision correction surgery for myopic and hyperopic patients
- Evaluate the current treatments for refractive errors, with particular attention to the differences between LASIK and SMILE
- Formulate strategies to manage complex cases (ie, refractive errors, corneal surface irregularities, keratoconus)

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Understanding Technology Advances in Laser Vision Correction Techniques

The options for laser vision correction have never been better or more advanced with wavefront-guided, wavefront-optimized, topography-guided, and small-incision lenticule extraction (SMILE) techniques at our fingertips. The following roundtable will discuss the current state-of-the-art approaches for various platforms and the challenges of SMILE compared to LASIK. We will also discuss real-world therapeutic applications of topography-guided and wavefront-guided treatments of abnormal eyes as well as the role of crosslinking in conjunction with laser vision correction. Finally, we will discuss the overall market in order to understand why laser vision correction is down in many countries despite the fact that our outcomes are better than ever before.

—Steven Dell, MD, moderator

COMPARING THE DATA: WAVEFRONT-GUIDED VS. WAVEFRONT-OPTIMIZED TECHNOLOGIES

Q | STEVEN DELL, MD: What is the current state-of-the-art approach in wavefront-optimized and wavefront-guided treatments? Where are we in terms of best practices and patient satisfaction?

EDWARD E. MANCHE, MD: Both wavefront-guided and wavefront-optimized technologies work extremely well. If you look at published meta-analyses comparing wavefront-guided and wavefront-optimized LASIK surgery, they show similar outcomes.[1] However, some studies show that wavefront-guided has better visual acuity (VA) outcomes, such as 20/16 or 20/12.5.[2] This is irrespective of the platform you are using.

For example, I performed a study comparing wavefront-guided LASIK using the WaveLight Allegretto Wave Eye-Q excimer laser to wavefront-optimized LASIK using the WaveLight Allegretto Wave Eye-Q excimer laser, and found better outcomes with the wavefront-guided platform.[3,4] The percentage of patients achieving 20/12.5 was close between the two systems, at 59% versus 50%, respectively (Figure 1).[3]

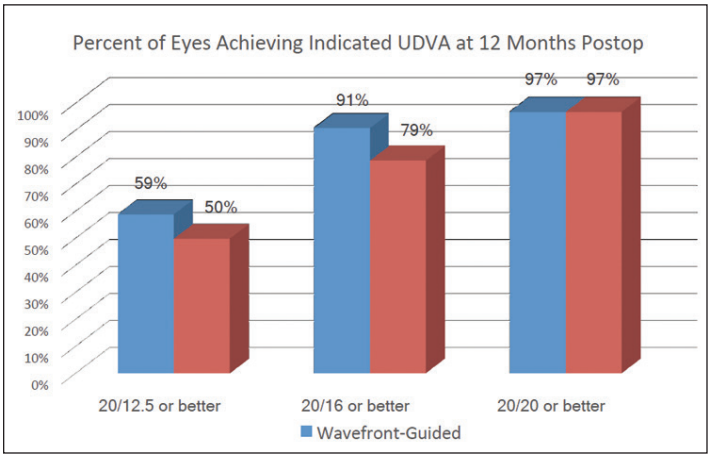

Figure 1. Allegretto wavefront-guided versus Allegretto wavefront-optimized.

I also performed a study using wavefront-guided LASIK on the CustomVue Star S4 IR excimer laser system compared to wavefront-optimized LASIK using the WaveLight Allegretto excimer laser system, and found better outcomes with the wavefront-guided system.[4,5] Fifty-six percent of eyes in the wavefront-guided cohort achieved VA of 20/12.5 as compared to only 41% in the wavefront-optimized system (Figure 2).[4] A study out of Germany by Moussa

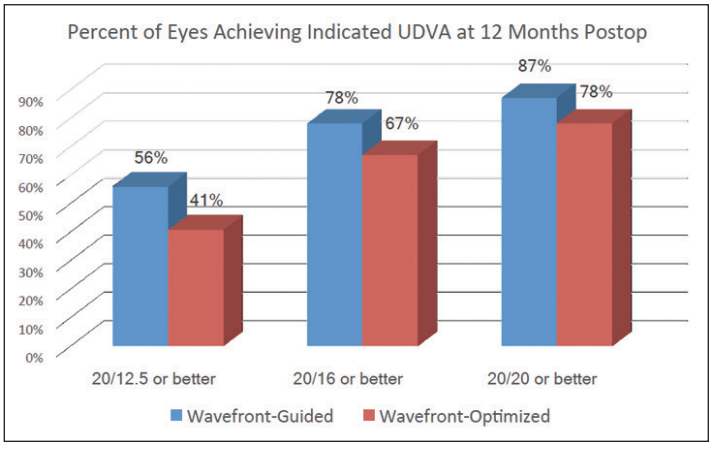

Figure 2. CustomVue wavefront-guided versus Allegretto wavefront-optimized.

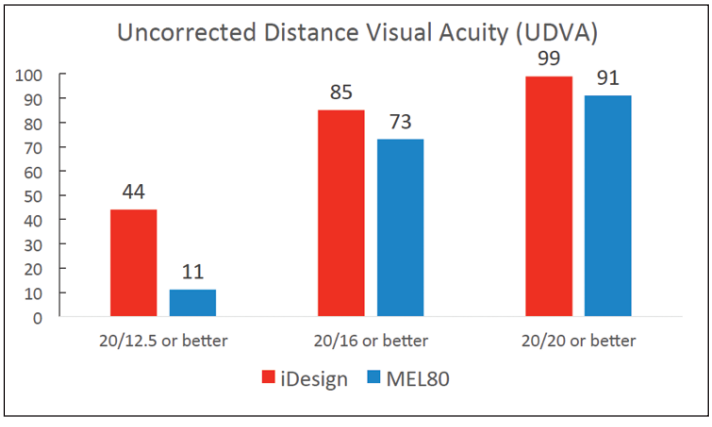

Figure 3. iDesign (wavefront-guided) versus MEL80 (wavefront-optimized).

et al compared wavefront-guided LASIK using the high-resolution iDesign Advanced WaveScan Studio System to the wavefront-optimized LASIK using the MEL80 laser system, and found similar results; wavefront-guided yielded better outcomes compared to wavefront-optimized.[6] The wavefront-guided iDesign achieved 20/12.5 in 44% of eyes, while the MEL80 only achieved this in 11% of eyes (Figure 3).[6]

I also just completed a LASIK study that enrolled 200 eyes of 100 myopic patients that was presented at ESCRS 2017.[7] We randomized each patient to undergo wavefront-guided LASIK in one eye using the iDesign and wavefront-optimized LASIK using the WaveLight Allegretto in the fellow eye. We found nearly the same outcomes up to about 20/20 VA. There were no significant differences in the induction of higher-order aberrations (HOAs) between groups. Both had excellent outcomes and excellent predictability. However, there was one big difference between them: at 20/16, 20/12.5, and 20/10 uncorrected distance VA (UDVA), we found significantly better outcomes using the wavefront-guided technology. In addition, 5% and 25% low contrast VA were better and there were greater gains in lines of corrected distance VA (CDVA) in the wavefront-guided group.

MOHAMED SHAFIK, MD, PHD: Both wavefront-guided and wavefront-optimized technologies are yielding excellent results. However, when we look at VA postoperatively, we find that more than 30% of patients corrected with wavefront-guided technology reach 20/16 or better. In comparison, that number is about 12% using a wavefront-optimized platform.[8] I think that if we are going to offer our patients the highest possible quality procedure, we have to give to them wavefront-guided ablation.

I will switch to wavefront-optimized ablation if I do not have a reliable, dependable map; if the patient has a small pupil; or if I am treating insufficient tear film.

ROBERT MALONEY, MD: Uncorrected vision better than 20/20 is an important driver of patient satisfaction. We know from Steve Schallhorn's work that the percent of patients dissatisfied halves for every additional line of uncorrected vision we achieve (personal communication). Patient satisfaction drives referrals, so it is better for the patient and better for us if we use technologies that result in the best uncorrected vision.

TOPOGRAPHY-GUIDED VS. WAVEFRONT-OPTIMIZED LASIK

Q | DR. DELL: We have clearly seen a number of studies showing subtle, but observable, differences in wavefront-guided versus wavefront-optimized LASIK. But what about topography-guided LASIK? Can it provide the same level as wavefront-optimized in terms of VA of 20/16 and better?

DR. MALONEY: We know from Pablo Artal's work that the lenticular aberrations in normal eyes are significant.[9] We do not yet have a prospective randomized study comparing the two methods. Until we do, my preference is wavefront-guided, which corrects the lenticular aberrations, over topography-guided, which only corrects corneal aberrations. Also, topography-guided is considerably more labor-intensive for the surgeon.

A. JOHN KANELLOPOULOS, MD: Dr. Dell raises a very good question. We have used the topography-guided procedure in the past to treat very irregular eyes. The lessons learned there do not only apply to the specificity and the accuracy of the topography-guided platform to normalize the cornea, but also on the fact that through these procedures we came to realize that the clinical refraction is a performance measurement and not a stable biometric value.

We are taught that the clinical refraction is a biometric, but it is not; it is a performance measurement. Through treating the very regular eyes, we found out that the best way to do this is to first normalize the cornea. The consequence of normalizing the cornea first is that the refraction would change. Clinical refraction is quite distant from the actual refraction we should target. Now extrapolating these principles to what we normally consider as "normal" eyes, we found that many corneas that we have traditionally thought are "normal" are actually functioning as slightly irregular due to angle kappa.

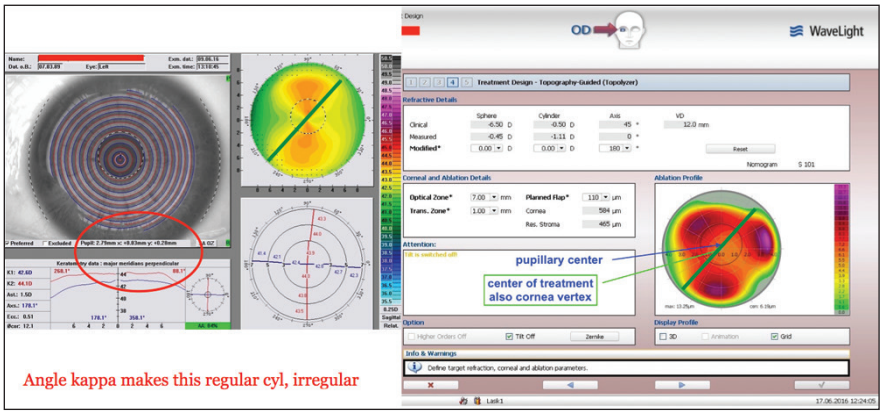

Figure 4. The angle kappa of this patient turns the regular cylinder into an irregular cylinder.

For example, you can have topographically 2.50 D of astigmatism at 90°. The patient refracts with 1.25 D of astigmatism at 75°, plus cylinder, because of significant angle kappa. The angle kappa makes the regular astigmatism function as coma for the patient, and the patients are choosing virtual cylinder to compensate for that coma within their clinical refraction. This confounds the refraction that we are getting clinically. The key takeaway here is if you do topography-guided procedure, you are correcting that coma (Figure 4).

We have been working for several years now on a new concept we introduced as topography-modified refraction (TMR), in which we incorporate data from the diagnostics that we use for topography-guided.[10] This is a big leap for refractive surgery because the gold standard until now has been clinical refraction. For example, if I have a 26-year-old with -6.00, 0.50 D of astigmatism and topographically that patient has 2.50 D of astigmatism, I am compelled

to treat more cylinder. We have found that the clinical data are superior to wavefront-optimized and wavefront-guided, in our hands.[10] So in essence, we modify the clinical refraction cylinder amount and axis based on the measured data from the topographer and then adjust the spherical equivalent accordingly (If our TMR calls to increase cylinder, we reduce the myopic sphere accordingly, if TMR calls for reduction of the clinical refraction cylinder, then we increase the sphere accordingly). The cylinder is always treated on the topography-suggested axis!

DR. DELL: How does the pupillary aperture impact the refraction?

DR. KANELLOPOULOS: Pupillary aperture and centroid shift after laser vision correction may change the visual axis. It is difficult to make sense of all these variables, but the core variable in regard to refractive astigmatism seems to be determined by the cornea. We have learned this from cataract surgery, and the same thing should hold true in corneal refractive surgery as well. It is very hard to believe that there is permanent, stable, lenticular astigmatism in any normal human eye.

DR. DELL: So you attribute the disparity between refractive and topographic astigmatism to changes in the posterior corneal curvature?

DR. KANELLOPOULOS: That could be part of it, but it could also be accommodative lens-based cylinder. Our data suggest that the majority of this difference derives from the fact that, in corneas that we traditionally consider normal and regular, patients are not seeing through the center of that cornea. If the angle kappa is more than 100 µm (in either/or the x or y axis), which is very common, then that regular astigmatism acts as an irregular lens for that patient, giving them prism and coma.

This is fine if you are doing wavefront-optimized because the bias from the clinical refraction is carried on to the wavefront-optimized procedure. But if you are performing a topography-guided procedure, by default, the topography will normalize that cornea in regard to the corneal vertex, which will change the refraction data. You have to take that into account if you do topography-guided and wavefront-guided for that same reason; on an eye that has angle kappa, the cornea shape will change and, thus, the refraction will change for that patient. Therefore, by preempting what the refraction will be in the end, you may get at least one or two lines of better correction, which is very beneficial. Nearly 59.1% of our patients improved to best corrected VA of 20/16 when we use TMR.[10]

DR. DELL: These are excellent results, based upon highly individualized and careful analysis. This clearly takes a lot of time and effort. How can the average ophthalmologist replicate this?

DR. KANELLOPOULOS: Wavefront-optimized LASIK today is brilliant and achieves solid results. This makes it difficult to argue in favor of a technology that makes it even better. Employing topography-guided treatments and TMR in virgin eyes requires mutual commitment by the clinician and the patient, alike, in order to justify the extra work and expense to achieve these results.

LASIK VS. SMILE

Q | DR. DELL: What state-of-the-art treatment do you offer a patient who comes to your clinic with presumably normal eyes?

GUSTAVO E. TAMAYO, MD: Any type of treatment will be effective in patients with normal corneas, low myopia, and without astigmatism. However, when it comes to complicated cases, most ophthalmologists will get better outcomes with wavefront-guided. It can be very difficult to determine the refraction in a patient with irregular corneas, and wavefront-guided systems take that out of the equation.

DR. KANELLOPOULOS: I think wavefront-guided is brilliant, and I agree with Dr. Tamayo's comments. But wavefront addresses only the central 6 mm of the cornea in regard to corneal aberrations. Normalizing the total cornea for that patient will not only address laser-vision correction but also any future need, such as using a premium lens later on. You have to look at it as an intervention for the lifetime of the patient.

DR. MALONEY: I am hesitant to recommend SMILE, because the published results are significantly inferior to modern LASIK, regardless of the platform one uses for LASIK. The largest study of SMILE published to date[11] found only 83% of eyes achieved 20/25 vision. In contrast, with LASIK 90% to 95% of eyes get 20/20 vision. However, SMILE is still early in its development, and we may see it catch up to LASIK over time.

DR. DELL: Where does SMILE, in its current form, fit into the discussion of tailoring the ablation pattern based on topography?

DR. MANCHE: SMILE was approved in the United States in 2016,[12] and I have been using it for about 6 months now. SMILE surgery works quite well. SMILE uses the VisuMax femtosecond laser to create an intrastromal refractive change in the cornea. Most studies have shown that SMILE and LASIK surgery yield comparable refractive outcomes.[13-16] There are a number of limitations in the United States compared to its use in Europe. We cannot treat cylinder in the United States; we can only treat spherical myopia.

SMILE has performed well in the patients I have treated, although it is different than LASIK. LASIK is a two-step procedure that uses two different lasers to alter the curvature of the cornea: a femtosecond laser, which creates the flap, and an excimer laser, which ablates the tissue. SMILE is a flapless procedure in which an intrastromal lenticule is created between two photodisruption planes and removed mechanically from an arcuate side cut of 2 mm to 5 mm.[14] It uses a femtosecond laser only; an excimer laser is not needed. The postoperative regimen for SMILE is similar to LASIK, and includes steroids and antibiotic drops for 1 week, with routine follow-up care for 6 to 12 months.

CASE STUDY 1: REFRACTIVE SURGERY IN A POST-CXL PATIENT

By Mohamed Shafik, MD, PhD

In this case, a 24-year-old woman with grade 2 keratoconus had undergone corneal crosslinking (CXL) 13 months previously. She presented with a stable, but irregular, cornea. Uncorrected visual acuity was 0.05, her manifest refraction was +0.75 -4.00 x 110. Her best corrected visual acuity was 0.3, and her central corneal thickness was 453 µm. Figure 1 shows the preoperative Pentacam bilateral images.

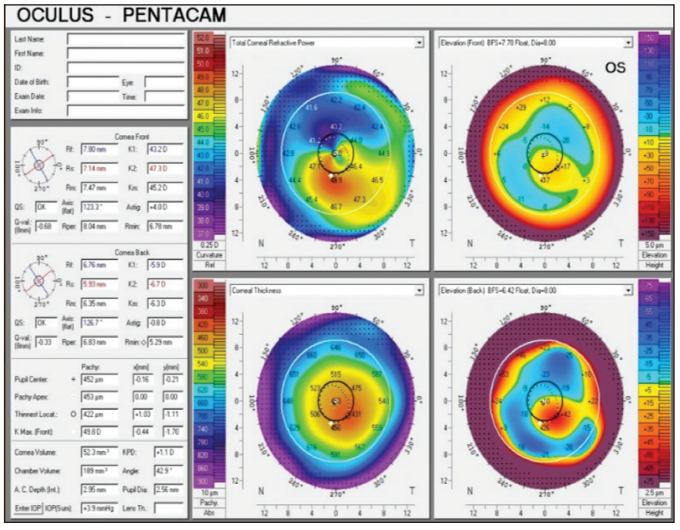

Figure 1. Preoperative Pentacam bilateral images.

I used the iDesign Advanced WaveScan Studio System MAP to create a customized ablation profile for this patient. Figure 2 shows the preoperative iDesign MAP. The arrow points to the exuberant coma that degrades the visual quality of the patient and that could only be properly treated by a wavefront-guided laser vision correction.

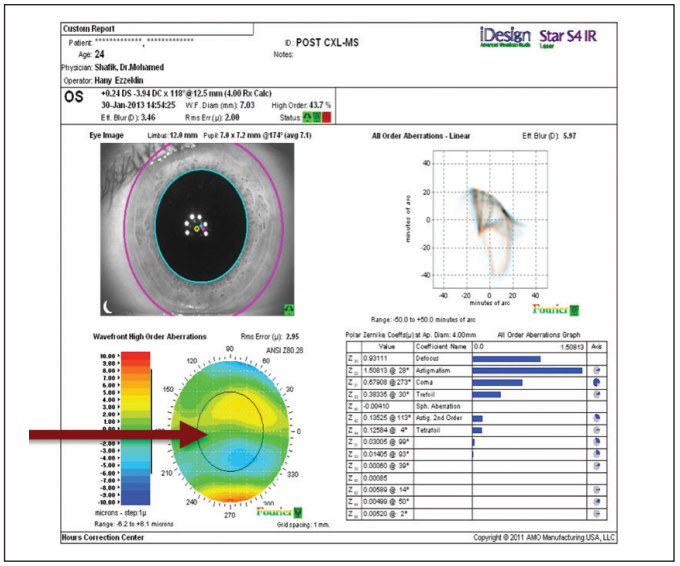

Figure 2. Preoperative iDesign MAP.

The iDesign system allows for the ablation profile design to be superimposed over the irregular cornea. Surgery is straightforward at that point. Figure 3 compares the preoperative and postoperative Pentacam images—there is substantially less steepening postoperatively, and the eye has fewer aberrations.

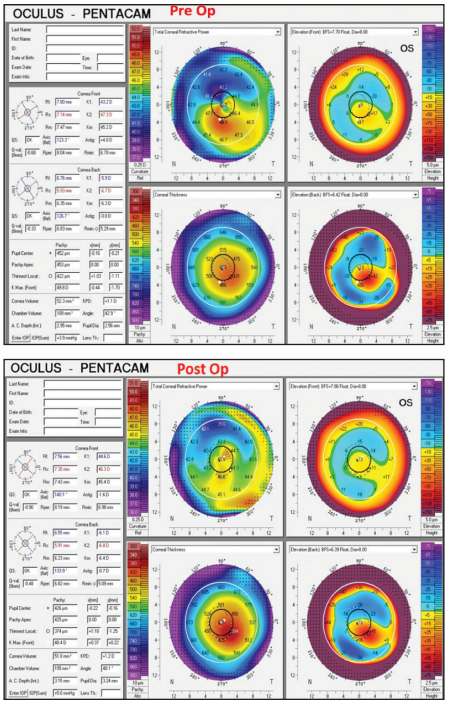

Figure 3. Preoperative versus postoperative Pentacam imaging.

The ablated tissue thickness was 47 µm. Three months postoperatively, the patient's manifest refraction had improved to -0.25 -1.00 x 155. There was a very significant improvement in corneal irregularity indices and aberrations. Her uncorrected visual acuity improved to 0.7, and her corrected distance visual acuity improved from 0.3 to 1.0. At 1 year postoperatively, she remains stable. Figure 4 shows the last reading we have with the iDesign. In my hands, these types of outcomes are why I choose to use the iDesign in these complicated cases.

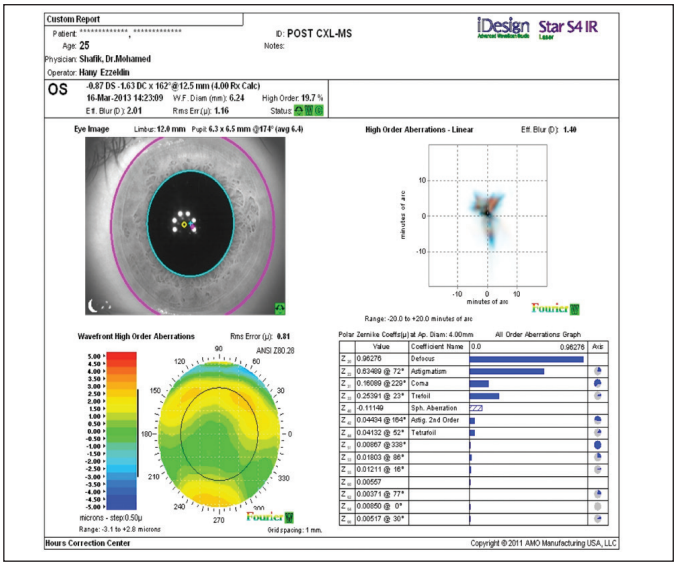

Figure 4. iDesign outcomes, 1 year postoperatively.

The advantage of LASIK is that surgery is painless and the majority of patients see extremely well on the first postoperative day. With SMILE, the surgery is also painless, but the patients do not see as crisply on postoperative day 1. Most patients' vision will not be as good with SMILE as compared to LASIK in the early postoperative period. Most SMILE patients describe their postoperative day 1 vision as "slightly blurry or hazy." It takes anywhere from several days to several weeks for the patients' uncorrected vision to catch up to where patients are with LASIK. However, it is not like PRK where the patient has pain and poor vision, which causes them to take time off work. SMILE patients typically can return to work on postoperative day 1 and continue on with their lives, but they do not have the immediate crisp vision as with LASIK. It is very important to explain the slower recovery to SMILE patients and minimize their expectations of excellent immediate postoperative vision.

At the same time, there are certain advantages to SMILE. Almost all published reports show that there is decreased denervation of the cornea, and some of the reports have shown that this does translate into less dry eye in the early postoperative period.[13-17] And there are a couple papers that were published that showed improved tear break-up time, tear osmolarity, and pain scores with SMILE.[18] SMILE also has some theoretical biomechanical advantages. The lamellar cut with SMILE may not induce as much weakening of the cornea compared to LASIK, so there is potentially better biomechanical stability.

Both technologies are excellent and provide patients with outstanding outcomes and exceptional safety. SMILE is somewhat in its infancy. I believe that SMILE surgery will continue to be refined and improved, and it will withstand the test of time.

DR. SHAFIK: I think SMILE is here to stay. However, it does have weaknesses.

The first is quality of vision. My colleague and I recently published data comparing SMILE with the wavefront-guided ablation in lower-order myopia.[15] This was a prospective, comparative study enrolling 110 eyes with low and moderate myopia. The wavefront-guided LASIK group included 51 eyes (51 patients) undergoing wavefront-guided LASIK using the STAR S4IR excimer laser and the iDesign aberrometer. The SMILE group included 59 eyes (59 patients) undergoing SMILE with the VisuMax platform. We were able to reach 20/20 vision in 100% of wavefront-guided patients, but only 75% of patients with SMILE. Furthermore, many patients are still complaining about night vision 3 months postoperatively. We concluded that SMILE and wavefront-guided LASIK are efficacious and safe procedures for the correction of low and moderate myopia, but the wavefront-guided approach allows for more predictable outcomes and better aberrometric control.

The second issue is the undercorrection of astigmatism. We have published data with a vector analysis for astigmatism comparing wavefront-guided LASIK and SMILE.[19] The study evaluated 107 eyes (55 patients); 52 eyes had wavefront-guided LASIK and 55 eyes had SMILE. No statistically significant differences were found in the 6-month postoperative sphere between the two groups ($P = 0.652$), but the postoperative manifest cylinder and spherical equivalent were significantly lower in the wavefront-guided LASIK group ($P < 0.001$). The 6-month postoperative cylinder was 0.50 D or less in all eyes in the wavefront-guided LASIK group and in 79.8% in the SMILE group ($P < 0.001$). Vector analysis showed a significantly higher difference vector ($P < 0.001$) and angle of error ($P = 0.021$) and a significantly lower correction index ($P = 0.001$) in the SMILE. The mean magnitude of error was −0.07 ± 0.20 (SD) and −0.20 ± 0.35 in the wavefront-guided LASIK group and SMILE group, respectively ($P = 0.012$). This study showed that astigmatism correction is a big issue because we still have an undercorrection with astigmatism in SMILE. We do not have proper centration or cyclotorsion compensation. The ablation profile itself is not that advanced.

The third issue is the supposed biomechanical superiority of SMILE and the development of ectasia. The biomechanical superiority of SMILE is based on a number of studies including a finite-element analysis by Roberts et al.[20] But when it comes to the clinical practice itself, there was no statistically significant difference in the biomechanical behavior of the eyes after SMILE and LASIK, and a number of studies have illustrated the development of ectasia after SMILE.[21-24] These cases illustrate the importance of a thorough preoperative assessment for possible keratoconus to avoid postoperative ectasia after SMILE. We have to apply the same contraindications and conclusions in SMILE that we apply in LASIK. We should not be overconfident of its supposed biomechanical superiority.

The fourth issue is dry eye. It is very difficult to evaluate patients for dry eye after refractive surgery. We have enhanced many patients who we diagnosed with dry eye. Yes, it is true that we cut less nerves with SMILE, and that it should theoretically translate into less dry eye postoperatively compared with LASIK.[25-27] Nevertheless, the majority of the clinical works prove that after 6 months, we have the same results regarding the quality of the tear film and its impact on vision.[17,26,28]

The fifth point is complications. With SMILE there are no flap-related complications, but we have a new set of complications such as the Bowman membrane roughness, the increase of the postoperative light backscatter values, and others related to the technology, such as suction loss.[29-33]

Lastly, re-treatment is a concern with SMILE. There is no single, evidence-based data on the correct way to do a re-treatment in cases of undercorrection or overcorrection. With LASIK and PRK, we do not consider under or overcorrection a complication because you can simply lift the flap and re-treat. But with SMILE, re-treatment for undercorrection is a big issue because you can weaken the cornea. Biomechanical stability is crucial. If you have an overcorrection, you have a big problem because you cannot treat those cases with SMILE.

These points lead me to be a bit conservative with SMILE use. We have to be clear on the indications and guidelines with our SMILE patients.

DR. KANELLOPOULOS: Over the past 2 years, we have had the opportunity to perform SMILE. There is no question that a smaller incision has many advantages compared to the larger one involved in LASIK. There is less exposure of cornea and stroma to environmental

"[LASIK and SMILE] are excellent and provide patients with outstanding outcomes and exceptional safety. SMILE is somewhat in its infancy. I believe that SMILE surgery will continue to be refined and improved, and it will withstand the test of time."

—Edward E. Manche, MD

factors, and because the procedure is performed under suction and globe stabilization, there is less active tracking and cyclorotation compensation. We did a study comparing contralateral eye treatments between SMILE and topography-guided LASIK.[16] The study included 44 eyes of 22 patients with bilateral myopia or myopic astigmatism. Treated eyes were divided into two groups: 22 eyes were randomized to treatment with topography-guided LASIK, and the fellow eye of each patient was treated with SMILE. Three months postoperatively, we evaluated UDVA, CDVA, refractive error, corneal keratometry, contrast sensitivity, and Objective Scatter Index. LASIK was superior to SMILE in UDVA; 86.4% of patients in the LASIK group and 68.2% of patients in the SMILE group had UDVA of 20/20 ($P < 0.002$) and 59.1% and 31.8%, respectively, had UDVA of 20/16 ($P < 0.002$). Spherical equivalent refraction (+/-0.50 D) was 95.5% for the LASIK group and 77.3% for the SMILE group ($P < 0.002$). Residual refraction cylinder (</= 0.25 D) was 81.8% for the LASIK group and 50% for the SMILE group ($P < 0.001$). Contrast sensitivity (6 cycles/degrees) was 7.2 +/- 1.01 in the LASIK group and 6.20 +/- 1.52 in the SMILE group. Objective Scatter Index measurements at 3 months were 1.35 in the LASIK group and 1.42 in the SMILE group.[16]

We found that the main difference between the two techniques likely derives from the eye tracking, cyclorotation compensation, and active centration control in the LASIK technology studied in contrast to the current technology available with SMILE-like procedures. The advantage of SMILE, when tracking and cyclorotation adjustment is available, is that it may be only needed when the patient interface engages and fixates the cornea. The excimer laser, however, needs these two principles active and dynamic throughout the procedure as the eye can move freely, and these movements include saccadic. Saccadic movements in SMILE are negligible as the eye is engaged throughout the "sculpting" part of procedure. I think that is very impressive for a procedure that has only started to catch up on as a mainstay treatment in the last 2 years.

The minor problems that we saw in SMILE when compared to topography-guided, TMR-adjusted LASIK were mainly in astigmatic correction. If you are not able to cyclorotate and center the treatment to the corneal vertex consistently and accurately, you will have less astigmatism correction. If you want to normalize the cornea to the vertex of that cornea and do TMR, it is impossible to do that with the current version of SMILE. But it is unfair to compare a procedure like SMILE, which is in its infancy, with a procedure that has been tried over and over again like LASIK. We have seen generations and generations of excimer lasers and femtosecond lasers addressing these issues.

SMILE will have a place in refractive surgery, probably for myopic patients in the range of -3.00 D to -7.00 D. But I do not think it competes with the technology we have available for LASIK today.

THE ROLE OF CXL IN IRREGULAR CORNEAS

Q | DR. DELL: How do you approach an eye that has had previous refractive surgery or forme fruste keratoconus?

DR. TAMAYO: Before wavefront was advanced enough to measure those irregular corneas, I was in favor of topography-guided ablation. Topography-guided regularizes the cornea, but then changes the refraction completely. Today, I believe the solution for these corneas is to combine topography-guided with wavefront-guided ablation.

My approach is simple. Whenever an irregular cornea is measured by wavefront-guided, I will proceed with wavefront-guided ablation. I take into account the thickness of the cornea and the stability of biomechanical properties. When the cornea is measured, I then tell the patient that they may end up having two procedures: first, the regularization of the cornea with topography-guided ablation, and second, declaration of the visual refractive error that they may end up having.

DR. DELL: How does the hybrid solution wavefront-guided system work for treating irregular corneas?

DR. TAMAYO: The hybrid solution wavefront-guided ablation allows me to see much more and treat much more irregular corneas compared to the wavefront system we had before.

DR. DELL: Are there adjustments that you find you need to make on the diopter correction or general trends you have noticed?

DR. TAMAYO: There are several factors that influence the final result. For example, I use crosslinking (CXL) quite a bit in patients with irregular corneas. CXL applanates the cornea, so the hyperopic shift must be taken into account. Second, we may be treating corneas that are thinner than normal, meaning the effect of the treatment may be greater than in a thicker cornea. You may have to decrease the number of diopters you want to treat. Finally, you must proceed with caution when it comes to the number of microns you can take from irregular corneas.

DR. DELL: Do you look at the ablation depth and then compare that to the spherical equivalent to see if it makes sense in a highly irregular cornea? Do you anticipate that there will be more tissue removal?

CASE STUDY 2: TREATING IRREGULAR ASTIGMATISM

By Gustavo E. Tamayo, MD

This study illustrates the case of an 18-year-old who presented with irregular astigmatism as a result of keratoconus. You can see from the Pentacam images in Figure 1A just how irregular the astigmatism is, but also how nicely using a customized iDesign Advanced WaveScan Studio System treatment flattened out the cornea (Figure 1B); the images in Figure 1B were taken 2 years postoperatively. The posterior and anterior elevations are high and the inferior curvature is greater than the superior. You see that corrected in Figure 1B.

For me, the images are even more striking when analyzed on the iDesign. Figure 2 shows the right eye, preoperatively and postoperatively. This patient presented with a manifest refraction of -2.25 -5.02 x 36, and the irregular astigmatism beautifully illustrated. Figure 2B is at 2 years postoperatively, where the patient now has an RMS error of 0.68 µm and a manifest refraction of +0/15 -1.31 x 47. Plus, you can see how virtually all the higher-order aberrations were resolved.

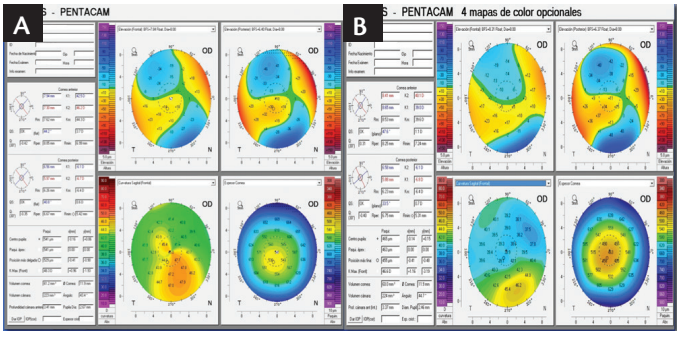

Figure 1. An example of keratoconic eyes preoperatively (A) and 2 years postoperatively (B).

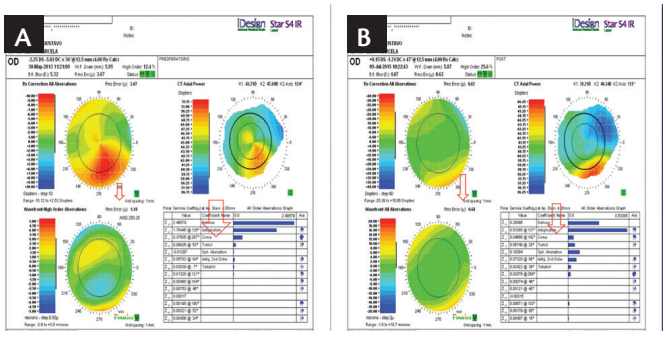

Figure 2. Same patient preoperatively (A) and postoperatively (B), using the iDesign.

DR. TAMAYO: It is very important to see the amount of tissue you are going to remove and then adjust around it. I see many cases in which the astigmatism has to be decreased, for instance, in order not to remove a large amount of tissue in a thin cornea. There is no magic number to the amount of microns you can take from the cornea. The further you are from the 350 µm left on the cornea after your treatment, the better.

DR. SHAFIK: I have used the iDesign System on irregular corneas in early and moderate keratoconic eyes after CXL. The wavefront ablation profile allows you to address emmetropia at the same time because you can tailor your treatment to address the sphere and cylinder measured in a subjective way. After corneal CXL, we might face some almost emmetropic corneas, but it is the HOAs in the form of coma that we want to address correctly. The second pathology I address is the corneal irregularity after radial keratotomy. The third is the post-LASIK irregularity, eg, eccentric ablation. I now do a sequential wavefront-guided PRK for crosslinked, keratoconic eyes. I wait a year after the CXL until the cornea is stabilized, and then I start to read the cornea with the iDesign System to get real-life, dependable maps. (See the Case Study 1).

DR. KANELLOPOULOS: I see irregular corneas being in two categories: ones where the anterior cornea surface is irregular but the posterior is regular, and ones where both surfaces of the cornea are irregular. The presence of cornea transparency is a variable that makes things even more difficult.

I think topography-guided and wavefront-guided LASIK are very efficient in giving us results for corneas with anterior surface changes and no opacity. Wavefront has the advantage of attaining better emmetropia, but it is limited to mild irregularities. In the calculations that I have seen, wavefront is more tissue-hungry, and there are many limitations on the number of treatments that you can do. Furthermore, it is very difficult to treat very irregular corneas with wavefront, even with the iDesign System.

For corneas that have irregular anterior and posterior surfaces, such as in keratoconus, we can only intervene and potentially improve the surface/anterior of the cornea. Residual posterior irregularity will limit the visual benefit (such as in oblique keratoconus treatments).

Cornea scarring confounds things and limits us to topography-guided LASIK, because the wavefront methods cannot be applied in these cases.

DR. MANCHE: From a refractive standpoint, it makes sense to do CXL first, allow 6 to 12 months for stabilization, and then perform topography- or wavefront-guided treatment second. But from a corneal strength standpoint, it makes more sense to treat first with topography- or wavefront-guided LASIK, and do CXL second. Does anyone have a strong opinion on which approach is preferred?

DR. KANELLOPOULOS: I think that both ways are valid. It really depends on the individual surgeon and their comfort level. When we

compare the sequential CXL first followed by normalizing the cornea 6 months later to doing both procedures at the same time, there was a synergistic effect to the amount of flattening when you use both procedures simultaneously. The disadvantage to doing them simultaneously is that the refractive effect of the CXL procedure is unknown. I think the jury is still out on which way to go, but I do a simultaneous procedure. However, I want to clarify that this is a therapeutic procedure, and the goal of the laser intervention is to normalize the cornea. This cannot be viewed as PRK combined with CXL.

DR. MALONEY: Dr. Kanellopoulos has done very nice work on the combination procedure. It is worth noting that these are advanced techniques, and these corneas should be approached cautiously. It is not worth performing CXL, which can rarely produce corneal haze or a persistent epithelial defect in order to prevent a rare complication, ectasia, after LASIK. CXL should be reserved for those eyes whose risk of ectasia is on the order of one in a hundred or higher.

DR. DELL: These patients are extremely difficult to manage in the postoperative period. They can be difficult to re-epithelialize, which can have its own set of hazardous consequences. What are your pearls for managing these patients?

DR. KANELLOPOULOS: These patients need to be monitored by the surgeon because they can end up with significant scarring. One intervention we have tried over the years is giving patients platelet-rich plasma as part of their postoperative regimen. But, ultimately, it is very difficult to image and nomogram an eye that has been crosslinked because it appears that they do not laser in a nomogram that we are familiar with. It is counterintuitive to remove some of the most biomechanically stable cornea you have created with CXL, because CXL is not uniform throughout the whole cornea. It is more intense in the superior lamellar or the exterior lamellar and then less in the inner lamellar.

DR. MANCHE: When you do the simultaneous procedure, do you also use mitomycin-C (MMC)?

DR. KANELLOPOULOS: Yes, I do. I specifically use 0.02% solution for 20". I am familiar with colleagues internationally that do not. I have found that using MMC helps prevent PRK-related scarring.

DR. MANCHE: Corneal CXL causes apoptosis. Excimer laser ablation causes apoptosis. When you perform excimer laser ablation at the same time combined with adjunct MMC, you risk creating a perfect storm. I have seen patients who have had trouble re-epithelializing and who have had very tumultuous recoveries after simultaneous PRK/CXL/MMC treatments. Some of these patients have fluctuating vision months or years later. We have to take great caution when combining three modalities in an eye with questionable corneal topography.

DR. TAMAYO: I use MMC in all my cases at the end, which I have found to be extremely important. If you use MMC right after the treatment, but before the CXL, you increase the risk of having a funny epithelial growth. My advice is if you do a simultaneous procedure, you should use MMC at the end, once the accelerated CXL is complete.

DR. KANELLOPOULOS: When considering what and how much of the refractive error to treat my experience dictates that we should not automatically think that we have to treat myopia and myopic astigmatism. We are trying to normalize the cornea and improve CDVA. In some cases the actual refractive error may increase postoperatively, but with a much improved CDVA, dramatically improving visual function and potentially paving the way for a soft contact lens or even phakic IOL, or clear lens extraction as a final refractive adjunct procedure.

LASER VISION CORRECTION ENHANCEMENTS

Q | **DR. DELL:** Some patients with normal corneas who have undergone cataract surgery or refractive lens exchange need an enhancement with laser vision correction. There is a spectrum of IOL types we can use, from diffractive multifocals, to segmental bifocals, to extended-depth-of-focus lenses. How does laser vision correction fit in? What is our standard for treating a patient who has a small amount of refractive error?

DR. KANELLOPOULOS: I have a strong opinion on this. To me, this is the only time where you should avoid using a topography-guided approach. Once you have an artificial lens in the eye, there may be lenticular tilt present, lenticular astigmatism, and optical decentration (of the IOL in regard to the line of sight) that current topography-guided methods cannot address. Wavefront-guided or wavefront-optimized would be a better approach, in my opinion, in these eyes.

DR. TAMAYO: I tend to divide my treatments into two groups: patients with an IOL that corrects to 20/20 and patients with an IOL that does not correct to 20/20. I have seen many multifocal lenses that are inserted in patients with irregular corneas, which is a bad thing to start with. Once a patient has an IOL on a cornea that is irregular, then you will not be able to correct to 20/20 vision. I have found wavefront-guided to be an excellent option in those cases.

DR. MANCHE: If you look at the literature, there is no real difference in outcomes, whether you use wavefront-guided, wavefront-optimized, or conventional treatments. Some people are nervous if they have a multifocal lens. They worry that they will get an unsatisfactory outcome if they do wavefront in those cases. But that does not appear to be the case and, in my experience, wavefront-guided and wavefront-optimized do equally well regardless of the IOL type.

DR. MALONEY: I routinely correct small refractive errors with LASIK in patients after IOL surgery. I generally do not use wavefront-guided treatment because the IOLs are often not perfectly centered on the

pupil, and the optical quality of the cornea is not as good as it is in younger patients.

DR. DELL: I think there are some caveats. For example, the wavefront aberrometer will measure and try to correct the zones of a zonal multifocal IOL like the ReZoom or a segmental bifocal IOL like the MPlus. Furthermore, you have to really look at the wavefront refraction that is generated when measuring a patient with a Tecnis Symfony IOL.

DR. MANCHE: I agree; you do have to be careful with zonal multifocal IOLs. If the wavefront aberrometer picks up on the wrong zone and indicates the eye is -4.00 D when their uncorrected VA is 20/30, there is clearly something wrong. You need to make sure that the aberrometry and manifest refraction are consistent before treating with wavefront-guided ablations.

DR. SHAFIK: In those cases, I spend some time contemplating whether the real problem will be fixed with laser vision correction or simply by explanting the lens and changing it. Sometimes it is related to the lens itself or even to the personality of the patient. I have had many cases where I had to explant the lens because, although I was very satisfied with the outcome, the patient was not.

DR. DELL: That is a good point. If the patient's complaints are not abolished by spectacle correction or a contact lens trial, then you are wasting your time trying to perform laser vision correction. When patients are unhappy with an IOL, they do not have one chief complaint, they have 14 complaints. The refractive error is just one of many issues. Therefore, you have to quickly identify whether elimination of that problem alone will solve enough of the other problems.

THE LASER VISION CORRECTION MARKET

Q | DR. DELL: Overall market growth of laser vision correction is down throughout the world. Why do you think that is? What can we do to make the market grow?

DR. KANELLOPOULOS: The AAO and International Society of Refractive Surgery has looked into this and found through survey data that laser vision correction volume is consistently down.[34] It is still an enigma for many of us, both on the clinical standpoint and also on the demographic standpoint. For example, more than 50 million people wear contact lenses in the United States.[35] Each year, about 5 million drop out of that pool, but 5 million more come in. Those new 5 million people are, to me, the ideal patients for laser vision correction. Yet only a tiny fraction of that pool actually has laser vision correction today.

Laser vision correction is more efficient and accurate than ever before. So it is very puzzling to try to interpret why the market growth is down when the technology is actually better. Maybe it is because we are dealing with a different generation of patients. Maybe the procedure was too commercially exploited for a period of time, and now there is a negative impression of laser vision correction from a few (but significant) outliers. Maybe the refractive goals of patients have changed, because they spend so much time on their smartphones and tablets. Maybe they value more intermediate vision than distance and near. But I have a hard time understanding that in 2018, a fed-up contact lens user will not choose to have laser vision correction.

"What can we do to make the market grow?"

—Steven Dell, MD

DR. DELL: How have the economic forces affected the market in Greece, for example?

DR. KANELLOPOULOS: Well, the market overall has been affected. In times of economic crisis, people are more selective and educated about elective procedures, which drives overall numbers down. But the positive side to that is the patients who do choose to have laser vision correction become more informed and educated, and they have specific goals in mind with what they want the procedure to achieve.

DR. DELL: One argument I have heard is that the market for laser vision correction will not grow until we have a dramatic, revolutionary advance in the field. Currently, we have multiple platforms that can achieve outcomes of 20/20 or better in 94% of patients.[3-5] If that number became 98% of patients achieving 20/20 or better, would that change anything?

DR. SHAFIK: No, I do not think it would, and this is why. In my country, Egypt, we have treated most laser vision correction candidates between 18 and 40 years old. The implantable collamer lens is a serious competitor to laser vision correction in patients under 40. I also think the implantable collamer lens is preferable to laser vision correction in this population. I think the market is down because of this competition. The price of laser vision correction is also an issue. Many centers have high overhead expenses, and they actually lowered the price of laser vision correction to accommodate more patients. The result was bankruptcy. They were not charging enough for the procedure, and they could not pay for the equipment. In order to drive the market back up, we have to target patients with presbyopia over age 40. They are a large population and may be willing to pay more for laser vision correction.

DR. MANCHE: It is interesting to note the differences between Egypt and the United States. Dr. Shafik, you may have worked your way through every available candidate in Egypt, but that is not the

case in the United States. I would say significantly less than half of the eligible patients between 18 and 40 years of age have chosen to have laser vision correction. In the United States, the demographics are in our favor. Millennials are coming of age, and more and more of them are having laser vision correction. Millennials are also a larger group than Baby Boomers by nearly 10 million (83.1 million vs. 75.4 million, respectively).[36] Anecdotally, I would say the average age of my patients has dropped by about 5 years over the last decade. I see many patients in their mid- to late 20s, when before it was patients in their mid- to late 30s with more of the disposable income. Hopefully we are catching the early wave, and it is going to propagate itself.

DR. TAMAYO: I also think it is strange that the overall numbers have dropped when we have such fast, accurate, predictable procedures with excellent results. It may be due to bad publicity. Many physicians do not take laser vision correction seriously. They jump into it before they are ready or qualified to make up for the loss of cataract patients. The bad publicity comes from the doctors who do not learn how to perform the procedure properly. You must invest money, equipment, and time to attend meetings and learn proper technique. It is not an easy endeavor. There are some patients who are not candidates for laser vision correction, and we need physicians who know not to treat them.

I think that physician education is the first thing that we should address so we do not have undereducated physicians performing surgeries. It does happen; I see it all the time. So, no, I do not believe the solution is a fancy new technology or even better outcomes. We need to go back to the fundamentals and teach physicians what an excimer laser is, what the correction means, how a correction is produced—basic concepts. Increasing our physician education will create better results throughout the community and, perhaps, a better reputation for the procedure as a whole.

DR. DELL: It is supremely ironic that the era of highest treatment volumes with laser vision correction came when we were using the most primitive technology compared with what we have today. Not only are we able to achieve much better results than in the mid-1990s, but today we have the ability to correct some of the problems created by obsolete technology. I think this is something we are all wrestling with and will continue to wrestle with.

I want to thank all of our participants for a highly informative session. I learned a lot, and I think this will be a valuable resource for our colleagues. ■

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UNDERSTANDING TECHNOLOGY ADVANCES IN LASER VISION CORRECTION TECHNIQUES

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___ NP
___ Nurse/APN
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___ Other

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___ >20
___ 11-20
___ 6-10
___ 1-5
___ <1

Patients Seen Per Week (with the disease targeted in this activity)
___ 0
___ 1-5
___ 6-10
___ 11-15
___ 15-20
___ 20+

Region
___ Northeast
___ Northwest
___ Mid-West
___ 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

Training of Fellows ___ Yes ___ No

LEARNING OBJECTIVES

DID THE PROGRAM MEET THE FOLLOWING EDUCATIONAL OBJECTIVES?	AGREE	NEUTRAL	DISAGREE
Summarize advantages of laser vision correction surgery for myopic and hyperopic patients	_____	_____	_____
Evaluate the current treatments for refractive errors, with particular attention to the differences between LASIK and SMILE	_____	_____	_____
Formulate strategies to manage complex cases (ie, refractive errors, corneal surface irregularities, keratoconus)	_____	_____	_____

POST TEST QUESTIONS

1. **PLEASE RATE YOUR CONFIDENCE ON YOUR ABILITY TO EVALUATE THE CURRENT TREATMENTS FOR REFRACTIVE ERRORS, WITH PARTICULAR ATTENTION TO THE DIFFERENCES BETWEEN LASIK AND SMILE. (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 HOW OFTEN YOU INTEND TO APPLY ADVANCES IN LASER VISION CORRECTION TECHNIQUES TO "REAL-WORLD" PATIENT ASSESSMENT, TREATMENT, AND MANAGEMENT. (BASED ON A SCALE OF 1 TO 5, WITH 1 BEING NEVER AND 5 BEING ALWAYS).**
   a. 1
   b. 2
   c. 3
   d. 4
   e. 5

3. **WHICH LASER VISION CORRECTION APPROACH IS CONSISTENTLY ABLE TO ACHIEVE VA OUTCOMES OF 20/12.5 IN MORE THAN 50% OF PATIENTS?**
   a. Topography-guided
   b. Wavefront-guided
   c. Wavefront-optimized
   d. SMILE

4. **WHEN IT COMES TO COMPLICATED CASES, MOST OPHTHALMOLOGISTS WILL ACHIEVE BETTER OUTCOMES WITH WHICH LASER VISION CORRECTION APPROACH?**
   a. SMILE
   b. Topography-guided
   c. Wavefront-guided
   d. Wavefront-optimized

5. **COMPARED TO LASIK, WHICH IS NOT CONSIDERED AN ADVANTAGE OF SMILE?**
   a. Crisp, clear vision immediately following surgery
   b. Decreased denervation of the cornea
   c. Less dry eye in the early postoperative period
   d. Better biomechanical stability

6. **COMPARED TO LASIK, WHAT IS AN ADVANTAGE OF SMILE?**
   a. Quality of vision
   b. Undercorrection of astigmatism
   c. Postoperative enhancements
   d. No flap-related complications

7. **WHICH APPROACH IS BEST FOR PATIENTS WITH CORNEAL SCARRING?**
   a. Wavefront-guided
   b. Topography-guided
   c. Wavefront-optimized
   d. SMILE

8. **AT WHAT POINT SHOULD MMC BE USED DURING SIMULTANEOUS CXL AND CORNEA NORMALIZATION?**
   a. Right before treatment
   b. Right after the treatment, but before CXL
   c. At the end, once CXL is complete

9. **WHICH APPROACH IS NOT RECOMMENDED FOR LASER VISION CORRECTION ENHANCEMENTS?**
   a. Topography-guided
   b. Wavefront-optimized
   c. Wavefront-guided

10. **WHAT CAN BE DONE TO ENCOURAGE MARKET GROWTH OF LASER VISION CORRECTION WORLDWIDE?**
    a. Increase advertising
    b. Lower the price of laser vision correction
    c. Create new technologies that achieve better outcomes
    d. Increase physician education to achieve better results throughout the community

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 as required by the Accreditation Council for Continuing Medical Education (ACCME).

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.

_____