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UNDERSTANDING TECHNOLOGY ADVANCES IN REFRACTIVE FEMTOSECOND LASER PLATFORMS

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Understanding Technology Advances in Refractive Femtosecond Laser Platforms

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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. 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 refractive surgery.

LEARNING OBJECTIVES

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

- Summarize advantages of femtosecond laser vision correction surgery over microkeratomes for myopic and hyperopic patients.
- Discuss newer techniques in refractive surgery that include small-incision lenticule extraction and corneal collagen crosslinking.
- Formulate strategies to manage complex cases (ie, refractive errors, corneal surface irregularities, keratoconus).

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Understanding Technology Advances in Refractive Femtosecond Laser Platforms

A number of advances in femtosecond lasers and overall surgical technique have made refractive surgery safer and more efficient than ever before. Market growth continues to stagnate, however, requiring refractive surgeons to rethink patient messaging and education. The following roundtable brings together thought leaders in refractive surgery to discuss how to reposition the refractive surgery market, the differences and benefits between microkeratome and femtosecond laser approaches, and other technological advances that will improve overall patient outcomes.

—Perry Binder, MS, MD, moderator

ENCOURAGING MARKET GROWTH

Q | PERRY BINDER, MS, MD: The refractive surgery market has decreased in recent years. Refractive lens exchange is definitely a factor, but those patients who don't undergo a refractive lens exchange still aren't having LASIK. What are the reasons for this? How can we, as individuals and as a group, help the market grow?

SUMIT "SAM" GARG, MD: In the United States, some of the growth challenges are due to the economy, even though it has bounced back since 2009. In that time, the market has changed. Older patients who were getting LASIK as a stopgap to cataract surgery are now often opting for refractive lens exchange. The overall market decrease is an ongoing lull from the economic downturn. It's going to take some time for it to rebound. The good news is we are now starting to see an uptick in volumes.

GEORGE WARING IV, MD: Historically, the two barriers to market penetration have been fear and cost. To reduce fear, refractive surgeons have a real opportunity to educate patients on their options and the safety of those options through a direct-to-consumer marketing campaign. This approach has been very successful for the contact lens market. Refractive surgery is one of the best-studied surgical procedures in the history of medicine. We now have peer-reviewed literature to support the merits of laser vision correction relative to contact lens use.[1,2] This is a fabulous opportunity to disseminate this information and educate the public.

CHRIS BLANTON, MD: It comes down to fear and money. We know through Dr. Prices' study that there is a continuous risk of complications for contact lens wearers.[3] The study had data from 20 sites across the United States and enrolled 1,800 subjects, aged 18 to 60 years, who had LASIK or continued using contact lenses. Price et al found that LASIK significantly reduced visual disturbances at night among former contact lens users and decreased night driving issues overall.[3] Dry eye symptoms after LASIK did not increase, either. LASIK also significantly reduced the self-reported rates of eye infections, ulcers, and abrasions each year.[3] Furthermore, the cost of refractive surgery and contact lenses are going to even out over time.

Fear is based on a lack of patient education, which is the biggest problem. Patients do not understand what we are capable of doing or how safe the procedure is. A direct-to-consumer marketing campaign could resolve many of these issues.

I think some of the fear may come from informed consent, which can be alarming for patients. I explain to patients that they have a greater risk of complications from daily contact lens use than refractive surgery.[3] Refractive surgery lasts 10 minutes, and patients are potentially done for the rest of their lives. With contact lenses, patients are inserting a foreign body and toxic solutions into their eyes every day. When you put it into those terms, the fear subsides. But you have to get patients in your office to explain that to them, which is why a direct-to-consumer marketing campaign would be helpful.

DR. GARG: Another challenge is that optometrists want to keep patients in contact lenses. They don't refer patients for refractive surgery, despite the risk of infection from daily contact use.[4,5] After a patient has an infection they become poorer candidates for refractive surgery. We need to see these patients before they have issues with contact lens intolerance, infection, or scarring.

DR. WARING: We need to think about refractive surgery in terms of a public service. Instead of a direct-to-consumer marketing campaign, maybe we should create a public service announcement supported by data.

MIGUEL TEUS, MD, PHD: The message we must send to potential customers is that refractive surgery is a safe, successful procedure that is better than wearing contact lenses. Night vision and dry eye both improve on average after refractive surgery.[3] The technology has greatly improved in the last 15 years.

DR. BINDER: Have word-of-mouth referrals declined?

DR. BLANTON: I don't think they have, no. About 40% of my business is from word of mouth. When a patient has an excellent outcome, I take every opportunity to give them my business card and ask for referrals.

DR. GARG: Word of mouth can be challenging when there are surgeons in our community who are trying to get through the volume without quality outcomes. The quality may be good, but it's not excellent. Yes, 20/20 is amazing vision. But with the technology available now, there's no reason we can't have outcomes better than 20/20.

DR. WARING: Although we typically set our patient expectations in line with the mantra of "undersell and overdeliver," with modern-day excimer platforms it is not uncommon to improve patients' best corrected acuity. Not only does the opportunity exist to improve their uncorrected vision to be better after refractive surgery than their corrected vision with contact lenses, but patients can avoid the chronic dry eye issues and other potential complications that come from long-term contact lens use. There are calculators available that show patients they will likely save money over a lifetime if they have refractive surgery compared to wearing contacts for the rest of their lives (Figure 1).[6] These are all wonderful opportunities for patient education initiatives.

DR. BINDER: What can industry do to help promote the refractive market? What are your thoughts on industry talking about why refractive surgery is best for patients overall, rather than promoting one aspect of a particular laser over another?

DR. TEUS: The message should be that refractive surgery—with all the various technologies—is good for patients, not that a specific laser provides the best outcomes.

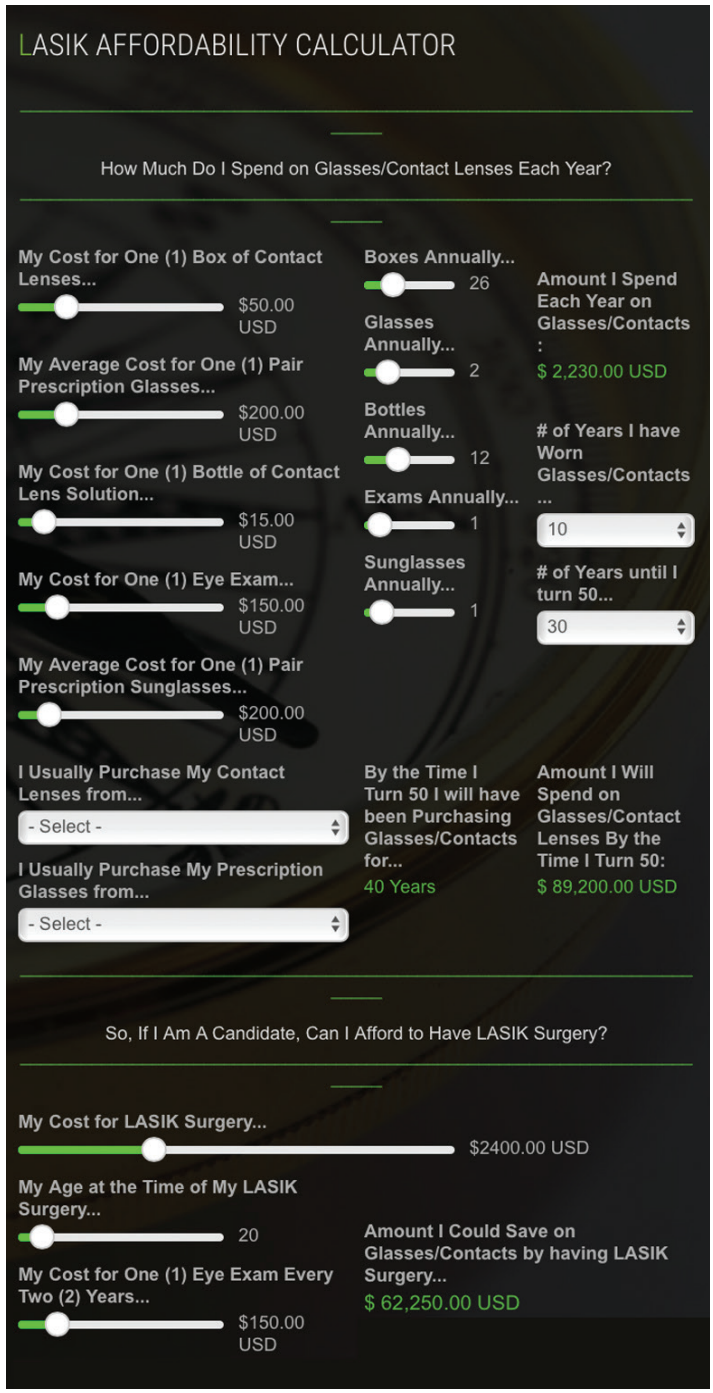
DR. GARG: The value of collective promotion is one of the lessons that came out of Shire's lifitegrast for dry eye coming to market. Direct competitor Allergan's cyclosporine 0.05% penetration went up despite the fact that Allergan lost part of the market share to lifitegrast. Shire did an excellent job of educating patients and eye care providers about the importance of dry eye treatment, not just the importance of lifitegrast. I think that's where the refractive surgery industry needs to go, including optometrists. The message needs to be the overall value of refractive surgery generally, and why it is superior to other corrective options.

DR. WARING: We do have formal organizations that are coming together to help grow the market. The American Refractive Surgery Council is a great example of industry and physicians working together with a common goal of education patients about the benefits of refractive surgery as a whole.

MICROKERATOME VERSUS FEMTOSECOND LASER

Q | DR. BINDER: Let's presume I currently only use a mechanical microkeratome. Why should I go out and purchase a femtosecond laser?

DR. BLANTON: The reason you should purchase a femtosecond laser is for its increased safety profile. Mechanical microkeratomes are relatively safe, but femtosecond lasers are far superior.[7-10] With a femtosecond laser, I've never had a buttonhole. Nor have I had a flap issue where I couldn't finish the case the same day. The American Refractive Surgery Council's website notes that flap complications happen in 0.37% when surgeons use a femtosecond laser.[11] For years, we've heard that the femtosecond laser can improve the risk of flap complications tenfold (from about 1 in every 1,000 patients with a



Courtesy Refractive Surgery Alliance Society: refractivealliance.com/lasik-affordability-calculator

Figure 1. This calculator shows patients how much money they will likely save over a lifetime if they have refractive surgery compared to wearing contact lenses for the rest of their lives.

microkeratome to about 1 in every 10,000 patients with a femtosecond laser). This is a huge leap forward for patients and an increased safety profile that surgeons should feel obligated to provide.

Another critical benefit of the femtosecond laser is the ability to customize the flap with the IntraLase device. Surgeons can dial in whatever they need for that particular patient in terms of refractive error, the ablation bed, and the side cut. These can all be adjusted in a way that makes it a better experience for the patient. For me personally, the big benefit of the femtosecond laser was that I don't have to worry about stromal hydration like you have to with a microkeratome. My results skyrocketed. When you use a femtosecond laser, your enhancement rates decrease and your acuity levels increase, which, in my hands, clearly makes it a better procedure.[9,12-16]

DR. TEUS: In addition to those points, it's important to switch to a femtosecond laser because we know that the standard deviation of the central flap thickness is much lower. The manual aspect of the microkeratome is challenging. The automation of the femtosecond laser makes it a safer procedure overall.[17]

DR. BINDER: When determining standard deviation, it's important to look at the volume of eyes. As you increase the number of eyes you operate on, your standard deviation, your range, is going to increase. It's also important to look at the range of preoperative corneal thickness that you're going to operate on. Thicker corneas are going to get thicker flaps with mechanical microkeratomes, and the reverse with thin corneas. We know from the standard deviations in the literature that we're looking at between 8 and 12 µm, plus or minus, for 65% of the population with a femtosecond laser.[9,18] It's almost twice as high with mechanical microkeratomes when you factor in the volume of eyes overall.

DR. GARG: With the femtosecond laser, the guesswork is done; you get better uniformity and consistency. I can safely say that using a femtosecond laser is a better procedure, from multiple perspectives, than using a microkeratome.

DR. BINDER: I think what people also tend to forget is, because of the anatomy of a mechanical microkeratome flap, the microkeratome has to cut into the cornea deeper in the periphery. That alone makes using microkeratomes a structurally more weakening procedures compared to a femtosecond flap.

DR. WARING: A number of studies have evaluated safety, efficacy, intended versus achieved flap thickness and variation, and morphologies in femtosecond flaps.[19,20] Anterior segment optical coherence tomography (OCT) became commercially available soon after the advent of femtosecond lasers for creating LASIK flaps. Multiple studies demonstrated that femtosecond flaps were planar as opposed to meniscal flaps created with most mechanical keratomes,[21,22] the importance of which was illustrated through the work of John Marshall et al.[23] The thicker that you cut in the periphery, the more

"The automation of the femtosecond laser makes it a safer procedure overall."

—Miguel Teus, MD, PhD

biomechanical effect you have on the cornea. Now, recent American Society of Cataract and Refractive Surgery (ASCRS) survey data show that three-fourths of LASIK surgeons use femtosecond lasers to create their flaps.[24] This transition didn't happen overnight, but now that we understand its importance, most of us are using a femtosecond platform.

DR. BINDER: Dr. Teus, you've done some comparative studies. What are the achieved flap thickness and the ranges of deviation from target to flap thickness in the platforms that you studied?

DR. TEUS: That paper compares flap thickness homogeneity between the IntraLase and Victus, which is a dual platform.[25] The more heterogeneous in thickness the flap is, the more the cornea surface is affected, leading to higher-order aberrations (HOAs). We found out that dual platforms, devices designed for both cataract surgery and flap creation, are worse than IntraLase in terms of flap thickness homogeneity.[25]

We have tried platforms with a curved patient interface, and we induce a little increase in intraocular pressure (IOP) due to the suction pump.[26] The IntraLase induces a higher IOP increase[27] due to the suction pump compared to the Victus, but the Victus had worse refractive results because the flap thickness homogeneity was too low.[25]

DR. BINDER: Was flap thickness homogeneity one of the 19 points you measured across?

DR. TEUS: Yes. It was in the horizontal axis that we measured from the center at different points with the OCT. We measured not just the central thickness but the whole profile on the horizontal axis. We found it was quite different between platforms.

DR. BINDER: The Victus and the LenSx are both dual platforms. How does the flap quality thickness predictability deviate from target, how does that compare to the femtosecond laser whose primary goal is to make flaps? How do bed smoothness and homogeneity differ between platforms?

DR. TEUS: In my experience with the LenSx, the flaps are thicker than intended at about 10 µm. And flap thickness homogeneity is about 5 µm worse in terms of difference between maximum and minimum, done with the gold standard IntraLase. It's also worse

Figure 2. Central flap thickness.

with the Victus. The center flap thickness is okay with the Victus, but the heterogeneity is worse with a 10 or 11 µm difference between the maximum and the minimum thickness, on average.

In another study we measured central flap thickness at 1 day, 1 week, 1 month, and 3 months after surgery.[28] We expected no inflammation after the first day and week, but an increase in epithelial thickness thereafter and epithelial regrowth within 3 months. So you're going to end up with a flap that is 5 to 10 µm thicker than what was cut by the machines. With any device you should expect an increase of about 6 to 10 µm 3 months after surgery. We found that this was true with the IntraLase iFS 150, but this was not happening with the LenSx and the WaveLight FS200. With the latter two lasers the flap was thicker than expected in the early postoperative period (Figure 2). I believe that the higher pressure that the iFS 150 patient interface applies over the cornea facilitates the gas to escape to the periphery, while the lower pressure of other patient interfaces allows the gas to permeate into the surrounding stroma thus causing some sort of long-lasting inflammation or edema in the early postoperative period.

RECENT ADVANCES IN FEMTOSECOND PLATFORMS

Q | DR. BINDER: My center currently has an IntraLase FS 60 laser. Why should I upgrade to the iFS 150?

DR. GARG: Two reasons: speed and patient comfort. The procedure is much faster with the iFS 150. It leads to a smoother flap and less chance of error, because you're getting through it more quickly and efficiently.

DR. WARING: The iFS 150 is a great example of how often recent innovations improve upon current technologies and really help our patients. For example, we now have the ability to create tunnels for intracorneal ring segments and pockets for presbyopic inlays. And, importantly, we have a more efficient laser platform that allows us to use a tighter spot in line technology, which gives us more flexibility to do lamellar corneal work and/or work deeper in the cornea. We looked at this early on with scanning electron microscopy, looking at different lasers and how they behave in different depths

"We now have the ability to create tunnels for intracorneal ring segments and pockets for presbyopic inlays."

—George Waring IV, MD

of the cornea (unpublished data). We found that an advanced femtosecond laser gives one the ability to use a tight spot in line with a correlate energy that was appropriate for that spot in line in order to have smooth beds as the posterior stroma behaves like a different cornea compared to anterior stroma.

DR. BINDER: I do want to point out that whenever you do a study with scanning electron microscopy or forced electron microscopy, the back of the flap will always be rougher than the bed. That's just the way the anatomy is after you cut it, regardless of the platform you use.

Why would someone want to switch from an FS 60 to a iFS 150?

DR. BLANTON: We did a study that compared our FS 60 results to our iFS 150 results.[29] We did about 100 eyes in each group, and we discovered that there was clearly a trend toward better visual acuity and statistically significantly fewer enhancements on the 150 kHz platform, probably based on bed smoothness. The induction of aberrations is lower in the 150 kHz device. We had a 0% enhancement rate at 1 year in the 150 kHz group and a 4% enhancement rate with the 60 kHz group.

Speed is a factor. For example, if you use a 60 kHz device to do transplant surgery, it's going to take you 2 minutes to cut the cornea for a penetrating keratoplasty, but 45 seconds to perform the same procedure on the 150 kHz. This is a big deal; you don't want patients sitting there for 2 minutes if they don't have to be. In my experience, the 150 kHz is better for all those reasons, and I find it better when I'm creating tunnels or pockets, using rings, performing transplants, or performing lamellar surgery.

DR. BINDER: How important is attempted versus achieved central and homogeneous flap thickness in terms of uncorrected and BCVA, reduced HOAs, and enhancement rates? Do you think that you're getting better visual acuity results and fewer induced HOAs with a smoother bed and a more homogeneous flap?

DR. TEUS: Absolutely. In my experience, I have found that if you have a laser that cuts a flap that is heterogeneous in thickness, a spherical error will remain, and you will need to perform enhancements. The more irregular in terms of thickness the flap, the higher the rate of HOA induction. That is just as important as the roughness of the surface. If you apply excimer laser ablation over the rough surface of the femtosecond laser, it becomes smooth.

SMILE VERSUS LASIK

Q | DR. BINDER: There are many high-quality studies comparing small-incision lenticule extraction (SMILE) to LASIK.[30-32] What are the pros and cons to SMILE compared to LASIK?

DR. GARG: There is less chance of biomechanical instability with SMILE. However, it's very much in its infancy. One big disadvantage in the United States is its narrow therapeutic range: sphere up to 8.00 D with up to 0.75 D of cylinder. That's going to limit the number of eyes that we'll be able to treat with the technology. On the plus side, it's just one laser. But you won't get the same "wow" factor you often get with LASIK, because of the microaberrations that build on one another.

DR. BINDER: The 3-month data of acuity is equivalent between SMILE and LASIK, but patients see better at day 1 with LASIK than with SMILE. With SMILE it takes a few weeks for that "wow" factor to set in.[32] There is supposed to be less dry eye with SMILE. Is there any good evidence to support that claim?

DR. TEUS: You still have dry eye after SMILE, but there does seem to be a difference in dry eye between SMILE and LASIK. It's a small difference, and it may not be clinically relevant.[33-35] Dry eye after surgery is not the same as common dry eye. After surgery, patients typically have normal tear film, normal tear volume, and normal osmolarity, but they feel as though their eyes are dry. This is mostly due to dysaesthesia because the cut nerves are regenerating in an abnormal way, and they fire the wrong sensation. After LASIK, the number of patients who have moderate to severe dry eye before surgery reduces from 20% to 10%, according to the PROWL studies.[36]

DR. BINDER: How do you enhance an under or overcorrected SMILE procedure?

DR. WARING: In the United States, you'd enhance with advanced surface ablation. In Europe, they have the ability to alter the cap thickness. This is an off-label procedure in the United States. Altering the cap thickness may allow one to perform thin-flap LASIK over the SMILE for a quicker recovery. I do think SMILE will be an important tool in our refractive toolbox. It's early in the pipeline, particularly in the United States where surgeons only have treatment for myopia, so that really limits its applicability.

We know that other applications are going through the US Food and Drug Administration (FDA) approval process and should be available soon. With that said, with our current femtosecond LASIK technology with high-definition, wavefront is excellent. Having the ability to treat and image the 1,024 eyelets of information and microrefractions, and then be able to deliver that treatment, pushes us in a new realm of outcomes. Although there are potential benefits with SMILE over LASIK, no procedure is fool-proof. There are reports of ectasia after SMILE, despite its benefits.[37]

DR. BINDER: The other thing to consider is that with SMILE your diameter is limited to a maximum of 8.4 mm. Therefore, for certain hyperopic procedures, that may not be the best option. Second, there's no way you can use computer software to center where you're going to put that lenticule. It's always geometrically centered on the cornea. Saccadic eye movements can affect where you're going to center, and there's no cyclotorsional adjustment until you put the suction on. Then you can rotate the ring anyway you want. The applanation suction is lowest, so the longer the procedure takes, the greater the risk of suction loss. These are all negatives. Furthermore, every new procedure comes with unique complications, such as a retained piece of lenticule. When that happens, you are stuck with an irregular astigmatism and few options. The only thing you can do is to convert to a flap and then go in, lift it out, and then do PRK. That is a significant challenge.

DR. BLANTON: The SMILE procedure has theoretical advantages over LASIK. The issue for me is, until the SMILE procedure is driven by an aberrometry-based lenticule cut, you're not going to achieve the same results we currently achieve with LASIK. We're also missing iris registration with SMILE, which is very important for lining up the aberrations and lining up the axis of astigmatism. Until we can achieve these two things with SMILE, it will prevent it from developing into a commonly used procedure. But if someone can marry those two technologies, then SMILE will become the procedure of choice.

MANAGING IOP INCREASE IN FEMTOSECOND PLATFORMS

Q | DR. BINDER: When you put a suction ring on an eye, with all of the femtosecond technologies, you increase IOP. What does the literature tell us about how that increased pressure impacts outcomes?

DR. TEUS: I've done studies where we've measured the real IOP using porcine eyes.[26,27,38] We compared cannulation in the anterior chamber to cannulation in the vitreous chamber. We compared several lasers and have found significant differences (Figure 3). With the iFS 150, IOP induced by suction is quite high with approximately 80 mm of mercury. On the other hand, LenSx and Victus only

"The 3-month data of acuity is equivalent between SMILE and LASIK, but patients see better at day 1 with LASIK than with SMILE."

—Perry Binder, MS, MD

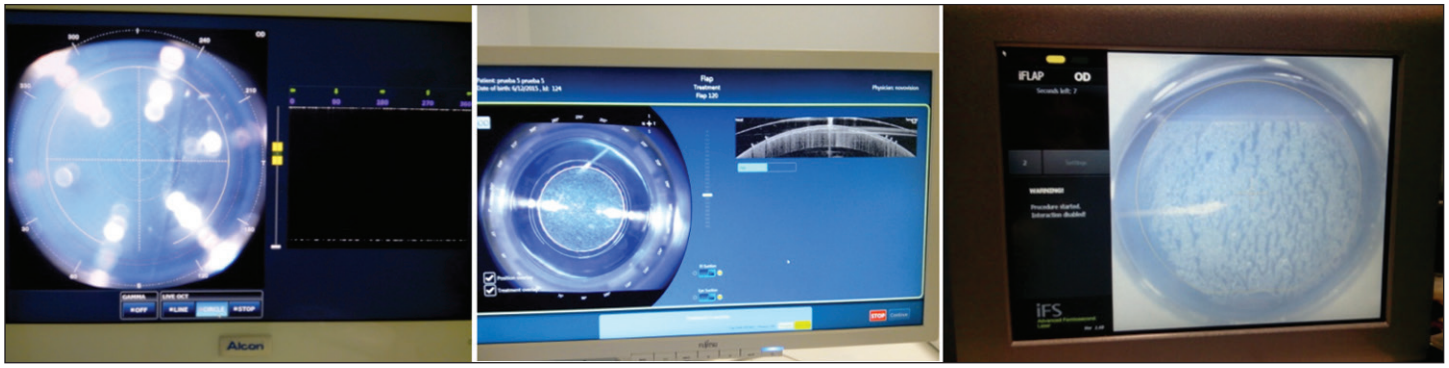


Figure 3. Dr. Teus measured and compared the real IOP increase while performing a FemtoLASIK corneal flap with the LenSx, Victus, and the IntraLase iFS 150 devices (with curved and flat interfaces, respectively).

increased by 20 mm of mercury. The IOP was very high in order to obtain a good quality flap. You can cut perfectly with high IOP. Then you should try to lower the IOP if you need to while keeping the same quality of flap. I see no reason to go away from high IOP during surgery.

DR. BINDER: Dr. Blanton, as the medical monitor for the IntraLase, you have access to the results from about 8 million eyes. Have you had any cases of optic nerve atrophy or central retinal artery occlusion with IntraLase suction?

DR. BLANTON: To the best of my knowledge, that has never been reported with the IntraLase.

DR. TEUS: We have measured the retinal nerve fiber layer thickness perioperatively before and after surgery with IntraLase LASIK for myopia, and compared the results to a myopic group that underwent surface ablation, and there's no difference.[39]

DR. BINDER: And in your studies, was there an adverse effect of that high pressure on the bed smoothness?

DR. TEUS: On the optical density of the flap with LenSx, the optical density was worse than with the IntraLase or the iFS 150.[40] We used atomic-forced microscopy, which is one step forward from electron microscopy. We found that the same flap is quite heterogeneous (in terms of roughness) at different areas, and you'll have different smoothness depending on the energy you use. The IOP may be related to the degree of optical density of the flaps in the early postoperative period. There is clearly an increase in optical density during the first days postoperatively with less energy intraoperatively. But, in my experience, IOP rise does not have an adverse effect on the optical quality of the eye.

DR. BINDER: Do differences in wound architecture have any effect on refractive and safety complications after femtosecond LASIK? Does flap customization benefit vision, refraction, and safety?

DR. BLANTON: Yes. The biggest factor is being able to dial-in on your flap thickness, thereby preventing ectasia. Ectasia is the one catastrophe that we have had in LASIK surgeries,[12,13,20,37] and we want to avoid that as much as possible. I think the fact that you can do a bevel-inside cut, allowing the flap edge to be more solidly healed and decrease the instance of flap striae, is an important thing. Bed smoothness is critical as well. The ability to customize your wound is a big leap forward in terms of better results for our patients.

DR. WARING: I completely agree. I think the architecture—and being able to customize the architecture of the flap edge—is one of the major breakthroughs with multiple platforms. IntraLase led the way with that. When you have the ability to create a true side cut, it makes sense geometrically that the flap will more naturally lie in that position. You can better assess flap gutter symmetry intraoperatively and, therefore, decrease the incidence of micro-striae. In my experience, there's a lower risk of flap slippage as well. There are many safety benefits, which can translate directly into improved visual outcomes.

DR. BINDER: What side cut parameters are you using?

DR. GARG: I use 110° to give a little bit of a bevel so that it sits nicely. It's helpful to have that kind of predictability, especially for surgeons just learning refractive surgery. It takes the guesswork out of the equation and gives them more confidence with the procedure, both of which translates into better outcomes for patients. More predictability leads to happier patients with less follow-up. They get on with their lives and spend less time in our offices.

DR. BINDER: How do you recommend surgeons start out with the bevel side cut?

DR. BLANTON: We recommend they start at 120° for the iFS 150; 110° is what I use right now. The reason for that is you get the benefit of the bevel-in, but you're not going in too steeply. If you're too steep, you start eating into your available bed diameter for treatment, and the procedure takes longer. In my hands, 110° allows you to get the bevel-in, but you don't start to lose bed, and it doesn't take more time to make the flap. Right now, the official recommendation is 120°, but most experienced surgeons use 110°. It's the magic number for the side cut for all these reasons.

"OBL can cause problems with pupil tracking and iris registration software systems. With a lot of OBL, the dissection is more difficult, and there's a risk for flap tear."

—Chris Blanton, MD

The other advantage to that side cut is the decrease in risk of epithelial ingrowth. Architecturally, it makes it harder for the epithelium to get underneath the flap. That has made me a little bit more comfortable lifting flaps after femtosecond procedures, with regard to avoiding epithelial ingrowth.

INTRAOPERATIVE, POSTOPERATIVE COMPLICATIONS

Q | DR. BINDER: Are there differences in operative and postoperative complications between femtosecond lasers, and is the management different between individual femtosecond laser complications?

DR. TEUS: For LASIK surgery, the only difference is in the rate of enhancements. There are no real differences in complications between platforms. Suction loss was about the same. I'm not sure it's a complication, but one difference is with the lasers working with a spiral pattern. With low IOP rise, you can sometimes see a circular ridge in the back. With the Victus you have real-time OCT, and you can see that the gas may accumulate in a circular fashion. Then, the depth at that particular point is different. I've seen that with the LenSx and the Victus; curved interface and low IOP with suction in both devices.

DR. BINDER: Did the spiral patterns affect bed smoothness?

DR. TEUS: No, all flaps have an equal roughness that depends mostly on the atomic force microscopy at the nanometer level.

DR. BINDER: Let's move on to discussing opaque bubble layer (OBL).[41-43] Does OBL present any issues for you?

DR. GARG: It can cause an issue with sometimes picking up the pupil tracker, which is more an annoyance than a real problem. It doesn't affect the flap very often, but it will depend on the eye.

DR. BLANTON: I have found there are two kinds of OBL: pocket-related OBL and satellite or scattered OBL. Preventing pocket-related OBL is just a matter of making your pocket more efficient. You see that type of OBL right away. When the raster pattern starts, you need to go back and either tighten up your spot and line or increase your pocket and get some better venting. Satellite or scattered OBL occurs later in the surgery. Typically, the energy levels are more important. If you bump the energy up a little bit, you're going to get a better flap in terms of less OBL.

OBL can also cause problems with pupil tracking and iris registration software systems. With a lot of OBL, the dissection is more difficult, and there's a higher risk for flap tear. Of course, we need to do everything we can to minimize it, but there are solutions once you identify what type of OBL you have. There are things you can do to your laser to prevent it or at least decrease the incidence of it.

DR. BINDER: Can flap tears happen with all laser platforms, or are they unique to one platform in particular?

DR. BLANTON: It can happen with all laser platforms because it can be surgeon- or patient-related. Any time there is OBL, this makes it just a little bit more difficult to dissect the flap.

DR. WARING: If you do have OBL that's affecting your pupil tracking or treatment, you can massage it out manually. That will often clear things up rather quickly. You can also wait; time will clear it out. One of the real benefits of the advanced technology is the efficiency of these femtosecond laser platforms. You can reduce the number of incidents of OBL and have a very efficient smooth cut.

DR. BINDER: How do you manage an undercorrection with the femtosecond laser?

DR. TEUS: If it's an undercorrection, I lift the flap at 3 months. This tactic is no problem, up to a year. Between 1 and 5 years, you may have a problem with epithelial ingrowth because you break the scar at the edge of the flap and then the epithelial cells may get in. If it's 5 years after surgery, I perform what I call a mini flap,[44] which is a flap smaller in size and more superficial or at the same depth as the original. That works well. I wouldn't try to lift flaps after 5 years.

DR. BINDER: When you make that mini flap, what is your attempted flap thickness compared to the original flap thickness?

DR. TEUS: I measure at the slit lamp, and the flap thickness depends on whether there is a positive or negative ablation. Negative ablation is no problem. A flap diameter of 6 or 7 mm would be okay for positive ablations. For me, it's most common to see patients 10 years after the original procedure. These are presbyopic patients with bilateral myopia, so I adjust the dominant eye.

DR. GARG: Early on, flap lifts work quite well. I usually get an OCT to see where the flap actually ends up, and it's pretty close to target for these eyes. Management also depends on the amount of

correction you need to fix. If there's a big shift, you'll want to figure out why that is happening and make sure you're not missing something. Enhancements don't always have to be LASIK enhancements. You always have to look at the overall optics of the eye. The lens is a big part of that and may need to be addressed (depending on the age of the patient).

DR. WARING: Typically, if it's an early re-treatment, meaning that we've allowed the patient to stabilize, I'll do a flap lift if it's within a year. Those patients do very well. Historically, we would lift 5 years or even over 10 in some circumstances, but your risk of epithelial ingrowth issues may increase the longer you wait. It's not common, but it's certainly more common after a flap lift enhancement, and it's more common the older the treatment is. For these patients, we've shifted more toward advanced surface ablation with mitomycin C (MMC). You don't typically have to worry about your flap thickness with these enhancements, because enhancements are often small treatments ablating a small amount of tissue, and older flaps were often thicker.

DR. BLANTON: The good news is that the need for doing these enhancements has substantially decreased. We're now capable of getting our enhancement rate to lower than 2% with the current technology, whereas this was up around 8% in the days of conventional microkeratome procedures. If you determine early on that an enhancement is needed and you want to re-lift the flap, it should be done within the first year. After the first year, I'll go to advanced surface ablation because of epithelial ingrowth. The issue there is you have to re-educate the patient on what to expect. They won't get rapid visual recovery, which needs to be communicated ahead of time. It's a safer procedure for their eyes, which they also like to hear.

DR. BINDER: If you do PRK over an interface, there is increased interface inflammation that you have to plan on. Do you use more steroids in those cases than you normally would after a regular PRK?

DR. BLANTON: I haven't had to change my regimen, but obviously MMC made a huge difference in every kind of surface ablation that we're doing. I feel extremely comfortable using MMC. In my standard steroid regimen for PRK, I've always followed the FDA original protocol.

FUTURE IMPROVEMENTS

Q | DR. BINDER: As we do our surgery with our femtosecond platforms, we have the ability for visual changes as we look through the microscope, and we have a virtual image that we can see on the screen. How comfortable are you with that virtual image on the screen? Is it helpful to you, or do you just look at the eye and see how it's going?

DR. TEUS: I look at the eye. I'm not comfortable with virtual images, as they tend to confuse me. For instance, with the Victus, you see the real-time OCT scan, you see the gas accumulating, and then you're thinking of other things. We need to keep the patient relaxed without moving and the suction on, so I prefer to have that control.

"Enhancements don't always have to be LASIK enhancements."

—Sumit "Sam Garg, MD

DR. GARG: I prefer the video image. I like the real-time image. I don't necessarily have to look through the oculars, but I do look at the image.

DR. WARING: I think surgeons, in general, are comfortable with oculars, and they like looking through microscopes and seeing what's going on. But I actually am very comfortable with the iFS 150 screen as well. It's real-time, ergonomic information that's easier on your neck. Staff can see that real-time information as well, so everyone is on the same page.

DR. BLANTON: When the monitor first came out, some surgeons really did not like it. They didn't like their view. But most surgeons rapidly adapted to the monitor, and we don't hear many complaints about it now. I like how ergonomic it is. Our profession has a significantly higher incidence of cervical disc disease than the rest of the population because we're constantly craning in the microscope. The monitor helps reduce that.

DR. BINDER: What would you change with the IntraLase laser to make it better?

DR. GARG: As surgeons, we're always looking for innovative changes. It's fast now, but it could be faster. There is some nuance to suction and getting it to dock. That could be easier. There can always be improvements.

DR. WARING: There are already improvements in the pipeline, so we do have these advancements to look forward to. I agree it could be faster. Smaller footprints are always nice. There may be a trend toward solid-state technology, which makes the lasers a little bit less susceptible to environmental changes and a little more robust. The ability to not decrease your treatment zone if you do have to decenter your flaps would be a nice advancement. I'd also like to be able to couple potential wavefront-guided technologies into small lenticular extractions.

DR. BINDER: The number one complaint I've seen is about the microscope. There's a big difference between what we had with the

"We need to get a femtosecond laser that vaporizes down to a 0.25 µm."

—Chris Blanton, MD

FS 60 versus the iFS 150 in terms of depth perception.

DR. BLANTON: We are doing LASIK surgery right now because an excimer laser takes a 0.25 µm pulse off every time it strikes the cornea. When you use the femtosecond laser, it is vaporizing 1 µm. We need to get a femtosecond laser that vaporizes down to a 0.25 µm. When you have that level of precision, then you can be aberrometry-driven, and you can have a SMILE procedure that is the best procedure for a patient.

DR. BINDER: It is clear that the future of refractive surgery is promising. Our results continually improve, the technology is improving as well, even if only incrementally. We need to continue to educate the consumers on the enhanced safety of these procedures in addition to their ability to produce excellent visual outcomes. If we are successful, the longevity of refractive procedures cannot be underestimated. ■

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UNDERSTANDING TECHNOLOGY ADVANCES IN REFRACTIVE FEMTOSECOND LASER PLATFORMS

Release Date: March 1, 2018
Expiration Date: March 30, 2019

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City _____ State _____ Zip _____

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DEMOGRAPHIC INFORMATION

Profession
___ MD/DO
___ 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
___ 1-5
___ 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 femtosecond laser vision correction surgery over microkeratomes for myopic and hyperopic patients.	_____	_____	_____
Discuss newer techniques in refractive surgery that include small-incision lenticule extraction and corneal collagen crosslinking.	_____	_____	_____
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 APPLY UPDATES IN FEMTOSECOND LASER PLATFORMS IN THE CLINIC BASED ON THIS ACTIVITY. (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 FEMTOSECOND LASER PLATFORMS 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. **TRUE OR FALSE: REFRACTIVE SURGERY IS SAFER THAN WEARING CONTACT LENSES OVER THE LONG TERM.**
   a. True
   b. False

4. **THE FEMTOSECOND LASER IS SUPERIOR TO MECHANICAL MICROKERATOME IN THE FOLLOWING WAYS EXCEPT:**
   a. Increased safety profile
   b. Flap customization
   c. Less suction on the eye
   d. Better uniformity and consistency

5. **HOW DO YOU ENHANCE AN UNDER OR OVERCORRECTED SMILE PROCEDURE IN THE UNITED STATES?**
   a. Alter the cap thickness
   b. Through advanced surface ablation
   c. PRK
   d. None of the above

6. **WHAT IS THE OPTIMAL TIMING TO LIFT THE FLAP TO ENHANCE A FEMTOSECOND LASER PROCEDURE?**
   a. 5 years
   b. 3 years
   c. 2 years
   d. 1 year or under

7. **WHAT IS THE ENHANCEMENT RATE WITH THE CURRENT FEMTOSECOND LASER TECHNOLOGY AVAILABLE?**
   a. 4%
   b. 2%
   c. 8%
   d. 1%

8. **MRS. JONES IS A 33-YEAR-OLD WOMAN WHO PRESENTS IN YOUR OFFICE SEEKING TO GET RID OF HER SPECTACLES. SHE'S NEVER HAD AN ISSUE WITH THEM, BUT SHE DOES NOT WANT TO CONTINUE WEARING GLASSES. HER RECORDS SHOW SHE HAS COMPOUND MYOPIC ASTIGMATISM. WHAT IS THE RECOMMENDED BEVEL-IN SIDE CUT EDGE ON THE iFS 150?**
   a. 120°
   b. 90°
   c. 45°
   d. 150°

9. **WHICH OF THE PLATFORMS DISCUSSED HAS BEEN NAMED AS MORE LIKELY TO CREATE FLAP TEARS?**
   a. LenSx
   b. IntraLase
   c. Victus
   d. None; it's patient and surgeon dependent

10. **UP TO HOW MANY DIOPTERS OF SPHERE CAN BE TREATED ON-LABEL IN THE UNITED STATES WITH SMILE?**
    a. 10.00 D
    b. 8.00 D
    c. 6.00 D
    d. 5.00 D

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.

_____

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