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Cataract & Refractive Surgery TODAY

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Is 20/16 the New 20/20?

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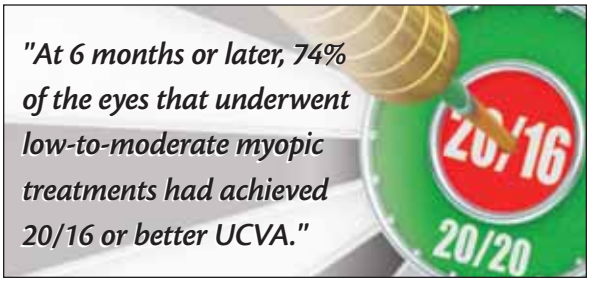
CustomVue FDA Data Review

A brief history of wavefront-guided clinical trials and current real-world performance with Colman R. Kraff, MD.

Dr. Vukich: You were a clinical investigator for the FDA trials of the VISX CustomVue wavefront-guided LASIK platform (Abbott Medical Optics Inc., Santa Ana, CA) in 2003.[1] Although CustomVue did not include Fourier algorithms or iris registration at the time, what kind of results did the technology achieve? How has the technology improved since then?

Dr. Kraff: The FDA multicenter clinical trials on the CustomVue wavefront-guided LASIK platform showed that, at 6 months or later, 74% of the eyes that underwent low-to-moderate myopic treatments (up to 6.50 D of myopia) had achieved 20/16 or better UCVA. Ninety-four percent of the eyes were 20/20 or better uncorrected. We also saw excellent results with the high myopes (up to 11.00 D of myopia)—65% of those patients achieved 20/16 or better at 6 months.

Since Abbott Medical Optics Inc. brought the VISX and the IntraLase technologies under one roof, it has advanced them into a comprehensive laser vision procedure. The CustomVue wavefront-guided system now includes Fourier algorithms, which increase the amount of data for treatment planning and thereby provide more accurate treatment maps. Iris registration was also introduced in 2005,



which accurately positions the treatment on the cornea, accounting for cyclotorsional rotation and pupil centroid shift. New IntraLase technology, the iFS, allows surgeons to make fully individualized flaps, which further enhance the wavefront-guided results.

Patients are aware of these achievements and now understand that wavefront-guided and femtosecond ablations are the safest and most advanced technologies for refractive surgery. Patients are increasingly requesting this state-of-the-art, fully customized procedure.

Dr. Vukich: We have seen some instrumental advances since the clinical trials. What has been your personal real-world clinical experience with the technology, after the trial and through today?

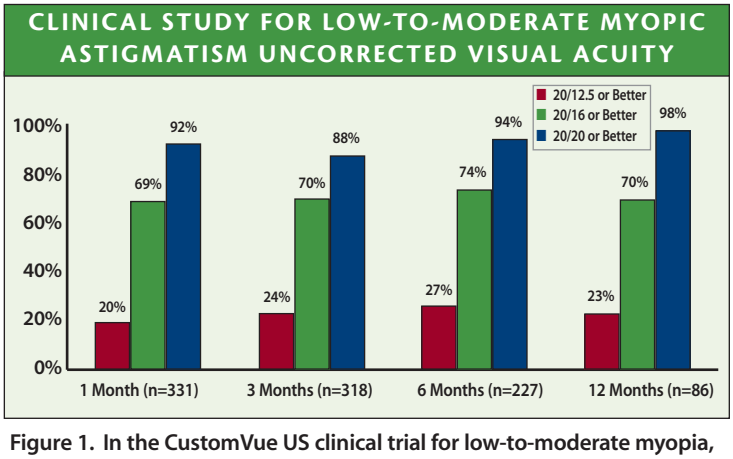


Figure 1. In the CustomVue US clinical trial for low-to-moderate myopia, with or without astigmatism, 70% of eyes achieved 20/16 or better UCVA, and 98% achieved 20/20 or better UCVA at 12 months.

Dr. Kraff: Since my involvement with the clinical trials, I have seen refractive surgery move toward wavefront-guided ablations and thinner, customized LASIK flaps as standards of care. In terms of flap creation, I am confident that the IntraLase will cut the flap thickness I desire for every eye. I do not worry that the flap will be thicker or thinner than what I target, which was a concern with mechanical microkeratomes. Also, the laser's level of precision and accuracy gives my patients better outcomes and widens the range of patients who can undergo LASIK.

For excimer lasers, the STAR S4IR with CustomVue has the broadest range of approvals for any FDA-approved excimer platform. Wavefront-guided ablations are my procedure

of choice for eligible patients. I have seen great improvements in outcomes with the platform's technological advances over the years since the clinical trial, and I continually see excellent 20/16 and 20/20 results.

Dr. Vukich: It sounds like wavefront-guided procedures and femtosecond technology has significantly benefitted your practice. What advice would you give a colleague who has not yet used this equipment?

Dr. Kraff: As with any technology, it is important to remember that results with the iLASIK suite will vary from surgeon to surgeon and from those of the clinical trials. However, in my opinion, results with the iLASIK system are outstanding. Because the procedure now includes iris registration and Fourier algorithms, I would expect the quality of the system's results to be the equal to or better than those seen in the CustomVue clinical trials. Now that physicians have more latitude in changing the laser's optical zones and ablation zones, this treatment produces better quality of vision at night and other low-light situations.

For me, wavefront-guided ablations and femtosecond flap creation have produced clear advantages. My results have been equal to or better than those of the 2003 CustomVue FDA trials, and my rate of enhancements is very low (less than 2%). Factors such as longer experience, better ablation profiles with Fourier, improved treatment accuracy with IR, and more consistent flap creation with the IntraLase have all contributed to better quality results, fewer enhancements, and happier patients in my practice. I have never seen a reason to switch platforms.

I am also impressed with the reliability of the two lasers and AMO's response time in servicing. Even the best machines need servicing sometimes, but my busy refractive surgery practice cannot afford down time. Abbott's response time is second to none, in my opinion. If I have had an issue with one of the lasers or needed a part exchanged, I almost never have had to cancel a day of surgery. ■

Colman R. Kraff, MD, is Director of Refractive Surgery at the Kraff Eye Institute in Chicago. He has been a principal investigator and consultant for Abbott Medical Optics Inc. in its clinical trials, but he acknowledged no financial interest in the company or its products. Dr. Kraff may be reached at (312) 444-1111; ckraff@kraffeye.com.

1. Customview clinical study for low to moderate myopic astigmatism. Data on file with Abbott Medical Optics Inc., Santa Ana, CA; 2003.

HIGHER-ORDER ABERRATIONS: WHICH ABLATION PROFILE IS BEST?

A brief discussion of the differences between wavefront-guided and wavefront-optimized technologies with Jack T. Holladay, MD.

Dr. Vukich: Your retrospective study[1] showed that wavefront-guided procedures significantly improved higher-order aberrations over wavefront-optimized ablations. What is the clinical significance of this finding?

Dr. Holladay: There are now several studies that demonstrate that reducing higher-order aberrations improves visual acuity, contrast sensitivity, and overall visual performance. The three most prominent studies that support this conclusion are Steven Schallhorn, MD's analysis with naval aviators,[2] the study by Prieto et al[3] with deformable mirrors, and my retrospective study.

Visual performance is comprised of an optical system, a sensory system, and a neural processing system. A better optical system will ensure better performance of the patient's visual system. The Prieto study showed that by correcting all of an eye's aberrations with a deformable mirror, the retina or sensory system becomes the limiting factor in vision. My research and other studies have shown that wavefront-guided ablations are more effective than wavefront-optimized treatments at reducing all aberrations and thereby providing the patient the best chance to achieve his best vision.

Dr. Vukich: Do you have any patient selection criteria for performing wavefront-guided procedures versus conventional or wavefront-optimized procedures?

Dr. Holladay: My study showed that wavefront-guided ablations provide the best results for the vast majority of patients. Furthermore, my research has shown that more than 70% of individuals have more than 0.2 µm of higher-order aberrations. These patients' quality of vision will especially benefit from the reduction of higher-order aberrations. The 30% of people with less than 0.2 µm of preoperative higher-order aberrations would have similarly excellent outcomes, as long as their surgery does not induce these aberrations. Wavefront-guided ablations have a significantly lesser risk of increasing higher-order aberrations, which is particularly important for patients who already have low amounts. Individuals who have never had to neural-adapt to these aberrations will be less satisfied with their vision than their counterparts with higher amounts of preoperative higher-order aberrations.

1. Holladay JT. Wavefront-guided ablation vs wavefront-optimized ablation. Presented at: The World Ophthalmology Congress. June 28, 2008; Hong Kong.
2. Stanley PF, Tanzer DJ, Schallhorn SC. Laser refractive surgery in the United States Navy. *Curr Opin Ophthalmol.* 2008;19(4):321-324. Review.
3. Prieto P, Fernández E, Manzanera S, Artal P. Adaptive optics with a programmable phase modulator: applications in the human eye. *Opt Express.* 2004;23;12(17):4059-4071.

Care Without Compromise

A discussion about the clinical value of wavefront-guided procedures and femtosecond flap creation with Louis E. Probst, MD.

Dr. Vukich: I understand you have evolved your technology selection over the past several years. Please describe your transition from conventional to wavefront-guided laser vision correction and from using a mechanical microkeratome to 100% IntraLase flap creation.

Dr. Probst: I have used the CustomVue customized wavefront-guided technology on the STAR S4 excimer laser (Abbott Medical Optics Inc., Santa Ana, CA) exclusively for the past 5 years.

Customized wavefront-guided laser vision correction provides a number of advantages over conventional treatments. For example, the unique iris registration technology can measure the pupil's centroid shift and compensate for cyclorotation. This feature is particularly beneficial in eyes that have astigmatism, because a perfectly aligned axis improves the uncorrected visual acuity and decreases the need for enhancements. Although this benefit is particularly evident in eyes with mixed astigmatism, I believe it applies to all eyes with more than 1.00 D of astigmatism, and it is also important to place the treatment where it was measured for other patients.

Another clinical advantage is an advanced wavefront-guided treatment profile, which allows for a faster and more effective procedure. It treats and reduces the induction of higher-order aberrations, so more patients enjoy rates of 20/16 and 20/20 outcomes and experience fewer postoperative nighttime vision problems.[1] Thus, CustomVue laser treatments are clearly superior to conventional ablations.

When I started using the IntraLase FS femtosecond laser (Abbott Medical Optics Inc.) approximately 4 years ago, I initially upcharged LASIK patients $500 per eye if they opted for the IntraLase FS to create their flaps. People who chose the mechanical microkeratome did so because of price; although my staff and I informed them that the IntraLase FS provided greater safety and efficacy, they did not want to spend the extra money. I grew more comfortable with the IntraLase laser and more impressed with its safety and reliability, however, and was using it in more than 90% of my patients within approximately 6 months.

Thus, I began to feel that I was compromising patients' outcomes by using a mechanical microkeratome instead of the IntraLase laser. I decided that I did not feel comfortable using the microkeratome on any patient when I knew I would choose the IntraLase FS for myself or a family member or a friend. So, 3.5 years ago, I made the choice to perform 100% of my refractive surgeries with the CustomVue platform and the IntraLase FS laser—the iLASIK suite.

To my surprise, my decision became a selling point for my staff and me. Now, when our counselors present the option of iLASIK surgery to patients, they say, "Dr. Probst feels that these technologies are the best, and he doesn't feel comfortable offering any other options." If the patient still wants surgery with a microkeratome, the counselors tell him that they will have to arrange that with a different surgeon, and that response often gives the patient pause. Since I made this commitment, our iLASIK conversion rate has increased

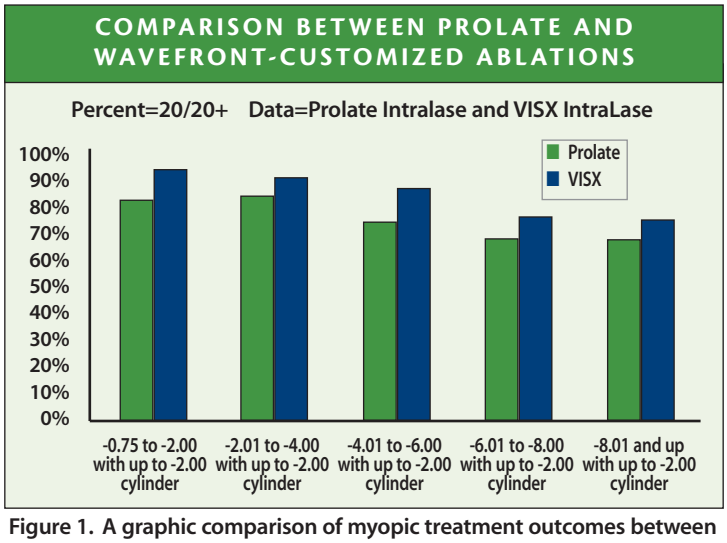


Figure 1. A graphic comparison of myopic treatment outcomes between a prolate laser treatment and the CustomVue laser treatment, both with IntraLase flaps.

from about 90% to approximately 98%. I can accept losing a handful of patients every year because I know I am giving my patients the safest, most effective refractive procedure, which I believe is my duty as a refractive surgeon. We ophthalmic surgeons should be committed to providing vision care without compromise, and that is what I think the iLASIK platform delivers.

Dr. Vukich: You have conducted careful analyses of refractive technologies and outcomes over your years of experience with laser vision correction. Will you comment on your results?

Dr. Probst: TLC maintains an extensive database and data analysis system into which our physicians enter every patient's outcomes. This gives us the opportunity to compare the results of all the different refractive technologies and from each TLC center. Our data show 3% to 5% greater rates of 20/20 outcomes with the IntraLase versus mechanical microkeratomes. The real advantage of the FS laser, however, is its safety profile. The data from all 75 TLC centers throughout the US show that mechanical microkeratomes' incidence of aborted or adverse events is four to six times higher than with the IntraLase FS. Although elective surgery patients may tolerate enhancements, they will not tolerate a complication, and problems with microkeratome-made flaps can be difficult to fix. The IntraLase's cut is so controlled and precise that its incidence of adverse events is much lower. Even if a surgeon has a rare adverse event with the IntraLase, he or she can interrupt the procedure without fragmenting the flap like a microkeratome or alternative femtosecond lasers will do. This safety profile and the reduction in stress for patients and surgeons are the main reasons why TLC surgeons now use the iLASIK suite in 90% of surgeries, and we hope to increase that rate to 100% as soon as possible. The iLASIK enhancement rate is below 2% at most TLC centers.

Dr. Vukich: Have you considered laser platforms with alternative technology, such as the wavefront-optimized procedure? What influenced your decision in this regard?

Dr. Probst: My colleagues and I evaluated the wavefront-optimized laser technology, and when we analyzed our data between the two technologies, we found that the wavefront-optimized platform's results, although reasonable, are not as good as those with wavefront-guided treatments. Looking across the board in 2.00 D increments (from -0.75 to -8.00 D), CustomVue corrections consistently produce 5% to 10% more 20/20 outcomes than the Allegretto Wave platform (Alcon Laboratories, Inc., Fort Worth, TX) (Figure 1). So, although a wavefront-optimized ablation gives a better result versus conventional treatments, it is not as good as CustomVue. Surgeons should also be aware that wavefront-optimized ablations do not include taking a wavefront measurement of the eye before the procedure. The Allegretto Wave system adds the standard spherical aberration correction to every prescription, and some patients receive too much correction. Therefore, a small number of patients will actually suffer worse vision after a wavefront-optimized treatment.

In short, my TLC colleagues and I have been far more impressed with the results from the CustomVue wavefront-guided platform. In addition to producing more 20/20 and 20/16 results, it has iris registration, which accurately places the treatment on the eye, offers advantages for patients with high astigmatism, and minimizes the induction of higher-order aberrations. The wavefront-optimized platform does not offer similar features. As a company, we have chosen the iLASIK platform, because we believe it is the best laser refractive technology currently available.

Dr. Vukich: How are you adapting to the current economic environment without sacrificing the value of your patient care?

Dr. Probst: My colleagues and I are foremost concerned with surgical safety and results, and we feel that the evidence confirms that the iLASIK platform offers the best surgical results with the greatest safety. Although better technology costs more, we as surgeons have an obligation to offer the best procedures and to educate patients about their advantages. I do not think selling a cheaper surgical procedure is in the best interest of our profession or our patients. Clearly, refractive surgery is increasingly moving toward femtosecond flap creation and customized wavefront-guided excimer ablations. So, why wait? From a business perspective, you want to be positioned as using the top technology as early as possible. You do not want to be a late adopter who is catching up to your colleagues. ■

Louis E. Probst, MD, is National Medical Director of TLC The Laser Eye Centers. He is a consultant to Abbott Medical Optics Inc. and TLCVision. Dr. Probst may be reached at (708) 562-2020.

1. Schallhorn SC, Tanzer DJ, Kaupp SE, Brown M, Malady SE. Comparison of night driving performance after wavefront-guided and conventional LASIK for moderate myopia. *Ophthalmology*. 2009;116(4):702-709.

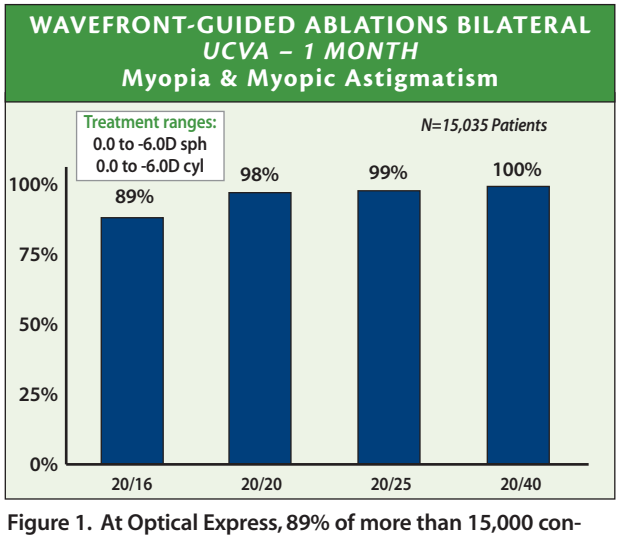
Measuring Quality of Vision in LASIK

Captain (Ret.) Steven C. Schallhorn, MD, describes the importance of wavefront-guided ablations and femtosecond flap creation for Navy fighter pilots, NASA astronauts, and Europe's largest provider of refractive surgery.

Dr. Vukich: Dr. Schallhorn, as an expert in measuring quality of vision, why do you think physicians find it difficult to measure visual quality in terms other than anecdotal patient observations?

Dr. Schallhorn: Simply put, there are many problems measuring visual quality. For one, there are no standards for testing quality of vision. There are a host of different metrics, including contrast sensitivity and glare tests. While many of these tests have been available for years, they've never really caught hold and are not routinely used. A central problem is that there is not a strong correlation between contrast test results and the patient's visual experience, both function and symptoms. Some patients have relatively poor contrast sensitivity yet state they have a high quality of vision, and vice versa.

Because we do not yet have a full appreciation of how objective measures of quality of vision are related to functional vision, I still consider the gold standard to be the quality of vision as voiced by the patient. This is also the most clinically relevant measure, and it can be quantified in a psychometric questionnaire. However, questionnaires can be cumbersome to score, database, and analyze, which can make them difficult to utilize.



(Data from Optical Express Group.)

Figure 1. At Optical Express, 89% of more than 15,000 consecutive patients with low-to-moderate myopia and/or astigmatism achieve 20/16 or better bilateral UCVA when treated with a wavefront-guided ablation.

Dr. Vukich: What can practitioners do to better assess quality of vision?

Dr. Schallhorn: The most important clinical assessment of a patient's quality of vision is what they say about it. Asking patients specific questions about their night vision, night driving, and/or glare and halos is the easiest and most cost-effective method.

Dr. Vukich: You were significantly involved with the studies that led NASA to approve LASIK for its astronauts. Please describe some of your studies that influenced that decision. In your opinion, what paved the way for that approval?

Dr. Schallhorn: My colleagues and I have been involved in refractive surgery research since the early 1990s. Although the type of LASIK we performed years ago resulted in good visual outcomes, we were not satisfied that the technology provided the best visual quality for our Navy pilots. This accelerated our interest in examining improved technology, specifically a wavefront-guided ablation profile and femtosecond flap creation. From our comprehensive research we found that, independent of any other variables such as flap-creation devices, wavefront-guided ablations provided a better outcome and, most importantly, an improved quality of vision.[1] Also, independent of the ablation profile, using a femtosecond laser to create the flap also provided a better quality of vision and faster visual recovery. Most significantly, when we combined these two technologies, we found the sum to be greater than the parts.[2]

Some of the background studies that helped pave the way for the NASA approval were the comprehensive PRK studies, which demonstrated that laser vision correction provided a tremendous benefit to aviators, being both safe and effective.[1] We also looked at environmental issues, such as the stability of the LASIK flap, as well as quality-of-vision studies.[1-3] Our research showed that wavefront-guided procedures were more predictable than conventional ablations, with 88% of patients achieving 20/16 or better at 3 months postoperatively on the CustomVue platform. We also showed that the IntraLase provided faster visual recovery than a mechanical microkeratome. One week after surgery, 77% of patients in that study achieved 20/16 UCVA or better, compared to 58% with a mechanical microkeratome.[1]

The key study that led to NASA's approval of LASIK was an evaluation of night-driving performance after LASIK. We compared conventional LASIK performed with a mechanical microkeratome to what is now called *iLASIK* (the CustomVue wavefront-guided platform and the IntraLase laser).[3] We found a significant improvement in night-driving performance after the iLASIK procedure from pre- to postoperatively. These patients also showed a significant improvement compared to those who received the conventional treatment. This was the first time a postoperative improvement in night driving, a visually demanding and performance-based task, had been quantified. These studies—most significantly, the night-driving evaluation—were instrumental in NASA's decision to evaluate and eventually approve LASIK for its astronauts.

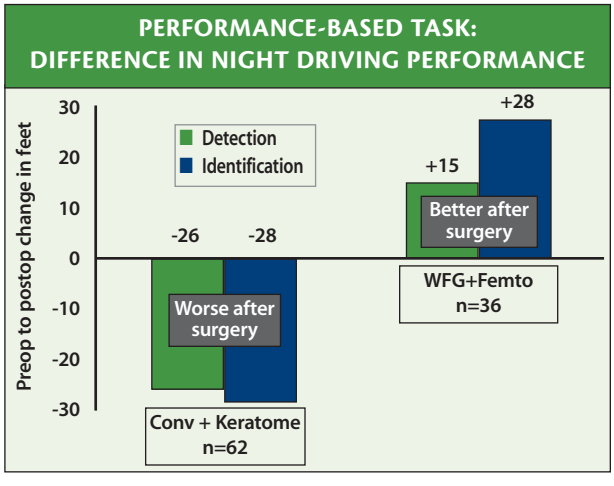


Figure 2. The Night Driving Simulator study demonstrated a dramatic difference in detection and identification tasks between conventional LASIK, using a mechanical keratome, and wavefront-guided LASIK using a femtosecond laser for flap creation. The WFG group had a significant improvement in this performance-based task, especially when compared to conventional/keratome eyes. This study was key to NASA's approving LASIK for astronauts.

Dr. Vukich: You are the Medical Director of Optical Express (Glasgow, United Kingdom). Please describe this company and why it is unique.

Dr. Schallhorn: Optical Express is the largest provider of laser vision correction in Europe, with more than 230 locations in eight countries, including the US. The company is unique because of its outstanding clinical and patient care model, its sound clinical governance, and the high volume of patients it treats.[4] In addition, it has an impressive electronic medical records system into which every patient's results are automatically entered. Surgical outcomes are monitored with a system of checks and balances. This allows the company's biostatistics team and International Medical Advisor Board to analyze a vast amount of information for the purpose of improving patient care.[5]

The premium LASIK option at Optical Express is the CustomVue treatment combined with the IntraLase femtosecond laser flap creation (iLASIK). We chose this technology because it produces better outcomes than standard ablations and mechanical microkeratomes. Despite the greater cost, most Optical Express patients choose to have this premium option.

We continually conduct a thorough evaluation of patients' outcomes at Optical Express. We are seeing excellent results, especially with the combination of wavefront-guided ablations and femtosecond flap creation. One recent analysis of 15,035 patients who underwent bilateral surgery to treat low-to-moderate myopia with up to 6.00 D of astigmatism showed that 98% achieved 20/20 bilateral UCVA or better at 1 month postoperatively, and 89% achieved 20/16 or better.[6]

The capability to analyze such a large number of outcomes could have a significant and positive impact on clinical practices moving forward. Currently, we are evaluating LASIK exclusion criteria through our large database, and we look forward to sharing this analysis and additional studies with the community in the future. ■

Captain (Ret.) Steven C. Schallhorn, MD, is in private practice in San Diego and is Chief Medical Director of Optical Express. He is a consultant to AcuFocus, Inc., and Abbott Medical Optics Inc. Dr. Schallhorn may be reached at steveschallhorn@opticalexpress.com.

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GETTING THE MOST OUT OF iLASIK

Suggestions for improving outcomes with wavefront-guided procedures from William B. Trattler, MD.

Dr. Vukich: Will you describe some of the physician variables involved in getting excellent results with wavefront-guided procedures? What steps can physicians take to improve their outcomes?

Dr. Trattler: Patient selection is very important to better outcomes. In particular, preoperative topography is critical for determining whether a patient is eligible for LASIK. iLASIK (Abbott Medical Optics Inc., Santa Ana, CA), which produces 100-µm flaps, has been shown to provide better corneal biomechanical stability compared with conventional LASIK with metal microkeratomes and traditional flap thickness.[1] However, it is still important to avoid creating flaps on patients whose topography is suspicious for forme fruste keratoconus. Surgeons should also carefully evaluate the ocular surface for signs of dry eye and blepharitis, which should be treated prior to iLASIK treatments.

Another important step in optimizing outcomes is determining refractive targeting. For patients over the age of 40, I typically perform contact lens testing to determine whether they will tolerate minimonovision/blended vision. For myopic patients in their 20s, I target a final refraction of +0.40 D, which will give them excellent vision and also will leave room in the eye in case their myopia slightly progresses over time.

Obtaining excellent wavefront captures is a final critical step before a wavefront-guided treatment. My staff and I bring patients back on a separate day from their initial evaluation so we can perform their WaveScan captures with the room's lights off. During the capture, we instruct patients to focus on a distant target. We evaluate the refraction output to make sure it is consistent with our manifest refraction, and then we carefully evaluate the centroids to make sure they are of high quality. Optimal centroids will appear clear and bright, while less-than-ideal centroids may look smeared or appear faint or washed out with some missing areas. Also, on the Hartmann-Shack images, I pay close attention that the pupil is drawn correctly to include all of the centroids (data points). Centroids should be clear and not smudged or missing in a spot. Finally, the four Hartmann-Shack images should be centered within each box. If they are not, perhaps the patient is not looking properly at the fixation light. If many patients' Hartmann-Shack images are not centered, then the camera may need to be re-aligned.

Capturing a detailed WaveScan image also relies on accurate iris registration, which requires that the drawing of the outer iris boundary (OIB) is correct. If the OIB is not drawn correctly, then iris registration may not provide a well-centered laser treatment. Interestingly, eyes with large pupils may obscure landmarks on the iris for the software to identify. In these cases, we may need to turn the lights on low to constrict the pupil slightly so that the iris' landmarks can be identified.

Once all of these steps have been performed, we evaluate the wavefront maps to make sure that all of the WaveScans have an RMS error within .07 of each other. We typically take four WaveScan images, although only three images are required for clustering. Taking these steps to help ensure proper patient selection, appropriate refractive targets, and accurate WaveScan maps has helped me achieve more 20/16 and 20/20 outcomes with iLASIK technologies. ■

William B. Trattler, MD, is the director of cornea at the Center for Excellence in Eye Care in Miami. He has received funding for research, consulting and/or speaking from Allergan, Inc., Glaukos, Abbott Medical Optics Inc., Inspire Pharmaceuticals, Inc., ISTA Pharmaceuticals, Inc., Lenstec, Inc., Sirion Therapeutics, and Aton Pharmaceuticals. Dr. Trattler may be reached at (305) 598-2020; wtrattler@earthlink.net.

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