HIGH-TECH CONSTANT OF A CONSTA

BY ANNIE STUART, CONTRIBUTING WRITER

o achieve excellent postcataract results with toric intraocular lenses (IOLs), precise axis alignment is essential.

"A 3-degree misalignment can lead to a 10 percent loss of cylinder correction," said Kevin M. Miller, MD, at the University of California, Los

Angeles. "With 10 degrees of misalignment, you lose 33 percent of the effect, and with 30 degrees, you lose all of the effect.¹ Not only that, but the axis of residual astigmatism is at a different angle, often oblique."

High-tech systems can take much of the guesswork out of axis alignment. Some systems utilize intraoperative wavefront aberrometry; others link

keratometry or topography to a photograph of the eye. Five cataract surgeons provide insight into the features of five systems on the market. But first, here's a quick review of standard approaches.

Standard Ways of Finding the Target Meridian

"We can introduce significant error when mea-

suring preoperative corneal astigmatism," said Dr. Miller. He described the challenge of keeping a patient's head perfectly straight in a corneal topographer so that the measured axis of astigmatism is accurate. "It's easy to get a 10-degree tilt to the left or the right, which translates into 33 percent of lost effect, as mentioned above."

In addition, error may be introduced through manual placement of reference marks on the peripheral cornea—whether at 6- or 3- and 9-o'clock. "In placing the mark(s), you can easily be off by 5 to 10 degrees," said Dr. Miller. But even if you're dead on, your ink mark(s) can run or smear by 5 to 10 degrees, he said. This is before you've even put the patient under the microscope to mark the steep axis.

"Then the surgeon is expected to line up the toric implant on an already twice-removed stackable error," said Jonathan D. Solomon, MD, in private practice in Bowie and Greenbelt, Md. In addition, he said, the surgeon must consider the impact of posterior corneal astigmatism² and the healing process. Opinions vary about whether or not to leave patients with a bit of with-the-rule astigmatism to compensate for gradual shifts against the rule, said Dr. Solomon.

Improvements in orientation. Innovations in the past decade have helped overcome some of these problems. For example, Robert H. Osher, MD, at the University of Cincinna-

As technology evolves, cataract surgery outcomes also continue to improve. Can astigmatic patients now achieve emmetropia? A growing number of high-tech systems on the market may help put this brass ring within reach.

> ti and the Cincinnati Eye Institute, developed the Wet-Field Osher ThermoDot (Beaver-Visitec International). ThermoDot allows you to make tiny marks that can't diffuse or disappear during surgery, he said.

Dr. Osher also introduced the concept of iris "fingerprinting"—using anatomic landmarks to more accurately orient a toric lens during surgery, which he validated with intraoperative keratoscopy.³ Dr. Osher said that in early 2015, Eye Photo Systems would introduce its software for capturing images of the iris.

New Technologies

"Automated systems have gone further

[than other approaches] in eliminating stackable physician errors," said Dr. Solomon, "and can provide new cataract surgeons a degree of confidence that was previously unattainable."

Posterior corneal astigmatism. Although very expensive, said Dr. Osher, devices such as Ziemer Galilei, Oculus Pentacam, and i-Optics Cassini are able to measure posterior corneal astigmatism, which gets surgeons closer to a true reading of total corneal astigmatism. These devices may come as part of an integrated package. For example, Cassini is part of the TrueGuide system (see "Topography Plus Surgical Guidance," below).

Limbal registration. Some systems use limbal registration to aid in accurate alignment. "They capture a preoperative image and then recall it during surgery to generate the target meridian on the monitor or through the microscope," said Dr. Osher. This is how the Verion Image Guided System (Alcon), Zeiss Cataract Suite Markerless (Carl Zeiss Meditec), and TrueGuide (TrueVision 3D Surgical) function. In pilot studies using two of these systems, Dr. Solomon



Zeiss Cataract Suite Markerless from Carl Zeiss Meditec

and colleagues reduced alignment errors by 50 percent over manual approaches. These results are slated to be presented at ASCRS 2015 ("Toric IOL Performance During Cataract Surgery With Surgical Guidance System").

Intraoperative wavefront aberrometry. To help the surgeon choose the correct intraocular lens (IOL) power and then align the toric lens with the proper axis, two sys-

tems on the market use intraoperative aberrometry. These are Clarity Medical Systems' Holos IntraOp and Alcon's WaveTec Vision Optiwave Refractive Analysis (ORA) with VerifEye.

High-tech approaches will become the standard of care for nailing the refractive target and achieving emmetropia, said Dr. Osher. "In the meantime, surgeons will need to overcome some challenges, such as learning curves, costs, and increased chair time to explain options for astigmatism correction."

Intraoperative Wavefront Both ORA and Holos IntraOp can Aberrometry

measure phakic, aphakic, and pseu-

dophakic refraction of the eye, both cylinder and sphere. (However, Holos IntraOp cannot recommend a spherical IOL power from the aphakic refraction, said Dr. Miller.) Both instruments provide continuous, real-time refractive feedback for astigmatic correction when the surgeon is rotating toric IOLs, titrating limbal relaxing incisions or peripheral corneal relaxing incisions, and performing arcuate incisions with a femtosecond laser.

ORA system. "This system is an indispensable tool in my practice," said Dr. Solomon, "and with good patient fixation, you can get reliable, reproducible data." The ORA features a large dynamic range of -5 to +20 D, using Talbot moiré interferometry to determine the refractive state of the eye. The aberrometer calculates and confirms IOL power after cataract removal and IOL implantation, and determines the magnitude and axis of astigmatism after cataract removal and limbal relaxing incisions.

Entry of pre- and postop information into the Web-based data system, said Dr. Miller, helps optimize ORA IOL power calculation for each lens model and surgeon. What it doesn't do, however, is take previous outcomes into consideration, said James A. Katz, MD, in private practice in Chicago. "The system doesn't have the ability to improve surgeon nomograms."

Posterior astigmatism. ORA played a pivotal role in clarifying the impact of the posterior cornea following lens removal, said Dr. Solomon. "Prior to Douglas Koch's study on the role of posterior corneal astigmatism, aphakic measurements using the ORA system had demonstrated a need for adjustment based on total measured astigmatism."

Dr. Koch confirmed that the posterior cornea can have, on average, 0.3 D of astigmatism, added Kendall E. Donaldson, MD, MS, at Bascom Palmer Eye Institute. "This can have a significant impact on multifocal [IOL] patients, who are extremely sensitive to small degrees of astigmatism."

• Axis refinements. Calling it a very versatile system with multiple functions, Dr. Donaldson finds the ORA particularly helpful for refining the axis of a toric lens. "With a femtosecond laser, I make 10- to 15-degree instrastromal incisions at the steep axis," she said, "and then use the ORA to refine alignment in the eye. It will tell you, for example, if you have to

rotate 5 degrees one way or the other, and when no further rotation is recommended. This is very reassuring, especially when dealing with someone who has 7 to 8 D of astigmatism, where even a small degree of misalignment can have a dramatic effect."

VerifEye. ORA

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TrueGuide from TrueVision 3D Surgical

recently upgraded its system with VerifEye, which confirms that the system is stable before measurements are taken. VerifEye has a faster imaging processor—producing something closer to video than still-frame photos, said Dr. Donaldson. "With the old system, it would often take five to 10 minutes for accurate image registration and adjustments to toric alignment, but it's now closer to two to three minutes, depending upon ocular surface irregularities and patient cooperation."

Holos IntraOp system. New to market, Holos Intra-Op has proprietary scanning real-time technology that provides streaming video of intraoperative

wavefront data. "It gives extremely accurate wavefront results," said Dr. Osher, who used it in its prototype stage.

"The reason it took so long to come to market is because of the sensitivity and accuracy of the system," he said. "For example, even a squirt of balanced salt solution (BSS) on the cornea has an effect. The company had to work continually to improve the algorithm to get a more consistent set of measurements for the surgeon to interpret." With improvements in software, outcomes have improved, said Dr. Donaldson.

Challenges with these systems. However, patients who have undergone radial keratotomy can still pose a challenge for intraoperative wavefront aberrometry. "The more cuts and the smaller the optical zone, the greater the variability in results," Dr. Donaldson said. "You need to be more careful with these patients."

In addition, because aberrometers are mounted directly to the bottom of surgical microscopes, they take up a lot of space and often need to be wrapped in sterile plastic, said Dr. Miller. "This adds another step during the operation and can slow you down."

Eliminate preop test-

ing? If these systems could develop algorithms that correlate closely with postoperative refractive error, said Dr. Osher, then all the expensive preoperative testing could go away. Whether ORA or Holos IntraOp, he said, it's a very real possibility. "I wouldn't bet my entire retirement plan on it, but it's very promising."

Topography Plus Surgical Guidance



Verion Image Guided System from Alcon

Verion, TrueGuide, and the Zeiss Cataract Suite Markerless are three high-tech surgical guidance systems

on the market. The Cirle Surgical Navigation System is still in development, in partnership with Bausch + Lomb. Dr. Osher calls these a major step forward, and he refers to Verion as his "go-to system." With

PEARLS FOR PRECISION

Work together. "With any of these systems," said Dr. Solomon, "make sure you collaborate closely with the anesthesiologist so the patient can cooperate. Patient fixation is helpful."

Let there be light. In addition, said Dr. Solomon, use a microscope with high-quality illumination that allows you to clearly identify scleral/ limbal landmarks for registration when using systems such as True-Guide.

Reduce disruption. Minimize disturbances to the cornea, said Dr. Solomon. These can affect your measurements, especially when using aberrometers, added Dr. Miller. Factors that may have an influence include pressure from an eyelid speculum, dryness, viscoelastic on the cornea, and head tilt. "Make sure the IOP is in the upper physiologic range," said Dr. Donaldson. "Also, edema around the wound can throw off astigmatism measurements, so it's best to avoid torquing the wound too much during surgery."

Have a backup plan. Although Dr. Osher calls manual marking with a \$1 ink pen "prehistoric," he still recommends having a "parachute" such as an ink mark or ThermoDot in case a technology fails.

Meld measurements. Together with Andrew Browne, MD, PhD, Dr. Osher conducted research that involved taking K measurements with various technologies. "We found that using just one technology creates a 20 percent chance of an outlying measurement—greater than 0.5 D or 5 degrees off the norm when all technologies were averaged together."¹

Based on these findings, he recommends combining at least three technologies: manual K, automated K, and topography. "With melding, you can reduce outliers to less than 2 percent," he said. Take one step at a time. Each of these systems has a lot of bells and whistles, so Dr. Katz recommends learning the most important things first. "With the TrueVision system, for example, you would lose some accuracy without the Cassini, so get comfortable with it first.

"Also, remember that TrueVision doesn't have to be used heads-up," he said, suggesting a gradual move over to this newer approach.

"If I were just starting, I would use the surgical guidance to make my initial incision and to place the IOL," Dr. Katz said. "Then as I became more familiar with it, I'd use some of the more advanced functions, such as dynamic linkage of primary incision adjustments and toric IOL alignment, to manipulate the target residual astigmatism power and axis."

1 Browne AW, Osher RH. *J Refract Surg.* 2014;30(1):67-72.

the recent addition of markerless alignment, Dr. Osher said he will also bring the new Zeiss Suite into his armamentarium soon.

He does, however, continue to combine iris fingerprinting with the high-tech limbal registration these systems offer. The reason? Pupil dilation can cause changes to the blood vessels in the limbus; or blood, BSS, or anesthetic can alter the conjunctival



WaveTec ORA With VerifEye from Alcon

anatomy—but the peripheral iris anatomy remains consistent.

Verion. SMI developed the Verion system, and Alcon acquired the technology a couple of years ago, said Dr. Miller. "The Verion Reference Unit is a modified keratometer that takes corneal power measurements; captures a high-resolution reference image; and autodetects scleral vessels, limbus, pupil, and iris features—locking K val-

ues to the image. You know exactly where the steep axis is compared to the image of the eye, and the steep axis reticule within the heads-down display of the microscope tracks with the eye as it moves."

Information from the Reference Unit is then viewed in the Verion Digital Marker, which can be

used with the LenSx laser and most surgical microscopes. The Digital Marker software tracks with the eye and provides a digital overlay to assist the surgeon with placement of incisions and alignment of the IOL—in real time, said Dr. Miller. "It not only helps with toric lens axis alignment, but it also does a lot of other planning, including providing guides for relaxing incisions, guiding the capsulorrhexis, and creating a bull's-eye for lining up a multifocal lens at the end of surgery."

Although Dr. Miller speaks well of the Verion's capabilities and versatility, he said that the system still lacks the ability to measure the axial length of the eye. Calculating lens power must be done separately.

Zeiss Suite. With the markerless suite from Zeiss, said Dr. Miller, you get everything with one instrument—the IOLMaster 500, which measures the axial length of the eye, measures the K values of the cornea, and locks those K values to a picture of the eye.

"You take that image on a flash drive to the operating room and get the same functionalities as the Verion," he said. "But it lacks Verion's versatility, requiring use of Zeiss equipment—the IOLMaster, Callisto eye [for toric alignment], and OPMI Lumera 700, which is currently the best microscope on the market."

The efficiencies one gets with the Zeiss Suite really can't be beat, added Dr. Solomon. "You have the patient at one machine and have all the information from your typical workup delivered through an eye-

COST CONSIDERATIONS

Payment methods vary for the different high-tech systems and may involve a flat purchase, monthly fees, or click fees.

Click fees. "At UCLA, we own our IOLMaster 500, Callisto eye, and TrueVision instruments outright, but we are getting a LenSx laser system and the Verion Reference Unit/Surgical Guide on a clickcharge basis," said Dr. Miller, who prefers this click-fee arrangement, considering that obsolescence may become an issue. In return, he said, the company maintains the laser and keeps the software and hardware current.

Purchase. In contrast, purchasing a system means you can use it as much as you want, said Dr. Donaldson. "The more experience you gain, the faster and more proficient you become, and the more you want to use it."

Patient preferences. Will patients pay the extra costs? It depends upon the market, said Dr. Miller, who works in West Los Angeles. He's found that about 85 percent of his patients have been more than amenable to paying \$1,400 for traditional astigmatism management using the diamond knife approach.

Dr. Osher always reassures patients that, if money is an issue, they can have their astigmatism corrected with glasses. "I explain the options and say, 'You're going to be happy no matter what you choose.' But if they ask, 'Which approach is best?' I say, 'Toric correction is a better option.'"

Physician barriers. The biggest barrier to getting these high-tech systems and astigmatism-correcting IOLs used more is not the patient's ability to pay for it, said Dr. Miller. It's the surgeon's willingness to offer it. Many surgeons prefer to stick to reimbursable procedures, in part because they are accustomed to dealing with such payment processes rather than cash. Beyond that, he said, once patients' cash is on the table, their expectations are much higher. "Most surgeons don't want to get into the cash part of the practice or to risk having an unhappy patient if results are less than satisfactory."



Holos IntraOp from Clarity Medical Systems

piece on your microscope. The new markerless version now provides autoregistra-

tion. What the system doesn't have, however, is the ability to capture data off the back of the cornea."

TrueGuide. Compatible with any surgical microscope, this system provides a closed loop from planning and real-time surgical guidance to clinical outcome improvement, said Dr. Katz. "It's a cloud-based system, which allows input of patient data anywhere, improves workflow, and reduces the risk of transfer errors." TrueGuide also acts as an archiving system, he said.

The system can be used seamlessly with oculars or totally heads-up, which Dr. Katz prefers and which may help reduce the risk of repetitive motion injuries, he said. Small 3-D monitors can be integrated into existing microscopes to reduce the system footprint. However, the larger screen configuration option must be positioned slightly to one side. According to Dr. Miller, both the heads-up and off-axis view can take some getting used to.

Integrated with the i-Optics Cassini topographer, TrueCapture software suggests the treatment plan and IOL to use, making real-time calculations to link the incision location to IOL position and to drive low residual astigmatism, said Dr. Miller.

Unique to this system, said Dr. Katz, is its 3-D eye tracking, which helps align preoperative with intraoperative images without parallax errors. Surgical templates help guide the surgeon, and the system also automatically creates operating position profiles customized to each surgeon user. A regression analysis generated three weeks after surgery can help to improve future patient outcomes.

Notably, TrueGuide can acquire posterior (and anterior) corneal data via the Cassini Total Corneal Astigmatism integration, said Dr. Solomon.

The future: Integration of systems. Dr. Osher predicts that Verion and ORA will become an integrated system—part of a cataract suite that provides the entire preoperative and intraoperative experience. "There's some overlap between the systems, but they each have unique features, so I think integration will be synergistic. All the companies are realizing that this approach is going to be the standard of the future."

Dr. Katz agreed that further systems integration, such as the data transfer in development between the TrueGuide system with Cassini and the Lensar femtosecond laser, is the next step in creating a seamless surgical planning and execution process.

"To get the level of accuracy we're trying to achieve," said Dr. Donaldson, "I do think someday intraoperative aberrometry will become a universal component of cataract surgery. I foresee a similar evolution for the femtosecond laser's role in cataract surgery. We're lucky to have technology advancing at this rate. Even now, we can offer high-toric patients the best vision of a lifetime."

1 Visser N et al. *J Cataract Refract Surg.* 2011;37(8):1394-1402. 2 Koch DD et al. *J Cataract Refract Surg.* 2012;38(12):2080-2087.

3 Osher RH. J Cataract Refract Surg. 2010;36(2):351-352.

MULTIMEDIA EXTRA: Be sure to view the video on how to place a toric IOL that accompanies this article.



MEET THE EXPERTS



KENDALL E. DONALDSON, MD, MS Medical director and associate professor of clinical ophthalmology, Bascom Palmer Eye Institute in Plantation, Fla. *Disclosure: None.*

JAMES A. KATZ, MD Medical director, Golf Laser Vision; cataract/refractive surgeon, Midwest Center for Sight in Chicago. *Disclosure: Consults for Alcon and i-Optics; consults for and has commercial interest in TrueVision 3D Surgical.*

KEVIN M. MILLER, MD Kolokotrones Chair in Ophthalmology and chief of cataract and refractive surgery, David Geffen School of Medicine, University of California, Los Angeles and Stein Eye Institute. *Disclosure: Is an investigator and speaker for Alcon.*

ROBERT H. OSHER, MD Professor of ophthalmology, College of Medicine, University of Cincinnati; medical director emeritus, Cincinnati Eye Institute, in Cincinnati. *Disclosure: Consults for Alcon, Bausch + Lomb, Carl Zeiss Meditec, and Clarity Medical Systems.*

JONATHAN D. SOLOMON, MD Surgical/refractive director, Solomon Eye Associates in Bowie and Greenbelt, Md. Disclosure: Consults for Carl Zeiss Meditec and True-Vision Systems.