INNOVATIONS ADVANCING CATARACT SURGERY

Introducing new technologies and emphasizing others that are designed to promote more efficient cataract surgery with better outcomes

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The physicians are consultants for Alcon and received compensation for their contributions to this supplement.

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Technology integration, personalization, and visualization: These are all areas where there have been significant improvements for ocular surgery.

With each iteration of cataract surgery equipment, Alcon makes improvements to reduce surge after occlusion break. When these events occur, capsular rupture risk increases, as does the subsequent risk of retinal detachment and CME. You want to get it to zero, but it’s not zero yet. Hence, the advantages of improvements like the CENTURION Vision System with ACTIVE SENTRY handpiece and the INTREPID Hybrid Tip.

Another area of improvement is the Alcon LuxOR Revalia Ophthalmic Microscope, which has a larger and more stable red reflex than other microscopes, backlighting the lens and the cataract so surgeons can better orient where they are, among other innovative features. The NGENUITY 3D Visualization System is a game changer, both for vitreoretinal surgery, my specialty, and in the anterior segment, as my colleagues discuss.

In this supplement, Robert Cionni, MD, Lawrence Woodard, MD, Ashley Brissette, MD, and I describe our experiences with some of these technologies—and others—and how they are improving surgery, our outcomes, and ultimately the patient experience.

Steve Charles, MD

Integrating technologies from the clinic and OR for cataract surgery

Robert Cionni, MD

Clinic, operative planning, and surgery: Most of us have come to an understanding that you can’t separate the three, and one doesn’t happen without the other. In the past, each of these facets has been treated independently by companies that produce the products we need, but that’s changing.

A few years back Alcon came to the realization that you can’t separate the three, and one doesn’t happen without the other. In the past, each of these facets has been treated independently by companies that produce the products we need, but that’s changing.

It started in the clinic; we needed a better way to get information into surgical planning platforms. Originally, when we had our patients’ preoperative plan and corneal keratometry measurements made, those were transcribed into an IOL planning formula. There are some inherent problems with that. You get different measurements at different machines; there’s a real possibility of a transcription error; and there are different formulas from which to choose. In the end, there was a higher probability of making an error that could ultimately result in the wrong implant going into a patient’s eye. Another chance for error is when information is printed out but put in the wrong chart or doesn’t end up in the chart.

Alcon’s answer to that is the VERION Image Guided System. VERION digitally captures the data from your biometry and populates a surgical planning program, eliminating the need for transcribing the data. VERION, which dovetails with the ORA SYSTEM Technology, links to the operating room, providing the correct numbers and the correct implant for the correct patient without the need for a printout.

In addition to decreasing opportunities for mistakes, the VERION plan helps me improve my clinic efficiency.

Not long ago, I had a case where I didn’t have this technology available so we were working off a paper chart and plan. The calculation in this chart ended up being another patient’s calculation, resulting in the wrong implant going in. Had we been using the VERION technology, that would not have happened. In another case, a patient presented with differing K measurements due to a significant head tilt. This was an extreme example of a real issue that happens every day as small degrees of misalignment result from ocular rotational uncertainty. How do we know that the measured steep axis in the clinic will be properly identified in the OR? VERION manages this by capturing a reference image along with the keratometry. That reference image is digitally sent to the LENSX Laser and LuxOR microscope, where the image is matched to what is seen by the laser and microscope, thus the true steep axis is properly identified.

The final step in all this is the outcome. With the ORA SYSTEM with VerifEye Lynk technology that incorporates aberrometry with VERION, when the patient is seen postop, the postoperative result is entered into the ANALYZOR database. That information is used by Alcon to continually refine the IOL calculation formulas and stratify the data to specific case types such as post-refractive surgery, short eyes or long eyes. The more data that gets into the database, the better the calculations become and thus the better the predictability.

Microscopes present another opportunity for technology integration. The LuxOR has an overlay display with information from VERION that is seen through the oculars. This can help make toric IOL alignment or placement of manual corneal arcuate incisions or LIRs very precise. There is also a capsulotomy overlay guide that can be set to a specific size and personalized centration. Through the integration of the LuxOR microscope with VERION, the microscope now has a tremendous ability to track the eye, not only in the X and Y planes but also rotationally; this can help boost confidence that toric IOLs or arcuate incisions are lined up correctly. For toric IOLs, if one incorporates VerifEye Lynk technology, you will find your surgical efficiency and accuracy improves beyond what was possible with either of these technologies on their own. One can choose to follow the surgical plan or the intraoperative aberrometry-suggested toric magnitude and alignment. Either way, the chosen axis of alignment is shown on the overlay and tracked, so it is easy to place the IOL in the desired axis accurately.

If the surgeon chooses—and it’s what I choose to do—you can run through all the modalities of phacoemulsification and your
Robert Cionni, MD
Integrating technologies from the clinic and OR for cataract surgery

VerifEye Lynk steps using the phaco foot pedal, instead of having a nurse or technician push the buttons at the VERION cart. This has created a new level of efficiency in my operating room.

Another piece of technology that I have integrated into my OR in recent years is the NGenuity 3D Visualization System. Prior to operating off of a 3D display, I was having back and neck problems to the point where I was seeing a chiropractor almost weekly and was having trouble sleeping at night. That’s not a problem anymore, and I attribute most of that to being able to operate in a comfortable, relaxed position. NGenuity also allows me to position severely kyphotic patients any way I want without having to contort myself to see through oculars. A third benefit is that visitors, residents, and fellows can more clearly see and understand the moves I’m making in the eye because they are watching the same monitor I am. The clarity and depth of field with NGenuity is incredible.

With most of these technologies, there is improved efficiency and less potential for any postoperative surprises. What is the cost of an unwanted event? One cost is the possibility of needing a second surgery. With the changes in how Medicare pays us, one also has to consider how that additional surgery could affect your cost rating and its effect on your Medicare adjustment. Time spent in the clinic explaining a mistake to an unhappy patient is costly not only in time, but also in terms of your patient’s loss in faith. You might not just lose the patient but you could lose his/her referrals, and we all know that the best referral in the world is the word of mouth referral.

Taking all of this into consideration—if we can obviate the need for transcribing information from one machine to a software program, which lessens the possibility of an error, if the process can be more efficient (my plans are completed while I’m seeing the patient in the exam room), and if at the same time it improves the likelihood of a good outcome—even though there are expenses at the outset, the benefits far outweigh them.

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ORA SYSTEM with VerifEye+ Technology

Source: Alcon

VERION Image Guided System
• Reduces transcription errors
• Improves clinic efficiency
• VERION Reference Unit performs diagnostic measurements
• Measurement data automatically imported into the surgical planning system
• Surgical plan and reference image are uploaded into the VERION Digital Marker in the OR

ORA SYSTEM with VerifEye+ Technology
• Continuous intraoperative assessment
• Suggests IOL power and toric placement
• Surgeon optimization with ANALYZOR
Personalization and customization have become the expectation in nearly all aspects of daily life, and the ability to personalize products and customize procedures in medicine is starting to gain a foothold.

You can first personalize based on the type of practice you have. We all practice differently as surgeons. Some of us have a more refractive cataract practice, others have a more high-volume surgery practice, and some have a basic, pathology-driven practice. Just selecting products, technologies, and procedures that best fit your practice style is a form of personalization. A refractive cataract practice might choose to have the ORA SYSTEM Technology with VerifEye+ Technology and a LENSX Laser, while a high-volume surgery practice might benefit from the NGENUITY 3D Visualization System for enhanced visualization and surgeon comfort. You can personalize your purchases based on the style of practice you have, resulting in more practice efficiency in addition to better patient outcomes.

As far as customization at the product level, we’ve already had some ability to customize. In cataract surgery, for example, we’ve always had the ability to change certain parameters to adjust for the intraocular environment. But newer technologies are now allowing us to customize at a greater level because the products are able to adjust the settings more precisely and are better able to detect the changes that are happening during surgery. In that way, we are able to personalize the procedure more.

One of the ways Alcon is giving us the ability to customize and control our procedures more than we’ve ever been able to in the past is with its new ACTIVE SENTRY phaco handpiece, an advancement for the CENTURION Vision System. ACTIVE SENTRY moves the pressure sensors from the phaco machine to the handpiece, allowing the machine to respond more rapidly with ACTIVE FLUIDICS technology to the changing intraocular environment during cataract surgery. Prior to this innovation, it could take longer for the machine to detect and adjust for events such as post-ocular surge and shallowing of the anterior chamber. This was because the sensors are in the machine, connected to the handpiece via several feet of compliant tubing. Now, immediately the sensors can detect a change in the intraocular environment and relay that to the machine for automatic adjustments. I am now able to keep my anterior chamber environment more stable because the machine can more rapidly adjust to the fluid and pressure fluctuations that happen during surgery. This allows us as surgeons to control the intraocular environment better. With a machine that responds more quickly, we now have the ability to use higher vacuum levels and lower other settings, such as the IOP and the aspiration flow rate. We are able to keep the volume inside the eye more constant, reducing movement of the iris and the posterior capsule, while simultaneously using more aspiration and less phaco energy to remove the nucleus. All of these factors allow us to positively influence outcomes.

The sensor and subsequent adjustments are so seamless that it even prevents me from noticing that there has been a surge event. Traditionally, when there was a surge event, I would see the posterior capsule moving up toward the phaco tip. Now, there is much less of that movement. I see a benefit of ACTIVE SENTRY in cases with denser nuclei and in eyes that are more affected by fluctuations in the anterior chamber, such as those with floppy iris syndrome, but in the end, any case benefits from this technology because all of these events happen no matter what type of nucleus the patient has.

When initially evaluating the handpiece, I had ACTIVE SENTRY in one room and regular
CENTURION in the other, and there is no question that the anterior chamber environment is more stable with ACTIVE SENTRY. I had been so impressed with the traditional CENTURION handpiece that I doubted whether this technology would provide anything of benefit to me—and I’m a surgeon with very high parameters because I like the control that CENTURION provides—but when I tried ACTIVE SENTRY, I could tell the difference.

The benefits go beyond a more stable intraocular environment during surgery. Because I can use higher vacuum and still feel safe, I am aspirating the nucleus more and using phaco less, so I think I am using less ultrasound energy, which in the long run we know has the potential to be beneficial for the patient. I also think this increases my efficiency, reducing my time inside the eye and fluid usage, which could correlate with less corneal edema postop.

Phaco tip selection is another area where I can make personalized decisions based on the patient. A patient with soft to normal nucleus density or lenses that are prefragmented with a femtosecond laser are good candidates for the new INTREPID Hybrid Tip. This tip is essentially the same as the INTREPID Balanced Tip, but it has a rounded polymer end that gives it an added safety profile. This softer material, compared to metal, is gentler to intraocular tissue, if encountered during surgery, while still quite effectively emulsifying soft and moderate density nuclei.

I also use the LuxOR surgical microscope, which allows me to feel like I have more control when I’m inside the eye because I’m not focusing up and down as much with the foot pedal. This is due to its increased depth of field, which allows me to visualize tissues at various depths in the anterior chamber. Even more important to me is that LuxOR gives me greater visualization of the entire ocular surface and greater red reflex during cataract surgery because its objective lens is above the light source, compared to most microscopes that have the objective lens below the light source. The latest iteration called the LuxOR Revalia Ophthalmic Microscope will include an LED light source as opposed to halogen, which provides better contrast and detail of intraocular tissues. In addition, there are three light source color temperature selections to further allow the surgeon to customize the surgical procedure.

When we talk about customization and personalization, I think it’s important to discuss how the ORA SYSTEM with VerifEye+ Technology, in combination with the VERION Image Guided System and the LuxOR Microscope, enhances the surgical procedure. This combined system allows me to more accurately align toric IOLs and center multifocal IOLs, and it helps me generate better outcomes by tracking and monitoring my results using the ANALYZOR software. Through this system, I have all my data, which I can bring into discussions with patients. For instance, when a patient asks about my results with toric IOLs, I can say that 95% of my patients are within 0.5 D of my intended target. ANALYZOR allows me to quote data to patients, not just give them generalities, and I think that shows my patients that I am a conscientious surgeon who is concerned about achieving the best possible outcome for them.

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Visualization in cataract surgery

Ashley Brissette, MD

To achieve ideal visualization for cataract surgery, there are many settings for the operating microscope that need to be optimized—depth of focus, accommodation minimization (especially true for trainees), illumination, magnification, ergonomic positioning, etc. If these are not fine-tuned at the outset, many adjustments may be needed during the surgery, which is not ideal.

There have been some improvements to visualization in cataract surgery in recent years, for example, the quality of the optics and stereo coaxial illumination for the red reflex. This allows you to see every fine detail of the anatomy, even in complex cases, while not needing to increase the amount of light. I think this helps with patient comfort and safety as well. However, it can still be dependent on patient movement or tilting during the case, as the depth of field is limited with some microscope platforms.

While there have been advances in the realm of optics and illumination, just thinking about sitting at the microscope for a long OR day makes my neck hurt. I think we are getting better at recognizing the importance of ergonomics in surgery, but our work environment puts us at high risk for developing back and neck pain over our long careers.

We just opened a top-of-the-line surgery center at Weill Cornell Medicine, and the NGENUITY 3D Visualization System is one of the new technologies that we incorporated into our surgical suite. Our retina faculty were the first to jump on it, but I’ve started using it for the past few months for anterior segment surgeries—cataract, cornea, conjunctiva—and have been impressed with the system, both from a visualization standpoint but also in limiting my neck discomfort at the end of a long OR day.

I have a personal interest in ergonomics, and the more I talk to my colleagues, the more I realize how important physician well-being is to career longevity. I think the forward positioning of the operating microscope is a contributor to back and neck pain. Even for longer procedures, I find NGENUITY extremely beneficial to have not only improved depth of field and other visualization benefits but also being able to maintain a comfortable position. The first time I tried the system, I found that I was sitting and leaning forward just like I do at the microscope. I had to remind myself that I can sit back and break those old habits. When first getting started using NGENUITY, I made sure to try it on a less busy OR day so that I could play with the settings, color balance, and other features to get comfortable with the technology.

I find the image resolution similar to that of high-definition TVs and computers. The peripheral acuity is something that I was surprised to find I was missing with the analog microscope cases, especially in my cornea and conjunctival procedures. I find this feature gives an improved depth of field to the total operating space. In addition, the enhanced depth of field helps to maintain focus throughout a case so that you aren’t adjusting to keep structures in focus. Take, for example, a highly myopic eye with a deep anterior chamber. Normally, you would be adjusting the fine focus throughout the case as you reach down for nuclear pieces to bring to the iris plane for phacoemulsification, but with NGENUITY you can maintain the focus across this expanded space, which is especially helpful for challenging cases.

Our retinal colleagues are already comfortable with this technology, but I think anterior segment surgeons will adopt it in time. It’s been great as well for longer cases such as corneal transplants. An unexpected effect of NGENUITY in my OR is the team environment.
Viewpoint of a vitreoretinal surgeon

Steve Charles, MD

The NGENUITY 3D Visualization System is a major paradigm shift. I bought the first NGENUITY 3D Visualization System in the U.S., paying for it out of pocket because I saw so much value and potential in it. I’ve been using it exclusively since November 2016.

Vitreoretinal surgery requires 3D visualization. Because NGENUITY has paired small aperture CMOS sensors, it provides greater depth of field. This allows me to maintain focus despite a patient’s up-down head motion driven by respiration, an issue more pronounced in patients who are overweight or have COPD. With five times greater depth of field, the surgeon can maintain distance accommodation and avoid accommodation fatigue.

The surgeon’s image brightness, and therefore contrast, is virtually independent of patient macular light exposure, which is a safety advantage. A high dynamic range OLED display allows for photopic (all cone vision), rather than mesopic (cone-rod vision) as with a traditional microscope. Cone, or foveal, vision allows the surgeon to see high spatial details.

Another benefit is the huge 55” surgical display just 4 feet away. This surgical display offers image quality that continues to the corners of the plane. Typically, when you look through an operating microscope straight in, there is high-quality focus without much optical aberration. But if you look just a little above, below, left, right, the image quality deteriorates. Being able to see all four corners in perfect focus is a different experience. Now I’m able to look around on the field of view without moving the microscope; I am able to follow the folds in the retina and visualize membranes on the retinal surface, and I have better situational awareness.

While these are the core surgical and clinical benefits of NGENUITY, there are other benefits to this huge surgical display. Now everyone in the operating room can see the same view as the surgeon. Team coordination is markedly improved. If nurses see bleeding, they might offer me cautery or ask if they should increase intraocular pressure without me having to mention it. This has improved our OR efficiency.

For vitreoretinal surgery, NGENUITY populates information from the CONSTELLATION Vision System, such as vacuum level, IOP, mode, brightness, and a variety of other things. Each of the four corners of the screen has useful information, so instead of asking a scrub tech or trying to see the CONSTELLATION screen, which is too small and too far away, you can look right on the NGENUITY display, giving you more awareness of what you’re doing throughout the case.

This has been called by some “heads-up surgery.” The operating microscope blocks the view of the surgical display if it is placed directly in front of the surgeon. This requires it to be a little off to the left or right. I think calling it heads-up surgery is a misnomer, but I do consider it digitally assisted surgery.

When first getting started with NGENUITY, it’s important to have the surgical display set up properly. It has to be 4 feet away, not 10 feet away at the end of the table. Second, you have to have the aperture at the 30% mark, or you don’t get the increased depth of field. Finally, when doing vitreoretinal surgery, you have to initially focus on the cannulas, then focus down as you remove more and more vitreous and get closer to the cannulas. When you finally get on the retinal surface at the highest magnification, you optimize focus again.

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Steve Charles, MD

NGENUITY 3D Visualization System

- Up to 5 times extended depth of field*
- Up to 48% increased magnitude*
- Up to 42% increased resolution*
- Digital filters to enhance visualization, facilitate operating at lower light levels
- 55 inch OLED display with 8.3 million pixels of resolution
- Ocular-free design improves posture and may mitigate surgeon fatigue

*Alcon data on file, December 2017
Attention: Refer to the Directions for Use for the accessories/consumables and Operator’s Manual for a complete listing of indications, warnings, cautions and notes.

LuxOR Microscope
As with all ophthalmic microscopes, exposure during aphakia should be limited to reduce the risk of damage. During aphakia, limit exposure to red reflex light to no more than 7 minutes.

NGENUITY 3D Visualization System
Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Cataracts
The NGENUITY 3D Visualization System consists of a 3D stereoscopic, high-definition digital video camera and workstation to provide magnified stereoscopic images of objects during micro-surgery. It acts as an adjunct to the surgical microscope during surgery displaying real-time images or images from recordings.

Warnings: The system is not suitable for use in the presence of flammable anesthetics mixture with air or oxygen. There are no known contraindications for use of this device.

Precautions: Do not touch any system component and the patient at the same time during a procedure to prevent electric shock. When operating in 3D, to ensure optimal image quality, use only approved passive-polarized glasses. Use of polarized prescription glasses will cause the 3D effect to be distorted. In case of emergency, keep the microscope oculars and mounting accessories in the cart top drawer. If there are any concerns regarding the continued safe use of the NGENUITY 3D Visualization System, consider returning to using the microscope oculars.

Attention: Refer to the User Manual for a complete list of appropriate uses, warnings and precautions.

ORA SYSTEM Technology
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Cataracts
The VERION Reference Unit and VERION Image Guided System: VERION Reference Unit and VERION Digital Marker:

Indications:
- Significant central corneal irregularities resulting in higher order aberrations might yield inaccurate refractive measurements.
- Post refractive keratectomy eyes might result in higher order aberrations.
- The safety and effectiveness of using the data from the ORA SYSTEM have not been established for determining treatments involving higher order aberrations of the eye such as coma and spherical aberrations.
- ORA SYSTEM technology is intended for use by qualified health personnel only.
- Improper use of this device may result in exposure to dangerous voltage or hazardous laser-like radiation exposure.
- Do NOT OPERATE the ORA SYSTEM in the presence of flammable anesthetics or volatile solvents such as alcohol or benzene, or in locations that present an explosion hazard.

Attentions: Refer to the ORA SYSTEM Operator’s Manual for a complete description of proper use and maintenance, as well as a complete list of contraindications, warnings and precautions.

VERION Image Guided System: VERION Reference Unit and VERION Digital Marker

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Intended use: The ORA SYSTEM technology utilizes wavefront aberrometry data to measure and analyze the refractive power of the eye (i.e., sphere, cylinder, and axis measurements) to support cataract surgical procedures.

Cataracts
The VERION Reference Unit is a preoperative measurement device that captures and utilizes a high-resolution reference image of a patient’s eye. In addition, the VERION Reference Unit provides preoperative surgical planning functions to assist the surgeon with planning cataract surgical procedures. The VERION Reference Unit also supports the export of the reference image, preoperative measurement data, and surgical plans for use with the VERION Digital Marker and other compatible devices through the use of a USB memory stick. The VERION Digital Marker links to compatible surgical microscopes to display concurrently the reference and microscope images, allowing the surgeon to account for lateral and rotational eye movements. In addition, details from the VERION Reference Unit surgical plan can be overlaid on a computer screen or the physician’s microscope view.

Contraindications: The following conditions may affect the accuracy of surgical plans prepared with the VERION Reference Unit: a pseudophakic eye, eye fixation problems, a non-intact cornea, or an irregular cornea. In addition, patients should refrain from wearing contact lenses during the reference measurement as this may interfere with the accuracy of the measurements. The following conditions may affect the proper functioning of the VERION Digital Marker: changes in a patient’s eye between preoperative measurement and surgery, an irregular elliptic limbus (e.g., due to eye fixation during surgery, and bleeding or bloated conjunctiva due to anesthesia). In addition, the use of eye drops that constrict sclera vessels before or during surgery should be avoided.

Warnings: Only properly trained personnel should operate the VERION Reference Unit and VERION Digital Marker. Use only the provided medical power supplies and data communication cable. Power supplies for the VERION Reference Unit and the VERION Digital Marker must be uninterruptible. Do not use these devices in combination with an extension cord. Do not cover any of the component devices while turned on. The VERION Reference Unit uses infrared light. Unless necessary, medical personnel and patients should avoid direct eye exposure to the emitted or reflected beam.

Precautions: To ensure the accuracy of VERION Reference Unit measurements, device calibration and the reference measurement should be conducted in dimmed ambient light conditions. Only use the VERION Digital Marker in conjunction with compatible surgical microscopes.

Attention: Refer to the user manuals for the VERION Reference Unit and the VERION Digital Marker for a complete description of proper use and maintenance of these devices, as well as a complete list of contraindications, warnings and precautions.