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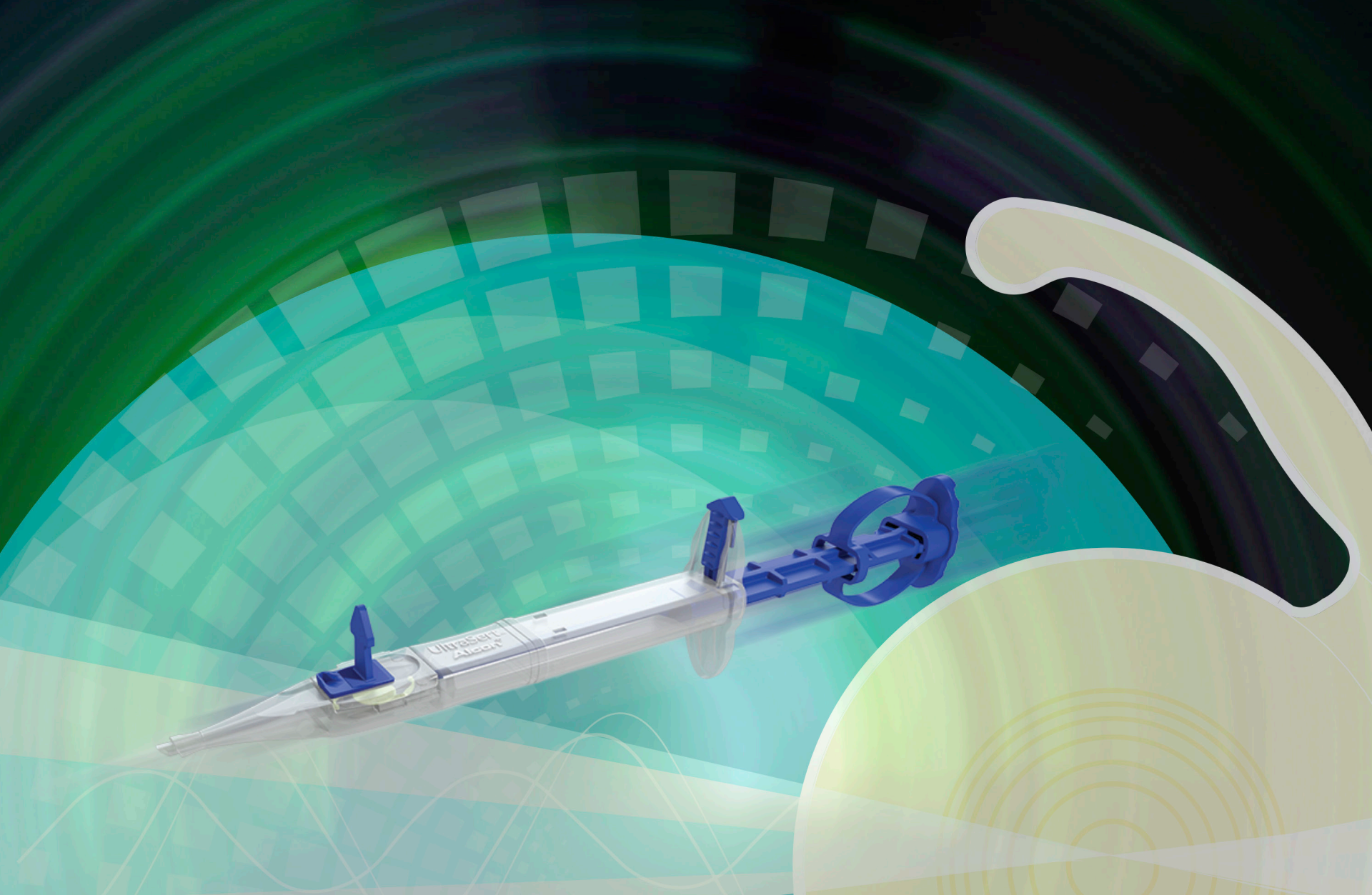
Innovative IOL technologies for the cataract surgeon



Innovative IOL technologies for the cataract surgeon

Moderator

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UltraSert Preloaded Delivery System with AcrySof IQ aspheric IOL

Simplifying IOL preparation for insertion and maximizing surgeon control in a single-use system allows for a more streamlined cataract procedure and enhanced sterility during IOL implantation. Because of this, single-use, preloaded IOL injection devices may be the future for implantation of all IOLs. The UltraSert Preloaded Delivery System with the AcrySof IQ aspherical monofocal IOL (Alcon, Fort Worth, Texas), which was recently launched, is the newest addition to what will be the growing number of single-use manufacturer-loaded IOL delivery systems. UltraSert demonstrates the advantage of integration of manual control with the convenience of a single-use, disposable, preloaded injection system that cataract surgeons can add to their surgical armamentarium.

Stephen Lane, MD: What are the benefits of a preloaded IOL? Which of these benefits was the most meaningful to you as you chose to start using the UltraSert device? In other words, what made you switch from manual (or a competitor) to UltraSert?

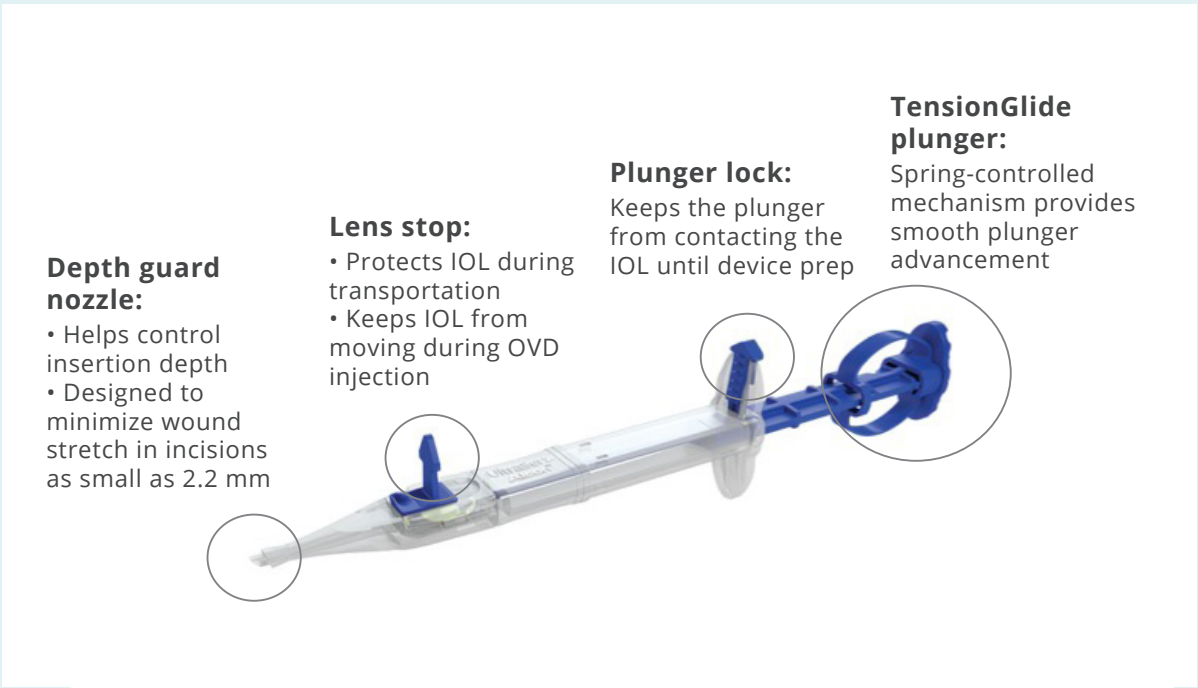
Richard Tipperman, MD: We need to look at this technology in terms of benefits for the patient, for the facility, for the staff of the facility, and for the doctor. With touchless delivery, there is a benefit across the board. It is a great product to deliver a lens very reproducibly each time. When we consider what is best for the patient, the facility, and the nursing staff, having the lens preloaded and being able to provide touchless delivery is a very strong positive. Surgeons need to realize that the small changes they will need to make in their technique to use this product are well worth it.

Lawrence Woodard, MD: I have been surprised by the beauty of an IOL that does not have imperfections due to handling. I realize how many times I have overlooked or ignored minor marks or imprints that technicians may have left on the IOL or that the metal plunger in the system may have placed on the IOL if it didn't fold perfectly. If these marks were not in the center of the visual axis, I would just move on. It is nice to see a clean optic each and every time.

Lisa Cibik, MD: I use a 2.2-mm incision, and it works well. The virgin lens is very gently placed inside the eye. One of the most serious problems encountered with preparing and using an IOL injector is having a partially or completely amputated haptic.

Dr. Tipperman: It's amazing how the lens always seems to be marked or scratched in a patient who is the mother of someone who works in your surgery center or in a patient with a very finicky referring doctor. This technology takes a great deal of worry out of the equation.

Dr. Cibik: This has to do with how the inserter is designed with the tension plunger and its spring-controlled mechanism. It allows the IOL to be inserted into



UltraSert Preloaded Delivery System with the AcrySof IQ aspheric IOL

the eye consistently and with limited scratches and trapped haptics.

Dr. Lane: Many of us have prepared the lens after it has come out onto the ocular surface, and the question of sterility is always an issue.

Dr. Woodard: There is always the possibility of contamination associated with delivering the IOL, whether it is from the ocular surface or from the delivery system. Obviously, we have all used many thousands of lenses over the years, and the Monarch system (Alcon) is one of the few things that we actually reuse. When I think about safety, I also think about the possibility of the haptic being pinched by the plunger. We all have great technicians who are very good at preparing lenses, but occasionally, the trailing haptic will get caught. We have all been in the situation where we have had to manually remove the haptic because it is pinched against the wall of the cartridge. This system was designed to help limit that problem. Additionally, we have a one-handed delivery of the IOL into the eye with the plunger, so we can use the second hand to stabilize the eye. I think that is a significant improvement over our current system.

Dr. Tipperman: I like the fact that the lens power and expiration date are printed on the injector. This gives the surgeon one more chance to verify that the correct lens is being implanted in the correct patient, and this can only be achieved with a preloaded lens.

Dr. Lane: Another feature that speaks to confidence is the consistency of being able to deliver a lens in the same way virtually every time with the same system. I assume that your scrub nurse is putting the OVD into the cartridge. Are they then advancing it for you? Or are you advancing it to the first stop and then injecting it from that point?

Dr. Woodard: I have the technician do it all and just hand it to me ready to go. That's the beauty of this system. It allows any technician, once he or she learns the technique, to very easily hand the IOL to the surgeon ready to be implanted and be confident that it's going to be delivered in the same fashion every time. Technicians find it easier to use than the Monarch system in a dimly lit room. Obviously, our technicians love it.

Dr. Cibik: The experienced technicians appreciate the UltraSert system because they don't have to worry about folding the lens. Surgeons can be confident that the lens is well-loaded, even with a less-seasoned tech.

Dr. Tipperman: That's an important point. This system is ideal for someone who operates in a general community hospital and only operates on eyes once or twice a month. In these situations, the nurses aren't comfortable with preparing the lenses, and that's where UltraSert shines. We have a great ophthalmic surgical staff in our center, but there is tremendous variability from one technician to another regarding who is good at loading lenses. Even in a busy ophthalmic center, this system helps remove variability and makes the day easier for the staff and the surgeon.

Dr. Woodard: There are times when I have fill-in staff because someone is sick, and a circulator, who is not as comfortable preparing lenses, may be serving as a scrub tech. Just about anyone should be able to prepare this lens from start to finish in about 10 seconds. It takes much longer than that with the Monarch system.

Dr. Lane: The idea is to keep the surgeon operating. When there is nothing for us to do except twiddle our thumbs for that period of time, there is a loss of production. While it might only be 2 minutes, it seems like 2 hours, and if multiplied by 20 cases in a day, that results in wasting 40 minutes.

Dr. Woodard: It also heightens the anxiety for patients, because they are wondering what is wrong and why nothing is happening. I find myself having to coach them through the process.

Dr. Lane: Many of us are choosing to use the ORA System (Alcon) to determine the IOL power. As we use the ORA System, we may decide to use a different

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"The experienced technicians appreciate the UltraSert system because they don't have to worry about folding the lens. Surgeons can be confident that the lens is well-loaded, even with a less-seasoned tech."

–Lisa Cibik, MD

lens power when using an AcrySof IQ monofocal lens, so we will have to open a different lens. The time it takes to do that is certainly much shorter with a preloaded system. When you change the lens, the scrub nurse is usually in panic mode because the lens is not available when the measurements are being performed. In my experience, this system allows for an easier flow and greater efficiency when using technology like the ORA System. Please describe any changes you made to your technique for delivery of the IOL with UltraSert.

Dr. Cibik: I stabilize the globe with my left hand through a lateral portal opening, while I deliver the lens with my right hand using UltraSert.

Dr. Lane: How would you compare UltraSert to AutoSert (Alcon) and UltraSert to Monarch in terms of smoothness?

Dr. Cibik: I think it's more similar to the Monarch than the AutoSert system as far as how it feels. There is a very smooth, comfortable, controlled delivery. I feel like I am in command of the situation. In my experience, the delivery is very reproducible, and I haven't found any problems with the haptic being stuck to the IOL optic or in the plunger.

Dr. Woodard: The UltraSert is a very consistent delivery system. When preparing the cartridge, it is very important for the technician to advance the plunger very slowly, especially the first couple of millimeters. If not, that leading haptic tends to straighten instead of folding along with the IOL. I have found that as long as the initial engagement of the IOL by the plunger is performed in a very slow and controlled manner, the leading haptic and IOL fold nicely every time to allow consistent delivery in the capsular bag.

Dr. Lane: One of our colleagues actually does the whole thing himself. The surgical tech puts the OVD in and then hands it to him. He made the observation that as he advances the lens down the cartridge, when he sees the leading haptic start to straighten out, he stops, waits just a second, and then advances again slowly. In other words, he stops, waits for the viscoelastic to come around, and then he goes. I haven't done that myself, but it certainly makes sense.

Dr. Woodard: For the first 100 or so cases, sometimes when the technician would load it, it would be perfect. Other times, the haptic was straight. Finally, I just started preparing all of them on my own under the microscope, and I visualized exactly that. Then I educated our technicians on that, and they now realize that they need to watch the leading haptic very closely. I don't load it myself much anymore.

Dr. Tipperman: We have used the Monarch injection system at our center. I really like it and think it works extremely well. When I first began using UltraSert to deliver the AcrySof IQ aspheric IOL, I put two hands on the UltraSert cartridge, pretty much just like a Monarch injector, and tried to inject the lens in the bag. I found that I would rotate the globe incredibly nasally and have to move the injector vertically to make the lens go into the bag. Adopting a one-hand technique makes a huge difference in terms of the control, the globe position, and patient comfort. Rather than pushing the plunger toward the hub of the injector with my thumb, I keep the cartridge chamber in the lip, but I am trying to pull the plunger flange back toward my thumb with the tip staying in the wound. That way, I don't put any pressure nasally toward the wound, and that seems to work well.

Dr. Lane: That's similar to my technique. The distal end of the cartridge has a depth guard nozzle on it. I find that small flange proximal to the nozzle end so valuable in being able to insert the distal end of the cartridge in through the wound and have it stop there so that I can't advance it anymore and potentially expand the size of the incision. With the UltraSert, I have less concerns about stretching my initial incision because the depth guard is an automatic "stop" as I am inserting the lens.

Dr. Cibik: We haven't seen any cracking in the tip with the UltraSert. It is a very consistent system, and that makes the techs a lot more comfortable. Also, with the UltraSert system, the IOL is delivered a little bit more vertically than it is with the Monarch or the AutoSert system.

Please refer to page 8 for important product information about the Alcon products described in this supplement.

ReSTOR +2.5 with ACTIVEFOCUS™ Optical Design

Dr. Lane: Multifocal IOLs continue to be a challenge. From a market share standpoint, it stands right about 7–8% of all IOLs implanted in the U.S. and hasn't budged for a few years. We have the ReSTOR +2.5 with ACTIVEFOCUS Optical Design joining the ReSTOR +3.0, which is the most recent addition to the AcrySof family of IOLs. What have you learned since using the ReSTOR +2.5 compared to your experience implanting the +3.0?

Dr. Cibik: Meeting patients' expectations is difficult. Patients are increasingly more demanding and more perfectionistic. Many of my patients—particularly those who are younger and still working in their mid-60s—are on a quest for not only excellent distance vision and high-contrast sensitivity, but also functional near vision in low light conditions. They are looking for a lens like +2.5 that has multifocal functionality with monofocal-like distance performance. And frankly, even some of my older patients are looking for—and will pay for—this type of outcome. I think patient education is very important. It is frightful to implant a multifocal lens and then have the patient be underwhelmed and unhappy. Patients' unhappiness is usually due to halos, glare, starbursts, and various other dysphotopsias, as well as decreased contrast sensitivity. With the ReSTOR +2.5, I have had happier patients. In fact, a lot of patients are overwhelmed. My staff is also happier because they see that the ReSTOR +2.5 patients are really appreciating their outcomes.

Dr. Tipperman: The successful +3.0 patients are the poster children for cataract surgery. They are terrific at all distances, and they are very happy; however, if you implant enough of these lenses, you will get patients who are good but not great. Their vision is adequate, but they wish it was a little bit better. **Warren Hill, MD**, says that everything in optics is a trade-off. I tell my patients that all of their choices are trade-offs. They can have a monofocal lens, which will provide great distance vision and no functional vision from arm's length on in. Or they can have the ReSTOR +2.5, which is designed to provide good monofocal-like distance vision and mid-range vision, but they might need glasses for reading occasionally. I find that most patients are comfortable with that approach because it gives them such a large sweet spot.

Dr. Woodard: Discussing patients' goals ahead of time is absolutely the most important aspect in managing patient expectations. Many multifocal patients do not want to compromise distance clarity, so we have all realized over time that many of these patients feel that their distance vision is not quite as crisp as they wish. That's where I feel the +2.5 with ACTIVEFOCUS Optical Design has had a significant impact in my practice. In many cases, my +2.5 patients are reporting very sharp distance vision and strong intermediate vision, and they do not feel like they compromised their vision. I think this is due to the increased negative asphericity as well as the larger monofocal zone in the center. Many of

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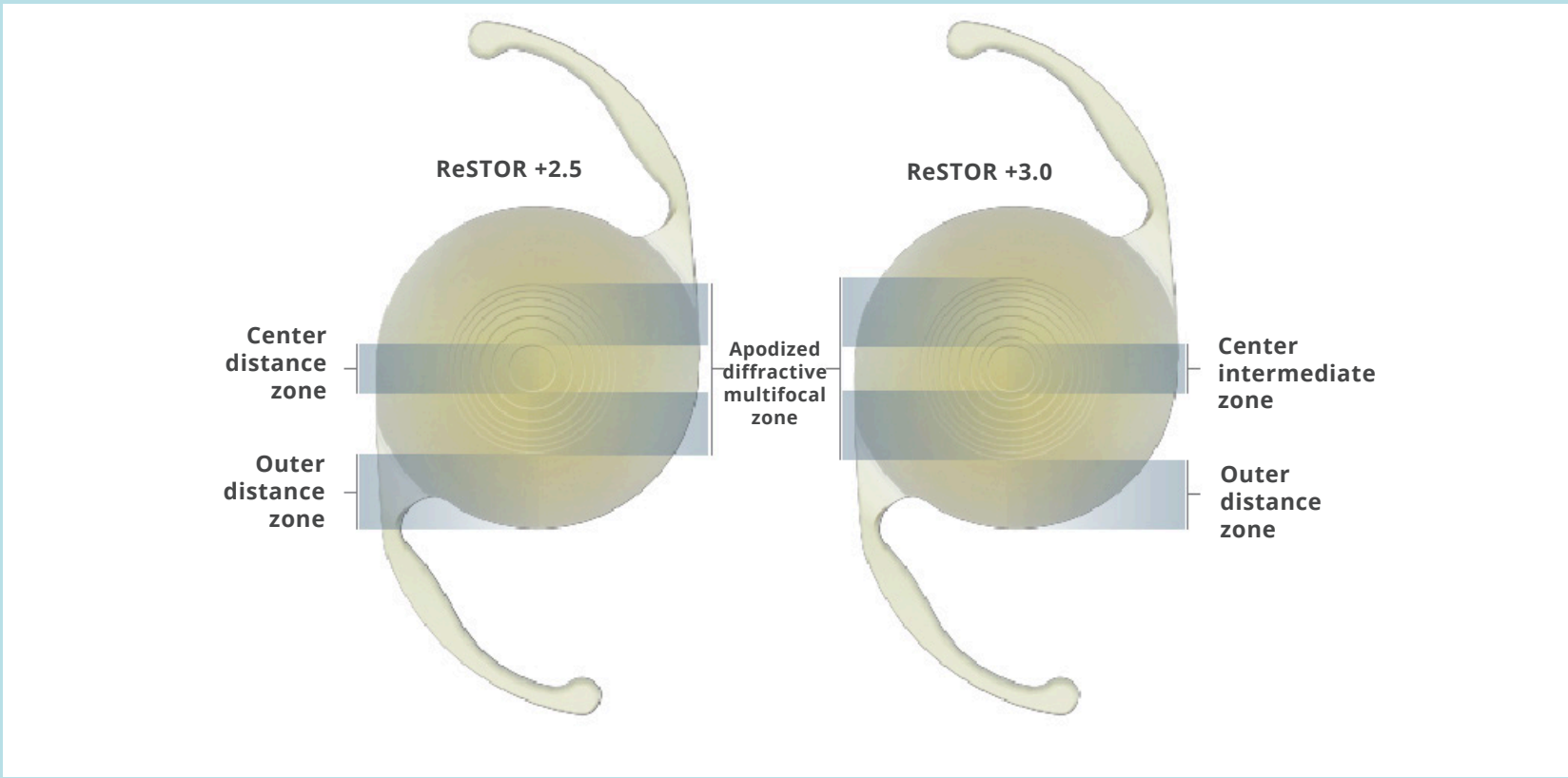

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ACTIVEFOCUS™
Optical Design

my patients feel that their distance vision is not compromised. This point needs to be highlighted when we are offering these lenses. As we all do, I ask my patients what they are willing to compromise and what they are not willing to compromise. Some will compromise reading but don't want to significantly compromise any distance clarity, so the +2.5 is the lens for them. If a patient says reading without glasses is most important, then I will go with a +3.0. We know that no lens solves all issues. However, this is an additional lens option in our armamentarium that allows us to better meet the needs of our patients. I have been ecstatic with this lens, and I have been surprised with the quality of near vision with the +2.5. I have found that they need to hold books a little farther away, but most people don't read small-print books anymore. Most people are reading tablets that they are holding a little farther away than traditional books.

Dr. Lane: Additionally, most of those devices are backlit. As with all multifocal lenses, lighting is the key.

Dr. Tipperman: I tell patients that I'd love to be able to give them a lens that will enable them to see well at all distances, but everything is a trade-off, and the price paid for stronger near vision is a potential for a drop-off in the quality of distance vision and glare and halos at night. If patients are not comfortable with their nighttime driving or distance vision, I can't fix that. Problems with near vision can be overcome by wearing reading glasses and adding light. If patients want better quality distance vision that will come with some mid-range vision and some near vision, the +2.5 can be the best option. Not all, but most of my patients tell me that they function well at intermediate and at near with a +2.5.

Dr. Cibik: Even physical stature can factor into patient selection. Many taller patients with longer arms do well with the ReSTOR +2.5.

Dr. Lane: Let's discuss visual disturbances in your experience with the +2.5.

Dr. Tipperman: I used to show patients the videos and DVDs, but now I just have a short discussion and explain that some people see circles around lights at night when they drive with multifocal lenses. Many patients don't find it bothersome, and in many patients, it goes away; however, a very small percentage of patients, and you can't predict this ahead of time, are bothered by that. After a brief discussion, there are very few patients who will be bothered by dysphotopsias from this lens, but it is a real thing and a real possibility. I do think we need to make patients aware of it in terms of informed consent, but it is fixable. If they notice it with a +2.5 in their first eye, we can always implant a monofocal in their second eye. That will usually give them pretty good quality distance vision for nighttime driving.

Dr. Cibik: I have implanted 238 eyes with the ReSTOR +2.5, and I've only had one patient who had significant complaints of halo and glare, particularly with nighttime driving. I discuss this possibility with every patient who is considering implantation of a ReSTOR +2.5 lens. In my practice, I have not had many patients complaining about severe halos or glare with the ReSTOR +2.5, and no one has ever required an explant. I think the hybrid optical design, which combines some of the best features of the Alcon monofocal and multifocal IOLs, is the reason for a good visual disturbance profile, even in a multifocal lens.

Dr. Lane: How are you targeting this lens for your patients? Tell me about the discussion that you have with your patients.

Dr. Woodard: A recommendation from the doctor means a lot to a patient. My discussion starts with my preoperative counselor/patient educator going into the room and discussing the various options

"Some [patients] will compromise reading but don't want to significantly compromise any distance clarity, so the +2.5 is the lens for them."

–Lawrence Woodard, MD

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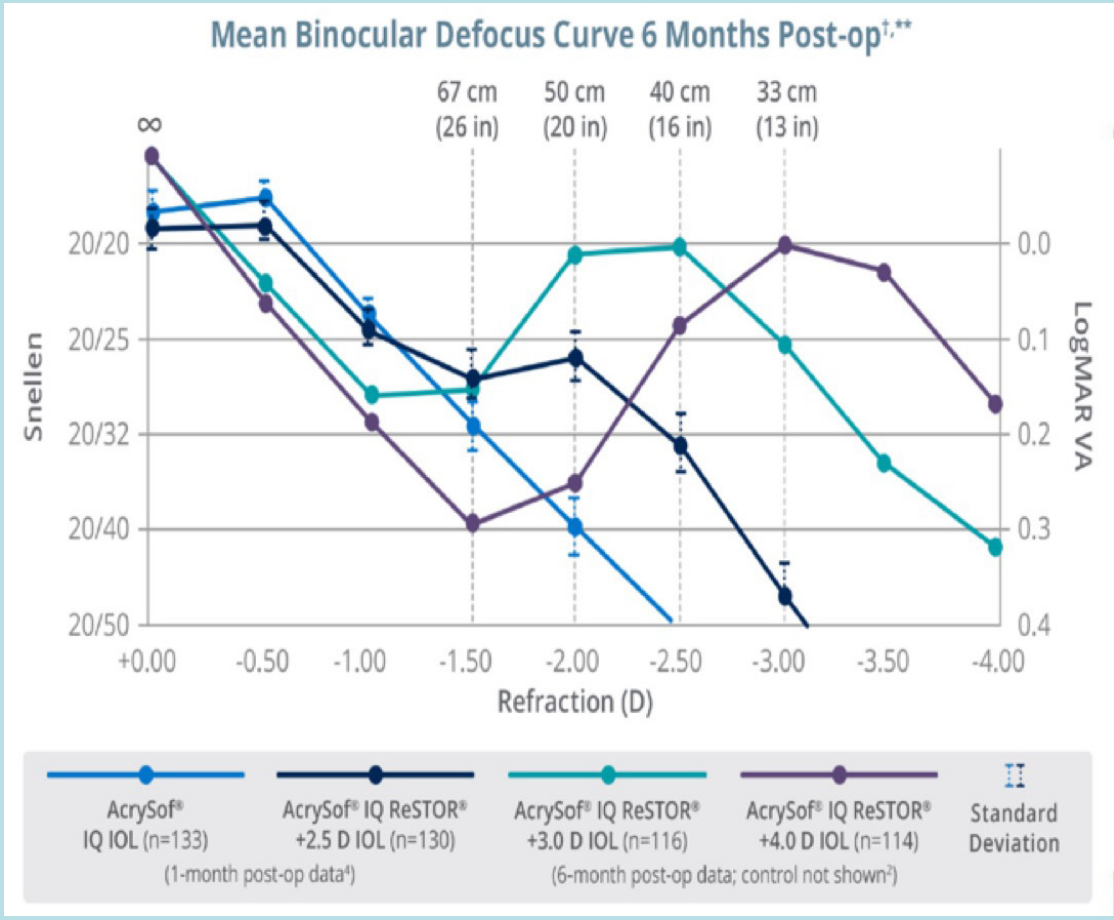
available for patients. So, patients are already aware of their options before I enter the room, which I think is important. When I get into the room, I ask the patient about the activities that are most important to him or her. I ask whether the patient drives at night, is a big sports person, reads a lot, is a musician, or is on the computer a lot. Then I find out what he or she is not willing to compromise. Patients are usually very matter of fact about this. I let the patient guide my recommendation based on the importance of his or her various activities. You can't go into a room telling a patient what he or she wants.



†Data for AcrySof® IQ ReSTOR® +2.5 D IOL, +3.0 D IOL, and +4.0 D IOL mean defocus curves are from the Directions for Use for each respective IOL.
1. The methodology used to derive all defocus curve data was the same test methodology for each IOL. No direct clinical comparison is implied.

Dr. Lane: Since the ReSTOR +2.5 with ACTIVEFOCUS Optical Design lens has become available, are you finding that you are using more multifocals than you used to?

Dr. Woodard: Absolutely. I think the lens is more forgiving, so I have broadened my criteria for patients who are post-LASIK. The topography doesn't have to be perfect. I have found that this lens is more forgiving in allowing these patients to still be happy. I always treat patients with ocular surface disease or dry eye before making a final decision. I would not implant any IOL in a patient whose ocular surface was significantly compromised.

Dr. Tipperman: With the +3.0, I typically implanted this lens in patients who were spectacle haters and wanted to wear spectacles as little as possible, and who wanted a multifocal lens. With the +2.5, it's different. Part of the informed consent for monofocal IOLs is telling patients that they will have good distance vision, and they will need reading glasses for arm's length on in. Now, there is a multifocal that will provide a lot more functional vision at some different distances without the need for reading glasses all of the time. I am talking about multifocals to a different category of patients now that I have the +2.5. I'll see how they are doing with their first eye. If they have good functional vision at multiple distances, I'll match the second eye with the +2.5. If they like the +2.5, are not having any unwanted optical images, and wish the reading vision was a little bit better, I am comfortable implanting the +3.0 in the non-dominant eye.

Dr. Cibik: It has increased the number of multifocal candidates in our practice because I think that there will be better patient outcomes and fewer patient complaints. I also think that has to do with the fact that I have great confidence in this lens. Prior to the availability of the ReSTOR +2.5 technology, I was very hesitant to use multifocal lenses in patients who had previous refractive surgery. After good counseling, I will consider the ReSTOR +2.5 in patients who have had myopic LASIK and in some RK patients. Also, in the past, I was reluctant to use a multifocal lens in anyone who had an occupation that involved nighttime driving. After extensive counseling, I have implanted the ReSTOR +2.5 in patients who do significant nighttime driving and they are happy.

Dr. Lane: It sounds like the addition of the +2.5 has expanded our armamentarium of what we are able to offer patients in terms of being able to allow some multifocality compared to the previous single offering of a +3.0 lens.

Dr. Woodard: The defocus curve chart made it clear to me why this lens is more forgiving. This chart shows that this lens performs much more like a monofocal and that the amount

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of defocus is very minimal from plano to –0.50 spherical equivalent (SE). In contrast, with the +3.0, at –0.50 SE, distance acuity significantly suffers. With a monofocal, however, if the patient is plano to –0.50 SE, he or she is still quite happy. With the +3.0, that patient is not very happy.

Dr. Lane: Have you changed your IOL choices with the introduction of ReSTOR +2.5 with ACTIVEFOCUS Optical Design?

Dr. Cibik: Since the FDA approved the +2.5 with ACTIVEFOCUS, it is now my presbyopia IOL of choice. I find the outcomes with ReSTOR +2.5 are much more reproducible and consistent.

Dr. Lane: Let's talk about the combination of a +3.0 and a +2.5 compared to a +2.5 bilateral. A recently published article discussed European experience that compared bilateral +2.5 implantation to a +3.0 and a +2.5 implantation.[1] Not unexpectedly, it showed that contralateral implantation of +2.5 and +3.0 has as sharp distance vision as bilateral +2.5, along with a nice range for intermediate vision. Suprisingly, near vision between the 2 arms was different, and mean BCVA showed a marked difference between the contralateral and bilateral groups. For people who want it all, that's what I routinely do and have had good success. For whatever reason, I usually implant the +2.5 in the dominant eye and the +3.0 in the non-dominant eye. The interesting observation that most patients have is their ability to see better at distance with a +2.5 lens than with a 3.0 lens. The two eyes work together well for near, intermediate, and distance vision. I have been very happy with that as an alternative.

In summary, UltraSert represents the newest entry in single-use IOL delivery systems and combines the control of a manually loaded device with a disposable preloaded injector. The system uses the TensionGlide plunger, designed for controlled delivery of the IOL into the capsular bag, and the depth guard nozzle, which is designed to preserve the size of the original corneal incision.

The addition of the ReSTOR +2.5 D with ACTIVEFOCUS Optical Design will help surgeons customize the multifocal IOL options they can offer their patients to maximize results and better manage patient expectations. It really is a multifocal/monofocal hybrid design, combining the best of the technology behind the AcrySof IQ monofocal IOLs with the visual range of the ReSTOR multifocal lens.

Reference

1. Nuijts RM, et al. Bilateral implantation of a +2.5 D multifocal intraocular lens and contralateral implantation of +2.5 D and +3.0 D multifocal intraocular lenses: Clinical outcomes. *J Cataract Refract Surg.* 2016;42:194–202.

Important product information

UltraSert™ Pre-loaded IOL Delivery System with the AcrySof® IQ aspheric IOL
Model # AU00T0
US-ULS-15-E-0452

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

Indications: The AcrySof® IQ aspheric intraocular lens ("AcrySof IQ") is intended for the replacement of the human lens to achieve visual correction of aphakia in adult patients following cataract surgery. This lens is intended for placement in the capsular bag.

Warning/precaution: Use the UltraSert™ Pre-loaded Delivery System ("UltraSert") at temperatures between 18 degrees C (64 degrees F) and 23 degrees C (73 degrees F). Use only Alcon viscoelastic qualified for this device. Do not use the UltraSert if the nozzle appears damaged or deformed. Follow the Directions for Use for correct order and sequence of steps to avoid damage to the IOL or the UltraSert.

Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use. Caution should be used prior to lens encapsulation to avoid lens decentrations or dislocations.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45 degrees C.

Attention: Reference the Directions for Use for Model AU00T0 for a complete listing of indications, warnings and precautions.

AcrySof® IQ ReSTOR® Family of IOLs

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

Indications: The AcrySof® IQ ReSTOR® Posterior Chamber Intraocular Lens (IOL) is intended for primary implantation for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate, and distance vision with increased spectacle independence. The lens is intended to be placed in the capsular bag.

Warnings/precautions: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Physicians should target emmetropia, and ensure that IOL centration is achieved. Care should be taken to remove viscoelastic from the eye at the close of surgery.

Some patients may experience visual disturbances and/or discomfort due to multifocality, especially under dim light conditions. As with other multifocal IOLs, visual symptoms may be significant enough that the patient will request explant of the multifocal IOL. Spectacle independence rates vary with all multifocal IOLs; as such, some patients may need glasses when reading small print or looking at small objects.

Clinical studies with the AcrySof® ReSTOR® lens indicated that posterior capsule opacification (PCO), when present, developed earlier into clinically significant PCO. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof® IQ ReSTOR® IOLs.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45 degrees C; use only sterile irrigating solutions such as BSS® or BSS PLUS® Sterile Intraocular Irrigating Solutions.

Attention: Reference the Directions for Use labeling for a complete listing of indications, warnings and precautions.

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