

# Cataract & Refractive Surgery TODAY

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## The Visian ICL



**Clinical adoption and patient  
selection with this new  
phakic option.**



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## MEET THE PANEL



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*The following roundtable discussion took place during the Aspen Invitational Refractive Symposium on February 25, 2006. Participants discussed the finer points of working with the Visian Implantable Collamer Lens.*

**Dr. Slade:** Phakic IOLs are a welcome positive addition to refractive surgery. They expand our range of treatment and give patients better surgical options for improved quality of vision. The latest phakic IOL to be approved is the Visian ICL (STAAR Surgical Company, Monrovia, CA) (Figure 1). For this roundtable, we asked a top group of investigators, researchers, and clinicians to discuss the ICL with us.

Everyone, please briefly introduce yourself and state your involvement with this lens as well as with other phakic IOLs. I have been an investigator with STAAR Surgical Company and have been implanting the Visian ICL for approximately 4 to 5 years. I was part of the group that worked toward its FDA approval.

**Dr. Vukich:** I have worked with the ICL for 7 years, and I have 7 years of follow-up on many of my first patients. I implanted approximately 200 ICLs cumulatively during three US clinical trials for myopia,<sup>1</sup> hyperopia, and toric corrections. I continue to serve as medical monitor for the ICL through the lens' roll out into general practice. I have not used any other phakic IOLs. I have focused on the ICL, developing my implantation technique for the lens and carefully following my patients through the clinical trials.

**Dr. Slade:** Rick Baker, OD, FAAO, who is my partner in Houston, has been involved in as much pre- and postoperative care of refractive surgery patients as any doctor in the country. Dr. Baker, please tell us what your experience with the ICL so far has been.

**Dr. Baker:** I was involved in its clinical trials and collected the patient data for the toric, hyperopic, and myopic versions of the lens. Since its approval, Dr. Slade and I started implanting the ICL in our office. I am very excited about the technology and the quality of vision my patients are experiencing very quickly postoperatively.

**Dr. Rowen:** I am an ophthalmologist in Baltimore, and I was involved with the Visian ICL's FDA investigation from December 1997, which is when I first implanted it. I implanted approximately 76 lenses in the study and have followed those eyes for the last 8 years. In February 2006, I began implanting these lenses in my practice. To me, the ICL's FDA approval means that I can finally treat high myopia with ease and with a lot of excitement. Incidentally, I have also implanted a few Verisyse IOLs (Advanced Medical Optics, Inc., Santa Ana, CA), and they are quite different.

*"I am very excited about the technology and the quality of vision my patients are experiencing very quickly postoperatively."*

*—Dr. Baker*

**Dr. Slade:** Would you consider yourself a current, active implanter of the Verisyse IOL?

**Dr. Rowen:** I have implanted four Verisyse lenses with excellent results, but I have always looked forward to getting the ICL back in my hands again. I prefer its smaller incisions.

**Dr. Slade:** Dr. Christenbury, you have had a lot of experience with the Verisyse IOL, and you recently began working with the Visian ICL to a large degree. Please tell us the location of your practice and your phakic IOL experience.

**Dr. Christenbury:** I practice in Charlotte, North Carolina. About 1.5 years ago, I had a long waiting list of patients on whom I did not feel comfortable performing LASIK—their corneas were too thin or too myopic—so I started using the Verisyse lens after it received FDA approval. I have performed perhaps 70 Verisyse procedures. I implanted the first couple under peribulbar anesthesia, but all the others I did under topical. Although I have had good results with the lens and it did not induce much astigmatism, its big limitations are the need for a large incision, sutures, and a longer recovery time than the ICL. I have implanted more than one dozen ICLs.

**Dr. Slade:** Did you ever perform bilateral surgery with the Verisyse IOL?

**Dr. Christenbury:** Never. I always waited about 2 weeks between implanting the Verisyse IOL in patients' first and second eyes, because they took a while to feel comfortable after the initial surgery.

**Dr. Slade:** Everyone, what does the FDA approval of the Visian ICL mean for your practice? How will you work this into your armamentarium?

**Dr. Vukich:** Now that the ICL is approved, we have to work on the procedure within our office. That is, how we



present ICL surgery to our refractive educators and how they communicate to patients that we have this new option available. Because this procedure is performed in the OR as opposed to a laser suite, there are logistics to work through. We must also make sure patients' questions are answered both accurately and adequately, and we achieve this by maintaining consistent awareness about the ICL throughout the practice. We must decide how to position this lens as an intraocular procedure, because it is different than what patients are familiar with. Building awareness and a patient base is our next challenge.

**Dr. Slade:** So, you looked at the lens' approval as the start of a need to educate your staff and patients?

**Dr. Vukich:** I see the ICL's approval as a wonderful new option for patients whom we either could not treat or were uncomfortable treating with laser surgery. My challenge is to transfer my confidence in the procedure to those candidates by answering their questions and working out the logistics of a smooth surgical flow, such as executing the peripheral iridotomy in an orderly fashion and when to see postoperative patients for follow-up. These mechanical and logistical considerations are now second nature with LASIK. The ICL just needs a different routine, and my staff and I are quickly assimilating it.

**Dr. Slade:** Dr. Baker, when the ICL's approval came, how did the procedure fit into our practice?

**Dr. Baker:** As Dr. Christenbury mentioned, during the past 2 years, you and I had been keeping a list of patients who were not candidates for LASIK because they were too highly myopic or had too-thin corneas. Thus, once the ICL gained FDA approval, we had a sizeable backlog of patients to contact. I was surprised by those to whom we presented the ICL as an option. We thought it would take them some

time to digest this new technology, but they made the mental conversion very quickly and were ready to schedule surgery before we were. They had to wait for us to figure out when to conduct their peripheral iridotomy, from where to order the lens, how long its delivery would take, what the cost of the procedure would be, on what days we would perform the surgery, etc. Logistically, we have to make this procedure as seamless as LASIK surgery—when the patient enters our office and gives us the green light to proceed with surgery, the staff must know what the next step is.

**Dr. Slade:** So, patients feel comfortable with it—how about the panel? Let's say you have a patient with a refraction of -6.00 or -7.00D and a thin cornea. Do you feel more comfortable recommending PRK or an ICL for this patient?

**Dr. Baker:** An ICL, no doubt. Quality of vision is better in the eyes we have implanted to date with this lens versus a strong-powered laser procedure, whether LASIK or PRK.

**Dr. Slade:** Dr. Rowen, the same question for you—what has the approval of the Visian ICL meant for your practice?

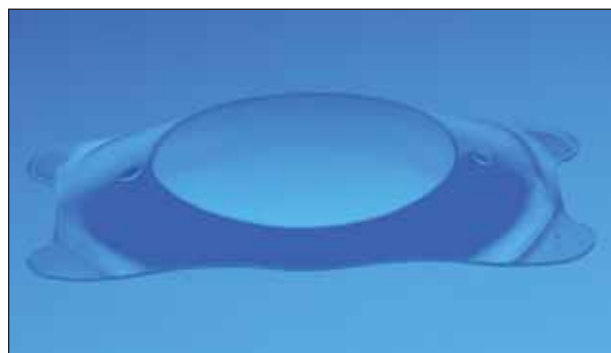
**Dr. Rowen:** I have also had to put many patients on hold because they were poor candidates for LASIK. I had Epi-LASIK available, but I was waiting for the ICL. In the clinical trial, I had implanted the lens in low myopes, from -3.00 to -15.00D, and these young people did absolutely beautifully. I think this technology can open up the field for a wide variety of patients whom we could not treat before.

**Dr. Christenbury:** I was excited when the first phakic IOL, the Verisyse, was approved, and I did not hesitate to use it. It appears a phakic IOL can offer a better quality of vision than a high LASIK correction. I was excited about the ICL's FDA approval because I could offer patients a shorter procedure with a smaller incision that does not require sutures. Also, the ICL is not visible to the patient.

### THE BEST CANDIDATES

**Dr. Slade:** Who is the ideal candidate? When LASIK debuted, we could treat high myopes, and we compared that procedure to PRK for low myopes. Initial thoughts with the ICL are to treat high myopes and then compare the outcomes to that of LASIK for low myopes. I just wonder if low myopes will fare better with a Visian ICL than high myopes? What do you think about this lens for low myopes? Who is your ideal candidate, Dr. Vukich?

**Dr. Vukich:** Your question recalls the days when LASIK was only for the patients for whom PRK was unsuitable. Then, we realized that LASIK is both safe and effective, and



**Figure 1.** This image shows a three-dimensional view of the ICL. The ICL is approved for use in myopia of -3.00D to -20.00D. The lens is currently available for physicians certified in its use.





*"With experience, surgeons will find that the ICL works exceedingly well throughout the approved range of -3.00 to -20.00D."*

—Dr. Vukich

we began to offer it to a broader range of refractive errors. I think we are going to see the initial uptake for phakic IOLs, and the ICL in particular, be for patients in whom we are uncomfortable with performing LASIK, either because of corneal irregularity, a corneal-thickness issue, or high myopia. These types of patients will be the logical early candidates for the ICL because there is no other treatment choice for them. I think that is where most surgeons will initially apply this technology. With experience, surgeons will find that the ICL works exceedingly well throughout the approved range of -3.00 to -20.00D.

In terms of attempted and achieved correction, it is relatively easier and more accurate to select the exact power of the ICL for low myopia. So yes, it will absolutely be appropriate for low powers, and as patients become more aware of the ICL as a treatment option and surgeons become more adept at integrating it, and I think it will increasingly be used this way. We have seen this occur internationally, where the ICL has been available for a long period of time.

**Dr. Slade:** Dr. Christenbury, what type of patients did you select for your first ICL procedures?

**Dr. Christenbury:** A couple of my first ICL patients came off the top of my waiting list, but the others I scheduled from my LASIK consultations. I feel that the implantation surgery for the Visian ICL is superior to that of the Verisyse IOL, because it does not require a stitch. We had patients from -7.00D to -14.00D. Interestingly, the first gentleman I treated was 25 years old and wore gas permeable contact lenses. When I checked his vision postoperatively that afternoon, his UCVA was 20/40. The next day, it was 20/20. He thought the quality of vision in his ICL eye was better than in his contralateral eye with the gas permeable contact lens. The next week, his ICL eye was 20/15, and he was ready to have his other eye implanted with the ICL. He asked why we did not operate on both eyes on the same day.

Two patients of mine were in the -8.00D to -12.00D range. I performed bilateral procedures on them both, and they were perfectly happy. At 1 week, one woman had 20/20 and 20/40 UCVA's; she was 20/40 in one eye because of 2.00D of cylinder. We knew beforehand that she had this

astigmatism and might need follow-up LASIK. The other patient was 20/20 and 20/25 bilaterally, and he could function on the first postoperative day. I would not consider bilateral implantation of the Verisyse IOL, because the patient most likely would not be able to function the day after surgery.

**Dr. Slade:** Dr. Baker, you deal with our referring physicians a lot. What do you think their acceptance level for the ICL will be? How do you plan to interact with them about it?

**Dr. Baker:** I think that as soon as they see a postoperative patient at the slit-lamp examination, they will be sold on the ICL. As far as choosing the first patients to treat, we should start with high myopes until we get comfortable with our logistics. I also think we should discuss the age of ICL candidates. Emotionally, I feel a little better treating 40-year-old than 20-year-old patients in terms of inducing an accelerated cataract, however slim the chance.

#### BILATERAL CONSIDERATIONS

**Dr. Slade:** Because we are talking about patient counseling and selection, let's discuss bilateral surgery. What are you telling patients?

**Dr. Rowen:** At the moment, I am not implanting the ICL bilaterally. I want to make sure that the outcomes are good, that my staff and I have the right powers, and that all our systems are in place. Anecdotally, however, my patients who received the ICL in one eye immediately wanted their other eye treated. The visual recovery is instantaneous. My considerations about performing the surgery bilaterally are the same as with doing any intraocular procedure bilaterally: its elective nature; the question of whether to take patients out of the OR and bring them back in; and my fear of potential contaminants. The last reservation is my main concern. Currently, I am only implanting the ICL one at a time, and my patients are very accepting of that. I have no immediate plans to try it bilaterally, although I may in the future.

**Dr. Christenbury:** I prefer and patients prefer bilateral implantation of the ICL. It is very important to conduct the first examination a few hours postoperatively. My biggest concern was IOP rise. Otherwise, I feel pretty confident in using separate instruments for each eye and prepping and draping the eyes separately. We treat the two eyes like two separate cases. I keep everything separate, I use all disposable instruments, we have two autoclaves, and we use a different lot of balanced salt solution. Any time we recommend something, there is a risk/benefit ratio, and the benefit for bilateral ICL surgery, in my opinion, far outweighs the risk.



**Dr. Baker:** What is the benefit?

**Dr. Christenbury:** The benefit is convenience for the patient. There is only one surgical day, the patient is anesthetized once, and he avoids the symptoms of visual imbalance.

**Dr. Baker:** I do not feel comfortable performing bilateral ICL surgery until I know that my staff and I can ensure perfect sizing of the lens in all patients. Patients could have a wound leak or even bump their eye or something. For now, I do not see the benefit outweighing the risk. Maybe when I gain more experience and am comfortable with the results over a large series, I will consider implanting the ICL bilaterally. For now, it seems like more risk for the convenience. We ophthalmologists have to proceed slowly and cautiously and turn out 100% good cases. We will only be as good as our worst cases.

**Dr. Vukich:** Three issues are keeping bilateral sequential intraocular surgery from becoming mainstream. One is speed of recovery of functional vision for the patient. I do not think that is a problem for the ICL. The second issue is the potential for endophthalmitis. When infections occur, they do so within the first few postoperative days. In fact, 80% of all endophthalmitis occurs within the first 16 days, and 20% is later than that. It becomes a question of how long do you wait to eliminate postoperative infection as a risk factor. Third, wound integrity is a consideration. If trauma from a fall or accident compromised the integrity of the wound in both eyes, the consequences could be tragic.

**Dr. Slade:** Do you see yourself ever performing bilateral intraocular surgery?

**Dr. Vukich:** *Ever* is a difficult limitation. When I first trained, almost no one considered the possibility that they would use only topical anesthetic or perform no-stitch surgery. For that matter, I did not know if I would ever operate outside of a hospital. As a profession, I think we have been pretty successful at turning heresy into standard of care.

**Dr. Slade:** My surgical team and I are not performing bilateral surgery now, but I think we may consider it at some point. Although Dr. Christenbury is in the minority among the practices represented here, there are reports that within the general population, he may be in the majority.

**Dr. Christenbury:** Before performing bilateral surgery, my staff and I place patients on preoperative antibiotic drops for 3 days. We have the patients perform lid scrubbing b.i.d. for 2 days preoperatively, and then we use preoperative antibiotic drops as well as intracameral antibiotics

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*—Dr. Christenbury*

intraoperatively. Finally, our patients start their antibiotic drops immediately after surgery that day, for every 2 hours while awake. Also, I like checking patients several hours postoperatively to ensure there are no IOP concerns. Most patients are 20/40 or better even hours later.

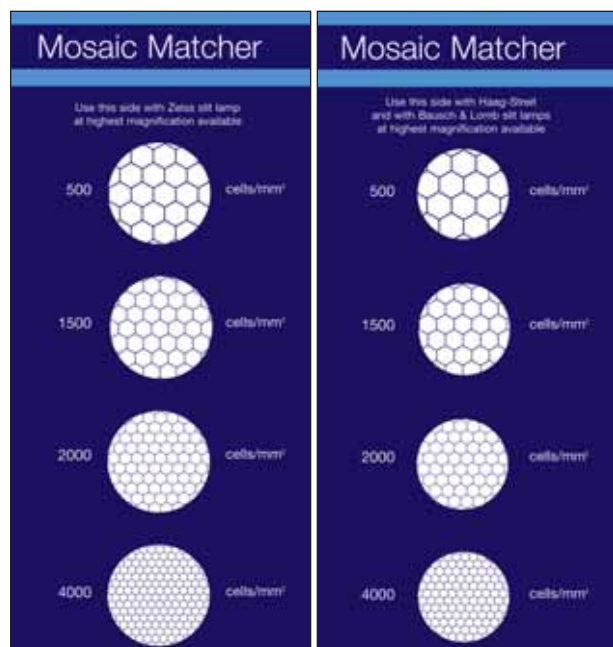
#### CATARACTS AND ENDOTHELIAL CELL COUNTS

**Dr. Slade:** When we presented our data on endothelial cell counts to the FDA panel, we saw an initial loss, but the loss was then stable through year 4. That work was well documented by Hank Edelhauser, MD,<sup>2</sup> at Emory University School of Medicine. The FDA requested, however, that we take preoperative cell counts. In our practice, we are simply using a Konan specular microscope (Konan Medical, Inc., Hyogo, Japan; distributed in the US by DataMed Devices, Inc., Phoenix, AZ) and documenting the cell counts.

**Dr. Vukich:** We have a Konan as well, so we are getting true automated endothelial cell counts. I think it is not really practical, however, for every practice to purchase and use one of these instruments. It is expensive and fairly limited in its application. I think we can use specular microscopy against photographic models as a reasonable standard. We are not looking for the exact number, we just want to make sure that patients have normal endothelial cell counts, or at least greater than a certain number. I think that would be an adequate documentation and safety check for the patient.

**Dr. Rowen:** I am using the Konan specular microscope also, because we were required to use it in the study. I use it the same way we did there, taking a picture and counting the endothelial cells.

**Dr. Christenbury:** My staff and I use the Konan specular microscopy instrument to measure endothelial cell counts preoperatively in most patients who may receive a phakic or pseudophakic IOL. I really want this documentation to assess the health of the cornea and follow patients' long-term care. We have gotten in the habit over the last few years of obtaining the same spector tests for anyone whose refraction is greater than -6.00D.



**Figure 2.** The Mosaic Matcher, developed by John Karickhoff, MD, provides a method for estimating the endothelial cell density at the slit lamp by comparing visualized images to known printed images. It may be used to estimate endothelial cell counts, and it negates the need to purchase expensive specular microscopes.

**Dr. Slade:** Knowing the data as well as you do, Dr. Vukich, do you worry about endothelial cell health in ICL patients?

**Dr. Vukich:** I have looked at this issue very carefully. Of course, it was a central point in the analysis of the clinical trial patients that we could safely use an IOL in someone as young as 21 and be able to extrapolate its efficacy over the course of a lifetime. The US FDA phase 3 ICL clinical trial has one of the largest data sets of patients and their endothelial cell counts of any clinical trial of any lens, and we have seen good stability over time. Therefore, I am very comfortable that this is not only a good choice for the patient, but a reasonable and safe implant over the course of a lifetime.

I do not believe that automated Konan cell counts will be the necessary standard in order to provide this service to patients. I think a thorough slit-lamp examination will be adequate to document endothelial cell counts (Figure 2).

**Dr. Baker:** In the trials, were there any issues with pachymetry measurements along with the cell counts, without testing function?

**Dr. Vukich:** The FDA labeling only requires documentation that the endothelial cell count was assessed. We do not

anticipate disqualification based on low cell counts to be a common issue.

**Dr. Slade:** We all seem comfortable with cell counts with this lens.

### INCIDENCE OF CATARACT

**Dr. Slade:** I want to talk about cataracts. We physicians must be comfortable with endothelial cell health and how many cataracts we induce. Cataracts were induced in the FDA trials, although more with earlier versions of the ICL than with version IV, which had very low rates of cataract inducement.<sup>1</sup> I am quite comfortable with this rate. Although I discuss the possibility with patients, I think that the risk of cataracts itself is low, as is the risk of complications from cataract removal. Dr. Baker, what do you tell patients about cataract formation, and how comfortable do you feel about it?

**Dr. Baker:** I told the patients in the clinical trials that there was a possibility for accelerating the formation of a cataract. The inducement rate was a very small percentage, but not zero. Typically, my staff counsels my patients about what we would do if they did develop a cataract, and the potential outcome of that scenario. We also discuss with patients our concern about IOP elevation and how we try to get ahead of the curve by performing an iridotomy prior to implanting their lens.

**Dr. Vukich:** At 3 years of follow-up, the rate of cataract development in the clinical trial was 1.9%, and that refers to patients who required some additional intervention due to visual issues. Reassuringly, we have not seen continued problems with cataract formation since the clinical trial closed.

**Dr. Slade:** Were those cataracts related to early patients of a particular surgeon and clustered around learning curves?

**Dr. Vukich:** There was some of that, but there were others that we investigators could not attribute to learning curves or other factors, despite our efforts to discover modifications we could make to the implantation technique.

**Dr. Slade:** Do you fear that a perfectly placed ICL with ideal vaulting will somehow induce a cataract over time?

**Dr. Vukich:** I have not seen it during the 7 years of follow-up with my patients. Although cataract formation is undesirable, it is reassuring that if it occurs, there is a remedy, and the remedy has a high likelihood of leaving the patient with excellent UCVA. This is how ICL surgery differs from LASIK,



where an effective treatment of a complication is not always easily available.

**Dr. Baker:** Did most of the lens opacities occur early?

**Dr. Vukich:** Yes, we generally saw them early on.

**Dr. Slade:** The anterior subcapsular cataracts were clustered early, and the nuclear sclerosis occurred more over time, which is expected, especially in a highly myopic group like this, which has earlier nuclear sclerosis than other patient groups.

**Dr. Baker:** I would not think that an ICL in this position would induce a nuclear sclerotic cataract. Could the occurrence possibly be coincidental?

**Dr. Vukich:** These patients were mostly high myopes, a population in which nuclear sclerosis is more common.

#### PREOPERATIVE WORK-UP

**Dr. Slade:** Let's move on to the preoperative routine with ICL patients. We want to talk about sizing, the anterior chamber depth, who gets astigmatism, where surgeons will perform the procedure, and pupil dilation. We will also discuss intraoperative complications and postoperative details. Dr. Vukich, you have done a lot of work on this, please tell us what this means with this lens procedure.

**Dr. Vukich:** The ICL occupies space and requires adequate depth within the chamber. It is approved for use in an eye with a 3-mm anterior chamber depth. With a little experience, however, this lens can be implanted in patients with lower chamber depths. There is an absolute minimum anterior chamber depth. In my experience, an anterior chamber depth below 2.8mm requires more technical skill, and a depth below 2.6mm should be avoided.

**Dr. Rowen:** I agree. We cannot minimize the importance of sizing. We still have yet to predict the proper size with 100% accuracy. The diameter of the lens is as critical as the anterior chamber space. We can think of it as a three-dimensional x-y-z plane, and there is only so much space in the angle to support this. Most patients do very well, but we must be aware that occasionally the lens might be too large. I use the Immersion ACD as my guide.

**Dr. Christenbury:** I do not have a lot of experience with the lens yet, but I have been measuring the anterior chamber depth with the IOLMaster (Carl Zeiss Meditec Inc., Dublin, CA), then measuring the corneal thickness and subtracting that measurement from the chamber depth. All of

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*—Dr. Vukich*

my patients so far have had at least a 3-mm anterior chamber depth. I think the STAAR ICL Calculation Web site (<http://www.staarvision.com>) asks you to input the anterior chamber measurement and then the corneal thickness, and then it calculates the chamber depth so you do not make a mistake.

**Dr. Slade:** Dr. Baker, how do you size? Is your approach adequate?

**Dr. Baker:** I use the Orbscan (Bausch & Lomb, Rochester, NY) to measure anterior chamber depth. Once I order the lens and go through the software, I just calculate the corneal thickness. I wonder, however, whether implanting the ICL is surgically more challenging than standard cataract surgery, or is it because of the concern of endothelial cell health?

**Dr. Vukich:** I think it is angle encroachment. If you are grading from 0 to 4, the ICL will consume approximately one grade from the angle due to the space it occupies. Therefore, if you begin with narrow angles, you really need an angle of grade 3, or grade 2 at the absolute minimum, to have adequate space.

#### ASTIGMATISM

**Dr. Slade:** What are your plans for treating astigmatism? Do you treat it at the time of surgery or wait and perform LASIK on the patient?

**Dr. Christenbury:** For pseudophakic patients, I find that the best results come from waiting a few months after a lens implantation procedure and then performing LASIK or PRK. I find that approach more stable and accurate than performing a limbal relaxing incision (LRI). Long-term, my experience has been that incisional techniques for astigmatism can change over a period of years. Refractions may be stable earlier than 3 months with the ICL.





**Dr. Slade:** I could not agree more. Dr. Baker and I started implanting the Crystalens accommodating IOL (Eyeonics, Inc., Aliso Viejo, CA) several years ago, and LRIs were recommended. We quickly remembered why we abandoned LRIs. Now we use LASIK in most astigmatic patients.

**Dr. Christenbury:** We are so committed to trying to provide great vision for the patient. In the long term, I do not think an LRI is the best procedure. It is better to counsel the patient that he might need to wear glasses or live with less than 20/20 vision until we can perform a laser touch-up.

**Dr. Slade:** What problems did you note, Dr. Baker, during that brief period when we performed LRIs?

**Dr. Baker:** I saw problems with predictability and the chance for inducing irregular astigmatism.

**Dr. Slade:** What about patient comfort and acceptance?

**Dr. Baker:** The patients' comfort was not a problem and their recovery was quick, but you cannot predictably reproduce the results.

**Dr. Christenbury:** LASIK is not as age-related as performing an LRI.

**Dr. Rowen:** I recently saw one ICL patient who had 2.50 to 3.00D of astigmatism, and I told her that her procedure would be two-stage. I would not think of tackling astigmatism at that level with LRIs. I might consider it at 1.00D of astigmatism, but I find sometimes that we use astigmatism to focus, depending on age. At this point, I am not going to correct it at the time of surgery. I will see how much patients' astigmatism bothers them after ICL implantation. This patient had 20/40 UCVA the next day and is functioning very nicely. She will need her astigmatism corrected, and I told her we will use LASIK. With these additional procedures, I think we have to consider the cost. Obviously, people could be enticed by the lower cost of the incisional option, although it is not really best for the patient.

**Dr. Vukich:** You do not want to operate on the axis or change your technique to use your incision to adjust the astigmatism. The way the lens unfolds, it orients very nicely to a temporal clear corneal approach, and I would strongly recommend that we not veer from that. Fortunately, I think the entire issue of astigmatic control is going to be self-limited. A toric version of the ICL has demonstrated absolutely phenomenal visual results, and it is in the approval process.

**Dr. Slade:** When will that be available?

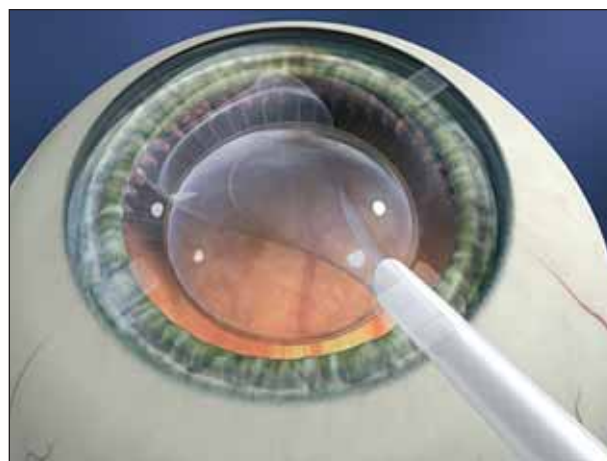
**Dr. Vukich:** The data have already been collected and analyzed and will be submitted to the FDA this summer.

**Dr. Baker:** In planning to perform secondary LASIK in an astigmatic patient, it might be beneficial to aim for a myopic spherical equivalent, because it is easier to treat compound myopic astigmatism with LASIK than mixed astigmatism. For example, one particular laser requires dilation for tracking, and the edge of the implant may make tracking difficult.

**Dr. Vukich:** The ICL is not meant to be used as part of a staged procedure. The astigmatic issue is temporary, and in the short term, we will have to make some adjustment to give our patients their best quality of vision. Eventually, we will have a toric ICL, and this will no longer be an issue.

**Dr. Slade:** Dr. Christenbury, your Verisyse population is one of the largest in the US. You made a telling remark that you have never performed a bilateral Verisyse procedure. Then, you said that you have implanted the ICL bilaterally from the beginning. What is your current position on the Verisyse lens?

**Dr. Christenbury:** Based on my 1-day and 1-week outcomes with the ICL so far, I think the results are superb. I do not miss making the larger incision, placing the sutures, and waiting 1 to 2 weeks for the patient's vision to clear as I did with the Verisyse. I am not sure if I am done with the Verisyse technology, but I think that the ICL is a better option for patients right now. If my ICL results continue to be this good, I may be done with the Verisyse. Despite having to dilate the pupil, implanting the ICL was easier than inserting and enclavating the Verisyse lens (Figure 3). It was



**Figure 3.** Once the ICL is injected through a 3-mm incision, it gently unfolds in the anterior chamber and is positioned behind the iris.



simpler. And I implanted the Verisyse under topical anesthesia. I enjoy the ICL more. After I constrict the pupil and wash out the viscoelastic, it is a beautiful-looking eye.

**Dr. Rowen:** I also implanted the Verisyse lens for the experience, so that when I came back to the ICL, I would know the difference. The Verisyse involves a more technically difficult procedure. We are not used to making 6-mm incisions. You cannot predict the closure; it is difficult to visualize—I was lucky that I did not induce too much astigmatism. Even with a normal pupil, you can have a problem with the incision. Not everybody is going to be able to make a 6-mm incision and close it properly so that they do not induce astigmatism, and you really do not know for 2 or 3 years whether the amount of astigmatism will drift. For me, knowing that for 8 years I have not induced any astigmatism with the ICL makes me very comfortable.

**Dr. Slade:** My only experience is having implanted three Verisyse lenses outside the US. These patients did fine, but I did not enjoy the procedure as much as implanting the ICL. I think there is much to be said for a procedure that is both enjoyable for the surgeon and efficacious for the patient.

**Dr. Christenbury:** Centration is critical with the Verisyse. You have to center the optic perfectly so the patient does not get edge glare. For a larger pupil, you must center the lens slightly inferiorly to the center of the pupil, so that there is more optic for the pupil, and the upper lid will cover the part of the pupil that is not as covered by the optic.

One other note: at the end of the ICL procedure, before constricting the pupil, it may look as if the optic is not perfectly centered, but do not touch it. The lens will center by itself. It is in the sulcus, and it will center as it settles. My patients early on are not complaining about night vision problems with this lens.

**Dr. Vukich:** As we talk about incision size and technique, I think we have to keep in mind that every one of these lenses will need to be removed some day. These patients will live to a ripe old age, they will develop age-related cataracts in their 70s and 80s, and we will have to remove these implants. I think it will feel very anachronistic to make a 6-mm incision 30 years from now to remove the Verisyse lens.

**Dr. Slade:** How do you explain the ICL?

**Dr. Rowen:** Removing the lens from under the iris takes some finesse. I place a Sinskey hook in the positioning hole and slide the ICL back and up over the iris if I cannot get it to float up with just using viscoelastic. Then, one must gently grab the edge of the haptic and maneuver it into the

*"For me, knowing that for 8 years I have not induced any astigmatism with the ICL makes me very comfortable."*

—Dr. Rowen

incision. Once there, it slides out very easily with a hand-over-hand approach using small curved forceps.

**Dr. Vukich:** It can be removed easily through a 3-mm incision, folding on itself as it is withdrawn. The ICL does not need to be disassembled or cut into pieces to be removed.

**Dr. Slade:** Could you use a 2-mm incision?

**Dr. Vukich:** I use the same incision that was created to implant the ICL. Interestingly, it has been my experience that clear corneal incisions reopen just as easily as a LASIK flap lifts, even some years later.

**Dr. Christenbury:** Any new procedure has a learning curve. I found that mine was with folding and loading the lens. The only other challenge is to obtain the ideal amount of viscoelastic to fill the anterior chamber for ICL insertion.

## COST

**Dr. Slade:** How much are you charging for this procedure?

**Dr. Baker:** Our costs, of course, are driven by the cost of the lens and the facility fee, which the patient pays. We do not currently own our own facility for performing this surgery. Using a facility almost doubles the cost into the \$4,500 range, compared with \$2,900 for a customized LASIK procedure using the Intralase FS laser (Intralase Corp., Irvine, CA).

**Dr. Rowen:** What do you charge additionally for a LASIK procedure that you have to perform over the ICL surgery?

**Dr. Baker:** Dr. Slade and I currently roll that cost in and tell patients that there are no additional professional fees. However, they pay for the disposables, supply costs, and processing fees. We also charge them \$300 for the laser card.

**Dr. Slade:** What is the ideal scenario from the patient's perspective? We use a stand-alone ASC for cataract surgery, but we have our own lasers for our LASIK patients.

**Dr. Baker:** The perfect scenario for us would be to perform ICL surgery in the same office in which we do laser



surgery. That way, whether the patient is better suited for the ICL or for LASIK, we could accommodate either on demand. Performing the ICL procedure in the office would be especially convenient, considering the logistics of doing the peripheral iridotomy.

**Dr. Vukich:** I am part of a surgery center owned by several partners. There is a financial imperative for the surgery center to run as a separate business, but it comes down to how to deliver this in a cost-effective manner for patients.

**Dr. Slade:** What do you charge for LASIK, and what do you charge for ICL implantation?

**Dr. Vukich:** We charge \$1,700 for LASIK and \$2,995 for the ICL.

**Dr. Slade:** Is the money that goes to your practice similar?

**Dr. Vukich:** Our profit margin is greater for the ICL. As far as delivering the service, we must consider whether it is cost effective for the surgeon's time. If you have a cataract or an intraocular practice already, it is very easy to incorporate this procedure into a normal cataract day. It flows very nicely and becomes an additional revenue stream.

**Dr. Slade:** Dr. Baker and I have been adding ICL surgeries to our cataract days. We do them in whatever order they flow. ICL implantation really does take less time than removing a cataract. However, I work out of two rooms, so that my staff has the other room set up for the next surgery by the time I am finished with the first. It works beautifully. This procedure will not throw your schedule out of rhythm.

**Dr. Rowen:** I work in a hospital and in a freestanding ASC. In the hospital, I work in two rooms. I find no disruption transitioning from cataract to ICL surgery. I think we need to negotiate a facility cost that works. This surgery does not use disposables, as does cataract surgery, and you really only need a bottle for irrigation. Then, other than for the Ocucoat (Bausch & Lomb), there are really no other costs. You can tell your facility what instruments you are bringing, the patient pays for the lens, and you can negotiate a price that is less than that of cataract surgery. Taking the time to negotiate a price with your surgery center may help make the procedure more affordable for the patient.

**Dr. Vukich:** From a surgeon's perspective, this procedure has very little barrier to entry. You do not need to purchase a laser and outfit a room with special environmental controls. Everything you need to implant an ICL you probably already have in your OR.

*"Not a single patient has opted to have the lens removed because he thought the glare was bothersome."*

—Dr. Vukich

**Dr. Christenbury:** I perform lens procedures in my office. I have four rooms identical to an ASC, with microscopes and pre- and postoperative areas that are certified for in-office surgery. It has the correct HVAC system, and we have an anesthetist who comes in for the day. We use topical anesthesia with sedation. It is very easy.

## DILATION

**Dr. Slade:** What do you use to dilate ICL patients, and what is your lower limit of pupillary dilation?

**Dr. Vukich:** This is an important part of getting the surgery to flow smoothly. I use 1% Mydracil (Alcon Laboratories, Inc., Fort Worth, TX), and 2.5% Neo-Synephrine (Bayer Corporation, New Haven, CT). I prescribe a dosing regimen of a minimum of three times, 10 minutes apart. Importantly, this regimen is continued for additional doses right up until the time the patient is called into the OR. That simple addition to our standing orders, which were, "continue for 10 minutes until call to OR," has made all the difference.

**Dr. Slade:** We do the same with cataract patients, except we use 1% Mydracil and 10% Neo-Synephrine. I like the patient to receive four to six sets of drops before surgery. Even with Ocucoat, you can push apart a pupil that is 9 to 10mm or larger.

**Dr. Vukich:** Bigger is better, but at what point do you switch the order and give the patient another set of drops? I think an 8-mm pupil is the outside small limit at which the procedure becomes technically more difficult than necessary.

**Dr. Rowen:** My patients come in dilated. I give them tiny bottles of Mydracil 1% and Neo-Synephrine 2.5% and start the dosing as early as possible. That way, I operate on whoever is ready, instead of waiting for dilation. Also, this week I used 10% Neo-Synephrine. The question is the dosing. You could probably get one or two doses of 10% Neo-Synephrine in, as long as the patient is receiving the drops up until the point of surgery. I agree that 8mm is about where the surgery becomes more technically difficult.



**Dr. Christenbury:** I use 1% Mydracyl and 10% Neo-Synephrine for dilation. Additionally, for any kind of dilated procedure, patients are given a small bottle of Mydracyl 1% at their consultation to begin the dilation process at home before arriving at the clinic the day of their procedure. They do not receive Neo-Synephrine until they enter the office.

### PUPIL SIZE

**Dr. Slade:** What is your upper limit on pupil size preoperatively?

**Dr. Vukich:** There is no upper limit on pupil size; that is the beauty of the way this lens functions within the eye. Large scotopic or mesopic pupils are not a contraindication for the ICL, and glare is not a common complaint among these patients. Some report that they have minimal glare at night, but they are not troubled by it. In the US FDA phase 3 trials, not a single patient has opted to have the lens removed because he thought the glare was bothersome.

**Dr. Christenbury:** I can tell you from my experience with the Verisyse (when optics are 5 or 6mm) that night vision complaints are rare with phakic IOLs. We carefully measure every patient's scotopic/photopic/mesopic pupil size with the Procyon infrared pupillometer (Keeler Instruments Inc., Broomall, PA). There are so many patients whose mesopic pupil is larger than the optic of the phakic lens implant, and very few of them complain of night vision problems.

### PUPIL MANAGEMENT

**Dr. Slade:** One issue is that the pupil can come down during surgery. How would you handle that, Dr. Rowen?

**Dr. Rowen:** I would reinflate it with Ocucoat. It is very important not to use too much or too little. With too much viscoelastic, it is hard to position the lens under the pupil and get it flat enough so that you have the right space in between where the lens is sitting and the crystalline lens. I feel comfortable with performing a little extra tucking if necessary. I would not be deterred by a pupil's constricting.

**Dr. Vukich:** Rarely, there will be patients in whom the pupil is more reactive, and the manipulation of tucking the footplates can stimulate the pupil to constrict. I keep a syringe of cardiac epinephrine 1 to 10,000 available just in case. I have not used it yet, but I have seen it used when proctoring other surgeons. It is a handy emergency tool. However, if you adequately dilated preoperatively, a constricting pupil is a rare problem.

**Dr. Slade:** Is there a point at which the pupil might come down to the extent that you would not implant the lens?

**Dr. Vukich:** Yes, that could theoretically occur, although I am not aware of a case in which that happened. Again, the ICL is a simple lens to explant once it is in the anterior chamber if the pupil is too small to comfortably implant it.

**Dr. Slade:** Would you agree that there could be a scenario in which it would be best not to implant that lens?

**Dr. Vukich:** Absolutely. If the pupil constricts to less than 7mm, it is best to come back another day or continue administering drops in your preoperative holding area and then return your patient to the OR 30 minutes to 1 hour later.

### IRIS PROLAPSE

**Dr. Slade:** How do we avoid and handle iris prolapse?

**Dr. Rowen:** The construction of the incision will help avoid iris prolapse. Obviously, the more posteriorly you enter the anterior chamber, the higher the risk is for iris prolapse. You want to create a long tunnel to prevent the iris from coming back out.

**Dr. Slade:** Is there a disadvantage to too long a tunnel?

**Dr. Rowen:** There could be striae, but I have not had a problem. The second culprit of iris prolapse is in evacuating the Ocucoat. During the study, I developed a technique in which I insert a chamber maintainer in the sideport incision with an irrigating bottle and then pass a syringe attached to a cannula through the incision. With the chamber reinforced, while irrigating from the incision, I never have a trampolining effect as the Ocucoat exits. Also, the iris remains in place, because the chamber is not flattening.

**Dr. Slade:** My current technique is to pass a syringe full of balanced salt solution through the stab wound. Then, with a forceps, I release the edge of the wound. This technique extracts the viscoelastic rapidly. However, why not use I/A?

**Dr. Rowen:** You will have more trampolining with I/A, which may potentially induce trauma.

**Dr. Slade:** Would you recommend I/A in there?

**Dr. Rowen:** I would not recommend it. I think there would be a problem with the optic.

**Dr. Vukich:** I think automated I/A is unnecessary and adds an additional instrument into the eye. Especially if the I/A handpiece has a silicone sleeve, it is easy to touch and dislocate the lens.





**Dr. Christenbury:** One technique I have tried is injecting a small amount of Miochol E (Novartis International AG, Basel, Switzerland) prior to removing the viscoelastic. Once the pupil starts coming down, then I either irrigate the viscoelastic through the wound or use careful bimanual I/A.

### VISCOELASTIC

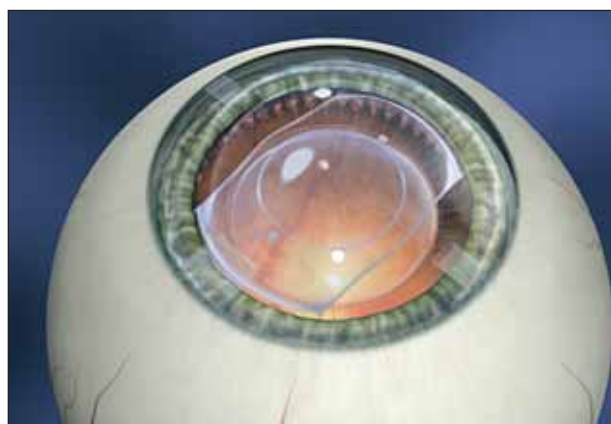
**Dr. Slade:** What is the best viscoelastic to use?

**Dr. Rowen:** Ocucoat is the easiest to remove. It is what we used in the study, and it worked perfectly. Has anyone heard of Miochol's inducing cataract? Is there any literature on it?

**Dr. Slade:** I am not aware of any literature on Miochol's inducing cataract, but you raise a good point. Even with a perfectly placed lens, we are also introducing irrigating solutions, drugs, air—some of these things may cause problems, and we may want to avoid using them in the anterior chamber. We have been using Miochol just as Dr. Christenbury does. We introduce it right after tucking in the lens to start the pupil coming down and to minimize the risk of iris prolapse. The drug also produces excellent vision the next day. It works somewhat better than Miostat (Alcon Laboratories, Inc.), which has a long duration of action. Furthermore, I find it helpful, after inserting the lens in the anterior chamber, to instill a little extra viscoelastic to force the lens down and tuck it in.

**Dr. Rowen:** One helpful technique with viscoelastic is to instill it where you can still see its rolls and avoid making it cohesive. If it becomes too cohesive, then it will readily fill the chamber.

**Dr. Christenbury:** Dr. Slade gave me a good tip: Inject the viscoelastic into the AC just until you see the iris push back.



**Figure 4.** This image shows the position of the Visian ICL behind the iris.

**Dr. Vukich:** Viscoelastic is added just until the point where you see the lens-iris diaphragm move the slightest bit, and then you know you have enough (Figure 4).

**Dr. Slade:** Do not try to blow it open.

**Dr. Rowen:** The lens will not unfold well, and it is hard to tuck and place.

**Dr. Christenbury:** Also, it is harder to overfill with viscoelastic when using the sideport incision for injection.

**Dr. Slade:** That approach also deepens the chamber bed, gives more control, and reduces the likelihood of shallowing when you open the large wound and ding the capsule.

### OTHER PEARLS

**Dr. Christenbury:** The one difference I found between ICL surgery and other intraocular procedures was the unfolding of the lens. Dr. Slade instructed me to push the lens through the injector until it is approximately 50% out, and then wait long enough for the lens to unfold until you see it leading from the plates. I have learned to be patient and just wait for the ICL to unfold—do not attempt to finish injecting the ICL before the leading footplates unfold.

**Dr. Vukich:** This is not a difficult surgery, but there is a very narrow path that surgeons need to follow. They should not deviate from the technique that we have learned is safe and efficacious until they have gained a fair amount of experience. I would encourage surgeons new to ICL implantation to not add elements that are not part of the ICL training. That is, do not use air to maintain the chamber, do not enter at different angles, and do not chase the astigmatic error with the incision. These are all things surgeons are comfortable doing in cataract surgery, but this is a different operation. Technically, it is not difficult, and with established techniques, we know the results will be excellent.

**Dr. Slade:** Set parameters are difficult for all of us to follow, because every surgeon wants to put his own twist to a procedure. After 100 cases or so, I am sure surgeons will try different techniques, but it is so important to do one's initial ICL cases exactly by the book.

**Dr. Rowen:** I do not think surgeons should ever deviate from this procedure.

**Dr. Vukich:** The technique will evolve with time, but let's initially execute it the way we know is safe and efficacious.



*"It is so important to do one's initial ICL cases exactly by the book."*

*—Dr. Slade*

**Dr. Slade:** To echo Dr. Vukich, it is not a difficult surgery; it is like cataract surgery without all the hard steps. It is a rapid and delicate surgery, however. Charles Williams, MD, who taught me the surgical technique, said to think of it as a "butterfly surgery," a delicate touch, a shifting of gears. That advice stood me well.

**Dr. Baker:** The results will depend upon the quality of the surgery, because the lens is going to perform well.

**Dr. Slade:** I agree. Let's segue into our postoperative discussion. Done properly, this procedure can elicit a "wow" factor from the patient at 30 minutes postoperatively. This is the same effect that contributed greatly to the growth of LASIK. Let's now talk about postoperative care with the ICL.

**Dr. Christenbury:** So far, my ICL patients have tried to contain their excitement. Most patients are 20/40 that same afternoon and 20/20 or 20/25 the next day. I have three employees who have scheduled their Visian ICL procedures.

**Dr. Rowen:** Before you perform the surgery, tell the patient to look around the room and remember what he sees. When he sits up after the procedure, ask him to look around the room again. In my experience, patients exclaim, "Oh, I can make out everything in the room." That is the "wow" factor.

### **PRESSURE RISE**

**Dr. Vukich:** Increased IOP is an important issue, and there are two ways to avoid it. One is to make the peripheral iridotomy sufficiently large. We have a tendency to make it small. The second is to adequately remove the viscoelastic. Make sure that you have sufficiently debulked the viscoelastic at a minimum and removed as much as you can comfortably. I perform two peripheral iridotomies.

**Dr. Slade:** How do you manage an IOP rise, if you get it?

**Dr. Christenbury:** Do you instill any drops at the beginning of the procedure to manage pressure?

**Dr. Slade:** Just Miochol.

**Dr. Vukich:** I instill Betagan (Allergan, Inc., Irvine, CA) at the end of the procedure.

**Dr. Vukich:** I manage pressure rise by burping the wound.

**Dr. Slade:** I would manipulate the paracentesis.

**Dr. Vukich:** Burping the paracentesis is probably somewhat safer than burping the wound. If you have too much viscoelastic in the eye, burping will make the viscoelastic come out fairly viscous.

**Dr. Christenbury:** If you think there is retained viscoelastic, I would burp the larger wound. It is difficult to get a lot of viscoelastic out of the paracentesis.

**Dr. Vukich:** Yes, and typically, you have to do it a second time. Wait 20 to 30 minutes, and do it again.

**Dr. Rowen:** The best approach is to make sure your peripheral iridotomies are adequate. Otherwise, if the pressure rises, the patient may notice pain or blurred vision. With an inadequate peripheral iridotomy, the iris would have a forward appearance, and you could have an issue. Then, you would have to return to the patient hours later and create an adequate peripheral iridotomy.

**Dr. Christenbury:** How do you know it is adequate?

**Dr. Rowen:** You should see that plume of pigment that comes through when you make the peripheral iridotomy, and then you should be able to see a good red reflex through it. Because it is difficult to view the red reflex through pupillary constriction, you may need to use retroillumination. The hardest scenario is a dark brown, thick iris, where pigment disperses everywhere.

**Dr. Baker:** How many peripheral iridotomies do you make?

**Dr. Rowen:** Two, approximately at the 11-o'clock and 1-o'clock positions.

**Dr. Vukich:** There is a point of diminishing returns. You can get dysphotopsias with peripheral iridotomies that are too large, too peripheral, or too numerous.

**Dr. Vukich:** Asking the patient if he sees the aiming beam is very effective. Usually, if you did not get through, he will see the aiming beam and will retroilluminate with it and then see the red. It is a good way to confirm completion of the iridotomy.



*"The results will depend upon the quality of the surgery, because the lens is going to perform well."*

—Dr. Baker

**Dr. Baker:** If you had an open peripheral iridotomy, is there any concern about being too peripheral? Can you conclude that with a large, vaulted lens?

**Dr. Rowen:** My ICL patients' lens placement during the past 8 years has been incredibly stable.

**Dr. Vukich:** The rationale for two peripheral iridotomies is simply to ensure that one is open.

**Dr. Slade:** You should make them at least 72 hours and up to 3 months in advance of the surgery.

**Dr. Vukich:** The problem with performing peripheral iridotomies too soon prior to the implantation is that the pupil is more reactive. Laser peripheral iridotomies cause an inflammatory response that requires a few days to subside. Also, pigment liberated by the peripheral iridotomy is more likely to deposit on the ICL.

**Dr. Baker:** Do you perform both peripheral iridotomies at the same time?

**Dr. Rowen:** I do both eyes at the same time.

**Dr. Slade:** I have been doing them bilaterally.

## ADOPTING THE TECHNOLOGY

**Dr. Slade:** Many surgeons who have no experience with the ICL wonder how to get involved. STAAR Surgical Company has offered courses for years that Dr. Vukich and I direct and teach. I would recommend first visiting a surgeon who is implanting this lens, watching the surgery, looking at that surgeon's postoperative results, and then deciding for yourself. Next, take the course. Also, take advantage of the user group meetings. What would you panelists recommend?

**Dr. Rowen:** I think the cataract surgeon will have an easier time getting into ICL implantation than a purely refractive surgeon who has not been in the eye for many years. We cataract surgeons just have to remember, as Dr. Slade said, that this is like operating on a butterfly's wing. It is an

extremely gentle, delicate procedure. There is no reason why a cataract surgeon who has good technique and a gentle approach cannot adopt the ICL. I would encourage anyone who is willing to take the plunge.

**Dr. Baker:** A cataract surgeon may be skilled initially, but I do not think the patients in his office will request the ICL until the public learns more about it. I think the first recipients of the ICL will be refractive patients who are seeking LASIK or another laser procedure and will be converted to the ICL by the physician.

**Dr. Vukich:** Cataract surgeons may not have the patients in their practice. Plus, there has never been a refractive procedure with a zero enhancement rate. I think we have to anticipate that a small percentage of ICL patients will require some secondary adjustment to achieve the deliverable endpoint they expect, and I think a refractive practice is capable of delivering that fine-tuning more consistently. Although this is an excellent technology, we still have to deal with the astigmatic component as well as patients' expectations. To that extent, a refractive practice I think will be better suited. Certainly, for a refractive surgeon who is also familiar with intraocular techniques, the transition will be seamless.

**Dr. Baker:** Dr. Vukich, do you think that once the public becomes informed that patients will accept this procedure quickly?

**Dr. Vukich:** I believe that will be the case. I live in a small community and have treated a sufficient number of ICL patients, and word of mouth is now generating a great deal of interest.

**Dr. Christenbury:** I think there are a number of contact lens wearers with a high correction who have been hesitant to undergo a permanent procedure. They may wish to have a procedure that is potentially reversible and that does not remove tissue. The Visian ICL would be a popular choice.

**Dr. Slade:** This is an exciting time for refractive surgery, made even more so by advances such as the ICL. As discussed in the panel, the ICL is an easily accessible technology for surgeons, and it will benefit us all to have it in our selection of options for patients. The ICL's results are superb, and soon we will have hundreds of surgeons doing thousands of cases. That is when its results will really shine. □

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