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## Right Patients, Remarkable Results With the **VISIAN ICL**





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# Right Patients, Remarkable Results With the Visian ICL

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# INTRODUCTION

By John A. Vukich, MD

My first experience with the Visian ICL (STAAR Surgical; Figure 1) was in December 1998, when I signed on as a principal investigator of the myopic Visian ICL and myopic toric Visian ICL FDA clinical trials. I then assumed the role of medical monitor for subsequent clinical trials more than a decade ago. Since that time, as STAAR's medical monitor, I have been involved with data preparation and regulatory submissions to the FDA and I have functioned as the point person for surgeons to field questions regarding patient care and patient-related issues.

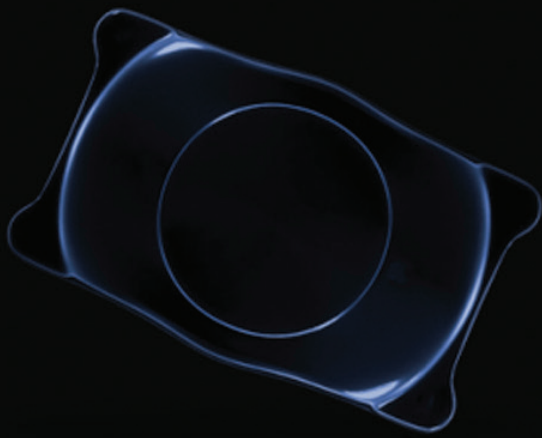
I have accepted all of these responsibilities because I believe that the Visian ICL represents tremendous innovation in terms of our ability to deliver high-quality visual outcomes to patients with virtually any myopic refraction. Over the past decade, we have seen steady market share growth, both in the United States and internationally, of the Visian ICL, which should be taken as a testimony to the quality of the product and the quality of the vision that it is able to deliver.

Advancement of the Visian ICL has been an international effort. Roberto Zaldivar, MD, of Argentina, stands as one significant pioneer involved in creating the earliest versions of the lens. In 1995, Dr. Zaldivar implanted his first Visian ICL, and to this day, he is instrumental in teaching us how to best use the Visian ICL and about the techniques and instruments that are now in use around the world. We look to Dr. Zaldivar for continued innovation in routine Visian ICL use, as refinements in surgical technique are constantly evolving.

Another pioneer is the man with whom I completed my first Visian ICL surgery, Juan Batlle, MD, in the Dominican Republic. He, too, has been heavily involved in demonstrating how to best use the Visian ICL and has trained more than 150 surgeons worldwide. He has been a mentor to me and to many surgeons around the world. He is one of the major figures in developing the Visian ICL as a routine procedure for myopic patients.

Yet another prominent figure in the history of the Visian ICL is Robert P. Rivera, MD, who, at age 58, passed away peacefully, surrounded by his loving family, on Wednesday, April 1, 2015, after a 6-month battle with cancer.

An accomplished and skillful surgeon, Rob was known to his colleagues as a great teacher and an innovator. He traveled the world training, teaching, and lecturing to



Courtesy of STAAR Surgical

## The Visian ICL: A Phakic IOL for Myopia

**Figure 1.** The Visian ICL is made from Collamer, a 100% biocompatible material created and used exclusively by STAAR Surgical. This IOL technology is FDA approved to correct myopia in adults ranging from -3.00 to -15.00 D with less than or equal to 2.50 D of astigmatism and can reduce myopia in adults ranging from greater than -15.00 to -20.00 D with less than or equal to 2.50 D of astigmatism.

physicians on procedures that have touched the lives of millions. His published papers, presentations, and videos have won several "Best Of" awards at meetings around the world. Rob was truly one of the most respected and gifted eye surgeons I have had the pleasure to work with. His contributions in our field have already affected millions of patients and will continue to benefit others in the future. We will miss Rob as a friend, and we are richer for the many contributions he has made to the field of ophthalmology.

With these pioneers in mind and with the more than 20 years of experience we now have regarding the Visian ICL, a virtual panel of world-renowned surgeons convened recently to highlight the proper techniques for patient selection and their various strategies for achieving remarkable patient outcomes.

Their collective experience illustrates that the Visian ICL is a viable option for our patients—one that can be offered as another option for refractive correction of myopic errors to supplement one's LASIK practice, not replace it. Not only does the Visian ICL work well, but it is predictable and provides a high-quality optical image that patients find satisfying. That, as much as anything, has driven the acceptance of the Visian ICL as not only an alternative, but, in many cases, the preferred option for many patients. ■

## OPENING REMARKS

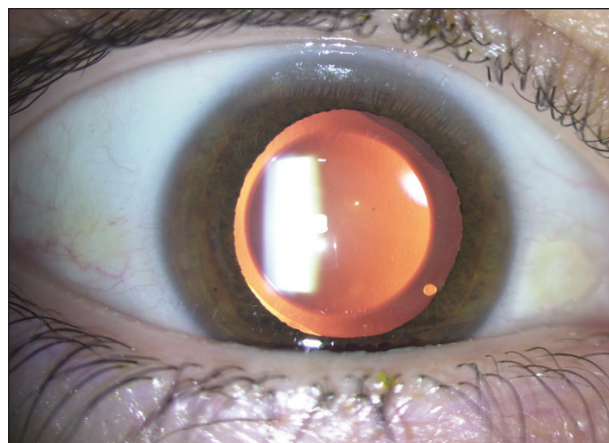
**John A. Vukich, MD:** Thank you, everyone, for your involvement in this virtual roundtable. We organized this panel of surgeons specifically because we are all in agreement that the Visian ICL is an excellent option for our myopic patients, and we have all been implanting this lens for many years—some of us since the clinical trials to gain FDA approval. With that said, I am sure that each one of us will walk away from this discussion having learned something new about patient selection and achieving the best-possible clinical outcomes. Dr. Cionni, let's start with you. What makes the Visian ICL an attractive option for myopic correction?

**Robert J. Cionni, MD:** I think the power of comparing the Visian ICL to LASIK hinges on a couple factors, one of which is the lower incidence of dry eye after surgery. Second, it does not alter the natural curvature of the cornea. This is important because, later down the line when these patients require cataract surgery, it is easier for me to calculate IOL power than with my post-LASIK patients. Corneal preservation with the Visian ICL is also important because, in essence, there is no increased risk of developing ectasia postoperatively—and that is powerful. The third factor that makes the Visian ICL such an attractive option is that the lens is removable, in the event that a patient is unhappy and requires or desires removal postoperatively.

I believe that the Visian ICL represents tremendous innovation in terms of our ability to deliver high-quality visual outcomes to patients with virtually any myopic refraction.

– John A. Vukich, MD

**Robert K. Maloney, MD:** Although the bulk of my practice is still LASIK, what is gratifying for me about the Visian ICL (Figure 2) is that my referring doctors really appreciate the quality of vision it provides. And so it is common for me now to get patients referred, not for LASIK, but for the Visian ICL. These patients have been instructed by their referring doctors that they are not good candidates for LASIK but that they would be for the Visian ICL. In that respect, it has been outstanding for our referring network to have a strong Visian ICL practice.



Courtesy of Robert K. Maloney, MD

Figure 2. The Visian ICL in situ.

**Robert P. Rivera, MD:** I have had a similar experience. I work in a busy refractive surgery center, in which Visian ICLs occupy probably 10% of our surgical volume. But, we continually see the Visian ICL part of the practice growing as more patients become aware of the procedure.

**Gregory D. Parkhurst, MD, FACS:** I think this is exactly what is so important about this roundtable discussion on the Visian ICL: It serves as a method of public education. First, it highlights the real benefits of refractive surgery, and second it promotes public confidence in refractive surgery in general. Today, we really have some excellent procedures—some of them are with lens implants and others are with laser technology—and it is important to be able to custom fit the right procedure to the right patient.

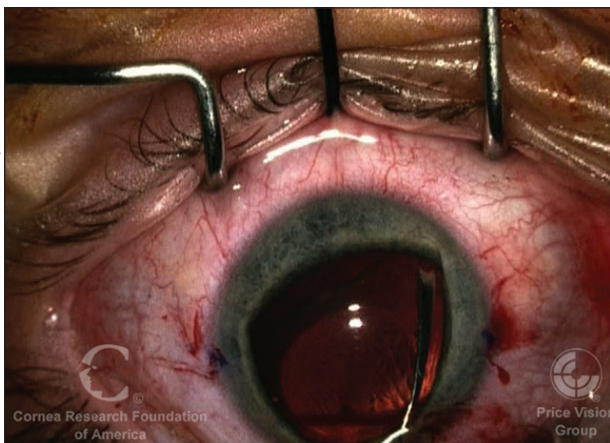
## SELECTING THE RIGHT PATIENT *Treatment Range*

**Dr. Vukich:** Great comment, Dr. Parkhurst. I think this is a useful segue into our first topic, which is proper tools for patient selection. Dr. Barnes, would you like to start the conversation by telling us your treatment range? At what refraction do you stop offering LASIK and start with the Visian ICL?

**Scott D. Barnes, MD:** Well, it is probably a little bit different for me because I am not in private practice and the military provides refractive correction at no cost for soldiers—whether it be the Visian ICL or LASIK. If I were on the civilian side, I would offer the Visian ICL to every patient who is a potential candidate; in other words, even those patients with normal-appearing corneas. For me, the range is what I can get by with knowing that the Visian ICL is only available down to -3.00 D, and the highest, I think, that we have gone is -18.00 D. In the military, I usually need a corneal reason (eg, too thin, inferior steepening) to consider the Visian ICL.



Courtesy of Francis W. Price, Jr, MD



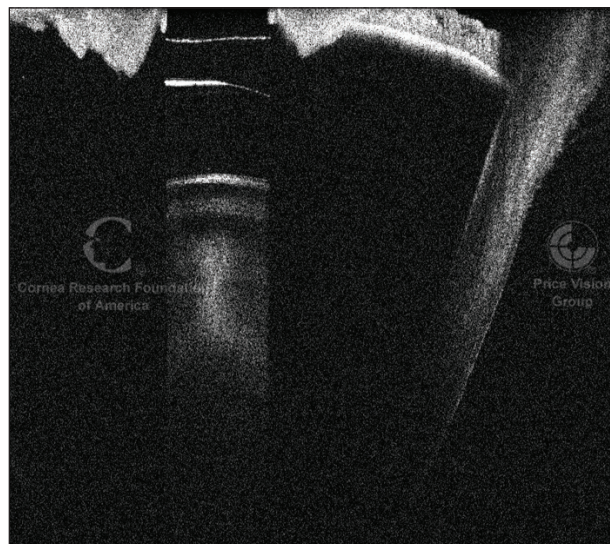
**Figure 3.** Intraoperative image depicting the tucking of the last haptic behind the iris during Visian ICL insertion.

Basically, for any soldier who has a refraction of  $-6.00$  D and above, we ask them to listen to the Visian ICL brief and the laser brief, which includes PRK and LASIK. These soldiers have an option to choose either procedure. However, for soldiers with a refraction of less than  $-6.00$  D, there usually has to be a reason why we do not perform LASIK or PRK, such as a thin cornea, irregular steepening, or suggestion of forme fruste keratoconus.

**Dr. Brinton:** I am comfortable using the Visian ICL over the usage range of FDA approval, and that is from  $-3.00$  to  $-20.00$  D. While the side effects of excimer laser ablation are minimal, they do increase with increasing dioptric power of treatment; this is not the case with the Visian ICL. Consequently, the Visian ICL works particularly well in patients in the  $-5.00$  to  $-7.00$  D range and above. I typically do not recommend LASIK in patients with a refraction of  $-7.00$  D or above, as studies have demonstrated superior results with phakic IOLs in this range.<sup>1-6</sup> In my practice, the Visian ICL is usually preferable to PRK beginning at  $-3.00$  D and above due to the relative comfort, speed of visual recovery, and resultant quality of vision with this lens-based treatment.

**Dr. Cionni:** When I see a patient who needs a significant LASIK treatment, one that requires a lot of tissue removal (typically  $-6.00$  D or more), then in that patient we introduce the option of Visian ICL. We can implant the Visian ICL in anyone with a refraction of  $-3.00$  D or worse; however, we generally suggest LASIK in this population unless the patient has a thin cornea or any sign of ectasia. It is right around that  $-6.00$  D range that we talk about the Visian ICL and its benefits as compared with LASIK.

**Dr. Maloney:** Definitely above  $-8.00$  D of myopia I prefer the Visian ICL. I will certainly consider it above  $-6.00$  D, depending on the patient's need for super quality vision.



Courtesy of Francis W. Price, Jr, MD

**Figure 4.** Intraoperative OCT image showing the Visian ICL.

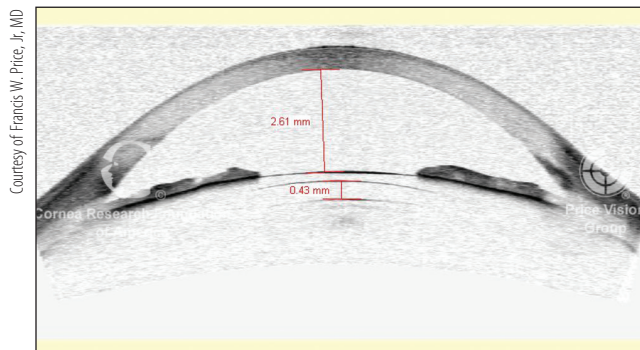
**Dr. Vukich:** Can you give an example of a patient with a myopic refraction around  $-6.00$  D in whom you would consider the Visian ICL?

**Dr. Maloney:** Take a patient who is a  $-7.00$  D myope, does a fair amount of night driving, and switched from wearing soft contact lenses to hard or gas-permeable lenses because his or her vision was not clear enough with soft lenses. In this patient, clarity and quality of vision is at a premium, and, to provide excellent quality of vision, I would recommend the Visian ICL.

**Dr. Parkhurst:** That is a good example. There are patients for whom we make a strong recommendation for LASIK, others for whom we make a strong recommendation for the Visian ICL, and others yet for whom we offer both procedures. In the latter group, we let these patients know the different risk-benefit ratios for each procedure and then let the patient decide which he or she believes is best for him or her.

Often our categorization of patients described above comes down to what the patient's refraction is. If the patient has hyperopia or up to  $-3.00$  D of myopia or significant astigmatism, and as long as the cornea is healthy, we recommend LASIK. On the other hand, if a patient has high myopia ( $-8.00$  D or above), especially if he or she has an irregular or thin cornea, and as long as the anterior chamber depth is adequate, we strongly recommend the Visian ICL procedure. If the patient is, generally speaking, between about  $-3.00$  and  $-8.00$  D and has minimal astigmatism, a healthy cornea, and adequate anterior chamber depth, we tell the patient about both options. Many times, patients have a quick, gut feeling about which procedure makes the most sense for them.

Many people are not as familiar with the Visian ICL procedure as they are with LASIK. So, sometimes patients



**Figure 5.** Anterior segment OCT showing anterior chamber depth and vault 1 month after Visian ICL insertion.

come in thinking, “I want LASIK. That is what my friend/family member had, and I just want that.” Other patients come in having heard about a biocompatible technology that is removable and results in excellent quality of vision, and they want to hear more about the Visian ICL technology. Some patients have an affinity to one technology that sounds best to them. But, for the patients who are candidates for both procedures, we present the relative benefits of each procedure and let the patient decide which sounds the best to him or her.

**Francis W. Price Jr, MD:** One of the nice things about the Visian ICL is that the end result is usually a well-positioned lens inside the eye (Figures 3 through 5) and exquisite vision. With regard to the treatment range, I start recommending the Visian ICL in patients with around -7.00 D of myopia. For patients with -10.00 D of myopia, I do not perform LASIK, as the quality of the vision is not stable over the long term.<sup>7-9</sup> On the other hand, several studies have shown good accuracy of the Visian ICL treatment for the refractive error, no matter what the diopter correction.<sup>7,8</sup> I also recommend the Visian ICL below -7.00 D of myopia if the patient’s cornea is too thin to allow us to do the appropriate laser correction.

**Dr. Vukich:** Dr. Rivera, what about you? At what refraction do you stop offering LASIK and start with the Visian ICL?

**Dr. Rivera:** I actually present the Visian ICL to all patients who are coming in for laser vision correction, so that they at least know that it is an option. I have found it interesting that many patients, even those in the -3.00 D of myopia range, who have been hesitant to have LASIK become interested in the Visian ICL as an option for refractive correction when they learn about it. One does not realize how many patients are alike in terms of their visual attributes until one starts presenting the Visian ICL in this way. I think, frankly, that I capture more patients wanting to undergo a refractive procedure to help their vision overall by always presenting the Visian ICL.

I actually present the Visian ICL to all patients who are coming in for laser vision correction, so that they at least know that it is an option. I have found it interesting that many patients, even those in the -3.00 D of myopia range, who have been hesitant to have LASIK become interested in the Visian ICL as an option for refractive correction when they learn about it.

– Robert P. Rivera, MD

**Dr. Vukich:** And you have no reservations using the Visian ICL instead of LASIK in that population?

**Dr. Rivera:** Not at all. I have many patients who are very good candidates for LASIK who, after hearing the discussion and doing their own research, have come back wanting the Visian ICL in place of LASIK.

**Helen K. Wu, MD:** I do a lot of surface ablation procedures, and, based on my criteria for LASIK, I have more liberal criteria for doing excimer laser corneal refractive surgery than somebody who just does LASIK. In any case, there is not a point dioptrically where I say to a patient, “You are not a candidate for laser vision correction anymore.” Nearing -10.00 D of myopia, by all my other criteria, laser vision correction is out of the question. But there is no strict cutoff in terms of that.

I generally offer the Visian ICL to all refractive patients when they fall into the FDA guidelines and the FDA-approved indications for the procedure. I talk to everybody about laser vision correction, and I talk to everybody about the Visian ICL.

For the most part, when patients fall into the standard -1.00 to -6.00 D, they elect LASIK. But there are also patients who are -3.00 or -4.00 D who come in knowing they want the Visian ICL. I do not have any rigid rules about where I turn off laser vision correction and turn on Visian ICL.

I do, however, have general guidelines for laser vision correction. First, total corneal thickness cannot be less than 400  $\mu$ m after laser vision correction—PRK or LASIK. For example, a patient with a total corneal thickness of 490  $\mu$ m who requires a 90- $\mu$ m ablation is the

lower limit of what I would accept for laser treatment. I also do not want to go below a central corneal power of 35.00 D when I am finished with laser vision correction. In other words, I do not want a cornea that is too flat afterward. I also do not want a cornea that is too thin afterward.

### **Corneal Thickness Considerations**

**Dr. Vukich:** That is a great point, Dr. Wu, and something worth discussing here. At what point, if at all, does corneal thickness play a role in when you recommend the Visian ICL for a patient's consideration?

**Dr. Wu:** I start to recommend the Visian ICL for patients with a corneal thickness of 400  $\mu\text{m}$  or less. Generally, for prospective refractive patients, in addition to corneal thickness, I also look at how much myopia the patient has, how old he or she is, and what his or her corneal topography looks like. Patients with collagen vascular disease like rheumatoid arthritis, or autoimmune diseases, with or without severe dry eye, I will automatically default to lens-based surgery. One of my first Visian ICL procedures was in a patient with a 460- or 465- $\mu\text{m}$  corneal thickness that was absolutely 100% normal in terms of corneal topography. But he was 23 years old and he wanted to be a firefighter. Even though his cornea was normal, he was young and his cornea was abnormally thin, and therefore I recommended the Visian ICL procedure. So, to me you should not just look at the corneal thickness. You have to look at the whole picture.

**Dr. Barnes:** If the patient is near 500  $\mu\text{m}$ —490, 495, 498  $\mu\text{m}$ —we look at his or her topography. I start to recommend the Visian ICL at a minimum residual stromal bed thickness of 275  $\mu\text{m}$ . So, if the patient's total corneal thickness is less than 500  $\mu\text{m}$ , I start to consider the Visian ICL.

**Dr. Brinton:** I recommend the Visian ICL as an option for patients with a total corneal thickness below 500  $\mu\text{m}$ , or 300  $\mu\text{m}$  residual stromal bed, or with more than -7.00 D of myopia.

**Dr. Cionni:** It is not just a matter corneal thickness. It also relates to how much treatment you have to perform. Generally, for patients with anywhere near a corneal thickness of 500  $\mu\text{m}$  preoperatively, I will explain that their cornea is slightly thinner than the normal cornea and, even though we may have enough residual stromal bed—for me that would be 300  $\mu\text{m}$ —the Visian ICL may be a better option. If we are doing a small treatment and they have a thin cornea that is going to leave over 300  $\mu\text{m}$ , I might say PRK or LASIK, and I also talk about the possibility of the Visian ICL, which does not remove corneal tissue like laser vision correction procedures do.

**Dr. Maloney:** For me, if a cornea is less than 480  $\mu\text{m}$  or my residual bed is less than 270  $\mu\text{m}$ , I will recommend the Visian ICL to patients.

**Dr. Price:** If the stromal bed will be below 300  $\mu\text{m}$  postoperatively, then I recommend the Visian ICL.

**Dr. Rivera:** If I have a patient who comes in at a -5.00 D, for example, if the residual stromal bed falls underneath 300  $\mu\text{m}$ , then I will certainly talk to him or her in more depth [about all refractive procedure options]. As the years have gone by, I have learned that it is not just about corneal thickness. Patient age, the possibility for enhancement after LASIK, corneal curvature, and the possibility for posterior cones may also affect postoperative outcomes and recommendation of the proper procedure. We continue to evolve in our knowledge of corneal factors that may, in fact, make our patients better candidates for something like a lens-based procedure. So, for example, a 45-year-old with a refraction of -5.00 D would be less concerning if he or she ends up with a residual stromal bed between 250 and 300  $\mu\text{m}$  than a 22-year-old patient with -5.00 D of myopia. This is because the 22-year-old is more likely to need an enhancement. In these cases, we would tend to stress the option of the Visian ICL.

**Dr. Vukich:** Dr. Parkhurst, you also mentioned considering other things in addition to corneal thickness. Can you elaborate?

**Dr. Parkhurst:** One thing that often comes up is irregular topography. Modern corneal laser scanning technology with Scheimpflug cameras and OCT now allows one to detect preclinical or suspicious forme fruste keratoconus, although we still do not have the perfect tool to screen who is at risk for ectasia. At times, we see several irregularities on topography that alert us to the risk for post-LASIK ectasia.<sup>10-13</sup> Maybe it is a thin central cornea, asymmetry of the corneal steepness, slight posterior elevation, or a combination of the aforementioned that make one suspicious of an increased risk for ectasia. So, in most instances, it is a combination of the residual stromal bed and what the patient's scan of the cornea looks like and reveals that influences the options we present.

### **Dry Eye and Ocular Surface Integrity**

**Dr. Vukich:** Thank you, Dr. Parkhurst, and everyone else, for sharing your parameters with us. Let's switch to a different topic that is still along the lines of patient selection, and that is: At what level of dry eye do you switch from LASIK to preference of the Visian ICL?

**Dr. Barnes:** Obviously we know that the cornea generally recovers from dry eye associated with laser vision



I agree that the Visian ICL is preferable in patients with dry eye because it avoids magnifying dry eye symptoms, even if the magnification is temporary and lasts only a few months in post-LASIK patients.

– Jason P. Brinton, MD

correction, and I do not have a scale for one treatment over the other. But if the patient is complaining about dry eye, using a lot of artificial tear treatment, and having difficulty wearing contact lenses or using the computer, I ask him or her to listen to the Visian ICL discussion.

I also tell these patients that I think the Visian ICL is a better alternative, because we just do not see the dry eye situation as much postoperatively as we do after laser vision correction. We do see it in some cases, but it is not as common and not as frequent as we see in laser patients.

**Dr. Brinton:** I agree that the Visian ICL is preferable in patients with dry eye because it avoids magnifying dry eye symptoms, even if the magnification is temporary and lasts only a few months in post-LASIK patients.

**Dr. Cionni:** Being in an arid climate here in Utah, a lot of patients have dry eye. In anybody who has any level of dry eye, I begin to talk about the difference in PRK or LASIK compared with the Visian ICL. Although after any eye procedure patients can perceive increased dry eye, it is less so with a Visian ICL than with LASIK in my experience. If a patient has any dry eye complaint and he or she is in the range of the Visian ICL, then I will talk about the possibility of the Visian ICL and tell them that, although the eye may seem a little bit more irritated immediately postoperatively, in reality it is less likely to worsen the dry eye than LASIK or PRK.

**Dr. Maloney:** For anyone with more than mild dry eye, I have a strong preference for the Visian ICL. It, in my experience, does not increase dryness.

Also, it is important to mention that I consider the underlying condition of their eyes, not how well the dry eye is controlled with drops. Now where that plays in is this: If a patient is on maximum therapy for dry eye, even if his or her ocular surface is perfect, I am hesitant to

recommend LASIK. If LASIK makes the patient drier, and it generally will, I have no treatment left to improve his or her vision or to control his or her symptoms.

**Dr. Parkhurst:** I am slightly on the other side of the fence. I always let patients know that, with modern LASIK technology, we still can have great success, even in the presence of mild or moderate dry eye.

**Dr. Price:** This is a really good topic. I am really aggressive with treating dry eyes now. Looking back to the time of my residency, dry eyes and how dry eyes affected vision was unappreciated. Today, whether it is the Visian ICL, LASIK, or refractive cataract surgery, dry eye treatment is really important, and more surgeons are beginning to realize that.

For the most part, we do not see dry eye as a limitation to any of our refractive surgeries because we use a combination of heat treatments to the eyelids, Restasis (cyclosporine ophthalmic emulsion; Allergan), artificial tears, supplements, and lid hygiene. We try to pick the best refractive surgery procedure for each patient, and from there we treat their dry eyes appropriately.

**Dr. Rivera:** When I was practicing in Phoenix, Arizona, in the middle of the desert, I thought we had a lot of dry eye incidents. But moving to Utah a few years ago, it is actually worse here because of our elevation. If I see corneal signs of dryness at the slit lamp, such as decreased tear breakup time, superficial punctate keratitis, decreased tears, or meniscus, I steer the patient toward the Visian ICL.

We are in the middle of a prospective study looking at changes in tear film osmolarity pre- and post-LASIK, pre- and post-PRK, and pre- and post-Visian ICL implantation. The general feeling is that the Visian ICL preserves the tear film in a more natural state.

Clinically speaking, I believe it is preserving the tear film more naturally. My Visian ICL patients come back with relatively fewer complaints of dry eyes compared with the laser patients.

**Dr. Wu:** Again, I am more apt to do surface ablation than the average surgeon, but I have more relaxed criteria for dry eye in the surface ablation patient than I do in the LASIK patient. I believe if a patient has fluorescein staining of the cornea that persists over a couple of visits, then he or she falls out of the LASIK criteria. Generally, if the patient is not easily treatable with PRK and has an underlying autoimmune problem that is causing dry eye, for example Sjögren syndrome, lupus, or rheumatoid arthritis, I automatically talk to them about the Visian ICL.

Fluorescein staining of the cornea would be a kind of a cutoff for laser vision correction, and where I would start

pushing the Visian ICL, because it does not affect dry eye and will likely leave patients with a better visual outcome.

## ACHIEVING REMARKABLE PATIENT OUTCOMES

### *Contrast Sensitivity and Higher-Order Aberrations*

**Dr. Vukich:** These have been excellent comments thus far. I think we all have a great understanding of the importance of proper patient selection and can appreciate all of the nuances that go into deciding between laser vision correction and the Visian ICL. Let's switch gears and talk about postoperative results. Dr. Barnes, have you seen improved contrast sensitivity in post-Visian ICL patients?

**Dr. Barnes:** Although we do not have documented clinical data to support that there is truly an improvement in contrast sensitivity postoperatively, I can share the information we do have from the patient perspective. Based on Snellen acuity, we definitely see a higher quality of vision with the Visian ICL. Also, when we compare the number of LASIK patients with the number of ICL patients who say that their quality of vision is better postoperatively than it was preoperatively with their contact lenses, we see that significantly more Visian ICL patients answer affirmatively—about 30% of LASIK patients and 75% of Visian ICL patients. And we often see this on the first day or week postoperatively, but certainly by the first month.

**Dr. Cionni:** I have not measured contrast sensitivity in these patients, either. What I can say is the way Visian ICL patients describe their quality of their vision compared with our LASIK patients is superior. That may relate to an improvement in contrast sensitivity or perhaps fewer higher-order aberrations (HOAs).

**Dr. Maloney:** Contrast sensitivity in Visian ICL patients is really striking, and their quality of vision is superb. Generally, 1 day after surgery Visian ICL patients are already seeing better than they ever have with glasses or contact lenses.

Early in my career, I made the mistake of doing the Visian ICL in one eye and LASIK in the other in some patients who were highly myopic in one eye and moderately myopic in the other. These patients always preferred their Visian ICL eye, even though it was much more myopic preoperatively. The reason was that the quality of vision was significantly better in a highly myopic eye with a Visian ICL than it was in a moderately myopic eye with LASIK. To me, that is a clear statement about the benefits of the Visian ICL in terms of quality of vision.

**Dr. Price:** We also have not done any studies on this. However, I was on the panel of presenters to the FDA on the Visian Toric ICL last year. I know of no other IOL that has presented better improvement in UCVA or BCVA to the FDA.<sup>1</sup>

**Dr. Rivera:** I have been doing Visian ICL surgery since it was first approved in the United States in 2005. Very early on, the “wow” factor that patients would express after Visian ICL implantation was remarkably different from that of our laser patients, and we continue to see that today. Visually speaking, and in my experience, my Visian ICL patients have excellent contrast sensitivity, excellent night vision, and lower incidence of glare.<sup>2,3,6</sup> Most of the time, Visian ICL patients are already amazed with their vision on postoperative day 1.

**Dr. Wu:** I have a similar answer to the others in that I do not routinely measure contrast sensitivity in post-Visian ICL patients. However, in terms of patient satisfaction, I have had zero Visian ICL patients complain about contrast sensitivity.

**Dr. Vukich:** Let's go around and answer the same question with regard to HOAs.

**Dr. Brinton:** Following refractive surgery, patients commonly report a decrease in the symptoms associated with HOAs, including ghosting of letters, halos, glare, and other nighttime vision complaints. While we see these metrics improve with LASIK, PRK, and refractive lens exchange, the difference seems to be particularly dramatic for Visian ICL patients.

**Dr. Cionni:** Likewise. My impression based on patient comments is that there are less HOAs after Visian ICL surgery than there are after LASIK. It would be an interesting study to look specifically at corneal aberrations with an aberrometer, post-LASIK compared with post-Visian ICL implantation.

**Dr. Price:** I have not measured HOAs, either. However, for each 1.00 D of myopia, there is a 2% reduction in image size with glasses versus contacts. Theoretically, the Visian ICL is actually better than this. For a -10.00 D myope, he or she will get more than a 20% increase in image size with the Visian ICL compared with image size with glasses because the correcting lens is closer to the nodal point in the eye. That is why higher myopes typically see an improvement in their BCVA and UCVA after the Visian ICL is implanted. It is also why they see better and function better at night with regard to HOAs.

**Dr. Rivera:** Agreed. Although I have not personally measured HOAs, my impression is that patients do



Courtesy of Gregory D. Parkhurst, MD, FACS

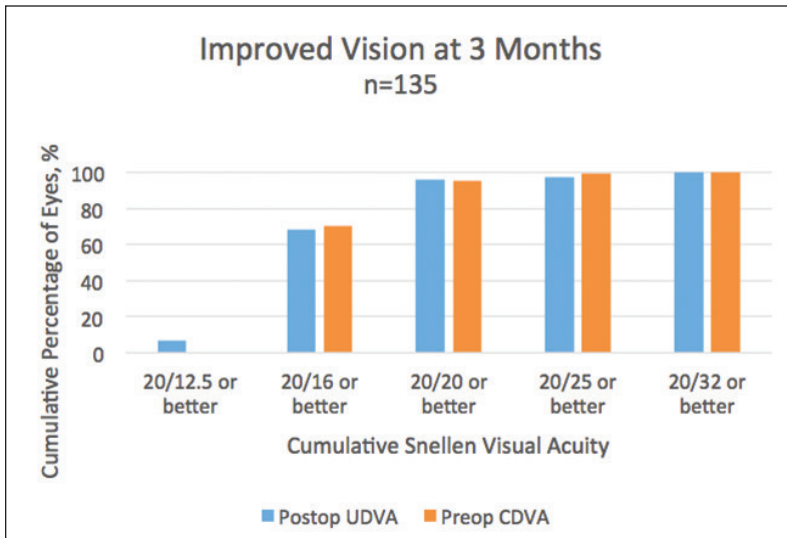


Figure 6. Comparison of postop UDVA and preop CDVA at 3 months.

Courtesy of Gregory D. Parkhurst, MD, FACS

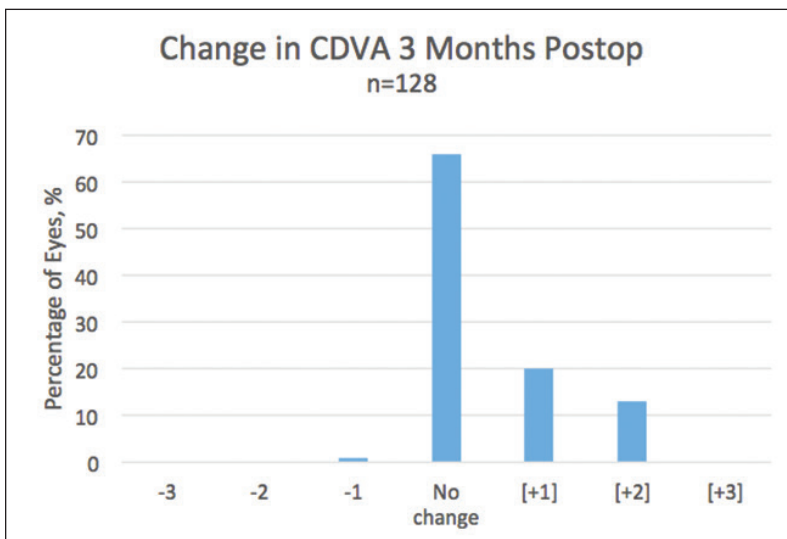


Figure 7. Change in CDVA at 3 months postop.

experience improvement. We have been doing some work with the Visiometrics HD Analyzer (MaxiMed), which measures light scatter and graphically reproduces what the patient sees. In that respect, patients' vision does seem to be better post-ICL implantation than after LASIK surgery.

**Dr. Wu:** Similarly, I do not check HOAs postoperatively in Visian ICL patients. Although we do see a slightly higher incidence of halos than what Dr. Parkhurst reported in his study,<sup>14</sup> they get better with time and no patient has ever wanted to have the lens explanted because of that, either, in my experience.

**Dr. Vukich:** Dr. Parkhurst, in your warfighter study published in *Journal of Refractive Surgery*, you found the following: 3 months postoperative, uncorrected distance

visual acuity (UDVA) of 20/20 or better was found in 129 of 135 (96%) eyes, and 91 of 135 (67%) were 20/15 or better. Manifest refraction and corrected distance visual acuity (CDVA) data were available for 128 eyes (Figures 6 and 7). Also, 42 eyes (33%) had improvement of 1 or more lines of CDVA, 115 eyes (90%) were within  $\pm 0.50$  D of emmetropia, and 127 of 128 eyes (99%) were within  $\pm 0.75$  D. No significant intra- or postoperative complications were observed. Has anyone else had similar results?

**Dr. Brinton:** Many Visian ICL patients are 20/20 in both eyes when they leave our office shortly after the procedure. Because it is an additive lens-based refractive procedure, there is minimal change during the healing process that affects the refractive power of the cornea. The refractive power of these eyes is stable quite early postoperatively.

**Dr. Maloney:** Visual outcomes are superb with the Visian ICL. When we do LASIK on high myopes, they usually report haze on postoperative day 1, even if they are seeing 20/20. With the Visian ICL, however, in my experience, vision is usually clear the day after surgery and stays clear.

In my experience, what I also like is that vision is stable almost immediately, eliminating the long, gradual period of stabilization that typically occurs after LASIK, particularly in patients who are

highly myopic (personal experience).

**Dr. Price:** I agree with all that has been said. The visual outcomes are on par with what Dr. Parkhurst and others have reported.

**Dr. Vukich:** Are your outcomes generally consistent, Dr. Price?

**Dr. Price:** Yes. With regard to UCVA and the achieved refractive effect, the Visian ICL is right on target—it does not matter whether the patient is a -3.00 or -16.00 D myope.

**Dr. Rivera:** I think the nice thing about Dr. Parkhurst's study is that it is possible to reproduce it in one's own patient population. That is to say that Visian ICL surgery

Courtesy of Gregory D. Parkhurst, MD, FACS

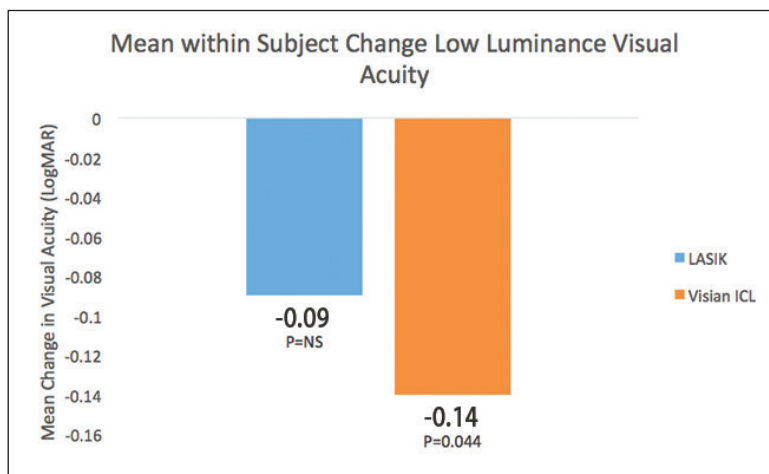


Figure 8. Comparison of LASIK and Visian ICL low luminance visual acuity.

Courtesy of Gregory D. Parkhurst, MD, FACS

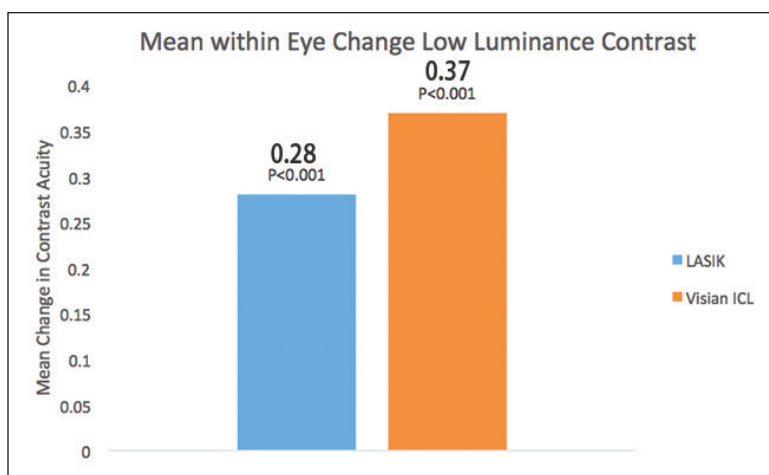


Figure 9. Comparison of LASIK and Visian ICL low luminance contrast.

is not only an excellent procedure, but it is reproducible across the board. Because the optics of it are so appealing to patients, when one actually looks at the metrics like Dr. Parkhurst did, one will find that the good results are not surgeon dependent.

**Dr. Wu:** I agree, and my results are similar to Dr. Parkhurst's as well.

### Gaining Lines of Vision

**Dr. Vukich:** What about the number of lines of vision that patients gain after Visian ICL implantation?

**Dr. Barnes:** One of the most difficult population groups involves those with astigmatism, as the FDA has not approved the toric Visian ICL used so commonly abroad. We studied a group of patients with 0.75 to 3.50 D of astigmatism, almost all with vertical corneal steepening generally between 70° and 110°. Of the 98 patients whom we studied, the average spherical equivalent was -7.64 D (range, -3.50 to -13.87 D). When

we looked at those patients as a whole, 71% gained at least 1 line of BCVA, 2% gained 2 lines, and another 2% gained 3 lines. Only 2% lost 1 line of vision and no eye lost more than 1 line.

When we compared preoperative BCVA to postoperative UCVA, 87% either maintained or improved lines of vision. To break that down further, 33% of patients gained 1 line of vision, uncorrected, compared with what they had with their glasses before surgery and 2% gained 2 lines of vision. To me, this was extremely impressive; remember, these are patients with astigmatism being treated only with the FDA-approved, nontoric ICL.

**Dr. Brinton:** A significant percentage of our patients have an improvement in both distance BCVA and postoperative UCVA versus preoperative BCVA. The FDA clinical trials on the Visian Toric ICL were instructive here: In total, 47.2% of patients were able to read 1 line or better with the Visian ICL beyond what they could see with their best preoperative correction.<sup>1</sup> That is the highest rate reported for any lens submitted for FDA clinical trials. In my experience, patients will notice if they see 1 line beyond what they could see in their contacts or glasses and notice this gain even before they hit the 2-line threshold we typically apply

in our clinical trials. As we know from the FDA data,<sup>1</sup> some patients gain 2 or more lines of vision as well.

**Dr. Maloney:** In my experience, too, it has been very common that patients gain 1 or 2 lines of BCVA.<sup>4</sup>

**Dr. Parkhurst:** Usually when we counsel patients preoperatively, we tell them the goal of refractive surgery is not necessarily to make one's best vision better, but rather to match one's best-corrected vision, with the advantage of not having to take contacts in and out or take glasses on and off.

Generally speaking, although our goal is not to improve BCVA, many times there is an improvement specifically with the Visian ICL procedure. This can happen sometimes with LASIK, too, but it seems to happen more commonly with the Visian ICL.

**Dr. Cionni:** Well said, Dr. Parkhurst. Most of my experience is based on patient remarks; I frequently hear how much better their vision is post-Visian ICL implantation



compared with what they have ever had in the past. I have a sense that they can improve quality of vision, including lines gained, but I do not have the direct data to support this. I think the likelihood of losing 1 line of vision, or not gaining 1 line of vision, is probably less than when we do LASIK.<sup>4</sup>

**Dr. Rivera:** Absolutely, and I do have some hard data to share, as I have studied my results closely in 65 patients who have undergone short-interval bilateral surgery (SIBS) and were amblyopic in one eye. Even in these eyes, 85% improved by 1 or more lines of vision after Visian ICL implantation.

**Dr. Wu:** Agreed; a significant number of my Visian ICL patients have also gained 1 or 2 lines of BCVA.

### Night Vision Benefits

**Dr. Vukich:** Dr. Parkhurst, can you give us an overview of what you found regarding night vision with the Visian ICL?

**Dr. Parkhurst:** Subjectively, we had found that our Visian ICL patients were at least as happy, if not more happy, than our laser vision correction patients in terms of satisfaction with correction.<sup>15</sup> Because it is hard to classify in scientific terms what is a “wow” factor, our study specifically looked at night vision performance as one quality of vision metric that goes beyond visual acuity and contrast sensitivity.

The concept for this study was born from the notion that, after cataract surgery, night vision disturbances can occur with certain IOLs used in cataract surgery. Although we did not expect that this would be a problem with the Visian ICL, we wanted to document whether or not that was the case with a controlled, prospective study. In order to have an appropriate population to compare our results, we enrolled 50 patients who were undergoing myopic LASIK and 50 who were undergoing the Visian ICL procedure. Patients were matched according to myopic levels (average, -6.00 D).

Using a night-vision performance test specifically designed to mimic looking through night-vision goggles, we tested night vision both in normal luminance and under dark conditions and compared the performances before and after surgery in both LASIK and Visian ICL patients.

Our results showed that both groups performed better under night-vision circumstances postoperatively than they did preoperatively. However, there was a statistically significant improvement in night contrast sensitivity and night vision through the night-vision goggles with the Visian ICL cohort as compared with the LASIK cohort. There was also a trend toward improvement in

night vision in the LASIK patients, but it did not reach statistical significance (Figures 8 and 9).

With the results of this study, personally, I felt confident that we were doing a good thing for the people who are serving our country under extreme conditions, at night when it is foggy and dark.

**Dr. Barnes:** We have not done a night vision study, but our patients, because they are in the military, do a lot of night-vision tasks. Although some patients talk about halos and circles at night, it is typically the younger patients and most commonly it is because their pupils can dilate quite widely. To control this, we prescribe Alphagan (brimonidine tartrate ophthalmic solution; Allergan) or Combigan (brimonidine tartrate/timolol maleate ophthalmic solution; Allergan).

The selling point for many of our soldiers who ask about the potential for night disturbances is the removability of the Visian ICL lens. With that said, of the patients who have reported some night-vision symptoms to me, they look at me like I am crazy when I remind them it can be explanted.

**Dr. Cionni:** Night vision is excellent with the Visian ICL. In the first week or so, in my practice some Visian ICL patients have reported seeing a “wavy line” that may be related to the peripheral iridectomy. Usually by the first week postoperatively this particular visual disturbance diminishes, and by 1 month it is rare to hear anybody notice night-vision disturbances anymore.

**Dr. Price:** I believe this is because the closer to the nodal point one gets, the fewer the visual distortions. We have never had any problems with pupil size with the Visian ICL, and I have even implanted it in patients with 9-mm pupils and they all do great at night.

**Dr. Wu:** I do not measure night vision objectively; however, subjectively, a small percentage of patients state that they see halos after Visian ICL implantation that they did not see before surgery but that they improve or go away with time. Generally, patients are extraordinarily happy with their night vision after Visian ICL implantation.

**Dr. Rivera:** In addition to what Dr. Price mentions about the nodal point, my impression is that the optics of the Visian ICL provide better night vision than LASIK.<sup>2,3,6</sup>

## CLOSING REMARKS

**Dr. Vukich:** This has been a fabulous discussion on postoperative outcomes, and the general consensus is that contrast sensitivity, BCVA and UCVA, and night vision are

all excellent with the Visian ICL. There is also a lower incidence of HOAs as compared with LASIK surgery.<sup>2,3,6</sup> Does anyone have any closing remarks to share?

**Dr. Barnes:** We should, to be complete refractive surgeons, offer all of the different options for refractive surgery. Both laser vision correction and the Visian ICL are great and complement each other, and, I believe round out the complete total practice.

**Dr. Maloney:** In all my years of experience implanting the Visian ICL, I have never had a patient ask me to take the Visian ICL out. It is really a measure of the spectacular patient satisfaction with the lens.

**Dr. Price:** I agree that the Visian ICL is an excellent lens, and one that is compatible with the eye; it does not seem to cause inflammation or dislocate easily.<sup>16</sup> I think the biggest advantage of the Visian ICL over LASIK is that it does not make preoperative measurements and future IOL power calculations for lens implantation any harder.<sup>17,18</sup>

**Dr. Brinton:** I agree. We have significantly more patients now who are asking for this technology than even 3 or 4 years ago. In my practice, the Visian ICL has gone from 5% of my myopic refractive practice to about 25% over that period of time.

Let me give you a bit more color: Some of our scientific-minded patients who have come in requesting refractive correction would not have appreciated us offering only one procedure. They do their research and come in with a list of questions. Among these patients in the higher dioptric ranges, most will opt for the Visian ICL.

I recently treated an ER doctor in the -6.00 D range OU who went to Pubmed and reviewed some of the literature on the Visian ICL, LASIK, and PRK. In our clinic visit, I provided him with some additional references. I told him to take his time with his research and then call us back when he was comfortable with his procedure of choice. He called back 1 week later and scheduled his Visian ICL procedure. He felt assured that the Visian ICL was most likely to give him the best outcome in his prescription range, with minimal down time.

In August of the past year, I received a call from one of my college classmates who had become an ophthalmologist and was wearing -7.00 D contacts OU. He asked if I would implant the Visian ICL bilaterally, and I did. He has a UCVA of 20/15 and has felt that his abilities as a cataract and refractive surgeon have improved significantly since having his vision corrected. In my experience, patients who do their research are highly likely to choose refractive surgery over glasses and contacts, and this is particularly true for the Visian ICL.

**Dr. Vukich:** Dr. Brinton, to follow-up, when was the last time you saw this much of an impact in a new refractive product?

**Dr. Brinton:** Never. As refractive surgeons, we have a number of excellent technologies at our disposal. When it comes to dramatic improvement in vision, quality of life, and patient satisfaction, however, the Visian ICL has few peers. This is partly because we follow conservative patient selection guidelines, but it goes beyond that. The quality of vision, even in low light conditions; the improved contrast sensitivity; the reports showing no increase in HOAs; the removability of the lens—these are all compelling arguments in favor of the Visian ICL.

**Dr. Vukich:** I think this is a strong end to our discussion on the Visian ICL. We all know how fortunate we are to have this technology, and I believe that indications will only expand the longer we continue using this lens. Thank you all for participating. ■

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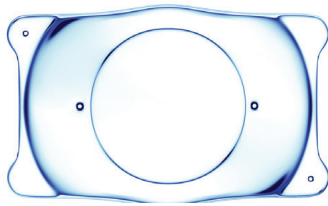
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## Patient Selection

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**STAAR Visian® ICL™ is indicated for placement in the posterior chamber of the phakic eye in patients 21-45 years of age that meet the criteria listed below.**

- Correction or reduction of myopia -3.0D to -20.0D with less than or equal to 2.5D cylinder at the spectacle plane
- Anterior Chamber Depth (ACD) of 3.0mm or greater
- Stable refractive history within 0.5 Diopter for 1 year prior to implantation

### **Visian ICL candidates include**

- All myopes starting as low as -3.0D through to -20.0D
- All patients being considered for PRK
- Eyes with larger pupils
- Eyes with thinner corneas
- Patients with dry eye
- Irregular or suspicious corneas

### **Patients NOT suitable for the Visian ICL**

- With an ACD of <3.0mm
- With anterior chamber angle < Grade III as determined by gonioscopic examination
- Who are pregnant or nursing
- Less than 21 or more than 45 years of age
- Who do not meet the minimum endothelial cell density as described in the Directions For Use (DFU)



