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VISIAN ICL

Highlights from the 2011 ICL/Toric ICL Experts Symposium

Standard Procedure, Exceptional Results

Reviewing 18 years of experience implanting phakic IOLs.

BY ROBERTO ZALDIVAR, MD

It has been more than 18 years since I first implanted a posterior chamber phakic IOL. My experience back then in the early 1990s has mirrored my current experience, as the majority of my patients across the decades have experienced excellent visual results after surgery. But many people are curious about those visual results—is this excellent visual quality really long term?

In my experience, yes, visual results have been stable over the years, and this has been true across the numerous phakic IOL models I have implanted. The key is to conserve the space between the crystalline lens and the implant. In 1994, I implanted a posterior chamber phakic IOL in one of my friends. He was hyperopic, and the lens I implanted was a 10.00 D Visian ICL (STAAR Surgical). Eighteen years later, my friend's vision is 20/20 in his right eye and 20/25 in his left. He is still happy with his visual results, and so am I.

BACKGROUND

The first generation of the Visian ICL was introduced in 1993-1994. This collamer lens was supported by the zonules. At the time, however, many surgeons were apprehensive of implanting phakic IOLs because of the associated complications, which included decentration, excessive vault, pupillary block, and iris chafing. In my experience with the original model, decentration was the most frequent complication. This was quickly overcome when, based on my suggestions, STAAR Surgical redesigned the ICL's haptics. These new haptics resembled feet and were designed to avoid rotation of the lens. Angulation was also incorporated into the new design, aiming to improve lens positioning within the sulcus.

Anterior subcapsular opacities were also common in the early days of phakic IOLs, largely because of inadequate vaulting once the lens was implanted. After this point in time, the main cause of the induction of anterior subcapsular opacities was surgical trauma, which is still very rare, as well as high-viscosity ophthalmic viscosurgical device (OVD) trapped behind the lens or the absence of vault. Another drawback frequently described was the pupillary block caused by excessive space between the implant and the crystalline lens. Shortly after this was discovered, we suggested that peripheral iridectomies should always be performed before posterior chamber IOL implantation. Therefore, the use of iridectomies changed the dynamics of phakic IOL surgery.

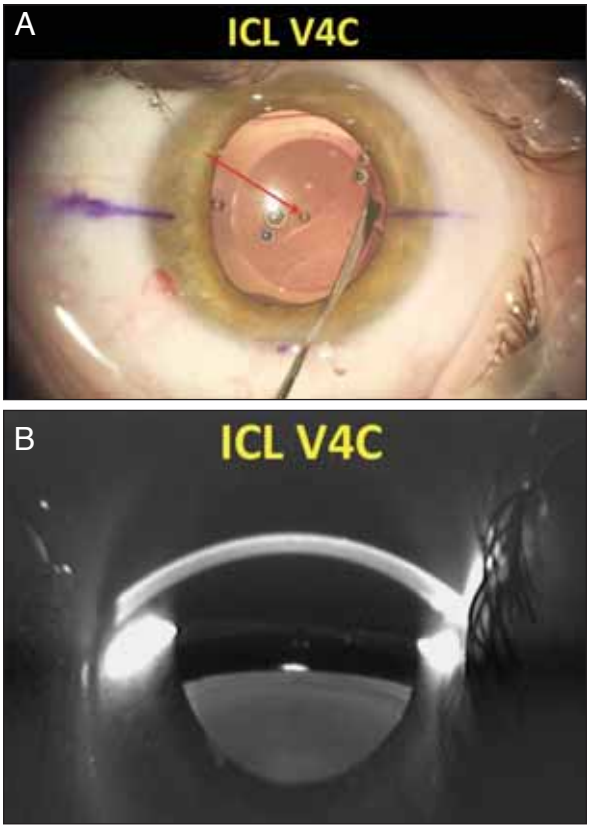

Figure 1. (A) The biomicroscopic postoperative image demonstrates the visibility of the Visian ICL V4c's KS-Aquaport, highlighted with the red arrow. (B) The Sheimpflug image reveals adequate distancing between the V4c ICL and the crystalline lens, which is called vault.

Once again, the dynamics are changing—this time by eliminating the need for iridectomies by adding a hole to the Visian ICL. This hole, the KS-Aquaport, allows a more natural aqueous flow without the need of an additional surgical procedure. The 0.36-mm aquaport, located centrally, defines the new design of the V4c ICL (Figure 1). This revolutionary posterior chamber phakic IOL is actu-

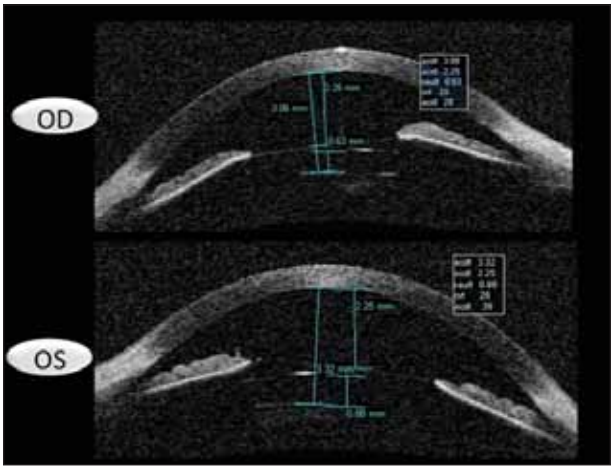

Figure 2. These optical coherence tomography images show postoperative ICL vaults of 0.63 mm in the right eye and 0.88 mm in the left.

ally a revival of the old Centraflow design, which we developed in 1994.

CASE STUDY

I have implanted the V4c in 12 eyes. Thus far, my most interesting case is a patient who has the V4c in his left eye and an older Visian ICL model in the right. Before surgery, UCVA in both eyes was counting fingers and BCVA was 20/20 with a manifest refraction of -9.00 -0.50 X 150° and -9.00 -0.50 X 10° in the right and left eyes, respectively. I implanted a -10.00 D V4c in his left eye and a -12.00 D ICM125VA in his right. After surgery, his UCVA improved to 20/20 in both eyes, and the modulation transfer function (MTF) and optical scatter index (OSI) were similar with both lens models (OD MTF: 36.6, OS MTF: 26.28; OD OSI: 1.1, OS OSI 1.0). The vault was 0.63 mm in the right eye and 0.88 mm in the left (Figure 2).

This patient is a prime example of the effectiveness of phakic IOLs, and this example especially highlights the usefulness of the Visian ICL V4c with the KS-Aquaport. With this model, I no longer have to perform a iridectomy prior to surgery, saving the patient a trip to the operating room and freeing up more time for my surgical staff.

CONCLUSION

Phakic IOL implantation is a standard surgery for me. I think that phakic IOL implantation with the Visian ICL V4c will be the future gold standard of refractive surgery. The most important concept that our learning curve and experience have provided is the knowledge that the quality of vision with this lens cannot be compared with the visual outcomes of any other IOL. The Visian ICL provides the best point spread function, the best MTF, and the best quality of vision. ■

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The Next-Generation Visian ICL

Optimizing fluid flow within the eye eliminates the need to perform peripheral iridotomy.

BY KIMIYA SHIMIZU, MD, PHD

Many studies have shown that visual performance after Visian ICL (STAAR Surgical) implantation is superior to visual performance after LASIK.[1,2] This was enough to persuade me to move toward implanting phakic IOLs and away from laser vision correction in the majority of my refractive surgery patients. Other surgeons, however, are looking for more advantages before making the switch. For instance, some feel that the need to perform Nd:YAG peripheral iridotomy (PI) days before a phakic lens implantation is a drawback because of the additional surgical visit. Additionally, PIs can be painful for the patient; they can often lead to significant changes in the aqueous dynamics after surgery, and they may occasionally cause cataract, bullous keratopathy, and damage to the corneal endothelium.

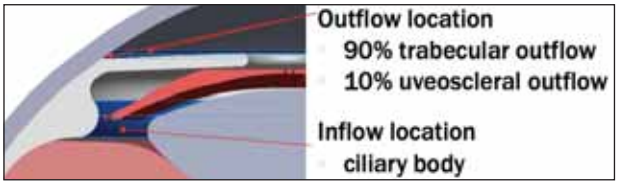

Figure 1. The in- and outflow locations for the V4c and the conventional ICL.

With the introduction of a new generation of the Visian ICL, the V4c, PIs before phakic IOL implantation are a thing of the past. This latest model may look strange with a hole in the middle, but this hole—the KS-Aquaport (KS-

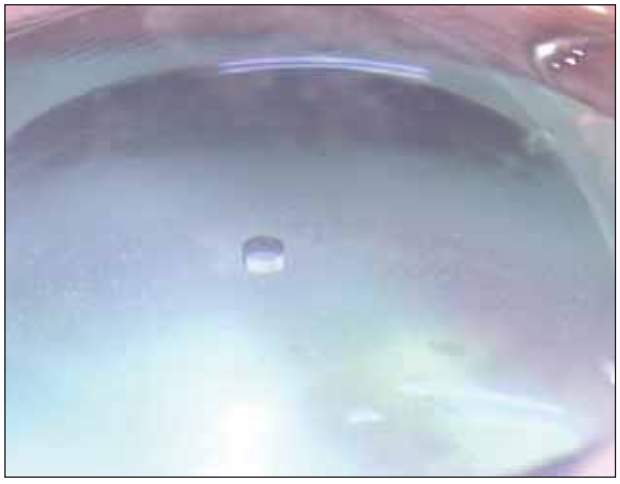

Figure 2. The movement of aqueous humor was confirmed in the porcine eye that received the ICL with a 0.36-mm hole.

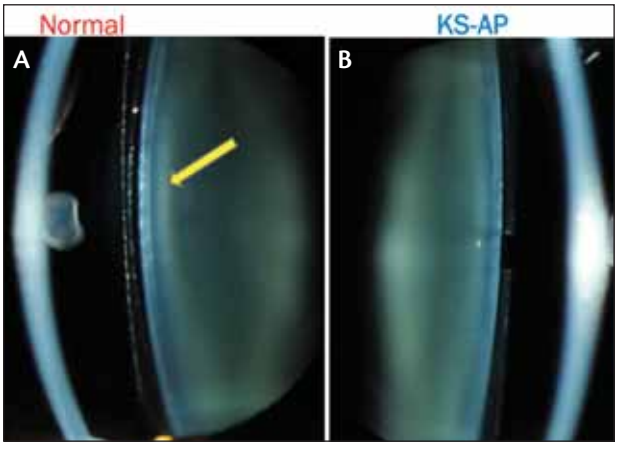

Figure 3. (A) Cataract formation was noted in one eye that received a conventional ICL; (B) no cataract formation was noted in the eyes that received the V4c with the KS-AP.

AP)—eliminates the need for a PI and creates a more comfortable and convenient experience for both the patient and the surgeon. By eliminating the need for PI, now phakic IOL implantation not only offers better visual performance than LASIK, but it also has equal efficiency.

COMPUTER SIMULATED MODELS

The V4c received the Conformiteé Europeéne (CE) Mark in April 2011; I helped pioneer the Centraflow proprietary technology used in this aquaport design. I have been working with STAAR Surgical since 2004 to investigate aqueous dynamics after phakic lens implantation in models with and without a hole located in the center of the lens. First, we simulated aqueous dynamics after phakic IOL implantation in models with and without a hole using 3-D eye models. Both ICLs were -9.00 D, 12.0 mm in length, and had a vaulting of 0.50 mm. With both lenses, the pore space between the posterior iris and the ICL was 0.05 mm and the angulus iridocornealis was 33º.

Figure 1 shows the in- and outflow locations for aqueous humor in phakic IOL designs with and without a hole; outflow locations involved 10% uveoscleral outflow and 90% trabecular outflow. The solid-state properties of the aqueous humor were equivalent to those of water, and the degree of viscosity was $7.1917X10^{-4}$ Pa·s at a 95º F. The quantity of aqueous humor produced by the ciliary body was set at 2.80 µL/min, and the initial pressure was set at 1 atmosphere.

Aqueous humor flowed between the ICL and iris in the conventional ICL model, but flow was not observed between the conventional ICL and the crystalline lens. When the hole was present, however, the flow of aqueous humor was observed between the ICL and the crystalline lens. The diameter of the hole in these simulations was at least 0.25 mm.

ANIMAL MODELS

We then conducted an animal study to confirm the movement of aqueous humor between the ICL and the crystalline lens. A phakic ICL with a 0.36-mm hole was inserted into one porcine eye and a conventional phakic ICL into the other. After surgery, the flow of aqueous humor was observed by injecting silicone powder behind the ICL in both eyes; movement was confirmed in the eye that received the ICL with a 0.36-mm hole. In this eye, the fluid moved from the lens equator toward the center, most likely resembling a normal aqueous flow pattern (Figure 2). In the eye with conventional ICL, we assumed that the aqueous fluid behind the ICL moved across the lens and toward the location of the PI.

We also examined optical performance by measuring the modular transfer function (MTF) of both ICL designs. At a spatial frequency of 100 cycle/mm, the MTF for the conventional ICL and the ICL with a 0.36-mm hole was 0.33 and 0.32, respectively.

PILOT, CLINICAL STUDIES

Our next step was to perform a pilot study. Implantation of the Visian V4c was performed in one eye of eight patients, with the contralateral eyes receiving a conventional ICL. Patients' average refractive correction was -8.70 D, and the average cylinder was 2.03 D. We demonstrated that, with the V4c, BCVA and UCVA were excellent, and there was no rise in intraocular pressure. Only one cataract was observed, and that was in an eye with the conventional ICL (Figure 3). Follow-up was 3 years.

We recently conducted a contralateral study in 42 eyes (21 patients) to compare results with the Visian ICL V4c to results with the conventional Visian ICL. PIs were first performed in those eyes that did not receive the V4c. At 1 day postoperative, the anterior chamber was clear

and there were no signs of pigment dispersion or hemorrhage in eyes that received the V4c. Additionally, there was less inflammation in these eyes, and visual performance was similar to visual performance with the conventional ICL. There were no postoperative complications such as glare and halo, and all patients were satisfied with their results.

CONCLUSION

The Visian V4c is an exciting development. It helps reduce the burden of phakic lens implantation by eliminating the need for PI. As we continue our observation of cataract formation after implantation of the Visian V4c, we are encouraged by the results from our preclinical and clinical studies and look forward to implanting more lenses in our patients. ■

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1. Kamiya K, Shimizu K, Igarashi A, Komatsu M. Comparison of collamer toric implantable contact lens implantation and wavefront-guided laser in situ keratomileusis for high myopic astigmatism. *J Cataract Refract Surg.* 2008;34:1687-1693.
2. Igarashi A, Kamiya K, Shimizu K, Komatsu M. Visual performance after implantable collamer lens implantation and wavefront-guided laser in situ keratomileusis for high myopia. *Am J Ophthalmol.* 2009;148:164-170.

Clinical Pearls for Implantation of the V4c

Inclusion of an aquaport in the center of the ICL boosts patient—and surgeon—satisfaction.

BY ERIK L. MERTENS, MD, FEBOPHTH

In June 2011, I implanted some of the first phakic IOLs with a 0.36-mm port located in the center of the optic. This aquaport, which is designed to restore more natural aqueous flow and eliminate the need for iridotomy, sets the Visian ICL V4c (STAAR Surgical) apart from the earlier model, the V4b. Because I no longer have to perform an iridotomy prior to lens implantation, the V4c has evolved the way I perform phakic IOL implantation. In this article, I share some pearls for implantation and highlight a recent case in which I implanted the V4c.

I initially implanted the Visian ICL V4c in five eyes with myopia (range, -6.00 to -8.00 D) as part of larger series of 100 eyes implanted with the V4c phakic IOL. These implantations were prior to the full market launch in countries that accept Conformité Européenne (CE) Mark approvals. I have now implanted 48 V4c implants (38 spheric and 10 toric) in approximately 7 months, and more than 1,300 V4c ICLs have been implanted across Europe.

ADDITIONAL PORTS

In addition to the proprietary KS-Aquaport in the center of the ICL, the V4c also has two 0.36-mm ports located just outside the optic. Designed to simplify the removal of ophthalmic viscosurgical device (OVD) after surgery, these holes also allow aqueous to flow over a wider surface are of the crystalline lens.

Figure 1. OCT image with vault measurement and KS-Aquaport visualization.

Inclusion of the aquaport as well as the two additional ports outside the optic of the V4c give the surgeon a

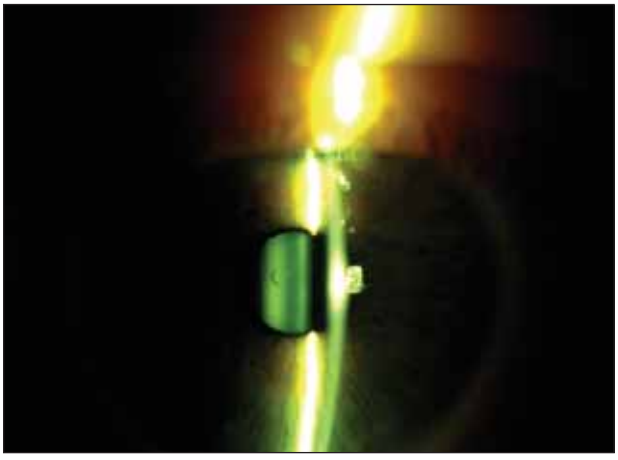

Figure 2. Slit-lamp picture; the KS-Aquaport is visible.

higher safety net and, as my patients have experienced, better surgical results. Specifically, the aquaport eliminates the need to perform Nd:YAG iridotomy or peripheral iridectomy before implantation of the ICL and therefore naturally the possible issues associated with these procedures. It also potentially reduces endothelial cell loss.

EASY TO PERFORM

The Nd:YAG iridotomy step has been completely eliminated with the V4c, making the overall procedure more in line with a LASIK procedure. It is faster, and it is more like a basic consultation surgery because implantation is done on the same day as the preoperative examination. During surgery, it is also easier to remove the OVD.

At the start of surgery, I load the V4c into an injector and fill the cartridge with an OVD. I then use a pair of forceps to pull the V4c into the tip of the cartridge until I can see all three holes. This will ensure that the lens will be delivered into the anterior chamber safely and accurately. Once the lens is in place, I irrigate the OVD from the anterior chamber, maneuvering the ICL to make some space and directing my irrigation port toward the aquaport. The OVD easily migrates from the anterior chamber, where it can then be aspirated safely.

POSTOPERATIVE FOLLOW-UP

One day after surgery, the aquaport is still visible and can be found slightly temporal to the pupillary center (Figures 1 and 2). Typically the edges of the lens are not visible, and therefore glare is minimized. To date, there has been no induction of higher-order aberrations after V4c implantation. We have not had to change our nomogram for the ICL.

In my experience, there have been no rises of intraocular pressure, no change in refractive outcomes, and no patient complaints or visual symptoms after surgery.

CASE STUDY

In one of my most recent cases, a patient presented with thick corneas in both eyes. He had low myopia, -0.75 D of sphere in both eyes. The sulcus-to-sulcus was 12.20 mm, and the white-to-white was 11.40 mm; I chose a lens one size larger than the software suggested, implanting a 13.2 VTICM0 instead of a 12.6. Postoperatively, the vault was 760 µm in the right eye and 620 µm in the left eye.

Just like all of my other patients implanted with the Visian ICL V4c, this patient was happy with his visual outcomes, and I was happy that the procedure took less time and was easier to perform than in the past. The combination of an aquaport in the center of the optic to alleviate the need for iridotomy and the additional ports outside the optic to ease removal of the OVD make the V4c my first choice for patients who are considering a phakic IOL. ■

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Evolution of Indications for the Visian ICL

Implantation of this lens is not just for patients with high myopia anymore.

BY ALAA EL-DANASOURY, MD, FRCS

Over the past several years, the Visian ICL (STAAR Surgical) has become my exclusive phakic IOL of choice. Before this time, I implanted various phakic IOL designs, but, based on long-term results and patient satisfaction, I reached the conclusion that the Visian ICL provided my patients with the best visual outcomes after surgery. I began using the ICL in a select population of patients with LASIK contraindications—mainly in those with high myopia, with thin or steep corneas, or with suspicious topography. Today, however, there are a variety of indications for phakic IOL implantation that continue to increase year after year.

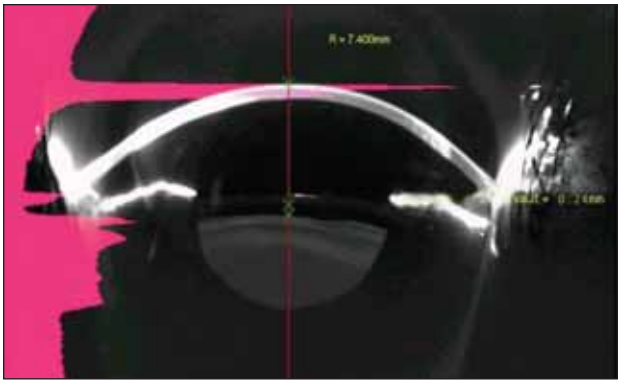

Figure 1. The ICL was implanted in a patient who previously underwent corneal grafting. In this case, the vault was 0.24 mm.

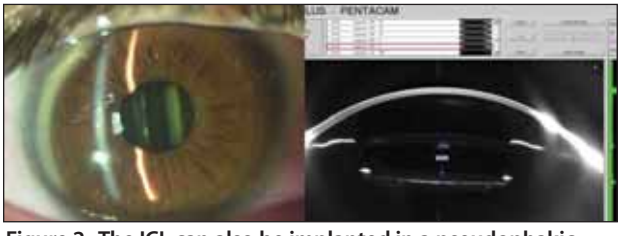

Figure 2. The ICL can also be implanted in a pseudophakic eye, with adequate space between it and the IOL.

ADDITIONAL INDICATIONS

Stable keratoconus. The first indication that I added was for patients with stable keratoconus. In these cases, I implant a toric ICL. The caveat is that the keratoconus (refraction and topography) must be stable for at least 2 years.

In the past 6 years of implanting the Visian ICL in this population, which includes more than 180 eyes, I have not had to do a single corneal graft. In a subgroup of 29 eyes with keratoconus that received the toric ICL to correct compound myopic astigmatism, all patients are happy with their spectacle-corrected vision. With the exception of three outliers, all were within ±0.50 D of intended correction at 12 months. Additionally, 68.9% of eyes gained at least 1 line of visual acuity (1 line, 37.9%; 2 lines, 20.7%; and 4 lines, 10.3%); 31% of patients did not gain or lose lines, and no patient lost more than 1 line of visual acuity. I also found that predictability with a toric ICL is similar to predictability with a standard ICL.

After implantation of an intrastromal corneal ring segment. I am now also comfortable implanting the Visian ICL in patients who need further correction after intracorneal ring segment implantation, as long as keratoconus is stable. These patients are usually good candidates for ICL implantation as long as they have acceptable BCVAs.

Corneal collagen crosslinking for keratoconus. Patients whose keratoconus is stable but still need correction after corneal collagen crosslinking (CXL) are also very good candidates for the Visian ICL. CXL has helped thousands of patients with keratoconus in my practice; however, many of these patients still seek refractive correction after surgery. Some surgeons are starting to treat, at least partially, the refractive errors associated with keratoconus using surface ablation techniques. I do not perform excimer laser ablation before, after, or simultaneously with CXL, partly because I am still waiting cautiously for the long-term results and predictability. This is also because I believe that the Visian ICL is the better choice to correct refractive error in these patients, provided their BCVA is acceptable.

I recently conducted a study to determine the safety and effectiveness of CXL after Visian ICL implantation. What I found is that even if keratoconus progresses many years after ICL implantation, it is safe to perform CXL with the ICL in the eye without affecting the properties of the lens.

After corneal graft. Visian ICL implantation is my procedure of choice to correct emmetropia after corneal

grafts, especially lamellar grafts. During preoperative counseling, I explain to the patient that approximately 1 year after corneal grafting the sutures will be removed and then in an additional 3 months, I will implant a Visian ICL (if the patient has 1.00 D or less of cylinder) or a toric ICL (if the patient has more than 1.00 D of cylinder) to correct residual emmetropia (Figure 1). I choose to implant the Visian ICL instead of performing LASIK because the predictability is much higher due to variable changes to the cornea after LASIK.

Pseudophakia. If a patient is pseudophakic and presents with a refractive surprise, I will now implant an ICL (Figure 2) because I feel that it provides the best possible results for these patients. This is the newest indication for me, with only four procedures to date. These patients are enjoying very good vision after secondary implantation of the Visian ICL.

INCLUSION CRITERIA

It is easy to see that the phakic IOL is not only for patients with LASIK indications, and in my practice we use the following protocol:

- If the patient has very high myopia (more than 8.00 D), the Visian ICL is the best (only) choice;
- If the patient has high myopia (6.00–8.00 D), the ICL is still my preferred choice, but I will give the patient the option of phakic IOL or femtosecond LASIK; and
- If the patient is myopic and has less than 6.00 D, then I will perform femtosecond LASIK. However, every now and then, when a patient comes in who knows a family member or friend with a phakic IOL and wishes to receive the same treatment, I will happily implant the Visian ICL even in patients with very low amounts of myopia.

With the Visian ICL's new improvements, the indications for phakic IOL implantation and the inclusion criteria will continue to expand. For instance, I am looking forward to treating patients with lower refractive errors. I have a lot experience with the Visian ICL over the past few years, and the bottom line is that sizing is excellent; the white-to-white measurement is good, the sulcus-to-sulcus measurement is very good, and there is no iris chafing.

CONCLUSION

Phakic IOLs are an attractive option for refractive correction. Therefore, the Visian ICL, as well as the toric ICL, are an essential component of any accomplished refractive surgeon's practice. Phakic lens implantation is not a complicated procedure; to me, this procedure keeps my refractive surgery patients very safe. I do not have to push the limits of LASIK, and new indications for the phakic IOL are continually developing, especially after release of the newest model, the V4c. ■

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