ADVANCING REFRACTIVE SURGERY

Strategies for EVO ICL Patient Success

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A New Refractive Surgery Option: EVO ICL™

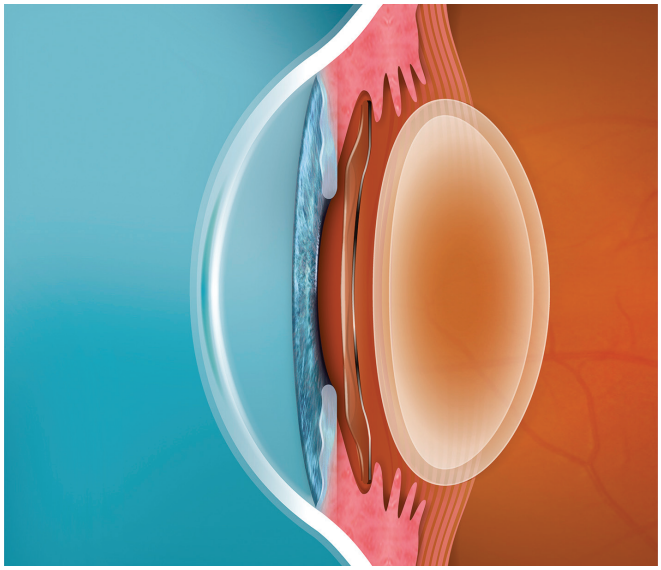
By Marc R. Bloomenstein, OD, FAAO

Interest in refractive surgery is booming again as the huge Millennial generation reaches their prime refractive surgery years. As Millennial patients, who are now age 25 to 40, come to our offices seeking freedom from glasses or contact lenses, it's important to be aware of new options. Also, consider the 6 million frequent replacement contact lens wearers that drop out each year in the U.S. alone.*

The recently FDA-approved EVO ICL™ from STAAR Surgical is a phakic IOL designed to be implanted behind the iris and in front of the natural lens. Surgeons around the world have already been using the EVO ICL for 10 years, so there is a significant body of literature demonstrating outstanding safety and effectiveness and very high rates of patient satisfaction.[1] In a survey of 1,542 patients implanted with the EVO ICL, 99.4% said they would elect to have EVO surgery again.

EVO ICL is made from STAAR's Collamer® material, a copolymer of poly-HEMA and collagen that offers UV protection and excellent biocompatibility.[2,3] The Collamer material, used in both the EVO ICL and its predecessor, the Visian ICL, now has a proven history of more than 20 years and more than 2 million ICL lenses sold worldwide.

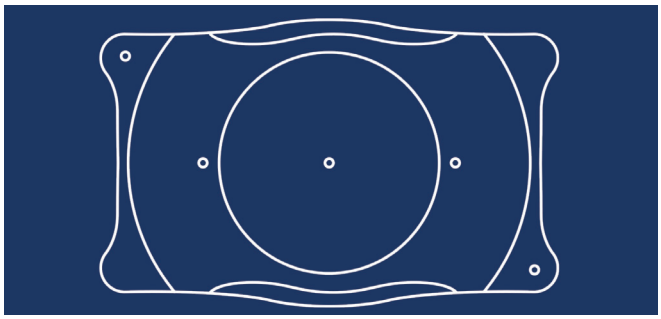
A significant barrier to implanting Visian phakic IOLs in the past was that they required a separate procedure, a peripheral iridotomy (PI), usually performed 1-2 weeks before the lens implantation. PIs can be uncomfortable and carry some risk of IOP elevation, pupillary block, angle closure, or postoperative glare. The new EVO ICL has a full-thickness, 0.36 mm-diameter central port designed to allow



physiologic aqueous flow through the lens. The central port eliminates the need for a preoperative PI. The other ports in the footplates and perioptic area, and the axis alignment marks facilitate orientation and alignment of the lens.

Who Are Candidates for ICL?

In my opinion, the EVO ICL should be considered for any moderate or higher myope. By correcting vision very close to the nodal point of the eye, it offers superb optical results.



The lens is indicated for phakic patients aged 21-45 with stable refractions who are seeking correction or reduction of myopia, with or without astigmatism, with SE from -3.0 to -20.0 D and cylinder from 1.0 to 4.0 D at the spectacle plane. The surgeon will check for an appropriate endothelial cell count and anterior chamber angle and depth to confirm candidacy.

For our very high myopes, EVO ICL is typically the only refractive surgery option. Increasingly, though, we are seeing it becoming the refractive procedure of choice for or many myopes, including any patient with thin or compromised corneas, preoperative dry eye concerns, topography unsuited for laser vision correction, a projected high rate of tissue removal with laser vision correction, or any other concerns around creating a flap.

The EVO ICL procedure doesn't induce or worsen dry eye[4] syndrome or night vision problems[5] and there is no risk of corneal ectasia.[6] Another significant advantage is that the EVO ICL is removable by a surgeon, if necessary. It doesn't change the corneal curvature or make IOL power calculation more challenging in the future. We all know post-LASIK patients who are just learning that they don't qualify for premium IOLs, or can't be assured of good outcomes, due to the difficulty of making accurate IOL calculations without the preoperative corneal measurements. The EVO ICL preserves the opportunity for these patients to achieve the best possible outcomes with whatever IOL technologies are available in the future.

EVO represents an important evolution of phakic IOL technology and an exciting new chapter in refractive surgery for our patients.

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*clspectrum.com/issues/2019/july-2019/where-have-all-of-the-contact-lens-wearers-gone

EVO ICL Outcomes: What To Expect For Your Patients

By Nicholas J. Bruns, OD, FAAO

The outcomes I see in our practice from the EVO ICL represent a tremendous step up from its predecessor, the Visian ICL. With the new EVO ICL, recently approved for use in the U.S., we are seeing the same outstanding levels of visual quality, with a much lower chance of side effects or complications. And with no requirement for preoperative peripheral iridotomies, the procedure is easier for patients and clinicians alike.

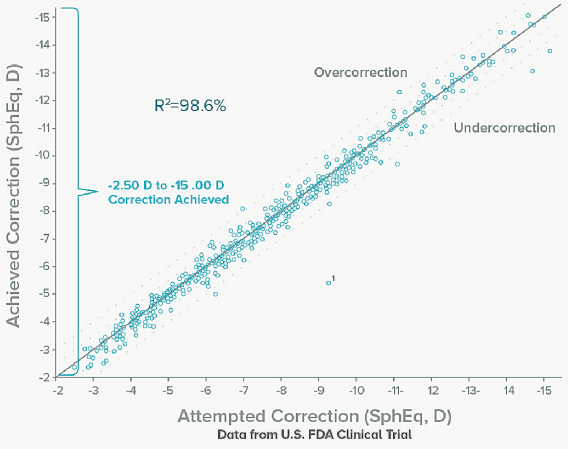
I used to think of the ICL as a great option for patients who weren't candidates for corneal refractive surgery—in other words, those whose myopia was too high or whose corneas were too thin for LASIK. Over time, my threshold for who is a good candidate has changed considerably. Today, I would argue that the overlap between EVO ICL and LASIK is larger than most practitioners realize.

FDA Clinical Trial Results

There are several ways to judge the results of refractive surgery procedures. The simplest is the visual acuity. For the 619 eyes implanted with the EVO ICL in the FDA clinical trial available for analysis, the mean uncorrected visual acuity (UDVA) 6 months after surgery was -0.059 logMAR, or 20/17 Snellen acuity.[1] UDVA was 20/16 or better in 58.5% of eyes and 20/20 or better in 87.6% of eyes. That's an amazing achievement, especially considering that patients started out with significant

Figure 1. Predictability

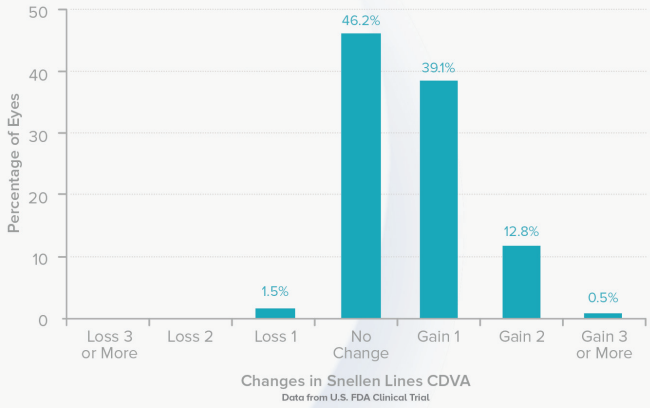
High predictability across a large diopter range.



1. In the U.S. FDA clinical trial, one eye experienced myopic shift due to nuclear sclerosis

Figure adapted from Packer, 2022.[7]

Figure 2. Change in Corrected Distance Visual Acuity



refractive error: Mean preop manifest refraction spherical equivalent (MRSE) in the study was -7.62 D, with myopia up to -15.00 D and cylinder up to +4.00 D.

The predictability of the correction was also excellent, with 90.5% of eyes within 0.50 D of the target refraction and 98.9% within 1.00 D (Figure 1).[1] What I have seen clinically was reflected in these trial results. While patients see very well shortly after surgery, the refractive outcome improves during the first postoperative month and remains very stable thereafter. The results of the 6-month FDA study also mirror what has been published in the international literature with much longer followup.[2]

What impressed me the most about the clinical trial results was that more than half the patients (52.3%) gained one or more lines of corrected distance visual acuity (CDVA)(Figure 2). I attribute this gain in lines of vision to the optical advantages of correcting vision so close to the nodal point of the eye. In our experience, it is difficult to achieve the same results with glasses or contact lenses.

Quality of Vision and Safety

Quality of vision also matters a great deal with elective refractive procedures. Patients have been dissatisfied with some technologies in the marketplace despite objectively good visual acuity, because they had poor quality vision under certain conditions. From the literature, we know that EVO ICL provides improved mesopic contrast sensitivity from preop to 6 months, with and without glare.[3] Moreover, the induction of higher-order aberrations (HOA) is low to nonexistent. There is no induction of spherical-like aberrations, and very low induction of coma-like and total HOA (0.05 and 0.04 µm, respectively).[4]

Finally, I am impressed by the very low rate of adverse events. In the FDA clinical trial, there were zero cases of pupillary block or anterior subcapsular cataract.[1] Only one eye implanted with a toric EVO ICL required surgical repositioning due to residual astigmatism. While there were some cases of transient IOP increase due to retained OVD or a postoperative steroid response, there were no IOP spikes related to blockage of aqueous flow through the central port, angle narrowing, pigment dispersion, or inflammation.[1]

We have experienced excellent refractive outcomes with no adverse events since introducing the EVO ICL in our practice in April. Both the safety and efficacy outcomes we have experienced, along with the published literature, give me great confidence in recommending EVO ICL as a refractive surgery option for a wide range of patients.

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Pearls For Successful EVO ICL Management

By Anu Ondhia, OD

With the recent FDA approval of the EVO ICL family of lenses, American optometrists will start seeing many more patients implanted with this technology. This presents new opportunities for collaborative care that are well within the capabilities of any optometrist who is currently, or is interested in, co-managing surgical cases.

The first step is to ascertain which patients are ideal candidates for this lens and what to expect in terms of refractive outcomes. As with any new technology, this can mean challenging your historical criteria and flow to keep up and evolve in the best way. Expectations for monitoring and follow-up should be reviewed with the surgeons to whom you refer. Patients will typically be seen at the surgery center for their Day 1 postop visit, then often return to their optometrist for the 1-week or subsequent follow-up visits, depending on surgeon recommendations.

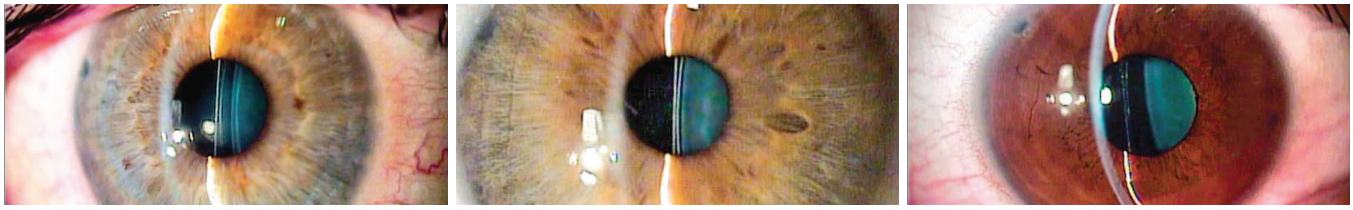
Here are four key elements for evaluation in ICL cases:

Intraocular Pressure (IOP)

A spike in intraocular pressure can occur following any surgical procedure. An IOP spike early in the postoperative period (Day 1-2) is rare, but is usually due to incomplete removal of ocular viscoelastics (OVD). When this occurs, you may see high pressure, and the patient may experience some ocular pain or nausea, although they could also be asymptomatic. In our practice, the surgeon would typically perform an anterior chamber paracentesis, or 'tap,' and release the extra fluid, followed by oral or topical pharmaceutical use to manage. The patient would then be followed within a few days to a week to ensure pressure has not become elevated again. In the rare case when an IOP spike occurs, an open line of communication with the surgeon regarding next steps is advisable.

Lens vault

Evaluation of the lens vault, the distance between the posterior surface of the EVO ICL and the anterior surface of the crystalline lens, is important and may take some practice to be able to judge accurately.



Figures 3, 4, and 5. Normal vault (3), Shallow vault (4) and High vault (5).

Vault should be assessed at every postoperative visit.

The optimal vault is 250-900 µm, or approximately 50% to 150% of the corneal thickness.[1] In the absence of symptoms, a shallower vault may be acceptable.[2,3] If the angle is closing or an anterior subcapsular cataract (ASC) is seen, removal may be necessary. Fortunately, these events are not commonplace. The occurrence of cataract with the current model is very rare. There were no cases (0.0%) of ASC in the FDA clinical trial for the EVO ICL at 6 months and none reported in a review of the worldwide literature covering 4,196 eyes implanted with EVO ICLs.[4] If you are concerned that the vault is too shallow, check the iridocorneal angle gonioscopically and then examine the crystalline lens carefully.

As with anything, there is a learning curve with comanaging ICLs and particularly assessing optimal vault. I would encourage you to work closely with your preferred surgeon and surgical center optometric colleagues to build efficiency and confidence in your new skills as well as seek secondary opinion and guidance. It will all be second nature before you know it!

Endothelial cell density

A major concern with earlier phakic IOL models was the potential for increased rate of endothelial cell loss. Given that the EVO ICL is a posterior chamber lens that sits in the ciliary sulcus, behind the iris, as opposed to being iris fixated as in older ICLs, endothelial touch is highly unlikely. In the FDA clinical trial of the EVO ICL, mean endothelial cell density declined 2.3 ± 4.0% from preoperative to 6 months. Two papers evaluating endothelial cell loss in ICL eyes found no significant change in endothelial cell density over 5 years.[5,6]

Other surgical complications

Post-ICL implantation, it is important to monitor patients for any surgical complications that should be referred back to the operating surgeon for management. Although, complications can occur after any intraocular surgery.

Post-Operative Observations

Optometrists can easily co-manage ICL patients with a skilled surgeon. During the early postoperative period, some patients may describe a ring-shaped dysphotopsia.[7] This symptom rarely persists beyond the first few weeks after surgery.

Post-operative patients, particularly former high myopes, typically experience a huge wow factor quite often, with gains noted in best-corrected vision. These near-instant outcomes are not dissimilar to those experienced with LASIK, in my opinion. A very high percentage (99.4%) of ICL patients surveyed have said they would choose to have the procedure again. The EVO ICL is available in a wide range of available powers, to meet the refractive needs of our patients. Based on data from the U.S. clinical trial and from international experience, we know that complications are exceedingly uncommon, and that the quality of vision patients can achieve with this technology is unparalleled. For all these reasons, I find it very gratifying to manage EVO ICL patients peri-operatively and trust that you will enjoy expanding your comanagement offerings, as well. ●

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