

VISIAN TORIC ICL DELIVERS EXCEPTIONAL VISUAL OUTCOMES



The single procedure is a long-awaited option for astigmatic myopes.

FRANCIS PRICE JR., MD

For moderate to high myopes who want better vision, the Implantable Collamer Lens (ICL) is an excellent option. I have used several different phakic lenses over the years, but my first choice has been the Visian ICL (STAAR Surgical Company) since it was approved in 2005. The advantage of this lens is that unlike other phakic IOLs, the material is foldable. I typically implant it through a 2.8-mm self-sealing incision.

Since November of last year, I have been implanting the newly approved Visian Toric ICL (STAAR Surgical Company), which gives us an opportunity to correct both myopia and astigmatism in one procedure. My outcomes have been excellent, mirroring the results seen in clinical trials.

A TORIC ICL WITH EXCEPTIONAL RESULTS

In the United States, the Visian Toric ICL is approved for use in 21- to 45-year-olds for the correction of myopic astigmatism with spherical equivalent ranging from -3.0 D to -15.0 D with cylinder of 1.0 D to 4.0 D. It also can reduce myopic astigmatism in patients having a spherical equivalent greater than -15.0 D to -20.0 D with the same amount of astigmatism. Patients must have an anterior chamber depth of at least 3.00 mm.

The Visian Toric ICL was proven safe and effective in FDA clinical trials. When we look at how well patients achieved goals

for spherical equivalent, 97.4% of eyes were within 1.00 D of the goal, and 76.8% were within 0.50 D.¹ The visual results were very stable as well. The mean MRSE (manifest refraction spherical equivalent) went from -9.38 D before surgery to 0.02 D at one week, barely changing to 0.03 D at 12 months.¹ The mean refractive cylinder improved from 1.95 D preoperatively to 0.50 D at 1 week and remaining stable at 0.52 D at 12 months.^{1,2}

Visual results for the Visian Toric ICL were like nothing I've seen before. At 12 months after surgery, 76.8% of eyes had best spectacle-corrected visual acuity (BSCVA) improvement of 1 or more lines.¹ In eyes with 20/20 BSCVA or better, all eyes had an uncorrected visual acuity (UCVA) of 20/40 or better, 89.3% were 20/20 or better, and 63.5% were 20/16 or better (Figure 1).¹

The most dramatic result of the study was that at 12 months after surgery, 76.7% of eyes had UCVA as good as or better than preoperative BSCVA.¹ That's a phenomenal, life-changing visual improvement.

Overall, the Visian Toric ICL has a high safety profile and provides a big improvement in vision. As reported in the FDA clinical trial, BSCVA was preserved in the majority of eyes (93.9%) reporting either no change or an improvement of BSCVA at 12 months as compared to before surgery. We always try to weigh the improvements we see against the risk of losing vision, but these results are excellent among refractive surgeries (Figure 2). In addition, more than 94% of eyes exhibited rotational stability of 5° or less at all postoperative time points throughout the first year.² By checking the lens and observing the stability of patients' refraction and vision, I am confident that the lens is quite stable in the ciliary sulcus.

AN ELEGANT PROCEDURE

For an experienced cataract refractive surgeon and certainly anyone who has implanted phakic IOLs, the Visian Toric ICL procedure is simple and elegant. To prepare, we need to measure the area where the lens implant will reside. We can do that indirectly with horizontal white-to-white measurements, which were used in the investigational studies. I personally

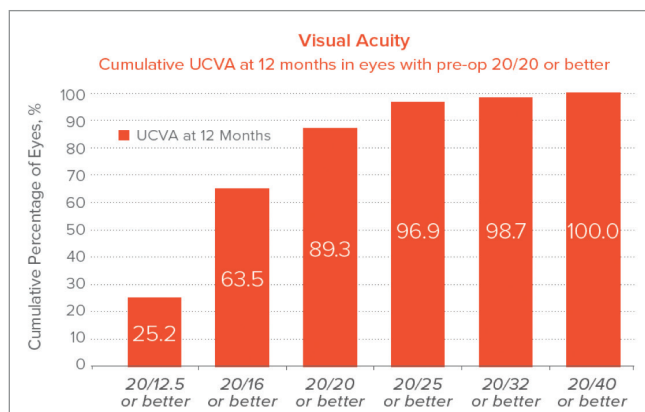


Figure 1. Visian Toric ICL - FDA Study: Effectiveness Data.¹

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use ultrasound biomicroscopy to measure the ciliary sulcus because it gives me an opportunity to verify that there are no abnormalities of the iris, such as iris cysts. Based on either the white-to-white or the sulcus-to-sulcus measurement along with an accurate refraction, STAAR's Online Calculation and Ordering System (OCOS) helps us determine the correct ICL size and power.

We also check that there is a normal endothelial cell count to ensure that the cornea is healthy.

Traditionally, the procedure is performed with two laser peripheral iridotomies. Many surgeons use two laser iridotomies prior to surgery (one superior nasal, one superior temporal), as was done in the studies. I do bilateral same-day ICL implants using two different sets of supplies and instruments for each eye to avoid adding to the risk of infection, however minute. At surgery, I do a surgical iridotomy.

ADDRESSING AN UNMET NEED

All patients are different, so we always like to have different options for vision correction. Visian Toric ICLs give us a safe, effective, elegant option for patients with myopia and astigmatism who in some instances did not have one before. Our primary alternative in many patients is to implant a phakic IOL and then do LASIK for the astigmatism—two procedures with two sets of risks. Refractive lensectomy can be a good option for patients older than 50, but the loss of accommodation and risk of retinal detachment make it a poor choice for young patients in their 20s and 30s and 40s.

In my practice, the Visian Toric ICL is a better option than ICL-LASIK combination or refractive lensectomy in most cases that meet its indications. It is a less traumatic procedure, without the risks associated with refractive lensectomy. There is no need to remove any tissue, so we aren't limited by the patient's corneal thickness as we are with LASIK. In my experience, the Visian Toric ICL is also a better option than rigid PMMA phakic IOLs because the incision is smaller, permitting greater predictability for astigmatism as well as easier removal of the ICL years later during cataract surgery. The small incision also causes only minimal disruption of the nerve supply on the ocular surface, so we don't induce a decrease in the blink rate or tear production.

All procedures have limitations and sweet spots, but the Visian Toric ICL is really a wonderful option to have.

CASE STUDY: VISION TORIC ICL FOR SIGNIFICANT ASTIGMATISM

The Visian Toric ICL gives us the ability to correct not only myopia, but also very large amounts of cylinder with amazing results. I recently implanted a Visian Toric ICL in a myopic patient with 3.00 D of cylinder in one eye and 4.00 D in the second eye. After surgery, one eye is 20/20 and the other is 20/15. To be able to get both myopia and significant cylinder correction like that is just phenomenal.

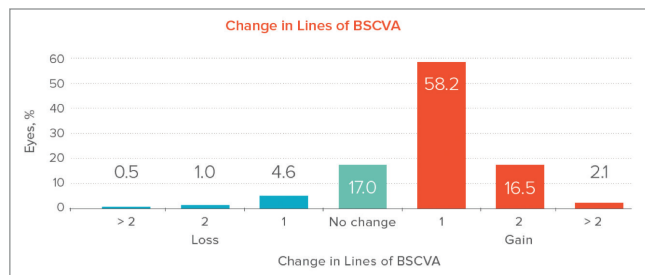


Figure 2. Visian Toric ICL - FDA Study: Change in BSCVA.¹

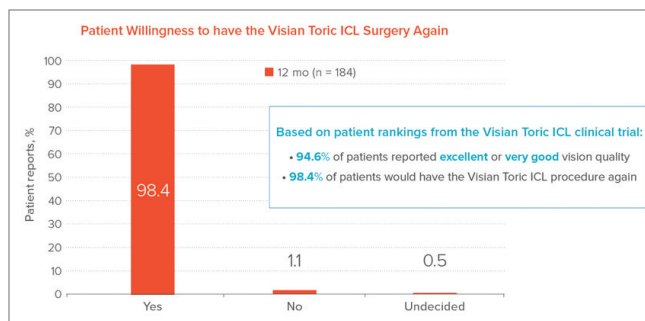


Figure 3. Visian Toric ICL - FDA Study: Patient Satisfaction Data.^{1,2}

Patient satisfaction with the Visian Toric ICL is excellent. There is certainly a “wow factor” associated with having clear, sharp vision by correcting both their myopia and astigmatism at the same time—particularly when UCVA exceeds presurgical BSCVA. In the FDA study, all 184 patients were satisfied with the procedure. Vision quality was reported as excellent or good by 94.6% of patients, and 98.4% said they would have the procedure again (Figure 3).¹

Patients who have that kind of transformative experience tell their friends and family, which can result in more patient referrals. Because the Visian Toric ICL's unique capabilities permits us to treat a broad range of myopia and astigmatism simultaneously, including some errors for which there are few or no other treatment options, we can also increase physician referrals. Thus, the Visian Toric ICL is a procedure that has expanded our clinical capabilities and has the power to improve our practice as well. ■

1. STAAR Visian Toric Implantable Collamer Lens (ICL) for Myopia (TICL): Directions for Use. STAAR Surgical.
2. STAAR Surgical Visian Toric Implantable Collamer Lens PMA Supplement P030016 Ophthalmic Devices Advisory Panel, March 14, 2014.

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