

Update on the Toric Implantable Collamer Lens

If approved in the United States, this lens will provide an important option for many patients.

BY JOHN A. VUKICH, MD

STAAR Surgical Company (Monrovia, CA) has been informed by the FDA that it will resume scientific review of the company's application for the Visian Toric Implantable Collamer Lens (TICL) for the correction of myopia and astigmatism. This application is an extension of the FDA's approval of the Visian ICL (STAAR Surgical Company) on December 22, 2005, for the correction of myopia.

In 1999, Tobias H. Neuhann, MD, was the first surgeon worldwide to implant the TICL. The lens obtained CE Marking in Europe in 2003, and it was approved in Canada in June 2005.

The TICL is currently available in 63 countries and has been implanted in more than 27,000 eyes. Internationally, this IOL is available in powers ranging from -3.00 to -20.00 D of myopia with up to 6.00 D of astigmatism.

The global popularity of phakic IOLs as an alternative to cornea-based refractive procedures continues to grow. For the past 5 years, the number of phakic implants used has experienced double-digit year-over-year growth. One reason is the availability of toric phakic IOLs that allow the correction of preexisting astigmatism. Currently in Europe and Asia, toric phakic IOLs account for 40% of all implants used based on manufacturers' sales reports. Based on surgeons' experience in the international markets, it seems likely that the FDA's approval of a toric model would increase US surgeons' use of phakic lenses as well. It is therefore worthwhile to review the indications for the TICL and how it might fit into a refractive surgery practice.

THE VISIAN TICL

The single-piece TICL has an optical zone that varies in diameter from 4.65 to 5.50 mm across its entire spherical diopter power range. The lens is available in

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0.50 D increments for both spherical power correction (range, -3.00 to -18.00 D) and cylindrical power correction (range, +1.00 to +6.00 D). The foldable implant can be inserted through a 3.5-mm or smaller clear corneal incision.

Appropriate candidates for the TICL are 21 to 45 years of age and have at least -3.00 D of myopia accompanied by 1.00 to 5.00 D of symmetrical corneal astigmatism. Eyes should have an anterior chamber depth of at least 3.0 mm (endothelium to anterior surface of the crystalline lens), and they should have healthy and otherwise normal endothelial cell counts. This phakic IOL is available in lengths of 12.1, 12.6, 13.1, and 13.7 mm.

STUDIES

Several published reports have demonstrated excellent visual quality after the TICL's implantation. In the FDA clinical trial, investigators studied 210 eyes with between 2.50 and 19.50 D of myopia and 1.00 to 4.00 D of astigmatism. At 12 months postoperatively, 77% achieved a postoperative UCVA better than or equal to their preoperative BSCVA. Ninety-seven percent of eyes achieved a postoperative BSCVA of 20/20 or better versus 83% preoperatively. The mean improvement in BSCVA was 0.9 lines.¹ In their prospective comparative study, Kazutaka et al reported that the TICL's implanta-

tion was superior to wavefront-guided LASIK in all measures of safety, efficacy, stability, and predictability for the correction of -6.00 to -20.00D of myopia.² In addition, Schallhorn et al reported that the TICL performed better than standard PRK in terms safety, efficacy, predictability, and stability for the correction of -8.00 to -16.00 D of myopia.³

COMPLICATIONS

Reported complications of the implantation of the Visian ICL include cataract formation, endothelial cell loss, pigmentary dispersion syndrome, and pupillary block.⁴⁻⁶ The surgical procedures for placing the Visian TICL are very similar to those for the spherical ICL. It is therefore reasonable to anticipate that the complications of the former's implantation will be almost identical to those of the ICL but with the addition of potential problems specific to a toric lens (eg, off-axis rotation).

Given the relatively low incidence of adverse events and excellent quality of vision with the ICL, it seems likely that phakic IOLs will remain an important option for many patients.

The correction of astigmatic errors is the next step in the evolution of phakic IOLs. With the recent progress on the FDA's review of the Visian ICL, it seems likely that this device will soon become available in the United States. ■

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