The STAAR Toric ICL

This lens reduced preoperative spherical and astigmatic errors with high predictability and good stability.

BY ERIK L. MERTENS, MD, FEBO

Refractive surgery options to correct moderate to high myopia and myopic astigmatism are limited. LASIK, PRK,[1-2] LASEK, and more recently Epi-LASIK, have lower predictability and safety compared with the treatment of moderate myopia with or without astigmatism.

Complications reported for laser correction of high refractive errors include corneal ectasia, low predictability, poor quality of vision under dim illumination, and regression.[3-4] Refractive lens exchange permits correction of the refractive error, however, accommodation is often lost in young patients and the risk of retinal detachment is high.[5] The implantation of IOLs in the eye has been part of cataract surgery practice for many years; it is only in more recent years, however, that these implants are available for refractive correction.

Most refractive surgeons believe that phakic IOLs will become the implant of choice for certain forms of refractive correction. Over the last few years, phakic lenses for correction of high ametropia have been implanted with satisfactory results. The accuracy of refractive implants in restoring vision is acknowledged[6] and regarded highly, because the insertion procedure offers a method of correction that is removable, predictable, rapidly healing and does not permanently alter the shape or structures of the cornea.

The difficulties now lie in convincing the patient. General patient consensus is that laser surgery is more attractive, because IOL implantation is far too invasive. Another option, however, is to suggest a toric ICL.

TORIC PHAKIC IOL

The new Toric ICL (STAAR Surgical, Monrovia, California) is made of STAAR's proprietary collagen copolymer, collamer. From November 2003 to present, 166 Toric ICLs have been implanted at the Antwerp Eye Center. The myopic correction ranged from -2.00 D to -14.00 D, and the cylindrical correction ranged from -1.00 D to -5.25 D.

Most refractive surgerons believe that phakic IOLs will become the implant of choice for certain forms of refractive correction.

PATIENTS AND METHODS

Patients between the ages of 18 years and 50 years with stable refraction for at least 1 year and astigmatism greater than 1.00 D, and who also had an otherwise normal ophthalmologic examination, were included in our study. Preoperative counseling (ie, outline of [1] potential intraocular surgery complications, [2] alternative refractive techniques, and [3] their respective benefits and risks) took place at initial consultation. Exclusion criteria were anterior segment pathology; anterior chamber depth from the endothelium fewer than 2.8 mm; abnormal iris function; recurrent uveitis; any form of cataract, glaucoma, retinal detachment, preexisting macular degeneration or macular pathology; chronic treatment with corticosteroids or any immunosuppressive treatment or state; and pregnancy.

SURGICAL PROCEDURE

Two Nd:YAG laser iridotomies at 10:30 o'clock and 1:30 o'clock were performed at least 1 week before sur-

gery. The horizontal axis was marked with a pointed marker at the limbus immediately before surgery. At the operation table, the left eye underwent surgery first. Povidone iodine 10% (Iso-betadine; Viatris, Bad Homburg, Germany) was applied to the eyelids; the patient was draped, and a lid speculum was inserted. Four drops of oxybuprocaine hydrochloride 4 mg/mL (Unicaine; Bournonville Pharma, Breda, Netherlands) was used to anaesthetise each eye. Three minutes before corneal incision, povidone iodine 5% was administered to the ocular surface. A paracentesis was placed superiorly for the left eye and inferiorly for the right eye, and methylcellulose 20 mg/mL (Ocucoat; Bausch & Lomb, Rochester, New York) was injected into the anterior chamber.

A 2.65-mm temporal clear corneal incision was made with a 30° stab knife and a 2.65 mm blade (Bausch &

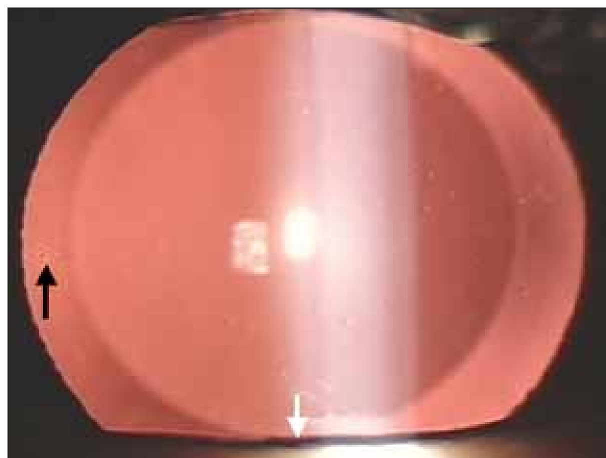

Figure 1. The Toric ICL was rotated according to implantation software.

TCL IMPLANTATION: A STRAIGHTFORWARD TECHNIQUE

In the case of treating myopic patients with astigmatism, the Toric ICL (TCL; STAAR Surgical, Monrovia, California) can provide beneficial results, said Bruce Allan, MD, from the Moorfield Eye Hospital, London, in a telephone interview with *Cataract and Refractive Surgery Today Europe.*

Dr. Allan began using the TCL earlier this year and described the implantation technique as “very straightforward.” The wound construction is identical to the standard ICL implantation technique, but unlike standard ICLs, the patient is marked preoperatively to control for cyclotortional changes after the patient is lying down. During this part of the procedure, the 0º and 180º points are marked at the slit lamp. The patient is then taken to operating theater, and with the degree maker, the surgeon marks the requisite point—identified on the implantation diagram that STAAR Surgical has provided based on subjective refraction along with keratometry information from corneal topography. Having marked the orientation of the TCL, a surgeon can align the lens as they position the footplates, meaning they do not have too much rotation to complete once the lens is sulcus placed, Dr. Allan said.

Completeness of astigmatic correction using the TCL depends on whether you are looking at postkeratoplasty keratoconus patients who may have a component of irregular astigmatism or a straightforward case of congenital astigmatism. Congenital astigmatism is predominantly regular, whereas postkeratoplasy astigmatism may have a significant irregular component. In the future, fine-tuning with topography-guided preliminary laser treatment may form a useful combination with TCL implantation to correct lower-order abberations. Many post keratoplasty patients require relatively high myopic and astigmatic corrections, which may be associated with a greater degree of haze and postoperative regression where the laser alone is used. Using the TCL to provide the bulk correction brings any laser correction down to the fine tuning level, and dual approach (ie, a variation of bioptics) may have a lot of mileage in the future of postkeratoplasty refractive correction. TCL implantation alone produces considerable benefit for most patients in this group.

According to Dr. Allan, postoperative lens rotation can be a downside to this procedure, but it is relatively infrequent compared with rotational problems experienced with in the bag toric IOLs used postcataract surgery, and easier to correct. He said the consensus view on correction is that it is worth trying a simple rotation once, and exchanging the TCL for a size larger if an axis misalignment recurs.

Dr. Allan says his own experience and results already presented for the TCL are very encouraging. “Given the choice between implanting a TCL or using a myopic ICL plus an incisional technique to correct astigmatism, I think there is no contest; the toric ICL is more reliable in terms of the visual result.” ■

Bruce Allan, MD practices at the Moorefield's Eye Hospital & Institute of Ophthalmology, in London. Dr. Allan states that he has no financial interest in the products or companies mentioned. He may be reached at bruce.allan@ucl.ac.uk.

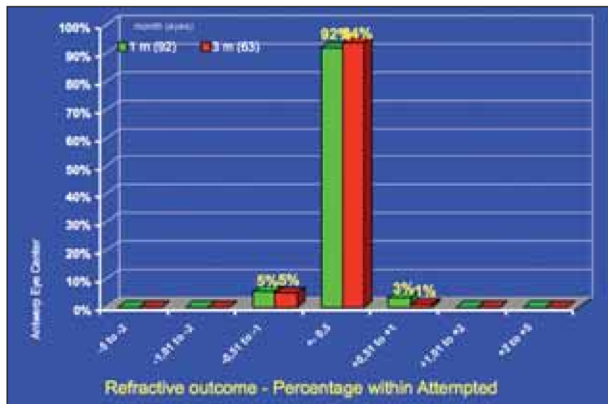

Figure 2. Eyes within 0.50 D of intended refraction.

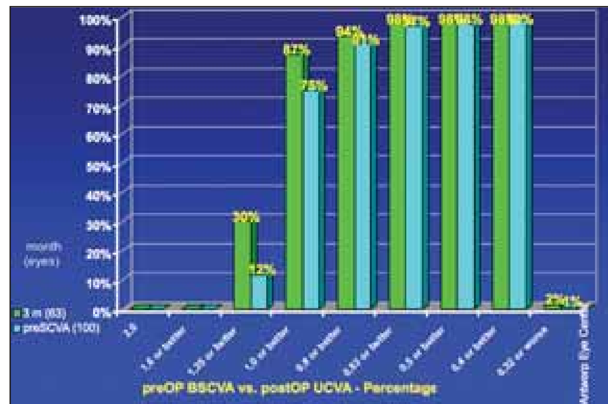

Figure 4. The efficacy index at 3 months.

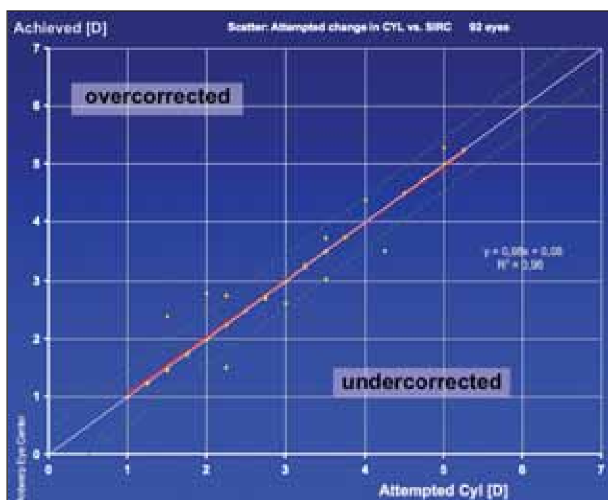

Figure 3. Eyes within 1.00 D of intended cylindrical correction.

Lomb). Methylcellulose 20 mg/mL was then readministered into the anterior chamber.

Under the microscope, the Toric ICL was loaded into the STAAR injector cartridge using Vukich ICL forceps (ASICO, Westmont, Illinois) and modified Aus der Au forceps (Janach, Como, Italy). The tip of the injector cartridge was then inserted into the temporal corneal wound, the Toric ICL was delivered, and the haptics were placed behind the iris with a manipulation forceps (Duckworth & Kent, Baldock, Hertfordshire, England). The Toric ICL was rotated according to the implantation software (ie, clockwise or counter-clockwise) (Figure 1).

The methylcellulose was irrigated out with copious Balanced Salt Solution (BSS; Alcon Laboratories, Fort Worth, Texas), and vancomycin 6 mg/mL was instilled into the anterior chamber. One drop of dorzolamide 20 mg, timolol 5 mg/mL suspension (Cosopt; MSD, Riyadh, Saudi Arabia); lomefloxacin 3 mg/mL (Okacin collyre; Ciba Vision, Duluth, Georgia); and a terracortril suspension (hydrocortisonacetaat 17 mg, oxytetracycline 5.7 mg, polymyxine B 11400 IE/g; Pfizer, New York, New York) were then instilled. Immediately after surgery, acetazolamide 250 mg (Diamox, Haupt Pharma, Berlin) was administered to minimize IOP. It was then readministered 1 day postoperatively.

In all cases, bilateral surgery was undertaken. The surgeon's gown and gloves were changed, and a separate set of surgical instruments was used. Povidone-iodine solution was instilled before surgery for a second time. A different lot of BSS, methylcellulose and vancomycin was used in all cases.

The patient's postoperative medication included infectoflam collyre (fluorometholone 1 mg/mL, gentamycin 3 mg/mL; Novartis, Basel, Switzerland) and indocollyre (indomethacin 1 mg/mL; Chauvin Pharmaceuticals, Surrey, UK) administered four times daily for the first week, tapering to one daily drop 4 weeks postoperatively. Additionally, hyabak collyre (sodium hyaluronate 1.5 mg/mL; Thea) and genteal gel (hypromellose 3 mg/mL; Ciba Vision) were administered four times daily for 1 month. Postoperative examinations were at 1 day, 1 week, 1 month, and 3 months.

RESULTS

Predictability. Three months after surgery, 94% of eyes (n=63) were within ±0.50 D of the intended refraction, and 100% were within ±1.00 D (Figure 2).

Predictability: Astigmatic correction. A total of 94.5% eyes (n=87 of 92) were within 1.00 D of intended cylindrical correction (Figure 3). Three ICLs were misaligned and needed to be rotated into the correct axis; all occurred without any problem.

Efficacy. Three months after surgery, the overall effi-

cacy index (ie, mean postoperative UCVA/mean preoperative BSCVA) was 112.2%. In 94% of eyes, postoperative UCVA was 20/25 or better; in 87% of eyes 20/20 or better; and in 30% of eyes 20/16 or better (Figure 4). All improvements in UCVA and BSCVA were statistically significant.

Complications. Three percent of eyes (n=5) required a secondary intervention. In two eyes, acute angle closure glaucoma occurred—due to excessive vault of the Toric ICL—where the lens needed to be explanted. This sizing issue, however, did not occur again, since we used the Vumax II (Sonomed, Lake Success, New York). This ocular high frequency ultrasound biomicroscopy (UBM) device accurately measures the sulcus-to-sulcus diameter. In our most recent 86 ICL implants, 16 eyes had a discrepancy in sulcus-to-sulcus diameter with respect to the white-to-white corneal diameter. By readjusting the ICL size to the sulcus-to-sulcus diameter, no more excessive vaulting occurred postoperatively. Three Toric ICLs were misaligned and needed to be rotated into the correct axis. The repositioning of these lenses was performed after approximately 1 month, because of a 15° to 25° deviation from the target axis. No potentially sight-threatening complications (eg, iris prolapse, iris atrophy, touch of the anterior capsule, persistent corneal edema, cataract formation, retinal detachment, endophthalmitis, serofibrinous reaction) were reported during follow-up.

CONCLUSION

With the introduction of the Toric ICL, the need for combining posterior chamber phakic IOL implantation with keratorefractive procedures (ie, bioptics) is significantly reduced, avoiding possible complications or problems (eg, flap striae, reduction in contrast sensitivity under low-light conditions, haze) of any additional keratorefractive procedure. Both spherical and cylindrical correction are combined in the Toric ICL, which aims to correct the total corneal astigmatism and lens astigmatism refractive error.[7] Three months after surgery, all eyes were within ±1.00 D of the predicted correction; 94% were within ±0.50 D. The UCVA was 20/40 or better in 98% of eyes and 20/20 or better in 87% of eyes. This level of efficacy is hard to achieve with other phakic IOLs or laser refractive procedures.

With the introduction of new generation UBM instruments such as the Vumax II, accuracy in sizing the Toric ICL has improved dramatically. In 18.6 % of eyes, another ICL size other than that suggested by the corneal white-to-white measurements needed to be implanted. By doing this, sizing became a nonissue in my practice (Figure 5).

Removability is an important consideration for both the surgeon and the patient, especially in comparison with other refractive corneal surgical procedures that permanently alter the cornea. The use of the Toric ICL in ametropia has advantages over corneal procedures (eg, predictabiltiy and stabiltiy of the refractive outcome). Interest in these lenses for the correction of refractive errors has increased.

Figure 5. Some eyes received an ICL that was larger than suggested by white-to-white measurements.

Data has shown that the Toric ICL reduced preoperative spherical and astigmatic errors with high predictability and good stability and was associated with extremely good visual outcomes and strong patient satisfaction. Complications were minimal and amenable to treatment. ■

Erik L. Mertens, MD, FEBO, is the medical director of the Antwerp Eye Center, in Antwerp, Belgium. Dr. Mertens states that he is a paid consultant for Bausch & Lomb and STAAR Surgical. He may be reached at e.mertens@zien.be; telephone +32 3 8282949; or fax +32 3 8208891. Dr. Mertens is a member of the CRST Europe *Editorial Board.*

1. Buratto L, Ferrari M, Genisi CM, Genisi C. Myopic keratomileusis with the excimer laser: one year follow up. *Refract Corneal Surg.* 1993;9:12-19.
2. Sher NA, Barak M, Daya S, et al. Excimer laser photorefractive keratectomy in high myopia. A multicenter study. *Arch Ophthalmol.* 1992;110:935-943.
3. Seiler T, Holschbach A, Derse M, et al. Complications of myopic photorefractive keratectomy with the excimer laser. *Ophthalmology.* 1994;101:153-160.
4. Seiler T, Koufala K, Richter G. Iatrogenic keratectasia after laser in situ keratomileusis. *J Refract Surg.* 1998;14:312-317.
5. Lee KH, Lee JH. Long-term results of clear lens extraction for severe myopia. *J Cataract Refract Surg.* 1996;22:1411-1415.
6. Bartels MC, Santana NTY, Budo C, et al. Toric phakic intraocular lens for the correction of hyperopia and astigmatism. *J Cataract Refract Surg.* 2006;32:243-249.
7. Mertens E. Integrating phakic IOLs in a private practice. *Ophthalmology Times.* 2006;2:1:28-29.