The Acrysof Toric IOL's FDA Trial Results

A look at the clinical data.

BY STEPHEN S. LANE, MD

Approximately 15% to 29% of cataract patients have more than 1.00D of corneal or refractive astigmatism,[1,2] which can prevent them from achieving the 20/20 visual acuity and spectacle freedom that they desire. A new option in astigmatic correction is the Acrysof Toric IOL (models SN60T3, SN60T4, and SN60T5; Alcon Laboratories, Inc., Fort Worth, TX), which is designed to focus the light otherwise scattered by corneal astigmatism and thereby minimize image distortion. This toric lens corrects for aphakia as well as preexisting or surgically induced corneal astigmatism. Based on the results of the FDA clinical trial, the Acrysof Toric IOL represents an effective option for treating astigmatism.

ABOUT THE LENS

The Acrysof Toric lens (Figure 1) is composed of an acrylic polymer that has UV and blue-light absorbers. The lens is built on the same platform as the Acrysof Natural Single-Piece IOL (Alcon Laboratories, Inc.). The toric lens easily folds in half and may be inserted through an incision measuring less than 3mm using the Monarch II injector (Alcon Laboratories, Inc.).

The Acrysof Toric IOL examined in the FDA clinical investigation was provided in three cylindrical powers at the IOL plane: 1.50, 2.25, and 3.00D (Table 1). In the future, additional power options will be offered. Initially, the Acrysof Toric IOL will be available in a spherical range between 16.00 and 25.00D in 0.50D increments.

The lens design has two major features that limit posterior capsular opacification (PCO). First, its biomaterial adheres to the capsular bag via a single layer of lens epithelial cells. The resulting lack of space through which essential, life-sustaining nutrients can pass ultimately leads to the cells' death. Subsequently, the Acrysof material adheres directly to the lens capsule via common extracellular proteins such as fibronectin and collagen IV.[3] This adhesive property also minimizes the lens' rotation—crucial to success with a toric IOL.

(Courtesy of Alcon Laboratories, Inc.)

Figure 1. The Acrysof Toric IOL, model SN60TT.

The design of the Acrysof Toric IOL's posterior optic edge also increases its ability to maintain a clear posterior capsule and ultimately reduces the need for an Nd:YAG capsulotomy.[3] A separate study showed that the IOL's square, truncated optic edge creates a barrier to the migration of lens epithelial cells, thereby leaving the visual axis clear of PCO.[4] The lens' Stableforce haptic design (Alcon

TABLE 1. THE AVAILABLE CYLINDRICAL POWERS OF THE ACRYSOF TORIC IOL

Acrysof Toric IOL Model	Cylindrical Power of IOL (D)	Cylindrical Correction at Corneal Plane (D)*
SN60T3	1.50	1.03
SN60T4	2.25	1.55
SN60T5	3.00	2.06

*Based on an average human eye.

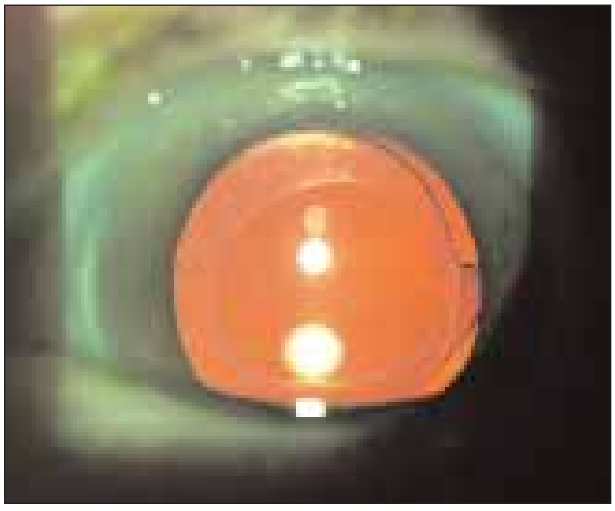

Figure 2. The surgeon has successfully placed the Acrysof Toric IOL within the capsular bag.

Laboratories, Inc.) provides maximum conformance to the capsular bag and thus offers the greatest possible surface area for adherence between the IOL and the capsular tissue. This quality, in turn, enhances the stability of the IOL and leads to a pronounced shrink-wrap effect (Figure 2) during the early postoperative period that locks lens into place within the lens capsule.

RESULTS OF THE US CLINICAL TRIAL

Study Design

A comparative, multicenter, prospective clinical trial of the Acrysof Toric IOL (models SA60T3, SA60T4, and SA60T5—a group referred to as SA60TT in this article) and a control IOL (SA60AT) assessed lens rotation, residual astigmatism, UCVA, and spectacle freedom for distance vision. Approximately 250 subjects received the SA60TT, and 250 subjects were implanted with the SA60AT. All subjects were followed for 1 year after lens implantation in their first eye, but only the 6-month data are available.

Stability Within the Lens Capsule

The Acrysof Toric IOL demonstrated excellent stability within the capsular bag. The average rotation was less than 4º from the lens' initial placement through 6 months postoperatively (Figure 3).

Astigmatic Refractive Cylinder

The three toric models (SA60T3, SA60T4, and SA60T5) were used in the clinical study to correct 1.50, 2.25, and 3.00D of astigmatism, respectively, at the IOL plane. The Acrysof Toric IOL significantly reduced or eliminated absolute residual refractive cylinder when compared to the control lens. Specifically, the SA60TT lenses were three times more likely to achieve a residual refractive cylinder of 0.50D or less compared with the control.

Visual Acuity

At the 6-month visit, approximately 66% of the unilateral toric subjects and 41% of the unilateral control subjects achieved a UCVA of 20/25 or better. For those pa-

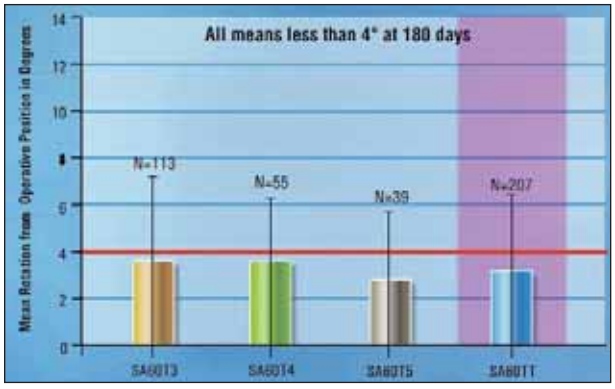

Figure 3. This chart presents the Acrysof Toric IOL's mean rotation by model.

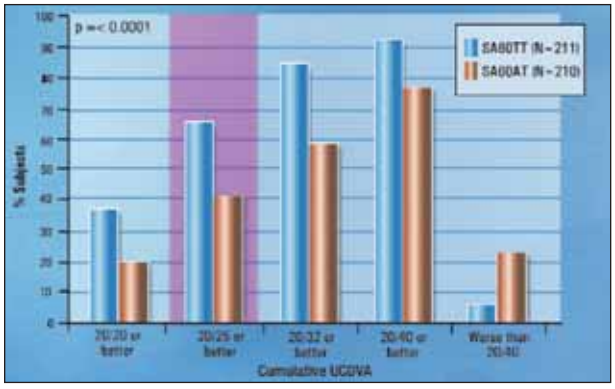

Figure 4. This chart shows the UCVA results from the US clinical trial of the Acrysof Toric IOL.

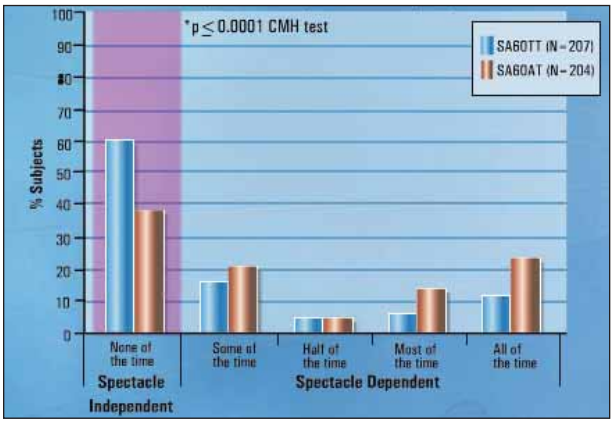

Figure 5. This chart indicates patients' level of freedom from spectacles for distance vision after undergoing the unilateral implantation of the Acrysof Toric IOL.

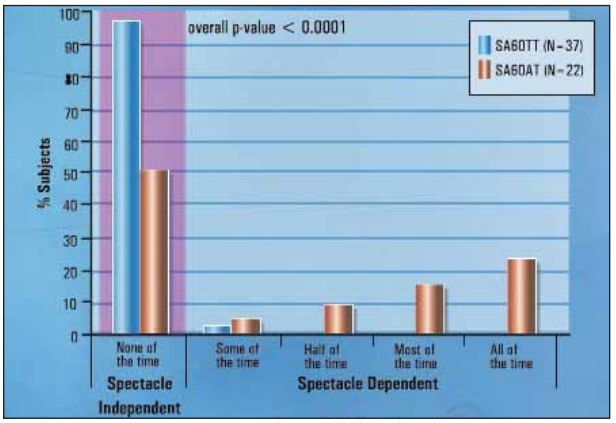

Figure 6. This chart indicates patients' level of freedom from spectacles for distance vision after undergoing the bilateral implantation of the Acrysof Toric IOL.

tients (n=37) who received Acrysof Toric IOLs bilaterally, 97% achieved 20/25 or better UCVA compared with 77% of controls (n=22) (Figure 4).

Additionally, the Acrysof Toric IOL significantly improved subjects' spectacle freedom for distance vision relative to the control lens. In the clinical study, 60% of the 207 patients examined at 6 months who received the toric lens in one eye achieved spectacle freedom for distance vision. Of the 37 toric subjects and the 22 control subjects who underwent bilateral IOL implantation, 97% of those who received the Acrysof Toric IOL achieved spectacle freedom for distance vision compared with 50% of the control subjects (Figures 5 and 6).

DISCUSSION

The importance of a lens' stability and lack of rotation within the lens capsule cannot be overstated with respect to the effectiveness of a toric IOL. For every 1° of off-axis rotation, 3.3% of the lens cylinder power may be lost. At 30° of rotation, the power of the IOL cylinder is totally gone. Clearly, the axial alignment of a toric IOL determines the efficacy of astigmatic correction, and the surgical placement of the toric IOL should be as accurate as possible. During the early postoperative period, IOLs may rotate within the capsular bag until they form a bioadhesive bond with the posterior capsule.[5] The Acrysof material allows this fixation to occur soon after the IOL's implantation.[3,6]

The optic design maintains the same thickness for the central optic in all models of the Acrysof Toric IOL as with the monofocal models SA60AT and SN60AT. The spherical equivalent, posterior, toric optic design results in slight variations in the edge's thickness around the circumference of the optic due to the different curvature of the principal meridians. This variation between the principal meridians changes as the cylindrical power changes from model to model. The importance of this design is that it provides a full 6-mm toric optic with a central optic thickness, IOL volume, IOL delivery characteristics, and A-constant that are consistent among all Acrysof Toric IOL models as well as the Acrysof IOL models SA60AT and SN60AT.

In the FDA trial, the Acrysof Toric IOL minimized PCO, provided excellent vision, and allowed maximal conformance to the capsular bag while minimizing the IOL's rotation. All of these characteristics are critical for accurate cylindrical correction.

Phacoemulsification with the implantation of the Acrysof Toric IOL provides an attractive alternative for cataract patients that may reduce their dependence on spectacles. ■

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