Interim Results of the United States Investigational Device Study of the Ophtec Capsular Tension Ring

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Purpose: To evaluate the safety and efficacy of the Ophtec capsular tension ring (CTR) in providing capsular support during and/or after cataract extraction in cases of a weak or partially broken ciliary zonule.

Design: Phase III multicenter, nonrandomized, investigational device study.

Participants: Twelve investigators at 9 sites enrolled 224 subjects and placed 255 CTRs.

Methods: Capsular tension rings were placed in patients who were found to have a weakened or partially broken ciliary zonule comprising <34% of the circumference of the lens capsule. Two CTR models were evaluated, with noncompressed diameters of 12 mm and 13 mm. Patients were examined preoperatively, intraoperatively, and postoperatively at day 1 and months 1, 3, 6, and 12.

Main Outcome Measures: Rate of successful stabilization of the capsular bag and intraocular lens (IOL) centration, complications, and adverse events.

Results: Interim results from this ongoing study indicate that immediately after surgery 98.8% of IOLs were centered and 1.2% of the IOLs implanted (3/251) were not centered. Subsequently, the prevalence of decentered IOLs was 1.7% (4/236) 3 months after surgery, 3.8% (8/211) 6 months after surgery, and 2.3% (4/172) 12 months after surgery. The primary complication was posterior capsular opacification, which is unlikely to be a complication of CTR insertion. Neodymium:yttrium–aluminum–garnet laser capsulotomies have been performed in 12.8% of eyes by 12 months (22/172).

Conclusions: Ophtec CTR models 275 and 276 safely provided capsular support during and after cataract surgery in cases where the zonule was weak or partially broken. *Ophthalmology 2005;112:460–465 © 2005 by the American Academy of Ophthalmology.*

Capsular tension rings (CTRs) are used to stabilize the capsular bag of the crystalline lens both during and after cataract surgery. The idea was first put forward in 1991 by Hara et al, who developed a closed silicone equator ring in rabbit eyes.[1] The concept was further developed by Nagamoto and Bissen-Miyajima (1994),[2] and the first CTR was implanted during cataract surgery by Witschel and Legler in 1993.[3] Capsular tension rings of varying designs are used widely now throughout the world.[4–6]

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The ciliary zonule is composed of delicate fibers that arise from the inner surface of the orbiculus ciliaris and attach to the anterior and posterior surfaces of the capsule close to the equator. During surgery, a CTR helps distribute stress around the entire equatorial area of the lens capsule whenever tension is placed on any section of the capsule during manipulation of the lens or removal of cortex. This stress distribution significantly reduces the likelihood of stretching or tearing the ciliary zonule.[6] After surgery, a CTR helps maintain the equatorial area of the lens capsule in a fully distended circle of 360°. This minimizes the risk of decentration of the intraocular lens (IOL) and may decrease, but not fully prevent, the risk of dislocation of the capsule/IOL complex.[6,7]

Capsular tension rings have gained widespread acceptance around the world for use in eyes with a loose, compromised, or partially absent ciliary zonule. Preoperative indications that a CTR may be required are a history of trauma; previous intraocular surgery; pseudoexfoliation syndrome; high myopia; or the congenital, metabolic, and endocrine disorders that affect the ciliary zonule, such as Marfan syndrome, Marchesani's syndrome, scleroderma, homocystinuria, spherophakia, porphyria, and hyperlysinemia. A CTR may also prove to be helpful in cases where exact centration of the IOL may be needed after surgery to

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achieve a satisfactory visual result, such as with multifocal IOLs.

Here we report the interim results of the phase III United States Food and Drug Administration CTR clinical study sponsored by Ophtec USA. In the study, the CTR was called the Oculaid, but it will be distributed in the U.S. under the name StabilEyes by Advanced Medical Optics (Santa Ana, CA).

Materials and Methods

This was a phase III multicenter nonrandomized investigational device study with 12 investigators at 9 sites: Eye Associates of Boca Raton, Boca Raton, Florida; Price Vision Group, Indianapolis, Indiana; Koch Eye Associates, Warwick, Rhode Island; Mackool Eye Institute, Queens, New York; Minnesota Eye Consultants, Bloomington, Minnesota; Jules Stein Eye Institute, Los Angeles, California; University of Iowa Hospitals and Clinics, Iowa City, Iowa; Rosenthal Eye and Facial Plastic Surgery, Great Neck, New York; and the Maloney–Seibel Vision Institute, Los Angeles, California.

The purpose of the study was to evaluate the safety and efficacy of the Ophtec CTR (Ophtec USA, Inc., Boca Raton, FL). The study was conducted with institutional review board approval. All subjects read and signed an informed consent form, and the work complied with the Health Insurance Portability and Accountability Act of 1996. The study was initiated in April 2001 with a planned enrollment of 100 patients, and data are reported here with a cutoff of August 2003. Patients were examined preoperatively, intraoperatively, and postoperatively at day 1 and months 1, 3, 6, and 12. At each visit, capsular bag integrity was reported, capsular bag contraction was rated by the surgeon on a subjective scale (none, mild, moderate, severe), and CTR postoperative performance and postoperative results were rated by the surgeon on a scale from 1 to 10 (with 10 being excellent). Intraocular lens centration was also reported (rated subjectively by the surgeon, centered or not centered) at the 3-, 6-, and 12-month dilated slit-lamp examinations.

The CTR was indicated for the stabilization of the crystalline lens capsule during and after cataract extraction (CE) and IOL implantation in the presence of a weak or partially broken ciliary zonule. Patients selected included those undergoing planned phacoemulsification CE with continuous curvilinear capsulorhexis. Inclusion criteria were conditions with suspected zonular compromise, risk for developing zonular compromise, preoperative signs of a weakened or partially broken ciliary zonule comprising <34% of the circumference of the lens capsule, and a structurally sound capsular bag during surgery.

Two CTR models were used in this study. Model 275 had a noncompressed diameter of 12 mm, and model 276 had a 13-mm noncompressed diameter. Model selection was based on surgeon preference, with the general guideline to use model 275 in normal eyes and model 276 in myopic and larger eyes.

For controlled placement of the CTR in the capsular bag, the CTR could be loaded into a tension ring inserter (Ophtec USA) and introduced through a corneal incision into the capsular sac. Alternatively, the surgeon could place the CTR manually with forceps or other instruments. The CTR could be placed in the capsular bag at any point during the surgery, at the discretion of the surgeon. Choice of IOL was also left to the surgeon.

Results

Patients

During the study, 255 CTRs were implanted in 224 subjects; females (n = 114) comprised 51% of the subjects, and the mean age was 67.8 years (range, 20–96; standard deviation, 17.4) (Table 1). Regarding the preoperative ocular indication for CTR use, surgeons were asked to select from the following categories: pseudoexfoliation syndrome, trauma, surgical trauma, Marfan syndrome, or other (Table 1). The study enrollment of 100 patients was achieved early, and as no alternative device was available in this country at the time of study, the Food and Drug Administration allowed the investigators to continue implanting the device once the planned enrollment was complete. As a result, devices were still being implanted at the time of the interim data analysis, and consequently, follow-up is <12 months in some cases. The number of eyes examined at each visit is shown in Table 1.

Table 1. Patient Demographics and Follow-up Numbers

Measure	Value	%
No. of patients enrolled	224	
No. of females	114	51
Mean age (yrs) (±standard deviation)	67.8 (±17.4)	
Preoperative indications for CTR use		
Pseudoexfoliation syndrome	113	44
Trauma	47	18
Surgical trauma	13	5.1
Marfan syndrome	3	1.1
Various other conditions	79	31
No. of eyes enrolled	255	
No. of eyes examined at follow-up*		
1 day	255	
1 mo	242	
3 mos	236	
6 mos	211	
12 mos	172	

CTR = capsular tension ring.
Subjects were still being enrolled at the time of this interim data analysis, so increasing numbers of eyes were not yet eligible for examination at the later time points.

Before surgery, the ciliary zonule was noted to be partially broken or missing in 15% of eyes (39/255) and weakened or lax in 85% of eyes (216/255). The broken/missing or weak/lax ciliary zonule was estimated to comprise between 1% and 15% of the circumference in 23% of eyes, between 16% and 30% of the circumference in 56% of eyes, and between 31% and 33% of the circumference in 17% of eyes.

Model 275 was implanted in 68% of cases (173/255). The CTR was placed using the tension ring inserter in 98% of cases and manually in 2%. The CTR was implanted before CE in 33% of cases (85/255) and after CE in 66% of cases (170/255).

Operative Results

Intraoperative complications were few, and are listed in Table 2. There were 3 cases of posterior capsular rupture, which led to the suturing of the IOL in 2 eyes. A third eye required suture fixation of the IOL also. A total of 6 eyes had vitreous loss or strands requiring vitrectomy during surgery, and there was one occurrence each of zonular dehiscence and anterior chamber collapse (during phacoemulsification). One adverse event was noted during surgery: posterior capsular disintegration occurred on implantation of one IOL. The surgeon noted this was not directly related to use of the CTR, no suturing was required, and the IOL was centered at the last visit (1 year).

Postoperative Results

Intraocular Lens Centration. Immediately after surgery, 98.8% of the 251 IOLs implanted were centered, and 1.2% were not