

Perspectives in Lens & IOL Surgery

Why capsular tension rings work

by I. Howard Fine, M.D., Richard S. Hoffman, M.D., and Mark Packer, M.D.



Capsular tension rings will soon be available in America. I'd like to share with you the experience I have gained over the past five years as a medical monitor for the unexpectedly long Food and Drug Administration study. These rings are a safety device that will benefit all patients at risk and be a source of enormous comfort on the part of physicians in dealing with the patient population.

*I. Howard Fine, MD,
Column Editor*

Capsular tension rings, first described by Witschel and Legler more than a decade ago¹ and in wide-spread use throughout the world, will soon be available for routine use in the United States through either Morcher, Stuttgart, Germany, (distributed in the U.S. by FCI Ophthalmics Inc., Marshfield Hills, Mass.) or Ophtec B.V., Groningen, the Netherlands, (distributed in the U.S. by Advanced Medical Optics, Santa Ana, Calif.).

I have acted as medical monitor for the Morcher capsular tension ring Food and Drug Administration-monitored study, and have gained a great deal of experience in their use.

They are indicated in, perhaps, as many as 2%-5% of all cataract surgeries and their use converts that patient population with loose, compromised, or partially absent zonules to a nearly routine cataract surgery case, rather than one associated with high risk.

Preoperatively, capsular tension rings are indicated in all instances of compromised zonular integrity, including all of the congenital, metabolic, and endocrine disorders, including Marfan's syndrome, Marchesani's, scleroderma, homocystinuria, spherophakia, porphyria, hyperlysinemia, sulfite oxidase deficiency, etc.

In addition to more commonly seen conditions like pseudoexfolia-

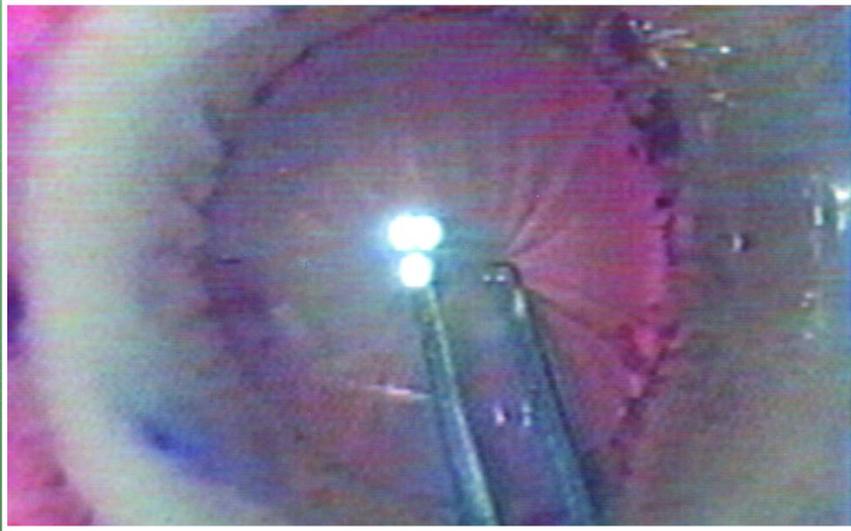
tion and high myopia (axial length greater than 26 mm), patients with cataracts that have suffered significant trauma in the past, and postvitrectomy patients, there are two additional patient populations that our clinical experience has shown are prone to have compromised zonular integrity: Patients that had previous glaucoma filtration surgery, as well as patients that had RK surgery with greater than eight incisions. Both of these last two entities were a surprise to us.

However, in thinking about these two situations, both share a common history: Shallow or flat chamber in the postop period. The former for obvious reasons, the latter due to the attempt to maximize myopic correction by making incisions as deep as possible with the increased risk of micro or macro perforations of the cornea.

We frequently saw in these patients the absolute sign of decreased zonular integrity — wrinkling of the capsule it was pinched by the forceps to initiate a capsulorhexis.

In addition, any intraoperative event that results in damage to the zonular apparatus is an indication for the introduction of a capsular tension ring in order to avoid further extension of zonular damage with possible loss of the cataract into the vitreous and/or early or late decentration of the IOL.

The capsular tension rings work



Wrinkling of the anterior capsule during an attempt to create a capsulorhexis by pinching the anterior surface of the capsule, indicative of a loss of zonular integrity.

effectively because they are open rings with a diameter larger than the capsular bag. They come in three different sizes, and when placed in the eye, they push against the equatorial region of the capsular bag, creating a situation in which one cannot apply focal forces to the capsule that results in focal forces acting on the adjacent zonules, because any force on the capsule is transmitted circumferentially to the entire zonular apparatus. They, therefore, make the surgery itself safer and the postoperative early and late centration of the IOL better.

We have found that they are most efficacious when implanted following capsulorhexis and a delicate cortical cleaving hydrodissection maneuver. This allows the capsular tension ring to add safety during the extraction of the cataract.

In most cases, with soft cataracts, we continue endolenticular phacoemulsification in the presence of the capsular tension ring, as usual. But for harder cataracts, we have more recently moved to hydrodissection of the lens out of the capsular bag and then we

carousel it in the plane of the capsulorhexis, emulsifying it from outside in, rather than disassembling it by cracking or chopping before emulsifying it.

In making a capsulorhexis, we always initiate the capsular tear toward the area of weakened zonules.

We will frequently, through a sideport incision, incise the capsule with a sharp needle, 180 degrees away from the center of the weakened zonular area. Then, usually through a sideport incision using a bimanual microincision capsulorhexis forceps, tear the capsule starting on each side of the capsular incision in the direction of the weakened zonules so that it can be torn from one side, toward the weakened side, and then again, from the other side of the initiated site toward the weakened zonules.

We try, generally, to make a very small capsulorhexis flap in the area of weakened zonules so that postoperative phimosis will not further stress that area. We leave a larger capsular flap 180 degrees away so that phimosis of the bag would move the IOL toward the

Capsular tension rings

by Rich Daly EyeWorld Staff Writer

The wait for FDA approval of capsular tension rings may be short lived.

Two manufacturers of capsular tensions rings (CTRs) and modified capsular tension rings (MCTRs) expect Food and Drug Administration approval by the end of the year.

Both Morcher GmbH (Stuttgart, Germany) and Ophtec USA (Boca Raton, Fla.) expect FDA approval this year for their basic CTR designs, which enhance the mechanical stability of a subluxated lenses capsule in the presence of weak or absent zonules.

The rings are designed to be placed in the capsular bag and to keep it stretched, according to the manufacturers. The device allows the weakened zonules to be supported by the remaining strong zonules.

"We hope to have approval of the ring by the fall," said Rick McCarley, president of Ophtec. "And that is based on the quality of the data I submitted."

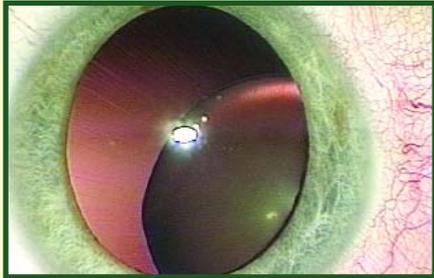
Morcher expects approval by the end of the year

The Morcher rings, widely used in Europe since their invention in 1991, are designed to stabilize the crystalline lens capsule in the presence of weak or partially absent zonules in patients 18 years or older, according to company representatives. Typical conditions the rings assist with include pseudoexfoliation, prior trauma, prior pars plana vitrectomy and Marfan's syndrome.

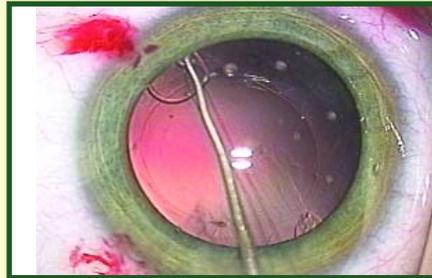
The indication of impending approval was greeted warmly by physicians that have used CTRs as part of the companies' trials.

"There's no question that it works," said Roger F. Steinert, M.D., associate clinical professor, Harvard Medical School, and in private practice, Ophthalmic Consultants of Boston, who worked on the Morcher

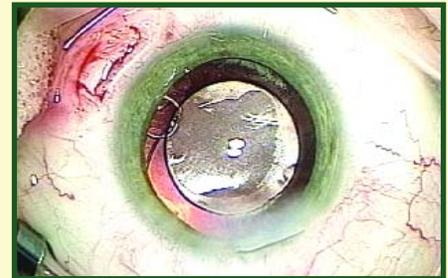
may soon hit U.S.



A young Marfan's syndrome patient before surgery



A Cionni modified capsular tension ring (model 1-L, Morcher GmbH, Germany) is placed (closeup)



A Cionni modified capsular tension ring (model 1-L, Morcher GmbH, Germany) is placed (farther away)

study. "It does exactly what it is supposed to do, and there are no complications."

Morcher's ring has been under study since 1996; more than 60 U.S. physicians have participated, according to Hillard (Hid) W. Welch, U.S. spokesperson for Morcher. The company expected to submit additional information on its investigations to the FDA in mid-July, requested as part of the agency's three-year-old review. The ring is under consideration for FDA premarket approval application (PMA).

In response to claims that Morcher failed to collect adequate data on its CTR studies and that contributed to the approval process, Welch denied such suggestions.

"It's just a continuing process. They wanted every 't' crossed and every 'i' dotted," Welch said.

In January 2002, the FDA's Ophthalmic Devices Panel, the agency's public advisory committee, recommended regulatory approval with conditions for Morcher's ring. The panel requested that Morcher present additional data from its studies for review, including data on the intraoperative estimate of intact zonules and evaluation of lens centration on postoperative dilated eye examination.

Morcher has included in its studies a CTR variation designed by **Robert J. Cionni, M.D.**, Cincinnati Eye Institute,

Ohio, for patients with more extreme zonular weakness or with very large degrees of dialysis or lens luxation needed sutures to fixate the ring.

His design has a fixation hook that comes off the ring and allows surgeons to suture it to the scleral wall without going through the capsular bag. The company does not plan to apply for FDA approval of the patented variation until after the basic CTR is approved, Welch said.

"With the first CTR, we could re-expand the bag with the ring and now we can center it and fixate it with the Cionni modification," said **Robert H. Osher, M.D.**, professor of ophthalmology, University of Cincinnati College of Medicine, Ohio, and medical director, Emeritus, Cincinnati Eye Institute. "It's ironic that it has been more than a decade since I implanted the first endo-capsular ring (the original name of the device) and this critical device is still not approved" in the United States, Osher said.

Ophtec researchers have studied a nearly identical basic CTR since 2000 with at least 12 physicians. The company submitted its FDA application May 1.

Confident of a relatively quick approval, Ophtec has already signed a domestic distribution agreement with Advanced Medical Optics (AMO, Santa Ana, Calif.), which will distribute

Ophtec's CTR under the name Stable Eyes, while Ophtec will market the device overseas as Ophtec Capsular Tension Rings.

Company officials continue to review a wide range of variations of the original design, including the addition of suture holes and increased thickness. Some of the variations may need to go through a lengthy PMA process or even undergo clinical trials, but others will likely require less scrutiny, McCarley said.

"We have new and different proposals from physicians almost every day that want us to make a new iteration of the capsular tension ring," McCarley said.

Physicians familiar with CTRs predict a wide range of missions for the devices, including a version with treatment chemicals incorporated in the design. 🌐

Contact Information

Cionni: 513-984-5133, fax 513-936-4881, rcionni@cincinnatieye.com

McCarley: 561-989-8767, fax 561-989-9744, ophtecrick@aol.com

Osher: 513-382-2969, fax 513-936-4881, rhosher@cincinnatieye.com

Steinert: 617-367-4800, fax 617-573-4912, rfsteinert@eyeboston.com

Welch: 508-771-6777, fax 508-775-9051, handj@gis.net

area of weakened zonules, thus helping to create better centration.

The introduction of the capsular tension ring is done either with forceps and a hook — the forceps advance it into the eye, and the hook guides intraocularly, or through the injection shooter (Geuder, Heidelberg, Germany).

We have also recently learned that we can use the injection apparatus through a 1.2-mm sideport incision by holding the injector up to the edge of the incision and advancing the ring intraocularly with one hand and guiding the ring intraocularly with a Lester hook (Katena Products Inc., Denville, N.J.) with the other hand. The trailing end of the ring can be brought directly under the capsular flap with the Lester hook.

We try to introduce the capsular tension ring in such a way that its initial entry under the capsulorhexis pushes against the capsule in the direction moving toward the area of weakened zonules rather than the area away from the weakened zonules. Because it can be introduced through a sideport incision, it is possible to do this with zonular weakness located anywhere within the eye.

In general, we like to implant the IOL with the haptics in the meridian of the weakened zonules to further push against the capsular fornix in that direction.

In cases of severe zonular dialysis, where implantation of the IOL may stress the bag even in the presence of a capsular tension ring, we favor the single-piece AcrySof acrylic IOL (Alcon, Fort Worth, Texas). It can be implanted into the capsular bag as a 3-mm by 6-mm rectangle with opening of the haptics in such a way as to not stress the capsular bag at all. This precludes the need to either compress or dial a trailing haptic into the IOL.

Cortical clean up can be somewhat more difficult with the presence of a capsular tension ring placed prior to phacoemulsification.

However, cortical cleanup in the presence of compromised zonules is more likely than any other part of the surgery to extend or exacerbate zonular damage.

We find that cortical cleanup in the presence of a capsular tension ring is best done by stripping cortex tangential to the capsulorhexis. That way, a triangular shaped mass of cortex is stripped from its attachment to the capsular fornix, starting at the distal edge of the base of the triangle, a few attachments at a time, rather than stripping centrally where the full base of the triangle of attached cortex is attached to the capsular fornix.

In addition, this maneuver can sometimes move the capsular ten-

sion ring centrally and add further stress to the zonular apparatus.

In our experience, we have found that there are basically no downsides to the capsular tension ring. In the few instances with capsular tension rings placed in eyes with zonular dialyses of up to 270 degrees, it was impossible without the use of a Cionni ring to stabilize the capsule. In these instances, it was much easier to deliver the cataract intact, because the capsular tension ring kept the bag from collapsing and dumping the nuclear contents into the vitreous.

In at least one instance, we have been able to insert a capsular tension ring into the bag to recenter an IOL that decentered late in the postoperative period.

The availability of capsular tension rings will be a welcome relief to American cataract surgeons. They add safety to a patient population whose surgery is frequently complicated. They are easy to use, and the learning curve is short.

I hope these suggestions, based on my experience, are helpful to readers of this column. 

Reference

- 1 Witshel, Legler, UF, "New approaches to zonular cases: The capsular ring," *Audiovisual Journal of Cataract & Implant Surgery*, 1993; 9:4.

Morcher Capsular Tension Rings are available in the USA exclusively from:

FCI Ophthalmics

P.O. Box 465

Marshfield Hills, MA 02051

Tel: 800-932-4202

Fax: 781-826-9062

www.fci-ophthalmics.com