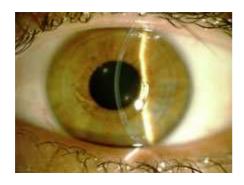
Refractive Surgery Ring segments still valuable for keratoconus treatment

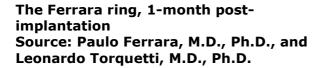
by Michelle Dalton EyeWorld Contributing Editor AT A GLANCE

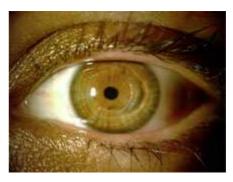
- Intrastromal ring segments can stabilize the keratoconic cornea up to 5 years after implantation
- Use of the femtosecond laser has made channel creation for ring segment implantation easier
- Corneal crosslinking may become a viable adjunct to ring segments (and vice versa)

The advent of the femtosecond laser has made creating the channel necessary for ring implantation a much easier process as well



Ferrara ring segment immediately after implantation; note the clear cornea and some bubbles inside the stromal tunnel





Keratoconus—a condition that may affect

as many as one out of every 2,000 people in the U.S.—can cause significant visual impairment that may necessitate a transplant in order to restore vision, if the condition becomes progressively worse or remains unidentified or untreated. Intrastromal corneal ring segments have been used for years as a treatment for mild myopia and keratoconus. Addition Technology's Intacs (Des Plaines, Ill.) received Food and Drug Administration approval in 2004; to date they remain the only ring segments with market approval in the U.S.

Several surgeons EyeWorld spoke to said the manual dissection system presented a significant surgical challenge—the advent of the femtosecond laser's use in creating channels for the ring segments has significantly reduced the amount of surgical time, which eases both patient and surgeon discomfort.

Surgeons have begun using the Intacs and ring segments such as the Ferrara Ring (not approved in the U.S.) to both stabilize and prevent the progression of keratoconus after laser vision correction surgery.

Crosslinking and ring segments

With the positive—albeit early—results from the corneal crosslinking studies now emerging, there is likely to be "less of an indication for ring segments in the future," said Richard L. Lindstrom, M.D., adjunct professor emeritus, Department of Ophthalmology, University of Minnesota, Minneapolis, and founder, Minnesota Eye Consultants, Minneapolis. He said he's most interested in the results from surgeons who are now combining crosslinking and PRK in a two-stage approach. "The goal for us as surgeons is to try and avoid a corneal transplant," he said, adding that in the near future ophthalmologists will "be treating keratoconus suspects much earlier. The earlier we can intervene, the better it will be for the patient."

Collagen crosslinking "consists of photopolymerization of stromal fibers by the combined action of a photosensitizing substance (riboflavin or vitamin B2) and ultraviolet type A rays from a solid-state UVA source," said Paulo Ferrara, M.D., Ph.D., director, Clinica de Olhos Paulo Ferrara, Paulo Ferrara Eye Clinic, Belo Horizonte, Brazil, and Leonardo Torquetti, M.D., Ph.D., consultant ophthalmologist, Paulo Ferrara Eye Clinic.

Conversely, "intrastromal corneal ring segments act by an 'arc-shortening effect' on the corneal lamellae and flatten the central cornea. The main advantages of intracorneal ring segments are safety, reversibility, stability, and the fact that the surgical process does not affect the central corneal visual axis," they said in an emailed interview.

Until corneal crosslinking is approved in the U.S., however, "we have to understand and use ring segments for keratoconus," said Daniel S. Durrie, M.D., clinical professor of ophthalmology, University of Kansas, Overland Park, Kan. "Corneal crosslinking is exciting, and could be a good additive to what we already know about corneal ring segments."

There are two basic approaches with corneal collagen crosslinking, said Perry S. Binder, M.D., co-founder, Gordon-Binder-Weiss Vision Institute, San Diego. Primarily, surgeons treat the eye with or without removing epithelium followed by riboflavin application and UV A.

Another approach as developed by John Kanellopoulous, M.D., Athens, Greece, involves using a femtosecond laser "to create a pocket in the keratoconus cornea, inject riboflavin into the pocket so it can be absorbed areas above and below the pocket," Dr. Binder said. A similar approach involves injecting recombinant human corneal collagen into the pocket, followed by riboflavin dye injection and subsequent UVA, and that creates crosslinking of the added collagen as well as the host's collagen, he said.

"You can then treat the eye with PRK to correct the refractive error," he said. At issue with this approach is which procedure to perform first—the crosslinking or the PRK, or to perform them the same day.

"If you perform crosslinking months after PRK, you'll know the residual prescription error of the eye," he said. "The negative is that you'd have to wait 3-6 months for the eye's final refractive error to be established. If you perform the PRK first, you have to guess the correction to perform with the laser. If you perform the PRK after the crosslinking, you will be removing crosslinked collagen, which is what you wanted to establish. Several surgeons now perform a partial PRK to correct the bulk of the refractive error and the same day they next perform the collagen crosslinking."

Crosslinking is gaining acceptance—"it's more than just doing a shape change to the cornea," Dr. Durrie said. "In the near future, this will become the primary treatment at first diagnosis of keratoconus. We'll be performing crosslinking on patients in their late teens, early 20s, long before we'd ever have to implant a ring segment. We could potentially avoid the progressive nature of the disease." Drs. Torquetti and Ferrara do not advocate use of crosslinking before ring implantation. "[Crosslinking] will drastically reduce the ring effect because

flattening of a 'rigid' cornea is more difficult to be achieved," they said. "The combination of CXL and ring implantation could be accepted only in the uncommon cases (about 5%) of disease evolution despite proper ring implantation."

The ring advantage

Very advanced stages of keratoconus (curvatures over 75 D and significant apical opacity and scarring) are contraindications for the Ferrara ring, Drs. Ferrara and Torquetti said. Other contraindications include hydropsis, thin corneas (less than 300 microns), and ongoing local or systemic infections, they said.

"Patients with intense atopia should be treated before the implant," they added. "In advanced keratoconus, the visual results may not be as satisfactory as in the earlier stages of the disease. In advanced cases the cornea is usually very thin, hyperprolate and with significant topographic astigmatism. It would require a thick ring to flatten the cornea and turn it less prolate; however, as a rule, one could not implant any ring with more than half-thickness of the cornea in the ring track, which limit the thickness of the ring to be implanted, consequently limiting the visual result." That said, they added "the results are very reasonable, even in advanced cases."

Early on, ring segments "weren't really holding up the cornea," Dr. Durrie said. "They spread the cornea from front to back and pushed it posteriorly and anteriorly; the shortened arc length flattened the cone." The challenge for surgeons was where the segment implantation should be placed, and whether one or two segments would suffice, he said.

"The debate continues today about the number of segments, how thick and thin and where to place them," he said. "Now that we can make the channel with the femtosecond laser, it's easy to rotate the rings in the channel."

The Ferrara ring features a 5 mm optical zone, "which produces more significant astigmatism reduction and cornea flattening, when compared with large diameter (6 or 7 mm) rings," Dr. Torquetti said. "Some have said the small rings could cause halo/glare in patients with wide mesopic pupils. This used to be an infrequent, but bothersome, complaint in the past."

Today, the Ferrara ring features a yellow filter designed to reduce those symptoms.

Femtosecond laser

Using the femtosecond laser to create the tunnels for the ring segments is a relatively new use. "The precision of the tunnelization is the main advantage of the femtosecond laser. However, the manual technique, once mastered, can produce exactly the same results as the femtosecond laser," Drs. Torquetti and Ferrara said.

They added hearing some reports of faster visual rehabilitation after the femtosecond laser when compared with the manual techniques, but very few papers have been reported in the literature.

Dr. Durrie prefers the femtosecond laser to make the incisional pockets, and then uses a Mastel ring to round the cornea even more. The decision to use one or two segments will be determined by how round he's able to get the cornea.

"Then, if the cornea is really flat above, we can steepen it with conductive keratoplasty. It's not a permanent fix, but it gives us better options," he said. The IntraLase (Abbott Medical Optics, Santa Ana, Calif.) femtosecond laser "gives a much more reproducible depth," Dr. Lindstrom said. "It makes the operation go really quickly. Suction is nicer, too, which makes the overall experience nicer for the patient and the surgeon. I never did like the channel maker ... it was an uncomfortable surgery for the patient. With the IntraLase, it only takes about 5 seconds to create the channel."

Dr. Durrie warned that a really loose channel will cause too much separation, but a really tight channel will not offer enough. "But since you can make the channel all the way around, you can rotate and monitor the rings to see how round you're making the cornea," he said. "Sometimes I've planned on two segments and ended up only implanting one."

Dr. Lindstrom offered these pearls: Keep the channels about 0.9 mm apart—the key issue is deciding the inner and outer diameters, with 6.6 mm and 7.5 mm typical for the inner and outer, respectively. "Mine are basically at 6.4 mm and 7.2 mm, so I'm about 0.8 mm apart," he said. "The smaller and tighter the channel, the more effective, but it's a compromise each individual surgeon has to determine—the smaller the channels, the more difficult the rings are to insert." Next, determine how deep the rings need to be set, Dr. Lindstrom said. "I do pachymetry over where I'm going to put the rings, just in case the cornea's thinner on the periphery. For me, it's a minimum of 450 micron depth as I place the rings at 400 microns."

He said he will soak the Intacs rings in moxifloxacin, and use a standard incision size of 1.4 mm, using a modified Sinskey hook to "open up the bottom of the channel a little bit."

He recommends suturing the incision , "and do not place the Intacs right under the incision, so they're not touching superior or inferior," with 10-0 nylon. Patient selection

Like most refractive procedures, patient selection is a major component. Dr. Lindstrom prefers the average Ks to be "55 or less, with a central cornea of at least 400 microns." He adds that eyes with surface scarring, nodules, or irregularity are not recommended for ring segment surgery. "Topography is an important diagnostic tool to evaluate the patient," he said. "I use the Orbscan or Pentacam to decide where the steep meridian is. I don't tend to use the thinner ring segments," but opts for the 350-micron ring instead for most patients. In general, patients with mild keratoconus usually fare best with one segment, while those with mild to moderate need to have two segments, Dr. Lindstrom said

In the future, "nothing will be more important than proper patient selection to determine who's a good candidate," Dr. Durrie said. He said intraoperative monitoring will become more standard, in efforts to round the cornea as much as possible.

"One other thing we've found is that when the cone is too steep in keratoconus, the sphere cornea is often too flat," he said. Some surgeons are, therefore, investigating using a ring "below, to flatten the feet part, and CK superiorly to steepen the cornea," Dr. Durrie said.

There is still an "awful lot of work to be done on our parts to determine who's a good candidate and who's not, based on monitoring them for the best shape possible. We need more studies and presentations to figure out how to best maneuver the rings."

Post-op care "is pretty straightforward," Dr. Lindstrom said, who prescribes moxifloxacin until the sutures are removed, and a topical NSAID and steroid "because it enhances patient comfort."

If there is residual refractive error, Dr. Lindstrom said he may perform PRK with mitomycin C 3-4 months after implanting the ring segments. "We got some pretty spectacular results," he said.

Potential futures

Current treatment options for keratoconus include contact lenses, the intracorneal segment rings, keratoplasty, and spectacles, and within that segment, "the intrastromal rings are a big part of the treatment regimen," Dr. Durrie said. Still being researched are corneal crosslinking and "some type of advanced surface ablation," he said.

Dr. Lindstrom said he can envision a day where CK and rings "round up the cornea and then we lock it into place with corneal crosslinking."

"In our opinion, the crosslinking just does not go to the origin of the disease," Dr. Torquetti said. "Theoretically, when the procedure is performed, the collagen bundles are 'frozen' and that prevents progression of the disease. However, the collagen turnover does not stop, which could lead to a treatment failure once the treated collagen was substituted."

Additionally, without long-term follow-up on crosslinking, ophthalmologists cannot know if the treatment may cause early onset of other morbidities, such as cataract or age-related macular degeneration, Dr. Torquetti said.

Conversely, the intrastromal rings "act as 'spacers', producing effects for an undetermined period of time. That is the rationale for its long-lasting effects," he said, adding long-term follow-up studies have confirmed the effects.

Dr. Binder said it's possible that in the future, surgeons will be implanting phakic toric IOLs in eyes with keratoconus, then performing some combination or collagen crosslinking and PRK on the eye.

"Corneas that do not progress will have no need for crosslinking, because the bulk of the refractive error will already be treated," he said. Dr. Kanellopoulous is now performing a "limited" topographically-enhanced PRK and crosslinking on the same day.

Ideally, "in the future, we'll see the comprehensive refractive surgeon, one with access to synthetic intracorneal lenses, phakic IOLs, toric lenses, and even accommodating lenses. Depending on how a patient presents, we'll be able to treat any refractive error. We'll have rings, CK, PRK, and crosslinking to allow us to do interesting treatments for our keratoconus patients," Dr. Lindstrom said.

Editors' note: Dr. Lindstrom has financial interests with Abbott Medical Optics (Santa Ana, Calif.), LensAR (Winter Park, Fla.), and LensTec (St. Petersburg, Fla.), and his center participates in the corneal crosslinking U.S. studies. Dr. Ferrara has financial interests in the Ferrara Ring. Dr. Torquetti has no financial or proprietary interest in the Ferrara ring. Dr. Durrie has financial interests with AMO and Alcon (Fort Worth, Texas). Dr. Binder has financial interests with AMO and participated in the corneal crosslinking U.S. studies.

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