Clinical outcomes after implantation of a new intrastromal corneal ring with a 210-degree arc length

Paulo Ferrara, MD, PhD, Leonardo Torquetti, MD, PhD

PURPOSE: To report the clinical outcomes of implantation of a new Ferrara intrastromal corneal ring segment (ICRS) with a 210-degree arc length in eyes with keratoconus.

SETTING: Private eye clinic, Belo Horizonte, Brazil

METHODS: Statistical analysis included preoperative and postoperative uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), refraction, and keratometry.

RESULTS: Eighty eyes (76 patients) were evaluated. The UDVA improved from 20/350 preoperatively to 20/136 postoperatively and the CDVA, from 20/125 to 20/50; the differences were statistically significant (P = .001 and P = .0001, respectively). Corneal tomography (Pentacam) showed corneal flattening in all eyes. The mean preoperative spherical equivalent decreased from −5.22 diopters (D) preoperatively to −2.26 D postoperatively (P = .050); the mean keratometry (K) 1 value, from 51.49 D to 47.40 D (P = .00014); and the mean K2 value, from 54.33 D to 49.14 D (P = .00022). Two patients required penetrating keratoplasty despite ICRS implantation.

CONCLUSIONS: A new ICRS with 210 degrees of arc was effective in treating keratoconus. It improved visual acuity and reduced corneal steepening in selected patients.


Keratoconus is a noninflammatory progressive corneal thinning of unknown cause in which the cornea assumes a conical shape and there is progressive irregular astigmatism and deterioration of visual acuity. One of the most effective methods of visual improvement in eyes with keratoconus is a gas-permeable rigid contact lens; however, many patients are contact lens intolerant. Several surgical options for keratoconus patients who are contact lens intolerant have been suggested; these include apex cauterization, epikeratophakia, sectoral keratotomy, lamellar keratoplasty, and penetrating keratoplasty (PKP). In 1986, Ferrara implanted modified poly(methyl methacrylate) (PMMA) rings in rabbit corneas and in 1994, he developed a better technique of corneal tunnel construction for implanting the rings.

Ferrara intracorneal ring segments (ICRS) have been used in several countries for the treatment of primary and secondary ectatic corneal disorders. The PMMA ring segments are inserted in the peripheral stroma, somewhat preserving the prolate shape of the anterior corneal surface. Many studies report the efficacy of intrastromal rings in treating corneal conditions such as keratoconus, post-LASIK corneal ectasia, post–radial keratotomy ectasia, astigmatism, and myopia.

The ICRS acts according to Barraquer’s postulate that tissue addition in the corneal periphery flattens the cornea; the ring diameter determines how much the cornea will flatten. Thus, the more tissue added (ring thickness) and the smaller the diameter, the greater the flattening and the myopic correction.

Ferrara rings have a PMMA triangular cross-section that provides an optical zone of 5.0 mm. They require 1

Submitted: November 14, 2008.
Final revision submitted: April 14, 2009.
Accepted: April 15, 2009.

From a private eye clinic, Belo Horizonte, Brazil.

Dr. Ferrara has a financial interest in the Ferrara intrastromal corneal ring. Dr. Torquetti has no financial or proprietary interest in any material or method mentioned.

Corresponding author: Paulo Ferrara, MD, PhD, Clinica de Olhos Dr. Paulo Ferrara, Avenida Contorno 4747, Conjunto 615, LifeCenter, Funcionários, Belo Horizonte MG, 30110-031, Brazil. E-mail: pfer rara@ferrararing.com.br

1604 © 2009 ASCRS and ESCRS
Published by Elsevier Inc.

0866-3359/09—see front matter
corneal incision and are implanted at 80% depth with an almost free-hand technique. A newer Ferrara intrastromal ring model has an arc length of 210 degrees (Figure 1). The segments are of acrylic Perspex CQ with an inner radius of curvature of 2.5 mm and thickness from 150 to 300 μm. The new model has the following 3 advantages over the conventional ring: (1) minimal astigmatic induction, (2) corneal flattening, and (3) implantation of a single segment. This study evaluated the clinical outcomes of implantation of the new ICRS, including corneal flattening and improved visual acuity.

PATIENTS AND METHODS

This retrospective review comprised records of consecutive patients who had implantation of a Ferrara ICRS with a 210-degree arc length. Statistical analysis included preoperative and postoperative uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), spherical equivalent (SE), and keratometry (K). Corneal topography and pachymetry were obtained using software included with the Pentacam rotating Scheimpflug camera (Oculus).

All surgeries were performed by the same surgeon (P.F.) using a previously described standard technique. The only difference in the technique was the placement of 1 tip of the ring approximately 15 degrees from the steepest meridian; in the conventional technique, when 2 ring segments are implanted, the steepest meridian is located where the incision is created. For ICRS implantation, the incision was frequently created at the 90-degree meridian. The segment thickness was based on the desired corneal flattening based on corneal topography (Table 1).

After surgery, ketorolac drops were used every 15 minutes for 3 hours. Subsequently, dexamethasone 0.1%-moxifloxacin 0.3% drops were used every 4 hours for 7 days and hypromellose, every 6 hours for 30 days.

Statistical analysis was performed using the Minitab software (Minitab Inc.). The Student t test for paired data was used to compare preoperative and postoperative data. The Pearson test was used to assess the correlation between ICRS thickness and corneal flattening (preoperative and postoperative K values).

RESULTS

The records of 76 patients (80 eyes) were reviewed. The main indication for ICRS implantation was keratoconus (Table 2). Table 2 shows the thickness of the implanted ICRS.

No intraoperative or postoperative complications occurred. The mean follow-up was 6.65 months ± 7.73 (SD) (range 1 to 36 months). Two patients required subsequent PKP due to progressive corneal scarring and worsening visual acuity despite ICRS implantation. Scheimpflug imaging showed that the ICRS was in a proper position related to the cornea in all cases (Figure 2).

The mean UDVA increased from 20/350 preoperatively to 20/136 postoperatively (P = .001) and the mean CDVA, from 20/125 to 20/55 (P = .0001). The mean SE decreased from −5.22 D preoperatively to −2.26 D postoperatively (P = .050).

The mean K1 value decreased from 51.49 D preoperatively to 47.40 D postoperatively (P = .00014) and the mean K2 value, from 54.33 D to 49.14 D (P = .00022). The mean keratometric astigmatism decreased from 3.65 D preoperatively to 2.69 D postoperatively (P = .0001) (Figure 3).

A positive correlation was found between ring thickness and the change in K values; that is, the thicker the ring, the greater the flattening effect on the cornea (Figure 4). The Pearson correlation value was 0.90 for the 150 μm ring, 0.97 for the 200 μm ring, 0.43 for the 250 μm ring, and 0.26 for the 300 μm ring.

DISCUSSION

This is the first study to report the clinical results of the new Ferrara ICRS, which has a 210-degree arc length and is especially useful in eyes with the nipple-type of keratoconus. Implantation of the new ICRS was efficacious in correcting keratoconus in our study. Postoperatively, there was a significant decrease in the K and SE values and improved UDVA and CDVA. By restoring a more prolate shape to the primary ectatic eye, the ICRS likely improves the optics of the keratoconic

<table>
<thead>
<tr>
<th>Desired Flattening (D)</th>
<th>Segment Thickness (μm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 2.00</td>
<td>150</td>
</tr>
<tr>
<td>2.25 to 4.00</td>
<td>200</td>
</tr>
<tr>
<td>4.25 to 6.00</td>
<td>250</td>
</tr>
<tr>
<td>&gt; 6.25</td>
<td>300</td>
</tr>
</tbody>
</table>
Table 2. Segment thickness implanted and indications for implantation.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Number of Eyes</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICRS thickness (μm)</td>
<td></td>
</tr>
<tr>
<td>150</td>
<td>21</td>
</tr>
<tr>
<td>200</td>
<td>22</td>
</tr>
<tr>
<td>250</td>
<td>26</td>
</tr>
<tr>
<td>300</td>
<td>11</td>
</tr>
<tr>
<td>Indication</td>
<td></td>
</tr>
<tr>
<td>Keratoconus</td>
<td></td>
</tr>
<tr>
<td>Stage I</td>
<td>14</td>
</tr>
<tr>
<td>Stage II</td>
<td>30</td>
</tr>
<tr>
<td>Stage III</td>
<td>19</td>
</tr>
<tr>
<td>Stage IV</td>
<td>12</td>
</tr>
<tr>
<td>Post-LASIK ectasia</td>
<td>3</td>
</tr>
</tbody>
</table>

ICRS = intrastromal corneal ring segment; LASIK = laser in situ keratomileusis

An eye, although higher-order aberrations were not evaluated in this study.

Astigmatic induction is minimal with any implanted segment with an arc length greater than 180 degrees. This is valuable in keratoconic corneas, in which the preoperative astigmatism is low and the intent is not to change the astigmatism or to change it minimally. This is usually true in cases with a nipple or central cone, which are the best indications for implantation of the ICRS with a 210-degree arc. The mean keratometric astigmatism decreased from 3.65 D preoperatively to 2.69 D postoperatively \((P = .0001)\). Although there was a statistically significant decrease in keratometric astigmatism after surgery, reduction was not large in a clinical sense. Corneal flattening is achieved by the same mechanism as by the standard ICRS with 160 degrees of arc; that is, it follows Barraquer’s postulate that central corneal flattening is achieved by adding tissue to the corneal periphery.16 Barraquer’s postulate was confirmed by the clear

Figure 2. Corneal tomography showing the exact location of the ICRS in the cornea.

Figure 3. Corneal tomography. A: Preoperative. B: Postoperative.
correlation between ring thickness and the amount of corneal flattening, as shown by the change in the mean K values from preoperatively to postoperatively. The thicker the ring, the greater the flattening effect. The Pearson coefficient was positive for all ICRS thicknesses; however, the values decreased as ring thickness increased, which could reflect less predictability of the amount of corneal flattening of the thicker ring.

Kwitko and Severo found that eyes with central keratoconus had significantly better results after symmetrical Ferrara ICRS implantation. These patients would have probably had a better result with the new ICRS with 210 degrees of arc, which was not available when their study was published. Implantation of a single segment is advantageous because it causes less corneal trauma and has a lower risk for infection, segment extrusion, and halos in the postoperative period. As a reversible procedure, the less tissue added, the less tissue would have to be subtracted from the cornea should that be necessary.

The technique for ICRS implantation is easy and reproducible. Attention must be paid to the depth of the corneal incision (80% of total corneal thickness), location of the incision (90-degree axis), ring centration based on central corneal reflex, and proper positioning of the tips of the ring according to the steepest meridian. The absence of preoperative and postoperative complications in our study was probably due to the surgeon’s extensive experience; once mastered, the technique is safe and efficient.

The Scheimpflug device used in our study images the anterior segment of the eye by rotating a camera. This rotating process supplies pictures in 3 dimensions. The tomography calculates a virtual model of the anterior segment of the eye. It is possible to move, zoom, and rotate it to show the exact position of the ring in relation to the ectatic area. This is useful for confirming proper placement of the ICRS. In some cases in which the procedure appears to have been successful, the visual acuity and keratometry do not improve, despite good positioning of the ring at the slitlamp. In these cases, tomography can show the implanted ring to be incorrectly positioned and can guide its repositioning.

In summary, the new Ferrara ICRS with an arc length of 210 degrees effectively treated and improved visual acuity in patients with selected types of keratoconus. It has the same advantages as conventional ICRS; that is, it is reversible, adjustable, and safe and is implanted under topical anesthesia, which helps avoid or postpone PKP. Further studies with more patients and a longer follow-up are warranted to confirm the results in this study.

REFERENCES