Ferrara intrastromal corneal rings for the correction of keratoconus

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Purpose: To evaluate the safety and efficacy of Ferrara intrastromal corneal rings in the treatment of eyes with keratoconus without central corneal scarring.

Setting: Vlemma Eye Institute, Athens, Greece.

Methods: Twenty-six patients with bilateral keratoconus, clear central corneas, and contact lens intolerance participated in the study. Videokeratographic corneal topography and ultrasonic pachymetry were performed in all eyes to identify the cone area and to select the thickness of the segments to be implanted, respectively. Ferrara intrastromal corneal rings were implanted around the center of the cone in 1 eye of each patient.

Results: The minimum follow-up after ring implantation was 6 months. In 2 cases, the rings had to be removed early in the postoperative period because of superficial implantation in 1 patient and asymmetrical placement in the other. The rest of the operated eyes demonstrated a reduction in astigmatism and spherical correction and improved uncorrected visual acuity. No eye lost best corrected visual acuity.

Conclusions: Ferrara intrastromal corneal rings reduced corneal steepening and normalized the central cornea in eyes with keratoconus. Ferrara ring implantation was a safe procedure that may be considered in patients who are unable to have other surgical techniques, particularly contact-lens-intolerant keratoconus patients whose only option is corneal transplantation.

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Keratoconus is a progressive, noninflammatory, and almost always bilateral disorder characterized by corneal ectasia, most typically inferior to the center of the cornea, with eventual corneal thinning, induced myopia, and regular and irregular astigmatism.[1,2] Its incidence is approximately 1 per 2000 in the general population. Rabinowitz[1] suggests that the diagnosis of keratoconus can be made on the basis of keratometry greater than 47.20 diopters (D), steepening of the inferior cornea of more than 1.20 D compared to the superior cornea, and skewing of the radial axis of astigmatism by more than 21 degrees. However, study of the anterior corneal topography with modern corneal topography allows the detection of even earlier, subclinical forms of the disease.

Keratoconus is considered a visually disabling disease and warrants disease management. In the early stages, spectacles and contact lenses are the usual treatment choices. Even in the early stages, however, the extreme dependence on optical correction for any kind of normal functioning is a daily concern for the keratoconus patients and has been shown to have an adverse affect on the quality of their personal and social life.[3,4] In more advanced cases of keratoconus, such as those with corneal scarring, most corneal surgeons agree that penetrating keratoplasty (PKP) is a viable treatment option.

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However, Kirkness and coauthors[5] report that even though apical scarring is a common indication for PKP, contact lens intolerance is the most common principal indication to have a transplant.[5] Various studies show that the results of PKP for keratoconus are positive, but the immediate operative risks and expenses as well as the need for life-long follow-up make the surgeon and patient reluctant to use PKP in this young and active population.[6,7]

Various other surgical options have been suggested for the treatment of keratoconus patients who are contact lens intolerant; eg, radial keratotomy (RK), asymmetric keratotomy, photorefractive keratectomy (PRK), phototherapeutic keratectomy, and laser in situ keratomileusis (LASIK). However, despite improvement in the postoperative spherical equivalent and uncorrected visual acuity (UCVA) in some cases, the risk of loss of best corrected visual acuity (BCVA), postoperative worsening of corneal ectasia and astigmatism, and even the need to perform PKP in other cases have led most investigators not to consider these as a primary solution for keratoconus or other corneal thinning disorders.[8,9]

Finally, epikeratoplasty is an example of a cornea-reinforcing procedure that can result in long-term reduction of astigmatism and improve both UCVA and BCVA in keratoconic eyes. Its major disadvantages are the relatively long healing and stabilization periods and the inferior quality of vision compared to PKP.[10–12]

Recently, the use of intracorneal rings (Intacs) has also been suggested for the correction of keratoconus.[13] Implantation of these rings in 10 keratoconic eyes resulted in significant reduction of astigmatism over a 10-month period. In our study, we evaluated the efficacy of another alternative to PKP in contact-lens-intolerant keratoconus patients without corneal scarring. The effect of Ferrara intrastromal corneal rings on the amount of astigmatism, the spherical equivalent, and the UCVA and BCVA were analyzed based on the preliminary results in the first 26 operated eyes.

Patients and Methods

Twenty-six patients with keratoconus referred to our practice for possible PKP participated in the study. The participants had keratoconic eyes with clear central corneas, low quality of vision, and corneal thickness of more than 400 μm around the cone area; they were contact lens intolerant. All patients signed an informed consent form and agreed to return for scheduled follow-up examinations for 24 months.

The preoperative and postoperative evaluations included UCVA, best spectacle-corrected visual acuity (BSCVA), slitlamp examination, manifest refraction, cycloplegic refraction, and videokeratographic corneal topography (Haag-Streit model CTK 922). The Ferrara intrastromal corneal rings are made of poly(methyl methacrylate) (PMMA); they have an external diameter of 6.2 mm, a triangular section, and a 600 μm base. In each eye, 2 160-degree segments were used. The segments are available in 5 thicknesses: 150 μm, 200 μm, 250 μm, 300 μm, and 350 μm. Selection of the appropriate ring was based on the refractive error in each eye: 150 μm rings were used in eyes with less than −4.00 D of myopia; 200 μm rings, with −4.25 to −6.00 D; 250 μm rings, with −6.25 to −8.00 D; 300 μm rings, with −8.25 to −10.00 D; and 350 μm rings, with more than −10.00 D.

The entire procedure was performed under topical anesthesia (proparacaine hydrochloride 0.5% [Alcaine®]). A circular Ferrara marker centered on the reflex of the microscope light on the cone area was used to create 2 concentric circles on the cornea. The difference in the radii of the 2 circles was equal to the width of the Ferrara rings, and therefore the area between them corresponded to the desired position of the rings' insertion channels. The corneal thickness at 6 sequential points of this area was measured with an ultrasonic pachymeter (Corneal Gage Plus, Sonogage).

Using a diamond knife set to 80% of the minimum corneal thickness, 2 radial corneal incisions were created antidiametrically between the 2 marked circles at the periphery of the cone and on its steep axis. A corneal spreader was then used to facilitate insertion of the double metallic arcuate guide (Ferrara spatula), which carefully elevated the cornea and simultaneously dissected 2 intrastromal channels around the cone area. No vacuum was used to create the channels.

The 2 PMMA segments were implanted around the center of the cone in the clockwise and counterclockwise tunnels (Figure 1). The stromal edges of the wound were approximated, and the wounds were closed using hydration. A therapeutic soft contact lens was applied to the eye for 48 hours.

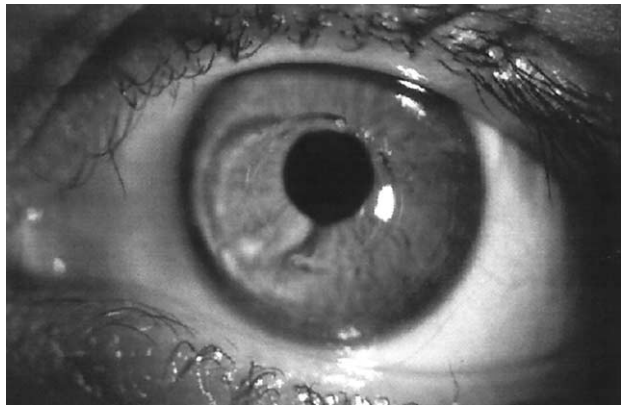

Figure 1. (Siganos) Slitlamp photograph of a keratoconic eye after implantation of Ferrara rings.

All patients were examined 1 day and 1 and 6 months after the procedure. Postoperative medications included a topical antibiotic–steroid combination (tobramycin 0.3% and dexamethasone 0.1% [TobraDex®]) 4 times a day for 2 weeks and artificial tears (Oculotect®) 4 times a day for 2 weeks.

Results

Eighteen men and 8 women participated in the study. The mean age was 29.6 years ± 9.61 (SD). The minimum follow-up was 6 months. Although placement of the rings was uneventful in all eyes, the rings had to be removed early in the postoperative period in 2 eyes. In 1 patient, this was secondary to superficial implantation of the rings at a depth of less than 60% of the minimum corneal thickness. The rings were removed to prevent them from extruding through the thin overlying cornea. In the other patient, the rings were removed because they had been placed asymmetrically in relation to the cone center. In both eyes, the UCVA and BSCVA returned to the preoperative values a few weeks later.

Table 1. Preoperative and postoperative refractive data.

	Preoperative				1 Month Postoperative				6 Months Postoperative			
Patient	Sphere	Cylinder	Axis	SE	Sphere	Cylinder	Axis	SE	Sphere	Cylinder	Axis	SE
1	−5.5	−1.0	135	−6.0	−1.25	−1.5	120	−2.0	0	−0.5	100	−0.25
2*	0	−2.5	105	−1.25	0	−3.0	100	−1.5	0	−2.5	90	−1.25
3*	0.5	−2.5	90	−0.75	0.5	−3.0	75	−1.0	0	−2.5	85	−1.25
4	−2.5	−2.5	170	−3.75	−0.75	−1.25	50	−1.375	0.5	−0.75	70	0.125
5	−8.0	−3.5	145	−9.75	−1.75	−3.5	105	−3.5	−1.5	−2.5	95	−2.75
6	−10.0	−6.0	150	−13.0	−5.75	−4.25	180	−7.875	−5.0	−2.75	180	−6.375
7	−9.0	−7.5	30	−12.75	−4.25	−1.5	180	−5.0	−3.75	−0.75	180	−4.125
8	−3.0	−4.0	135	−5.0	−1.5	−0.75	100	−1.875	−1.0	−2.0	95	−2.0
9	2.5	−6.5	90	−0.75	2.25	−2.0	75	1.25	1.0	−3.25	85	−0.625
10	0	−6.5	180	−3.25	2.0	−4.25	35	−0.125	3.25	−3.0	35	1.75
11	0.5	−2.0	65	−0.5	1.0	−1.5	25	0.25	1.5	−2.0	35	0.5
12	−1.0	−7.5	60	−4.75	0.5	−5.25	70	−2.125	0	−2.0	70	−1.0
13	−8.5	−7.5	180	−12.25	−2.75	3.75	90	−4.625	−1.0	−2.75	80	−2.375
14	−9.0	−2.0	145	−10.0	−1.75	−2.5	90	−3.0	0	−2.0	60	−1.0
15	−11.0	−2.5	100	−12.25	−3.25	−0.75	90	−3.625	−0.5	−0.25	75	−0.625
16	−4.75	−3.0	80	−6.25	−1.25	−1.25	35	−1.875	0	−1.0	45	−0.5
17	−12.0	−7.50	90	−15.75	−2.0	−5.25	60	−4.625	−0.5	−2.0	70	−1.5
18	−1.0	−3.5	25	−2.75	1.75	−3.5	80	0	2.75	−2.5	90	1.5
19	1.0	−7.0	140	−2.5	1.0	−5.0	35	−1.5	0	−3.5	50	−1.75
20	0	−6.5	105	−3.25	0.5	−6.0	90	−2.5	3.5	−2.5	85	2.25
21	1.0	−7.0	90	−2.5	3.0	−5.0	180	0.5	5.0	−3.0	160	3.5
22	−6.0	−6.5	100	−9.25	−2.75	−4.0	180	−4.75	0	−2.5	180	−1.25
23	−15.0	−2.5	70	−16.25	−6.5	−4.5	90	−8.75	−4.0	−3.25	90	−5.625
24	−13.0	−2.5	25	−14.25	−6.0	−3.75	60	−7.875	−5.0	−4.5	50	−7.25
25	−8.5	−1.5	70	−9.25	−3.5	−2.25	50	−4.625	4.0	−2.5	40	2.75
26	0	−3.5	90	−1.75	0	−2.75	90	−1.375	0.5	−0.5	60	0.25
Mean	−4.70	−4.42	102.50	−6.91	−1.25	−3.15	89.81	−2.83	−0.01	−2.20	86.73	−1.11
SD	5.07	2.23	43.79	5.02	2.53	1.51	45.14	2.57	2.48	1.02	42.175	2.56

SE = spherical equivalent

*Rings removed early in the postoperative period

In the other 24 eyes, astigmatism and spherical correction were reduced (Table 1). The mean UCVA improved from 0.07 ± 0.08 preoperatively to 0.20 ± 0.13 and 0.30 ± 0.21 after 1 and 6 months, respectively. The mean BSCVA improved from 0.37 ± 0.25 preoperatively to 0.50 ± 0.43 and 0.60 ± 0.17 after 1 and 6 months, respectively. The spherical equivalent and astigmatism showed considerable improvement at 1 month and continued to improve over the 6-month follow-up. The corneal ectasia and normalization of the central cornea was dramatic, as seen in the topographic images in Figure 2. No patient complained of nighttime glare or halos after the first month.

Discussion

Our preliminary results showed that implantation of Ferrara intracorneal rings in keratoconic eyes can result in a significant increase in topographical regularity and UCVA. The Ferrara rings appear to work by flattening the central and peripheral cornea, shortening the anterior chamber depth, and displacing the corneal apex closer to its physiological position in front of the pupil by reducing the paracentral ectasia commonly seen in keratoconic corneas. Although the effect and mechanisms by which intracorneal rings can flatten the cornea in eyes with low myopia is well documented and thought to be secondary to an arc-shortening effect of the corneal lamellae,[14–16] the structural changes responsible for the effect of the Ferrara intrastromal rings on the keratoconic eye topography are not known.

Our procedure offers 2 innovations compared to implantation of Intacs. First, the Ferrara rings are implanted around the center of the keratoconus and not around the center of the cornea and pupil. Second, the prismatic effect resulting from their shape could reduce glare associated with the use of Intacs for myopia in some patients (Figure 3).

The Ferrara rings also offer advantages over ablative or incisional procedures. The potential benefits include preservation of all stromal layers, possible elimination of wound healing as a determinant of surgical outcome, and relatively rapid visual improvement. In addition, Ferrara ring implantation preserves an intact globe, which is important in an active population such as young keratoconic patients, and the procedure is potentially reversible. It is also well known that keratoconic corneal tissue is thinner than normal tissue.[1] By using the Ferrara rings, one can avoid the decrease in mechanical strength induced by procedures such as RK, PRK, and LASIK.[8,9]

The superficial implantation and asymmetric placement of the segments that occurred in our patients are 2 possible complications associated with implantation of the Ferrara rings. Other possible intraoperative and postoperative complications are irregular astigmatism from decentration of the segments, epithelial ingrowth, infection immediately postoperatively or later due to contact lens wear, extrusion due to superficial implantation or eye rubbing, and migration of the segments due to eye rubbing or trauma.

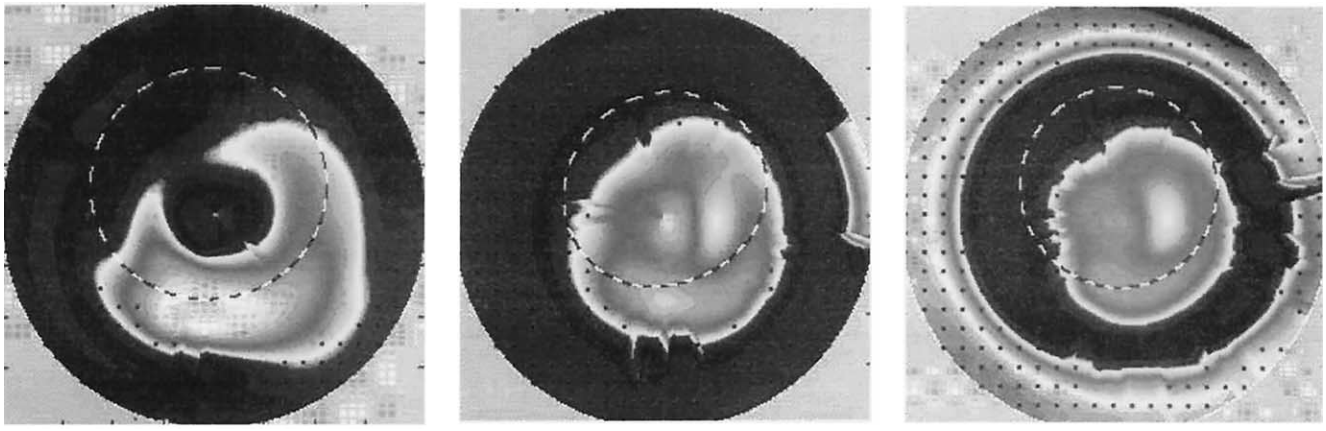

Figure 2. (Siganos) Corneal topography of a keratoconic eye before implantation (*left*) and 1 month (*middle*) and 6 months (*right*) after implantation of Ferrara rings. Preoperatively, the corneal astigmatism was 6.5 D; the UCVA, CF; and the BSCVA, 20/60. At 1 month, the corneal astigmatism was 4.0 D; the UCVA, 20/2000; and the BSCVA, 20/40. At 6 months, the astigmatism was 2.5 D; the UCVA, 20/50; and the BSCVA, 20/25.

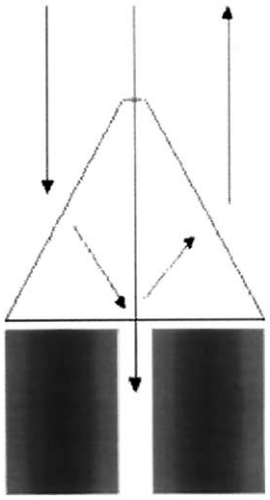

Figure 3. (Siganos) The prismatic effect of Ferrara rings.

For the past 100 years, refractive surgery has been used to improve the visual function in keratoconic eyes by modifying the corneal shape.[17] Although more patients and a longer follow-up are necessary to confirm the efficacy and stability of the effect of Ferrara intrastromal rings for the treatment of keratoconus, the rings could represent a safe procedure for contact-lens-intolerant keratoconus patients.

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