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ORIGINAL ARTICLE

Treatment of keratoconus with Ferrara ICRS and consideration of the efficacy of the Ferrara nomogram in a 5-year follow-up

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Purpose. *To investigate Ferrara intrastromal ring segments (FIRS) as a therapeutic opportunity to treat keratoconus (KC), to reduce the necessity for cornea transplant, and to improve quality of vision of patients with this disease. We demonstrate that the procedure is safe, reversible, and reliable, and can delay/stop the KC progression.*
Methods. *A total of 130 eyes of 83 patients with KC, intolerant to contact lenses, implanted with FIRS were considered. Average follow-up was 37 months with a minimum of 2 years and a maximum of 5 years. For all patients, manifest refraction, uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA) corneal map, Orbscan, and intraoperative pachymetry were performed and were compared to postoperative measurements.*
Results. *A total of 93.84% (122 patients) of the eyes gained lines of UCVA and only 1.53% (2 eyes) lost them. A total of 97.69% (127 patients) of the treated eyes gained lines of BCVA and no eyes lost them. The value of K1 and K2 were considerably reduced over 5 years. The preoperative value of K average of 49.27 D became 4.68 D postoperatively. Both the UCVA and the BCVA showed an increase. The UCVA changed from 0.14 lines preoperatively to 0.32 postoperatively while the BCVA changed from 0.40 to 0.59. The spherical equivalent changed from –8.34 D before the operation to –2.83 D after the operation.*
Conclusions. *FIRS make KC cornea more regular and the patients have increased corrected and uncorrected visual acuity postoperatively. The progression of KC was stopped and the cornea thickness minimally, but regularly, improved. (Eur J Ophthalmol 2010; 20: 865-73)*

Key Words. *Cornea, Ferrara rings, Surgery*

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INTRODUCTION

Keratoconus (KC) is a progressive corneal thinning and protrusion without evidence of inflammation. The disease probably starts in the first years of life, but is usually diagnosed during puberty and tends to have progression periods, alternating with periods of stability, until the adult age of 35–40 years, when it usually stabilizes. In more severe cases, however, it continues to progress.

Incidence of KC in the population varies from 50 to 230 cases for every 100,000 inhabitants, affecting both sexes, with a slight predominance in females (1). In our experience, we do not see any prevalence regarding sex, race, or eye. Genetic studies have improved substantially in recent years, but stronger scientific data to determine a specific gene are needed. However, KC seems to be autosomal dominant with low penetrance. Parents with KC may have a 15 to 67 times greater chance of passing this on to descen-

dants than in the normal population (2, 3).
KC is often associated with atopy and other allergic diseases (asthma, rhinitis, and seasonal conjunctivitis).
The topographic pattern reveals 3 basic forms of KC. The nipple is usually central or discreetly inferiorly nasal and the astigmatism is low, not exceeding 3 D. The oval or sag, which is more frequent and wider, is usually displaced temporally and inferiorly and presents a large degree of astigmatism. A combination of both nipple and sag (central and peripheral) occupies up to 75% of the cornea.
There are classifications that mix clinical, biomicroscopic, and keratometric characteristics, and are useful in clinical daily practice. We use the Amsler classification modified by Ferrara.
Fleming et al (4) proposed the first intrastromal ring segments, trying to change corneal curvature.
In the 1960s, fundamental studies were presented by Krwawicz (5), who observed persistent refractive alterations after insertion of corneal implants and their removal 10 days later. In 1969, Maurice (6) published a focal study where he attested that the portion of stroma anterior to the ring segment receives nutrients by diffusion and the nutrition is proportional to the diameter and depth of the implant. These observations permitted the development of the surgical technique on solid evidence and we understood that large diameter ring segments superficially implanted, at a depth <50% of corneal thickness, are inevitably extruded. The intrastromal corneal ring (ICR) implant was initially proposed to correct low to moderate myopia (7-9), but at present, the excimer laser technique offers a more simple, precise, flexible, and practical way to achieve the same result. In the case of KC, regularization of cornea curvature using the excimer laser is not advisable and reliable, because the reduction of tissue thickness causes a risk of increase of the disease. On the contrary, ICR preserves the original cornea structure and produces reduction of the irregularities caused by KC.
In 1991, Paulo Ferrara implanted the first Ferrara ring in an anisometropic and amblyopic eye. In 1994, in order to improve the ring implantation surgery and reduce complications, he developed the stromal tunnel technique using the Ferrara double spatula and, in 1996, he started to implant the rings in KC patients intolerant to contact lenses and waiting for corneal graft.
The corneal ring acts according to the postulates of Barraquer's thickness law. That is to say that the tissue addition on the periphery of the cornea results in its flattening and the ring diameter is proportionally inverse to this flattening intensity. Thus, the more tissue that is added (ring thickness), and the smaller the diameter, the higher the myopic correction (10). We can modify the shape of KC cornea surface by adding or removing tissue, but it is difficult to achieve predictable visual outcomes. According to Ferrara, the ophthalmologist who devised and developed this surgical technique, the main goal of the FIRS is orthopedic, and only orthorefractive as a consequent step (11).

PATIENTS AND METHODS

In this study, we considered only young patients with evolving KC, intolerant to contact lenses, who play sports avidly or who work in professions in which they experienced difficulty in carrying out their work functions. All the surgical procedures included in this study were performed with the same freehand tunnel surgical technique by the same surgeon (P.M.P.). Exclusion criteria were marginal pellucid degeneration, very advanced KC, curvature over 75 D, significant apical opacity, ectasia post–laser-assisted in situ keratomileusis, and post–penetrating keratoplasty high astigmatism.
A total of 130 eyes to be implanted in 83 patients (37 male and 46 female, average age 28.1±8 years) were considered. The average follow-up was 37.4±9 months (minimum 2, maximum 5 years), as follows: 17 eyes, 2 years; 33 eyes, 3 years; 37 eyes, 4 years; 43 eyes, 5 years. According to Ferrara's classification, 19 eyes had KC stage I, 54 eyes KC stage II, 41 eyes KC stage III, and 16 eyes KC stage IV.
All the rings implanted shared the following characteristics: made of PMMA CQ acrylic, 160° arc length, triangular transverse section base 600 µm, one hole on each extremity, ring thickness from 0.15 to 0.35 mm, 5.0 mm optical zone, with internal and external diameters respectively of 4.4 and 5.4 mm (Fig. 1). The first 26 procedures were executed with 2 radial corneal incisions separated at 180°, using a double Ferrara spatula to perform tunelization. All the other procedures were executed with only 1 radial incision and 1 single Ferrara spatula. Preoperatively, for all patients, after an exhaustive familial and pathologic anamnesis, slit-lamp examination, manifest refraction, uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA) (with eyeglasses because of total contact lenses intolerance), tonometry, endothelial microscopy, videokeratography, optical tomography Orbscan II™, and motility examination were performed. In order to confirm the correct depth of the im-

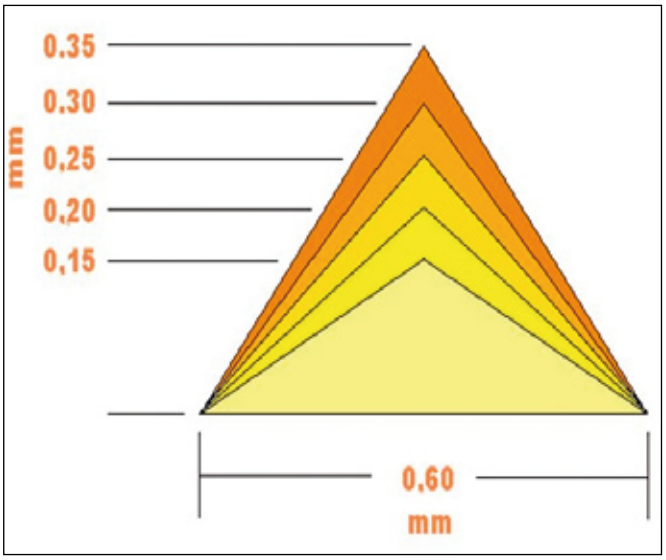

Fig. 1 - *The segment thicknesses vary from 0.15 to 0.35 mm.*

plant, ultrasonic pachymetry was always measured intraoperatively. Pachymetry is also important for the diagnosis, in measuring corneal thinning as well as evaluating its progression. When combined with topography, the increase of the inferior curvature and progressive thinning is the most sensitive method for diagnosis and patient follow-up (2). Regarding pachymetry, we emphasize that corneas presenting central thickness inferior to 500 µm should always be examined more carefully and fruste KC must be excluded, particularly in patients who want to have excimer laser refractive surgery.

When a patient was determined to be eligible for an ICR implant, the surgeon conducted a personal informed consent discussion, always in the presence of an assistant. The surgeon closely examined the risk/benefit ratio, emphasizing the realistic expectations, considering all possible and probable complications following surgical Bioptics (9) procedures to obtain the best possible final visual acuity.

Three days before surgery, we advise the patient to start an antimicrobial prophylaxis with fluoroquinolone antibiotic eyedrops, 2 times daily. This is continued on the day of surgery. In a quiet environment, to put the patient at ease, we give a comprehensive explanation about what to expect during the implant procedure. As we do not use any device to fix the eye, we ask the patient to cooperate by following the microscope light, in order to counteract the force we apply during tunelization, so as to keep the eye steady. We always use topical anesthesia, preferably with 4% lidocaine, but also with 0.4% benoxinate. A drop is instilled initially at the time of preparation, with 2% pilocarpine to obtain miosis. This is repeated 2 more times before surgery, to decrease the risk of toxicity for the corneal epithelium. If necessary, 1 hour before surgery we give the patient 5–10 mg of diazepam to be taken orally. The periocular skin, brow, and cheek are cleaned and disinfected with povidone iodine solution 10%. Lid margins and eyelashes are cleaned with Merocel™ sponges soaked with PVP-I 5% solution. Finally, with particular care, we wash the conjunctival cul-de-sac, instilling PVP-I 5% solution for at least 5 minutes. Draping is carefully performed to capture cilia and lid margins. During surgery, we use talc-free gloves to prevent extraneous materials from getting into the corneal tunnels and provoking inflammatory infiltrates.

Most procedures were performed using a wire lid speculum (Kratz-Barraquer type), Kremer forceps, Sinskey hook 0.20 mm, optical zone circular markers 5.0 mm, 7.0 mm, a radial incision marker, a diamond micrometer with a Ferrara blade, a Suarez spreader, and Ferrara spatulas, which were double in the first cases and then single. The Ferrara procedure must be centered on the visual axis. The surgeon asked the patient to stare at the microscope lamp bulb filament and, using the Sinskey hook, marked the bright corneal reflex on the patient cornea, independent of the pupil. The procedure must be done with a slightly moist cornea. The ring should be positioned at the cone base, wherever it may be, considering that very often the KC apex is displaced inferiorly. Then, we proceeded by delineating the 5.0 mm optical zone with violet gentian staining and marked the steepest corneal axis. We used a sterile pen (ethylene oxide) for each patient, applying minimal ink to avoid toxicity to the corneal epithelium. The radial incision must be done with the blade calibrated at 80% of the corneal thickness at the incision site. In order to improve accuracy, we performed intraoperative ultrasonic pachymetry before the incision. Then, with the Suarez spreader, we prepared the pocket-like structure, where the Ferrara double or single spatula was inserted to form the tunnels. The spreader blade must be parallel to the cornea plane, to avoid perforation or transverse implant, and must advance in the stroma with “snake-like movements,” without meeting too much resistance. If the surgeon meets great difficulty in proceeding in the cornea, it is to be suspected that the spreader is too superficial. The segments must be placed symmetrically inside the tunnels so as to be separated by the steepest meridian and easily manipulated du-

ring surgery by the positioning holes located at both ends. The tips of the ring must be pushed far from the incision to avoid extrusion risk. The postoperative therapeutic regimen consisted of applying 1 drop of sodium diclofenac 0.1% every 15 minutes in the first 3 hours postoperatively and 1 drop of lubricating artificial tears every hour in the first postoperative day and 5 times a day for 1 week following 1 drop of antibiotic-steroid association solution 5 times a day for 1 week.

The follow-up schedule was as follows: in the first hour after surgery, we performed an examination with the slit lamp to control the position of the implant, which should have been deep and far from the incision, and to control if in the area around the wound epithelial defects were present and, if necessary, to place a contact lenses bandage; at week 1, measurement of UCVA, manifest refraction, BCVA, and slit lamp examination; at 1 month, the same examinations of the first week postoperatively plus corneal topography, Orbscan II™, Pentacam™, ocular tension measurement, and endothelioscopy; and at 3, 6, and 12 months, the same examinations that were performed at 1 month.

RESULTS

K1 and K2 were considerably reduced over 5 years (Figs. 2 and 3). The K average changed from 49.27 D preoperatively to 45.68 D postoperatively (Fig. 4).

Both UCVA and BCVA showed an increase. The UCVA changed from 0.14 lines preoperatively to 0.32 postoperatively, while BCVA changed from 0.40 to 0.59 (Fig. 5).

A total of 93.84% (122 eyes) of the eyes gained lines of UCVA and only 1.53% (2 eyes) lost them. A total of 97.69% (127) of the treated eyes gained lines of BCVA; no eyes lost them.

Spherical equivalent changed from –8.34 D preoperatively to –2.83 D postoperatively (Fig. 6).

Pachymetry changed from 465 µm preoperatively to a minimum of 434 µm 1 year after the operation, and then rose to 458 um 5 years after the operation (Fig. 7).

The follow-up (about 5 years) is not long enough to ensure that ICRS is a definitive solution, but the cases considered did not manifest further degeneration.

Analysis of pachymetry before and after surgery showed that 80% of the implanted patients increased their corneal thickness centrally at the apex of the cornea, far from the ring. This explains why these corneas kept steady after surgery. Experimental studies in chicken eyes, presented at ARVO last year, reveal that there is a migration of stem cells from the periphery to the center of the cornea after ring implantation.

Central and peripheral flattening of the cornea preserves its physiologic asphericity and normalization of the corneal surface. This occurs through a tilting movement brought about due to the flatness of the ring's base, which makes the cornea flatten over areas corresponding to the segment ends and curves the cornea above the segment body.

The stabilization of KC evolution with intracorneal ring segments can diminish the apex opacity, as we observed in a young woman with degree IV KC. The patient was on a waiting list for a corneal transplant, but wanted to undergo FIRS implant to avoid the transplant. In one eye, an initial opacification was present at the corneal apex and at 3 months postoperatively the cornea

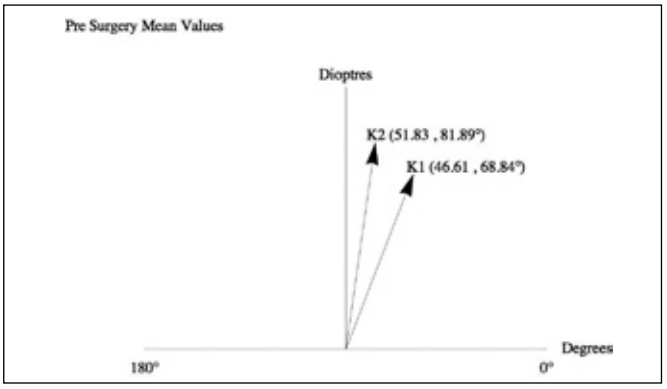

Fig. 2 - *Vector analysis of the keratometric values, pre-surgery mean values.*

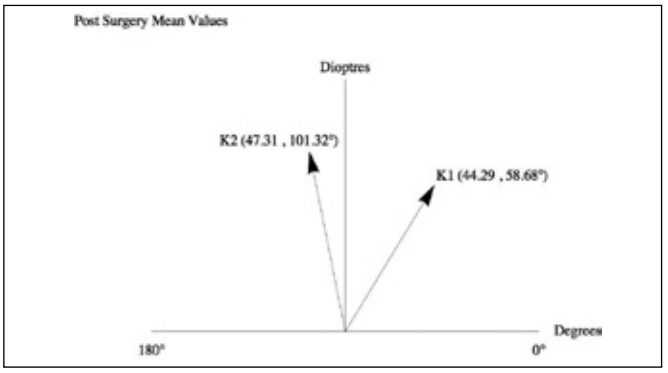

Fig. 3 - *Vector analysis of the keratometric values shows a considerable reduction of astigmatism.*

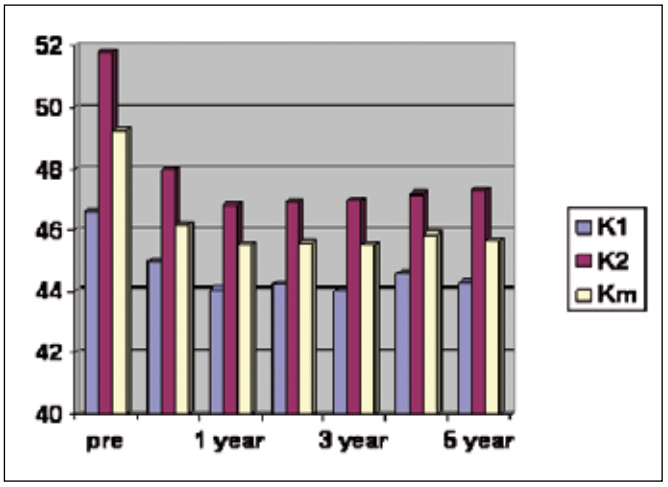

Fig. 4 - *K average: K1 and K2 are considerably reduced over 5 years.*

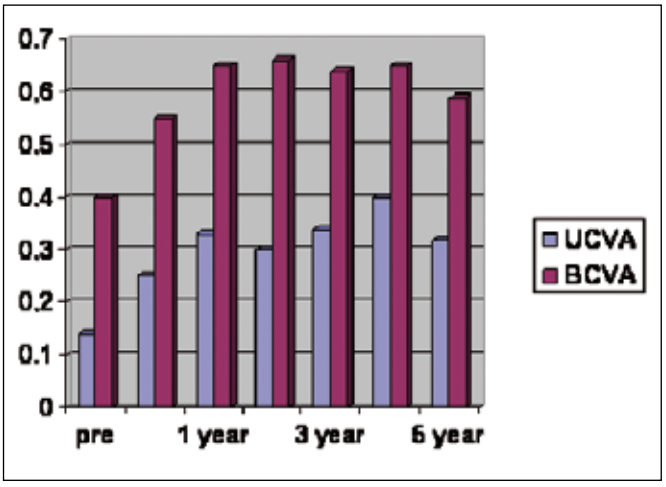

Fig. 5 - *Uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA) results are increased*

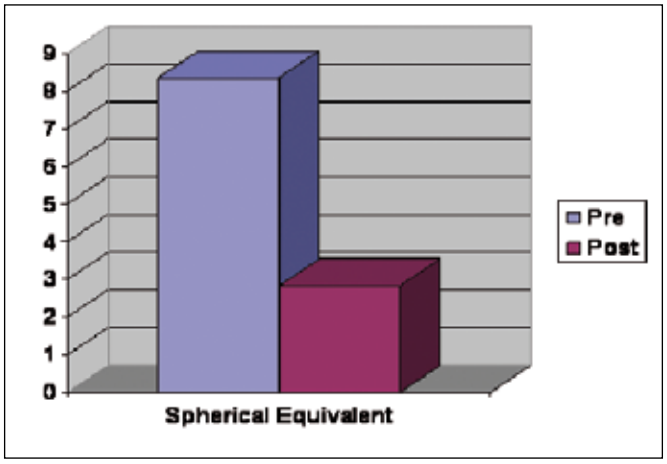

Fig. 6 - *Spherical equivalent results.*

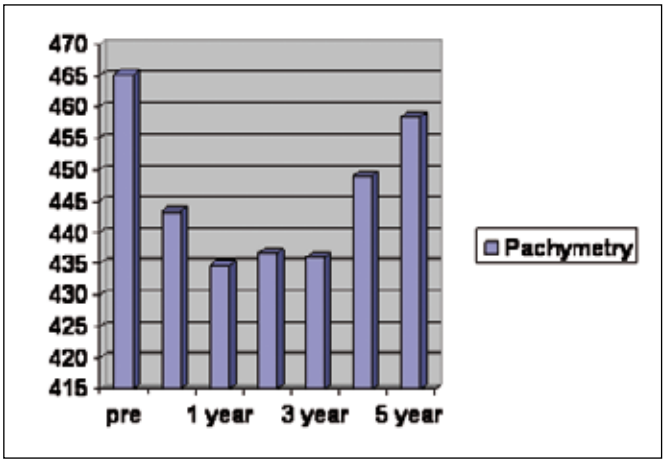

Fig. 7 - *Pachymetry results.*

appeared clear again.

We also observed a reduction of symptoms such as itching, photophobia, and ocular discomfort in FIRS KC patients.

Postoperative complaints and complications

Almost all patients complained of a foreign body sensation and a tear-filled eye for 12–24 hours, prolonged mild photophobia for a few weeks, and halos and glare that improved over some months. Two patients with small epithelial defects around the wound healed completely within 24 hours. One large epithelial defect was managed with a contact lens bandage and healed within 48 hours. In the opening phase of this study, 2 very shallow ring segments extruded. The first, 3 months postoperatively, extruded overnight with acute pain in a 35-year-old man. The day after the patient came to the clinic, melt of the stroma and a corneal abscess was found. The patient was hospitalized, the segment removed, and a completely surgical cleansing of the abscess was performed. The other segment was left in place and a strong local and systemic antibiotic therapy was started. Local re-epithelial medication, together with high doses of oral vitamin A, was also associated to the therapy. After 6 months, the situation stabilized, visual acuity improved, and the patients maintained good visual acu-

ity, with modest astigmatic spectacle correction. It should be noted that this situation could have been avoided if the segment, noted as being positioned too superficially, had been quickly explanted, considering that extrusion is a frequent possibility in this condition. The second case, in a 23-year-old student, we could define as almost an extrusion. This was because a few days after the implant of 2 segments, one of which was clearly too superficial, the patient complained of corneal pain and a sense of a foreign body. During a follow-up visit, we had confirmation from a slit-lamp examination that a segment was too superficial and that there was the onset of an epithelial alteration in correspondence to the proximal extremity of the same segment. We proceeded to export it directly at the slit lamp, after having made a small incision in correspondence to the point of placement. Even in this case, in the following months, when corneal healing was complete, the patient maintained an optimal BCVA with only one segment.

When we need to explant an intrastromal ring segment, the right strategy should be to reimplant the segment in a newly dissected stromal tunnel at the proper depth after a few months, when the healing has been completed. Some broken tips of the ring were present in 3 cases without any consequences. Four asymmetric implants were seen and were considered responsible for not having gained BCVA lines in 3 cases. During some surgical procedures, we had an occasional perforation in the second ring segment implant and the day after, in a routine control at the slit lamp, we found the distal part of the segment in the anterior chamber. No inflammation was present and the patient did not complain of pain. The ring was removed a few hours later and replaced after 3 months. We caused one undesired perforation at the cut point on the steepest meridian. The cause was an inaccurate intraoperative thickness measurement (ultrasound pachymetry). We put a Nylon 10/0 short stitch in and, a few minutes later, we moved the new cut a few degrees clockwise far away from the perforation.

One patient complained of monocular diplopia about 1 month after a 2-ring segment implant in a case of progressive KC, degree II. We decided to remove the superior ring and the symptoms disappeared, leaving 4 diopters of stable myopia that, 6 months later, were corrected with a bioptics procedure by implanting a posterior chamber phakic intraocular lens (BIOPTIC procedure).

In a 34-year-old patient, visual acuity in the left eye worsened and consequently there was a reduction of postoperative compliance and quality of life. The surgical strategy chosen, regarding a peripheral second stage cone, was that of an implant of 2 rings with different thicknesses. The patient had excellent visual results, with 0.9 uncorrected visual acuity. After approximately 2 years, at a checkup, the patient complained of monocular double vision, especially at night. After a careful examination, we decided to remove the superior segment, which was thinner and of minor orthopedic effect. The results confirmed our beliefs. The diplopia disappeared and visual acuity remained very good without correction and excellent with the help of a modest spectacle astigmatic correction.

In another patient, 27 years old, vision was worsening in both eyes, and the patient noted no improvement with optical correction. He was diagnosed with a peripheral bilateral cone, between the first and the second stages. Up until that moment, it had gone undetected, and the patient had always had good vision. The decline of vision was rapid and the symptoms were evolving. Given his profession as a fireman and a professional sportsman, correction with contact lenses was not possible and eyeglasses were unsatisfactory. After 6 months of observation, to correctly comprehend the evolution of the cone, we decided to proceed with Ferrara model intracorneal rings. After having implanted 2 segments per eye, the results were very good: UCVA was 0.8 per eye, BCVA –1.25 sphere. After 1 year, however, at a checkup, he said that compliance and visual performance at night, during work, and in certain sports competition situations was not sufficient enough for his needs. We evaluated the clinical situation, especially from a corneal point of view, and the stability of the pathology. Given the modest defect to be corrected, we did not find it opportune to turn to bioptics with a phakic intraocular lens. After having obtained a detailed patient consent, we introduced a photorefractive keratectomy strategy with a save tissue program of Chiron 217. After 3 years of follow-up, the pathology remains stable and UCVA is 0.1 in each eye.

NOMOGRAM CONSIDERATION AND DISCUSSION

Using the Ferrara rings implant technique contemplates the correction of corneal deformation. This technique is not only orthopedic. We consider the correct definition of this technique to be orthorefractive. The strategy is based on careful observation of the characteristics of the organ that we are going to treat and the segment we are going to implant. On the one hand, we consider the corneal pa-

rameters, a topographic map, pachymetry, diameter, and data of elevation, symmetry, and corneal sensibility. On the other hand, we have at our disposition technical data of segment: its thickness, diameter, dimension of the arch, and its form, which we know is triangular. The correct understanding of the mechanism of action of the segment permits us to anticipate the deformation that we will cause at the corneal level with respect to the preexisting form and therefore, on the basis of these observations, we develop the nomogram. The first step is to identify the type of cone that we are treating: central or peripheral. In the case of a central cone, we may find a bowtie type, where the astigmatism is symmetric and the keratometric values are elevated, or a nipple type, where amounts of astigmatism are modest and myopia prevails. In bowtie cones, astigmatism is symmetric and, therefore, we always implant 2 equal segments, the thickness of which will depend on the amount of astigmatism and the pachymeter map. In nipple cones, where astigmatism is modest, we must be careful not to cause an added astigmatism and, therefore, we tend to implant only one segment sufficient enough to lead to the necessary corneal flattening. A ring segment with an arch superior to 180° acts like a ring of 360°. Regarding the nipple cones, with a prevalence of myopic refractive defect and minimum astigmatism, Ferrara created a segment with a 210° arch, the choice of which will always depend on the refractive defect, the corneal map, and consequently to what extent we want to flatten the cornea.

The results obtained with this type of segment were not taken into consideration in the study. Peripheral cones have to be handled in a different way. Implanted asymmetric segments are necessary and, thus, it is necessary to evaluate the degree of asymmetry for the correct choice of the proper segment. The dislocation of the apex of the cone caused by the implant of segments may provoke the increase of associated myopia, because the anterior-posterior diameter of the treated eye is increased.

The pachymeter map is at the base of the choice of the thickness of the segment to be implanted in each case. The thickest segment must never exceed half of the value of the corneal thickness in the area where the path is created. This detail is necessary to obtain the most regular and homogeneous postoperative corneal profile possible to be able to adapt an eventual contact lens. The implant of a very thick ring, in relation to the corneal thickness, makes it difficult to adapt a contact lens.

The proper implant choice determines the proper correction and a regular surface favorable enough to permit excellent visual acuity in many cases, which is often surprising if compared to residual refractive data. Finally, the simulated keratometry supplies us with an astigmatism value to correct. It lets us define the number and the thickness of the segments that will be used and identifies the most curved meridian where the radial incision will be made.

More specifically, to determine the ring thickness to be adopted, the corneal maps were divided into 4 groups, based on the position of ectasia with respect to the steepest meridian. This meridian divides the ectasia into 2 parts in which the percentage of area was determined. The 4 groups represent different percentages of ectasia as divided by the meridian. Those considered were 0%/100%, 25%/75%, 33%/66%, and 50%/50%. The ring thickness was then determined by the Ferrara nomogram (Fig. 8: the first value is the ring closest to KC and the second is the ring farthest from KC, expressed in hundredths of mm) that also takes into account the preoperative spherical equivalent. Essentially, this nomogram increases the difference between the 2 ring thicknesses. As the KC is more asymmetric, the ring thickness increases as the spherical equivalent increases.

As little is known about the pathogenesis of KC from a theoretical point of view, the analyses of corneal tissue in vivo are not simple to perform (12-14) and the analyses in vitro are difficult to interpret because they do not guarantee the reproduction of the conditions that are actually present in vivo. We try to interpret, based on analysis of experimental data, the behavior of the cornea in the presence of a cone, after the implantation of intrastromal rings.

Our expectations were based on several considerations. In the elastic model (15), cornea behavior was analyzed by computer simulation.

Linear behavior means that stress (force) is proportional to strain (deformation). KC can be the consequence of lower tissue rigidity and the ICR effect depends on cornea rigidity distribution (11). Although the majority of studies confirm this hypothesis (13-15), some publications do not (12, 16), and recent studies question whether KC is formed by dilated tissue (17). The reasons for variation in rigidity could either be a modification of the elastic property of the chemical links of the tissue or a variation of the thickness (18, 19).

In the KC cornea, the implant action should be different than in a healthy cornea. This could be explained by rigidity decrease of tissue. Rigidity causes different behavior of the cornea after an ICR implant. In a healthy cornea, where the tissue is more rigid, the implant causes a great deal of

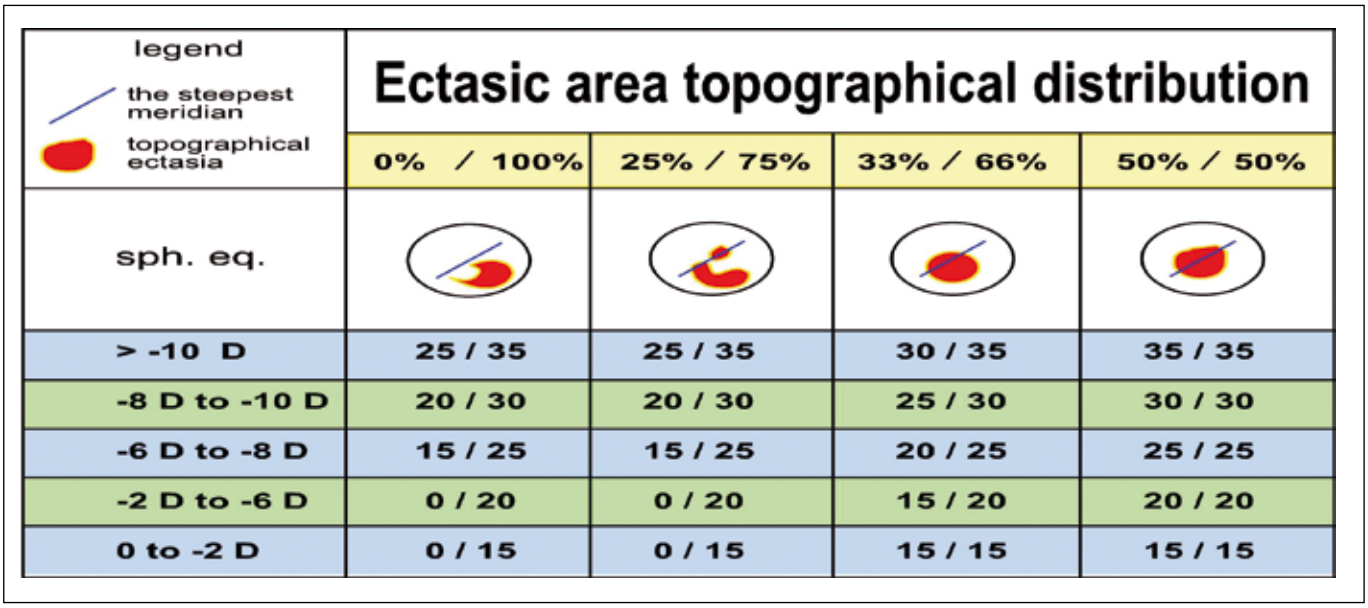

Fig. 8 - *Ferrara normogram: the first value is the ring closest to keratoconus (KC) and the second is the ring farthest from KC, expressed in hundredths of mm.*

flattening; on the contrary, the deformable tissue in a KC cornea stretches while it flattens, resulting in a lower flattening after implant. Analysis is difficult because the behavior is sensitive to small parameter variation and we do not have precise information on cornea elasticity. In this study, with our experimental data, we wanted to verify that the ring positioning criteria were reliable. We would also like to be able to conclude that the implant increases visual acuity, both uncorrected and corrected. Finally, we would like to see that progression of the corneal noninflammatory pathology is stopped or slowed, so that the corneal structure acquires a more regular aspect, reducing or annulling the KC pattern on corneal topography. In the majority of cases, corneal thickness increases not only by the effect of greater compacting of the corneal tissue, but also by the equally positive effect of being able to suspend the use of hard contact lenses, improving health and epithelial metabolism.

In this study, the analysis was based on 3 points: 1) preoperative and postoperative UCVA and BCVA; 2) the capacity of correctly implanted Ferrara rings to stabilize corneal pathology; 3) the confirmation from observation that the corneal thickness, in implanted corneas with a Ferrara ring, increased, even if modestly.

The results show a clear increase in visual acuity with a refraction defect reduction because the implant made the KC cornea more regular and shifted refraction towards emmetropia.Although the follow-up was not long enough to test if the degeneration process was stopped by ICR, the majority of the operated eyes manifested a stable situation and the central corneal thickness had a modest increase in the majority of the implanted eyes.

An analysis of the corneal maps showed that the effect of the ring was positive because the degree of flattening was greater in the ectatic region than elsewhere. This produced an effect of regularization of the cornea, which made it more spherical and regular. Preliminary computer simulations based on a linear elastic response of the cornea confirmed this.

With the positioning criteria presented in this article, the ring selectively flattens more curved meridians. Thus, the relationship between the positioning axis and the astigmatic flattening effect is still under investigation. It is also possible that the astigmatic flattening effect could be due to the elastic rearrangement of the cornea after the tension induced by the implant. This effect is regardless of the ICR position, even if a difference in response for different positioning criteria was already observed in some eyes operated on before this nomogram was adopted.

The implant results were homogeneous because the surgical technique used was the same and done properly after an appropriate learning curve.

CONCLUSIONS

The experimental refractive data are promising and in KC the implantation of intrastromal ring segments not only is considered a valid alternative to cornea transplant, but seems to have, in less serious cases, with evident tendencies to worsen, the ability to arrest or slow the evolving process of the pathology, improving the quality of vision with an increase in both UCVA and BCVA. A small but significant number of patients did not need eyeglasses after the implant. On the other hand, the principal aim of this therapy is not to achieve emmetropia, but to increase BCVA and, possibly, to stop the degeneration process. In this sense, it is possible that in the future the ring thickness will be determined by parameters different from the spherical equivalent. The earlier the surgery, the better the outcome. The implant is reversible and can be removed or changed in case of necessity.

We use intrastromal segments in ecstatic corneal disorders, biomechanics, and new material studies, but these preliminary results have demonstrated the efficacy of FIRS implant to treat KC. The percentage of cases with increased quality of vision is large and the procedure was found to be safe, reversible, and reliable. We need to verify if this surgical procedure can be a definitive solution. However, the analysis of the evolution of the corneas implanted gives important information on the behavior of this disease. It is necessary to determine whether the results are independent of surgeon training and performance of the same technique. This consideration is important and sends an encouraging message to surgeons who want to approach this therapeutic opportunity.

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