Clinical Outcomes After Complete Ring Implantation in Corneal Ectasia Using the Femtosecond Technology
A Pilot Study

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Purpose: To evaluate the clinical outcomes after implantation of the MyoRing (DIOPTEX GmBH, Linz, Austria) by means of femtosecond laser technology in eyes with corneal ectasia.

Design: Retrospective, consecutive, nonrandomized, case series.

Participants: A total of 12 eyes of 11 patients with ages ranging from 17 to 50 years were included. All cases were diagnosed with corneal ectasia according to the standard criteria: 1 case of post-LASIK ectasia and 11 cases of keratoconus. All cases presented with reduced best spectacle-corrected visual acuity, contact lens intolerance or discomfort, and central corneal thickness of more than 350 μm.

Methods: MyoRing inserts of 280 μm in thickness and 5 mm in diameter were implanted in all cases into an intrastromal corneal pocket created by means of femtosecond technology. Visual, refractive, corneal topography, and pachymetric changes were evaluated during a 6-month follow-up. In addition, corneal biomechanical changes were evaluated by means of the Ocular Response Analyzer (Reichert, Buffalo, NY).

Main Outcome Measures: Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refraction, keratometry, corneal asphericity, corneal higher-order aberrations, pachymetry, corneal hysteresis (CH), and corneal resistance factor (CRF).

Results: A significant improvement in UDVA was observed 1 week after surgery (P<0.001), which was consistent with the significant reduction in sphere (P=0.002) and cylinder (P=0.004). No significant changes were detected in these parameters afterward (P>0.263). Furthermore, a significant corneal flattening of a mean value of 8.03 diopters (D) was found (P=0.005). This keratometric change was correlated with the magnitude of corneal coma-like aberrations (r=0.830, P=0.003) and the CRF (r=−0.782, P=0.008). In regard to aberrometry, a statistically significant increase in primary spherical aberration was found 1 month after surgery (P=0.001). In addition, a significant reduction in higher-order corneal aberrations was found 3 to 6 months after surgery (P=0.027). Significant corneal thickening was also observed postoperatively in the central, nasal, and temporal areas (P<0.013). No statistically significant changes were detected (P>0.176) in corneal biomechanics. Explantation was performed in a very advanced keratoconus because of the extremely poor visual outcome.

Conclusions: MyoRing implantation using femtosecond technology in keratoconus allows successful corneal modeling, although the use of large diameters is advisable.

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Corneal modeling by inserting intrastromal implants has been proposed and investigated as an alternative treatment option in corneal ectasia.1 The use of these implants is aimed at minimizing the spherocylindrical error by modifying the central corneal curvature and inducing a reduction of corneal higher-order aberrations by generating a regularization of the corneal surface.1 It has been demonstrated that the addition of extra material at the corneal mid-periphery induces a displacement of the local anterior surface forward at this area and a flattening of the central portion of the anterior cornea caused by the morphologic structure of corneal lamellae (arc-shortening effect).2 The corneal modeling effect of intrastromal ring segments in different ectatic corneal disorders (keratoconus,3–14 pellucid marginal degeneration,15–22 and post-LASIK ectasia23–29) has been widely investigated. Intrastromal ring segments have been proven to be effective in improving visual acuity and reducing refractive error, mean keratometry, and corneal aberrations.3–29 However, the use of full-ring implants also has been proposed as a potential solution for the treatment of irregularly shaped keratoconic corneas.30–32

A new surgical option referred to as the “corneal intrastromal implantation system” (CISIS), in which the MyoRing flexible full-ring implant (DIOPTEX GmBH, Linz, Austria) is inserted into a corneal pocket, has been recently developed and proven to be effective not only in kerato-
conus but also in the treatment of moderate and high myopia. This complete ring is placed within the stroma through a small incision tunnel after creating an almost entirely closed intrastromal pocket. A mechanical device specifically developed for CISIS, the PocketMaker (DIOPTEX GmBH), has been used until now for the creation of this intrastromal pocket. MyoRing implantation using this mechanically guided procedure has been proven to be safe and effective in decreasing myopia, corneal steepness, and decentration of the corneal apex. However, it is well known that femtosecond laser technology allows the surgeon to program a corneal stromal dissection at a predetermined depth with an extremely high degree of accuracy, which avoids the potential inaccuracies of a mechanical dissection that is dependent on the surgeon’s manual skills. Theoretically, the use of femtosecond laser technology to create the intrastromal pocket required for MyoRing implantation would allow a more accurate stromal dissection, leading to better corneal aberrometric control with the implant. In a previous work of our research group, we demonstrated that intrastromal ring segment implantation using both mechanical and femtosecond laser-assisted procedures provided similar visual and refractive outcomes, but a more limited aberrometric correction was present in eyes with mechanical implantation.

The present study evaluates the visual, refractive, corneal aberrometric, pachymetric, and even corneal biomechanical outcomes after MyoRing implantation in eyes with corneal ectasia using the femtosecond laser technology for the creation of the intrastromal pocket required for the complete ring insertion. To the best of our knowledge, this is the first study reporting the outcomes of this new type of intrastromal implants using the femtosecond laser.

### Patients and Methods

#### Patients

This retrospective, consecutive, nonrandomized interventional clinical study included a total of 12 eyes of 11 patients with ages ranging from 17 to 50 years. All cases were diagnosed with corneal ectasia according to the standard criteria. A total of 11 keratoconus cases and 1 case of post-LASIK ectasia were included. Keratoconus diagnosis was based on corneal topography and slit-lamp observation: asymmetric bowtie pattern with or without skewed axes and the presence of stromal thinning, conical protrusion of the cornea at the apex, Fleischer ring, Vogt striae, or anterior stromal scar. Post-LASIK ectasia was diagnosed following these criteria: corneal thinning at slit-lamp examination, unstable topographic steepening (change of >1 diopter [D] for each 6-month follow-up period), progressive corneal thinning evaluated by means of ultrasonic pachymetry, decreased visual acuity, and unstable refraction (change of >0.5 D in the spherical equivalent for each 6-month follow-up period). Keratoconus cases were classified according to the Amsler–Krumeich and Alió–Shabayek grading systems.

The inclusion criteria of this study were corneal ectasia, reduced best spectacle-corrected visual acuity, contact lens intolerance or discomfort, and central corneal thickness of more than 350 μm. The exclusion criteria were active ocular diseases and spherical equivalent of plano or hyperopic. A particular scotopic pupil size was not considered an inclusion or exclusion criterion. Informed consent was obtained from all patients, which included explanation of all possible options of treatment. The study adhered to the tenets of the Declaration of Helsinki. Ethical board committee approval from our institution was obtained for this chart review.

#### MyoRing

The MyoRing is a flexible, continuous, polymethylmethacrylate ring that is inserted into an intrastromal corneal pocket via a small incision tunnel (Fig 1). The MyoRing is currently available in a diameter range of 5 to 8 mm and a thickness range of 200 to 400 μm in 20-μm increments. The width of the ring body is 0.5 mm. The anterior surface is convex and the posterior surface is concave, with a radius of curvature of 8.0 mm. This particular shape and dimensions permit folding, which makes implantation in the pocket feasible via a small incision. There is an available nomogram for implantation that is derived from theoretic calculations based on a biomechanical corneal model developed according to experimental data. This nomogram considers the corneal thickness at its thinnest point and the mean central keratometry reading.

#### Surgical Procedure

All surgical procedures were performed under topical anesthesia by the same experienced surgeon (JLA). An antibiotic prophylaxis consisting of topical ciprofloxacin (Oftacilox; Alcon Cusí, Barcelona, Spain) was prescribed to be applied before surgery every 8
hours for 2 days. The creation of the intrastromal pocket for MyoRing implantation was performed by means of the 15 kHz femtosecond technology (IntraLase, Advanced Medical Optics Inc., Santa Ana, CA) in all cases (Video 1, available at http://aaojournal.org). First, the pupil center was located and marked on the corneal surface with a Sinskey hook before applanation. This point was used as a reference throughout the procedure to locate the incision and the center of intrastromal dissection. This reference point also was used to properly position the MyoRing. A temporal corneal incision of ~70 degrees of arc-length was made, and afterward an almost entirely closed intrastromal pocket 9 mm in diameter and 300 μm in depth was created. The energy used for intrastromal dissection was 1.50 μJ. Once the pocket was created, the MyoRing was inserted in it via the previously made incision (Video 1, available at http://aaojournal.org). Although the MyoRing is made of polymethylmethacrylate, its particular design allows significant compression without the risk of breakage. Therefore, the MyoRing inflates to its original preoperative circular shape once placed into the pocket. No intraoperative complications occurred during the surgical procedure in any case. In this pilot study, only MyoRing implants of 280 μm in thickness and 5 mm in diameter were used.

Topical tobramycin and dexamethasone eye drops (TobraDex; Alcon Laboratories, Inc., Fort Worth, TX) were used postoperatively every 6 hours for 1 week and stopped. Topical lubricants were also prescribed to be applied every 6 hours for 1 month (Systane, Alcon Laboratories, Inc.).

Preoperative and Postoperative Protocol

A preoperative comprehensive examination was performed in all cases, including Snellen uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), manifest refraction, slit-lamp biomicroscopy, Goldmann tonometry, fundus evaluation, pachymetry by optical coherence tomography (Visante OCT, Carl Zeiss Meditec AG, Jena, Germany), and corneal topographic and aberrometric analysis with the CSO topography system (CSO, Firenze, Italy). This topographer analyzes a total of 6,144 corneal points of a corneal area enclosed in a circular annulus defined by an inner radius of 0.33 and an outer radius of 10 mm with respect to the corneal vertex. The software of this system, the EyeTop2005 (CSO), automatically performs the conversion of the measured corneal elevation profile into corneal wavefront data using the Zernike polynomials with an expansion up to the seventh order. In this study, aberration coefficients and root mean square (RMS) values were calculated for a 6-mm pupil in all cases. The following topographic and aberrometric data were evaluated and recorded with this device: corneal dioptic power in the flattest meridian for the 3-mm central zone (K1), corneal dioptic power in the steepest meridian for the 3-mm central zone (K2), mean corneal power in the 3-mm central zone (KM), corneal astigmatism in the 3-mm central zone (AST3), corneal astigmatism in the 6-mm central zone (AST6), mean asphericity for a corneal area of 4.5 mm in diameter (Q45), mean asphericity for a corneal area of 8 mm in diameter (Q8), higher-order RMS, primary coma RMS (computed for the Zernike terms Z40, Z60), coma-like RMS (computed for third-, fifth-, and seventh-order Zernike terms), spherical-like RMS (computed for fourth- and sixth-order Zernike terms), and higher-order residual RMS (computed considering all Zernike terms except those corresponding with primary coma and spherical aberration). The corresponding Zernike coefficient for primary spherical aberration (Z30) was also reported with its sign. Corneal biomechanics were evaluated by means of the Ocular Response Analyzer (ORA; Reichert, Buffalo, NY). This device delivers an air pulse to the eye that causes the cornea to move inward, achieving a specific applanation state or flattening (P1). Milliseconds after this first applanation, the pressure decreases and the cornea passes through a second applanated state (P2) while returning from concavity to its normal convex curvature. Two different pressures are then recorded (P1 and P2), and the difference between them is considered the corneal hysteresis (CH). In addition, the software of this instrument provides another parameter, the corneal resistance factor (CRF), which is calculated using a proprietary algorithm and is said to be predominantly related to the elastic properties of the cornea.41,42 These parameters, CH and CRF, have been proven to be reproducible in nonoperated healthy eyes.43

Postoperative visits were scheduled for the first postoperative day, the first week, and months 1, 3, and 6 after surgery. On the first postoperative day, UDVA measurement and slit-lamp examination (MyoRing position and corneal integrity) were performed. In the remaining postoperative visits, the same clinical examinations as preoperatively were performed. In all cases, a 6-month follow-up was completed except for 1 case in which MyoRing explantation was required.

Statistical Analysis

SPSS statistics software package version 15.0 for Windows (SPSS, Inc., Chicago, IL) was used for statistical analysis. Normality of all data samples was first checked by means of the Kolmogorov–Smirnov test. When parametric analysis was possible, the Student t test for paired data was performed for all parameter comparisons between preoperative and postoperative examinations. When parametric analysis was not possible, the Wilcoxon rank-sum test was applied to assess the significance of differences between preoperative and postoperative data, using the same level of significance (P < 0.05) in all cases. In addition, correlation coefficients (Pearson or Spearman depending if normality condition could be assumed) were used to assess the correlation between different clinical variables. It should be considered when reviewing the outcomes of the statistical analysis that the sample size was small, and therefore there was a limited statistical power.

Main Outcome Measures

Uncorrected distance visual acuity (UDVA), CDVA, manifest refraction, keratometry, corneal asphericity, corneal higher-order aberrations, pachymetry, CH, and CRF were the main outcome measures.

Results

A total of 12 eyes of 11 patients with a mean age of 34.80 years (standard deviation of 10.15 years) were included; 7 patients were male (63.64%) and 4 patients were female (36.36%). The distribution of right and left eyes was as follows: 3 right eyes (25%) versus 9 left eyes (75%). According to the Amsler–Krumelich grading system, 1 eye had a keratoconus grade I (9.09%), 5 eyes had a keratoconus grade II (45.45%), and 5 eyes had a keratoconus grade IV (45.45%). By considering corneal aberrations and using the Alió–Shabayek grading system, 2 eyes had a keratoconus grade I (18.18%), 3 eyes had a keratoconus grade II (27.27%), and 6 had eyes a keratoconus grade IV (54.55%).

Corneal opacities were observed in 2 eyes (16.67%). In 1 advanced keratoconic eye (grade IV), corneal crosslinking using the standard procedure and MyoRing implantation were performed simultaneously because of the significant progression of ectasia during the preoperative follow-up. In addition, in a very advanced keratoconic eye, the MyoRing was explanted 3 weeks after im-
Table 1. Summary of Visual and Refractive Outcomes During the Follow-up

<table>
<thead>
<tr>
<th>Value</th>
<th>Preoperative</th>
<th>1 Wk</th>
<th>1 Mo</th>
<th>3 Mos</th>
<th>6 Mos</th>
<th>P Value (Preoperative to 6 Mos)</th>
</tr>
</thead>
<tbody>
<tr>
<td>logMAR</td>
<td>1.36 (0.33)</td>
<td>0.70 (0.30)</td>
<td>0.69 (0.32)</td>
<td>0.60 (0.30)</td>
<td>0.61 (0.25)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>UDVA</td>
<td>0.70–1.78</td>
<td>0.22–1.17</td>
<td>0.15–1.00</td>
<td>0.10–0.82</td>
<td>0.15–1.00</td>
<td>(Student t)</td>
</tr>
<tr>
<td>Sphere (D)</td>
<td>−4.82 (5.50)</td>
<td>−0.20 (3.52)</td>
<td>−0.50 (1.15)</td>
<td>−0.71 (1.35)</td>
<td>+0.33 (2.57)</td>
<td>0.011</td>
</tr>
<tr>
<td>Cylinder (D)</td>
<td>−17.00 to +3.00</td>
<td>−6.00 to +6.50</td>
<td>−2.00 to +5.50</td>
<td>−3.00 to +5.50</td>
<td>−3.50 to +5.50</td>
<td>(Student t)</td>
</tr>
<tr>
<td>SE (D)</td>
<td>−12.00 to −1.25</td>
<td>−2.28 (1.13)</td>
<td>−2.07 (1.20)</td>
<td>−2.07 (1.30)</td>
<td>−2.43 (1.35)</td>
<td>0.006</td>
</tr>
<tr>
<td>logMAR</td>
<td>−8.19 (4.85)</td>
<td>−1.34 (3.33)</td>
<td>−1.54 (3.33)</td>
<td>−1.75 (1.22)</td>
<td>−0.88 (2.29)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CDVA</td>
<td>0.43 (0.24)</td>
<td>0.51 (0.23)</td>
<td>0.44 (0.26)</td>
<td>0.33 (0.22)</td>
<td>0.32 (0.18)</td>
<td>0.134</td>
</tr>
</tbody>
</table>

CDVA = corrected distance visual acuity; D = dipters; logMAR = logarithm of the minimum angle of resolution; SD = standard deviation; SE = spherical equivalent; UDVA = uncorrected distance visual acuity.

Visual acuity and refractive outcomes are shown. Ranges are shown in brackets below each mean value. Below each P value, the statistical test used is indicated.

Corneal Aberrometric Outcomes

Table 3 (available at http://aaojournal.org) summarizes the corneal aberrometric outcomes occurring after MyoRing implantation in the sample of eyes analyzed. A statistically significant increase in primary spherical aberration was found 1 month after surgery (paired Student t test, P = 0.001), which changed from negative (prolate or parabolic shapes) to positive (oblate shapes) values. In addition, anterior corneal astigmatism was reduced, but the change did not reach statistical significance (paired Student t test, P = 0.064).

Figure 3 shows the corneal topographic change in 1 specific case of the analyzed sample. As shown, a significant central flattening was generated by the MyoRing implant, as well as a reduction of corneal astigmatism and asymmetry.

Corneal Aberrometric Outcomes

Table 3 (available at http://aaojournal.org) summarizes the corneal aberrometric outcomes occurring after MyoRing implantation in the sample of eyes analyzed. A statistically significant increase in primary spherical aberration was found 1 month after surgery (paired Student t test, P = 0.001), which changed from a mean preoperative negative value to a large mean postoperative positive value. No significant changes were detected in the remaining aberrometric coefficients at any time point in the initial 3 postop-
erative months (paired Student t test, \( P \approx 0.103 \)). However, at 6 months a significant reduction was found in higher-order RMS (paired Student t test, \( P = 0.027 \)). A reduction close to the limit of significance level was also detected in primary coma (paired Student t test, \( P = 0.055 \)) and coma-like RMS (paired Student t test, \( P = 0.056 \)). Furthermore, the change in the RMS for corneal higher-order aberrations (postoperative–preoperative) was found to be correlated with the following preoperative parameters: \( Q45 \) (\( r = 0.810, P = 0.015 \)), \( Q8 \) (\( r = 0.738, P = 0.037 \)), and higher-order RMS (\( P = 0.976, P = 0.001 \)).

**Pachymetric and Corneal Biomechanical Outcomes**

A statistically significant thickening was observed 1 month after surgery in the central corneal 2-mm area (paired Student t test, \( P = 0.013 \)) and at nasal (paired Student t test, \( P = 0.009 \)) and temporal (paired Student t test, \( P = 0.001 \)) locations (2–5 mm) (Table 4). No significant changes were detected during the remaining follow-up (paired Student t and Wilcoxon tests, \( P = 0.133 \)), except for the thickness at the central 2-mm area, which experienced a decrease of small, but statistically significant, magnitude (paired Student t test, \( P = 0.020 \)) (Table 4).

In regard to corneal biomechanics, no statistically significant changes were found in CH and CRF at any time point of the follow-up, although a small trend to an increase in these parameters was observed (Fig 4). Significant correlations among preoperative ORA biomechanical parameters and postoperative RMS value for corneal coma-like aberrations were found (CH, \( r = -0.72, P = 0.04 \); CRF, \( r = -0.73, P = 0.03 \)).

**Complications**

No cases of ring extrusion or migration were detected. MyoRing explantation was only performed in a very advanced keratoconic eye at 3 weeks after implantation because of the extremely poor visual outcome and the need for keratoplasty. A mild haze around the ring was observed in most cases, especially in the initial postoperative period, but it was not clinically relevant and did not affect the visual axis.

**Discussion**

The concept of an intrastromal full ring as an additive refractive technique for the correction of myopia was first proposed by Reynolds in 1978.\(^4^4\) The initial full rings that were developed were inserted through a peripheral single corneal incision into a circumferential corneal channel.\(^4^5,4^6\) The technique for implantation of such implants was difficult with potential incision-related complications,\(^4^4\) which was the main reason that led to refashioning the implants

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**Table 4. Summary of the Pachymetric Outcomes (Central, Temporal, and Nasal Corneal Thicknesses)**

<table>
<thead>
<tr>
<th>Mean (SD) Range</th>
<th>Preoperative</th>
<th>1 Mo</th>
<th>3 Mo</th>
<th>6 Mo</th>
<th>( P ) Value (Preoperative to 6 Mo)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CCT (µm)</strong></td>
<td>457.64 (45.88)</td>
<td>482.20 (17.08)</td>
<td>479.20 (46.40)</td>
<td>468.70 (53.41)</td>
<td>0.051</td>
</tr>
<tr>
<td><strong>TCT (µm)</strong></td>
<td>489.64 (39.55)</td>
<td>550.40 (15.36)</td>
<td>553.17 (34.50)</td>
<td>545.86 (42.39)</td>
<td>0.003</td>
</tr>
<tr>
<td></td>
<td>416–564</td>
<td>533–572</td>
<td>516–612</td>
<td>497–630</td>
<td></td>
</tr>
<tr>
<td><strong>NCT (µm)</strong></td>
<td>517.27 (55.73)</td>
<td>566.40 (24.17)</td>
<td>554.83 (52.08)</td>
<td>568.14 (41.35)</td>
<td>0.008</td>
</tr>
<tr>
<td></td>
<td>415–609</td>
<td>545–596</td>
<td>496–647</td>
<td>522–648</td>
<td></td>
</tr>
</tbody>
</table>

CCT = mean corneal thickness in the central 2-mm area; NCT = corneal thickness at the area 2–5 mm from the corneal center nasally; SD = standard deviation; TCT = corneal thickness at the area 2–5 mm from the corneal center temporally. Ranges are given in brackets below each mean value.
into incomplete rings, renamed “intracorneal ring segment” (ICRS). In 2008, the concept of an intracorneal full ring for myopia correction (MyoRing implant) reappeared with an innovative implantation technique: an intrastromal pocket for placing the implant was created by means of a mechanical dissector. This technique was designated as “CISIS,” and it was proven to be a safe and effective technique for the correction of significant myopic and astigmatic refractive errors in healthy corneas. Mahmood et al and Daxer et al reported the applicability of CISIS for the improvement of visual function in keratoconus. The current study evaluated the visual, refractive, corneal aberrometric, pachymetric, and corneal biomechanical outcomes after MyoRing implantation in eyes with corneal ectasia but using the femtosecond laser technology for the creation of an intrastromal pocket.

At 1 week after surgery, a statistically significant reduction in myopia and cylinder was observed, with no significant changes during the remaining follow-up. These changes were of large magnitude. The mean change in sphere was 4.62 D, and the mean change in refractive cylinder was 4.47 D. These levels of refractive change were consistent with those previously reported after MyoRing implantation with mechanical dissection. However, the levels of myopic and astigmatic correction achieved in our study were larger than those reported in previous studies using ICRS for the management of keratoconus and post-LASIK ectasia. Only the mean change in sphere reported by Shetty et al after Intacs implantation in advanced keratoconus was of similar magnitude (mean change in sphere of 4.06 D). It should be considered that ring segment thicknesses implanted in eyes in previous studies on ICRS were even larger than those used in the current study (280 μm). Therefore, it seems that MyoRing implants have a greater potential of myopic and astigmatic correction in keratoconus than ICRS probably because of the more significant arc-shortening effect achieved with a completely circular mid-peripheral implant. This is a topic that should be addressed in the future by means of a randomized comparative study. As expected, the significant level of refractive correction achieved with MyoRing implants in our sample was in concordance with a significant improvement in UDVA. The mean improvement in UDVA was ~8 lines of logarithm of the minimum angle of resolution (logMAR), as shown in the previous works of Mahmood et al and Daxer et al. In these 2 previous studies, MyoRing implants were also used for keratoconus management, but mainly in grade II and III cases. However, in our sample a significant number of keratoconus grade IV cases were included.

In regard to corneal topography, a significant central flattening was observed 1 week after surgery, which was consistent with the refractive change induced. The mean change in KM was 8.03 D. This flattening effect is only comparable to that reported by Miranda et al (mean change in maximum keratometry of 9.60 D) after Ferrara ring segment implantation in severe keratoconus and to that reported by Mahmood et al and Daxer et al, who also used the MyoRing in keratoconus. The large flattening effect achieved by Miranda et al with Ferrara ring segments was probably due to the use of thicker implants and reduced diameters, which are factors proven to be related to a potentially more significant flattening. In addition, a slight but statistically significant regression of the flattening effect was observed in our sample at 6 months after surgery. This suggests that corneal biomechanical changes affecting keratometry and refraction can still occur despite ring implantation in some keratoconic cases, as has been described in previous studies. These changes did not necessarily imply a progress of the ectatic process; they also could be the consequence of the stabilization of the ring effect and the final redistribution of the corneal tissue. However, the analysis of changes in corneal asphericity revealed that the anterior corneal surface became less prolate and even oblate after MyoRing implantation. This was expected because a significant central corneal flattening was induced. The generation of a central flattening effect without following an aspheric algorithm induces an increase of corneal asphericity, as has been described after non-optimized procedures of myopic LASIK. A future, desirable improvement of these full-ring implants would be to control the pattern of flattening induced by these devices, with the potential of inducing an aspheric or customized pattern.

In addition to visual, refractive, and corneal topography outcomes, changes in anterior corneal aberrations were also evaluated in this study. To the best of our knowledge, this is the first study evaluating the corneal aberrometric performance of MyoRing implants. We found a late reduction of primary coma and coma-like corneal aberrations that had a significant impact on the RMS value for corneal higher-order aberrations. As previously suggested, it seems that a relatively long period of time is required for the stabilization of the MyoRing effect on corneal profile. Other studies have reported significant changes in corneal higher-order aberrations, especially in coma-like aberrations, after ICRS implantation in ectatic corneas. Intrastromal implants are then effective devices for reducing corneal irregularity and corneal aberrations. Another relevant finding of our series was the significant increase in primary spherical aberration after MyoRing implantation, which changed
from negative to positive. This was in part expected because of the significant change in corneal asphericity induced by the implant; an oblate central corneal shape was induced in most cases (Fig 3). The MyoRing diameter used in the current study was 5 mm. This relationship between a relatively small area of central corneal flattening and primary spherical aberration has been extensively studied and understood in the field of excimer laser refractive surgery.\textsuperscript{51} In addition, by means of a simulation model, Patel et al\textsuperscript{2} predicted that the large diameter (9–10 mm) and thin (0.1–0.2 mm) intracorneal rings were less likely to adversely affect corneal asphericity and therefore spherical aberration. It seems clear that a MyoRing of larger diameter should be used if the induction of positive primary spherical aberration is intended to be avoided. Indeed, we believe that the small and not significant increase in CDVA observed in this study was in relation with the significant induction of positive primary spherical aberration, because an induction of irregularity as a consequence of stromal dissection was improbable if we consider the high degree of accuracy of the femtosecond laser technology used for such purpose.

The analysis of corneal pachymetric changes revealed significant changes after MyoRing implantation. Specifically, a significant thickening of the central cornea was found, suggesting that corneal tissue redistribution occurs after the implantation of this type of ring. In a study using very high-frequency ultrasound technology, Reinstein et al\textsuperscript{52} observed a stromal thickening after Intacs implantation, accounting for astigmatic changes ascribable to orthogonal asymmetry. The modeling effect induced by MyoRing inserts is likely the consequence of an arc-shortening effect and a redistribution of stromal tissue. Corneal biomechanical changes were also evaluated by means of the ORA system. Two biomechanical parameters, CH and CRF, are provided by this instrument, which are said to represent the viscoelastic properties of the cornea, but it should be considered that there is no study proving whether these parameters are in relation with the standard mechanical properties used for the description of the elastic materials (Young’s modulus). However, despite not knowing the exact physical meaning of CH and CRF, they have proven to be useful for characterizing the biomechanical properties of the cornea, especially in ectatic corneas.\textsuperscript{41,52,53} In the current study, no significant changes were detected in CH and CRF after MyoRing implantation, although there was a trend to an increase in both parameters. This is consistent with previous studies showing no significant changes in ORA biomechanical parameters after ICRS implantation.\textsuperscript{39,54} Biomechanical changes are not occurring probably because the viscoelastic properties of the central cornea are not modified with these mid-peripheral intrastromal implants or the ORA system is unable to detect the subtle biomechanical changes induced. In future studies, this should be addressed and confirmed using standardized procedures for determining the Young’s modulus of the cornea.

Correlations of keratometric and aberrometric changes with different preoperative parameters were also investigated. Positive correlations of the keratometric change with preoperative corneal spherical-like and coma-like aberrations were found. The more aberrated the cornea, the larger the keratometric change. This seems to be in relation with the biomechanical properties of the implanted cornea. Indeed, it has been demonstrated that corneas with large levels of higher-order aberrations used to have an underlying biomechanical alteration,\textsuperscript{49} which likely presents a higher susceptibility of deformation. In addition, an inverse correlation was found between the keratometric change and CRF. The CRF is calculated as a linear function of the 2 pressures recorded during the ORA measurement procedure (P1 and P2), and it is said to be an indicator of the overall resistance of the cornea. From a mathematic point of view, CRF places more emphasis on P1, so it is more heavily weighted by the underlying corneal elastic properties.\textsuperscript{55} It seems that a more significant flattening could be induced in those corneas with altered elastic properties. The change in corneal higher-order aberrations (postoperative–preoperative) was correlated positively with preoperative corneal asphericity and negatively with preoperative corneal higher-order RMS. Therefore, it seems that a larger aberrometric reduction can be achieved with MyoRing inserts in prolate corneas with large amounts of corneal higher-order aberrations. This is an interesting finding that should be confirmed in the future with a larger sample of eyes because ICRS aberrometric and CDVA outcomes have been proven to be inversely correlated with the preoperative level of aberrations. Therefore, MyoRing implants may be an excellent option for the most advanced keratoconus cases, which are normally more affected by higher-order aberrations.\textsuperscript{37,56}

In conclusion, MyoRing implantation in corneal ectasia by means of femtosecond technology allows a significant reduction of myopic spherical error because of the central corneal flattening that is induced, especially in advanced cases. Longer follow-up is needed to corroborate the stability of visual, refractive, and aberrometric outcomes of these implants in the long term. In addition, the use of small circular intrastromal implants allows a more limited corneal aberrometric control because of the significant induction of positive spherical aberration. Therefore, a MyoRing of large diameter is recommended to achieve a better corneal aberrometric correction and thus a potential improvement in CDVA. This should be addressed and confirmed in future investigations. Furthermore, studies with larger samples of eyes are required to confirm our preliminary findings using robust statistical tests with sufficient power.

References


Footnotes and Financial Disclosures

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