Implantation of a Complete Intrastromal Corneal Ring at 2 Different Stromal Depths in Keratoconus

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Purpose: The aim of this study was to evaluate the clinical outcomes of intrastromal MyoRing (Dioptex, GmbH, Linz, Austria) implantation at 2 different depths of 250 and 300 μm.

Methods: This was a prospective interventional randomized controlled trial, a pilot study. Keratoconic patients with keratometry values between 48 and 52 diopters were randomly divided into 2 groups. A continuous intrastromal corneal ring of the same size was implanted at 2 different stromal depths of 250 μm (group 1) and 300 μm (group 2) using femtosecond laser technology for both groups. Visual and refractive outcomes, keratometry, corneal biomechanical characteristics, and higher order aberrations were compared at the 1-year postoperative follow-up.

Results: In both groups, uncorrected distance visual acuity significantly improved after MyoRing implantation, whereas neither of these showed any improvement in the corrected distance visual acuity. In addition, the mean central keratometry and spherical and cylindrical refraction reduced significantly in both groups, and spherical aberration increased significantly in both groups. On one hand, coma was reduced almost significantly in both groups, and on the other hand, corneal hysteresis and corneal resistance factor did not change significantly after the operation. None of the patients in both groups had intraoperative or postoperative complications. There were no differences observed in any of the measured variables of the 2 study groups.

Conclusions: An implantation depth of 250 μm has comparable outcomes with the previously applied 300-μm implantation depth. It may be appropriate for selected cases of keratoconus with lower pachymetry.

Key Words: MyoRing, implantation depth, keratoconus, femtosecond laser, intrastromal ring

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Keratoconus is an ectatic corneal disorder with progressive inferior corneal steepening.[1] Corneal remodeling and shape modification are concepts on which intrastromal rings are designed.[2] Incomplete rings available on the market for many years are Intacs (Addition Technology, Inc), Ferrara ring (Ferrara Ophthalmics Ltd), and Keraring (Mediphacos Ltd). Implanting a complete intrastromal ring, MyoRing (Dioptex, GmbH, Linz, Austria), is a new technique, which has been proven to be safe and effective in previous studies in the treatment of keratoconus especially in cases with high myopic refraction.[1,2] The ring is planned to be placed into an intrastromal pocket created with either a specified microkeratome[3] or a femtosecond laser.[1] The depth of the corneal pocket has been proposed to be 300 μm in the previous studies.[1,2] Different depths of implantation may have different effects and subsequently different refractive outcomes. Further, superficial implantation of the ring may cause epithelial defects and extrusion of the implant. In this study, we have compared the outcomes of MyoRing implantation at 2 different corneal depths (250 and 300 μm) in patients with keratoconus.

PATIENTS AND METHODS

The study design is a prospective interventional randomized clinical trial. Informed consent was obtained from all patients, after an explanation of all possible treatment options was given to them. Institutional ethical review board approval was obtained for the procedures and the tenets of the Helsinki Declaration were followed. All the patients were older than 20 years, diagnosed with keratoconus, and intolerant to contact lenses or glasses. Other inclusion criteria were mean central Pentacam (Oculus, Inc, Wetzlar, Germany) keratometry of >48 or <52 diopters (D) and ultrasound (Nidek UP1000) central corneal thickness of >380 μm. Patients with central corneal scars, plano or hyperopic spherical equivalent refraction, a history or existence of any ocular pathology or an ocular surgery, and pregnancy or lactation were excluded from the study. All the patients meeting the inclusion criteria were randomized to 2 groups to have a complete intrastromal corneal ring [MyoRing (Dioptex, GmbH)] implanted at 2 different stromal depths of 250 and 300 μm.

Examinations

All the patients underwent a complete ophthalmologic examination preoperatively and on the first postoperative day and on all follow-up visits (in the first postoperative week and the first, third, sixth, ninth, and 12th months thereafter). Uncorrected and corrected visual acuities and refraction were obtained. Corneal pachymetry (Nidek UP1000; Nidek

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Technologies, Gamagori, Japan), Pentacam imaging, corneal aberrometry (Tracey Technologies, TX), and ocular response analysis (Reichert, Buffalo, NY) were performed preoperatively and also on all the follow-up visits, except for the first postoperative day. All complications were recorded.

Surgical Technique

All procedures were performed by 1 surgeon (M.J.). Using the femtosecond laser (Technolas 520F, Munich, Germany), followed by a 4.5-mm-wide tunnel incision; a stromal pocket was created with a diameter of 9 mm and a depth of 250 or 300 μm (according to the allocated group) as described in detail by Alio et al.[2] We placed a tunnel incision on the steep meridian of the cornea (on either the superior or temporal side). The MyoRing (Dioptex, GmbH) was then inserted into the pocket. In this study, we used MyoRing implants of 240-μm thickness and 5-mm diameter for all patients. A bandage contact lens was placed on the cornea for 3 days with no suture on the incision site. Further, no intraoperative complications occurred during the surgical procedures.

Statistical Analysis

Data analysis was performed using SPSS (SPSS Inc, Chicago, IL). All data are reported as a range, with the average value and the standard deviation. The findings are considered significant if $P < 0.05$. The Mann–Whitney test and student *t* test were used for data analysis.

RESULTS

Twenty-one eyes from 21 patients were allocated to each group. Preoperative and demographic data of both groups are presented in Table 1. There were no significant differences in the preoperative data between the 2 groups. In both groups, uncorrected distance visual acuity (UDVA) improved significantly on all postoperative visits compared with that at baseline (Table 2). There was a nonsignificant improvement between consecutive postoperative visits in both groups. No significant changes occurred in the postoperative corrected distance visual acuity compared with preoperative values in either of the 2 groups. In both groups, sphere, cylinder, and keratometry values reduced significantly at the follow-up visits compared with preoperative values. No significant differences were observed between the follow-up sessions for any of these variables in either group.

No significant differences were noticed between preoperative and postoperative values (UDVA, UCVA, sphere, cylinder, and mean keratometry) of the 2 groups. We compared the value improvement of each visit between the 2 groups, and no significant difference was observed.

Spherical aberration in both groups increased significantly after implantation. In addition, coma reduced in both the groups ($P = 0.05$ and 0.08 in the first and second groups, respectively). There were no significant differences in any value between the 2 groups.

Both corneal hysteresis and cornea resistance factor reduced insignificantly for both the groups. No significant differences between the 2 groups were observed in these values. Comparative data are available in Table 3.

Also, as for the intraoperative and postoperative complications, both the groups were comparable. No patient developed corneal melting or extrusion of the ring. No epitheliopathy was found on slit-lamp examination. Despite normal results of the basic Schirmer test that was performed on all the patients before surgery and in every session thereafter, 4 patients in the first group and 3 patients in the second group complained of having foreign body sensation in the first few weeks after the procedure. This complication improved gradually, and no one had any complaint at the end of the 1-year follow-up. All the patients were asked about any annoying halo or glare at each session. Almost all the patients of both groups stated some grade of an annoying halo and glare around objects at the first postoperative visits, whereas after 1 year, only 1 patient from each group complained of seeing a residual halo and glare.

TABLE 1. Preoperative Variables Compared Between the 2 Study Groups

	Group 1 (250 μm)	Group 2 (300 μm)	*P*
Age, mean (range), yrs	27 (21–34)	25 (21–33)	0.6
Refractive error, D			
Sphere	−2.95 ± 2.46	−2.77 ± 1.45	0.85
Cylinder	−4.17 ± 2.14	−4.3 ± 1.0	0.9
Keratometry, D	49.59 ± 3.02	49.73 ± 2.37	0.9
UDVA, logMAR	1.16 ± 0.48	1.01 ± 0.34	0.4
CDVA, logMAR	0.26 ± 0.16	0.35 ± 0.18	0.28

Visual acuity and refractive outcomes are shown as mean ± SD. *P* values were calculated using the *t* test.

CDVA, corrected distance visual acuity; logMAR, logarithm of the minimal angle of resolution.

DISCUSSION

Altering the configuration of the cornea is an important issue in managing keratoconus.[3] Intrastromal corneal ring segments and recently a complete intrastromal ring (MyoRing) have been proposed to improve corneal regularity and reduce spherocylindrical errors.[1,4]

The MyoRing is designed to be implanted into an intrastromal pocket. Intrastromal pockets can be created using either a microkeratome[1–5] or a femtosecond laser.[2] Intraoperative complications of posterior corneal perforation have been reported by manual dissection of the tunnel for intrastromal ring segment implantation.[6] Rapidity, precision, and safety of the femtosecond laser and minimal stromal edema, good centration of the pocket, and easier channel creation have been proven in previous studies on Intacs.[7]

In concordance with previous studies, we found that the UDVA is mainly affected by MyoRing implantation, whereas the corrected distance visual acuity did not improve at all.[1,3] this improvement was found for both implantation depths quite early after surgery (the UDVA did not change significantly between the 1-week and 1-year visits). Changes

TABLE 2. Comparative Data in the 2 Groups Throughout the Study

	Preoperative	1 Wk	1 Mo	3 Mos	12 Mos
UDVA, logMAR					
Group 1	1.16 ± 0.48	0.54 ± 0.19	0.47 ± 0.12	0.42 ± 0.15	0.41 ± 0.17
Group 2	1.01 ± 0.34	0.49 ± 0.16	0.42 ± 0.12	0.40 ± 0.14	0.40 ± 0.14
CDVA, logMAR					
Group 1	0.26 ± 0.16	0.26 ± 0.17	0.25 ± 0.17	0.24 ± 0.16	0.24 ± 0.17
Group 2	0.35 ± 0.18	0.29 ± 0.15	0.26 ± 0.14	0.23 ± 0.13	0.23 ± 0.14
Sphere, D					
Group 1	−2.95 ± 2.46	−0.52 ± 0.96	−0.47 ± 0.62	−0.37 ± 0.73	−0.13 ± 1.12
Group 2	−2.77 ± 1.45	−0.72 ± 0.84	−0.59 ± 0.72	−0.4 ± 0.39	−0.17 ± 1.05
Cylinder, D					
Group 1	−4.17 ± 2.14	−1.83 ± 0.92	−1.79 ± 0.88	−1.82 ± 0.56	−1.57 ± 0.70
Group 2	−4.3 ± 1.0	−2.05 ± 0.81	−1.91 ± 0.78	−1.87 ± 0.83	−1.77 ± 0.79
Keratometry, D					
Group 1	49.59 ± 3.02	44.27 ± 3.08	44.06 ± 3.03	43.61 ± 2.86	44.16 ± 3.10
Group 2	49.73 ± 2.36	45.23 ± 2.82	44.82 ± 2.90	44.76 ± 2.84	44.77 ± 2.85

Visual acuity and refractive outcomes are shown as mean ± SD. *P* values were calculated using the *t* test.
CDVA, corrected distance visual acuity; logMAR, logarithm of the minimal angle of resolution.

observed between the mean keratometry value and 1-year postoperative value were 5.43 and 4.96 D in the first and second groups, respectively. This was in agreement with the findings of the study conducted by Daxer et al[3] (5.76 D) and much lower than that in other previous studies[1,2,5] (8–9.78 D). This can be attributed to the issue that patients with advanced keratoconus (mean keratometry >52) were excluded from this study, and the MyoRing has the greatest corneal flattening effect on advanced keratoconus with a thinner cornea.

No progression in the mean keratometry, refractive, or visual outcome was found between postoperative visits in the course of the 1-year follow-up, which was consistent with the findings of previous studies.[1–3,5] We believe that despite the stability of variables during the 1-year follow-up, a longer period of follow-up is required to confirm if the MyoRing can decelerate the progression of keratoconus.

In both groups, changes in lower order aberrations, spherical and cylindrical refractive errors were significant after ring implantation. Higher order aberrations also experienced significant changes. The reduction of coma, which was nearly significant, was consistent with that in the previous study by Alio et al[2] who reported a nonsignificant reduction of coma within the 1-year follow-up. Nonsignificance of the results of both studies can be explained by the small sample size. Spherical aberration increased significantly after the operation, which is because of the flattening of the central part of the cornea. This was consistent with the finding of a previous study by Alio et al.[2] In both groups, corneal hysteresis and cornea resistance factor showed no significant changes from preoperative to 1-year postoperative values. This finding is in agreement with that of the study conducted by Alio et al.[2]

TABLE 3. Comparative Data of Coma and Spherical Aberration and Ocular Response Analysis Between the 2 Groups

	Preimplantation, Mean ± SD (Range)	Postimplantation (1 yr), Mean ± SD (Range)	*P*
Higher order aberrations			
Group 1			
Spherical aberration	−0.27 ± 0.52 (−0.92 to 0.58)	0.92 ± 0.91 (0.10–1.92)	0.02
Coma	1.22 ± 1.09 (0.34 to 3.28)	0.65 ± 0.41 (1.03–1.08)	0.05
Group 2			
Spherical aberration	−0.52 ± 0.38 (−1.09 to 0.65)	0.81 ± 0.59 (0.30–1.90)	0.04
Coma	1.70 ± 0.92 (0.31 to 2.27)	1.06 ± 0.76 (0.20–2.20)	0.08
Ocular response analysis			
Group 1			
Corneal hysteresis	8.30 ± 0.35 (7.80 to 8.70)	8.6 ± 1.42 (8.10–9.02)	0.70
Cornea resistance factor	6.80 ± 0.70 (6.00 to 7.70)	7.1 ± 1.65 (6.45–7.75)	0.50
Group 2			
Corneal hysteresis	8.20 ± 0.94 (6.70–9.40)	8.26 ± 0.25 (8.00–8.50)	0.65
Cornea resistance factor	6.90 ± 0.70 (6.00 to 7.50)	7.20 ± 0.95 (5.80–8.90)	0.31

We found no significant complications in either group, but because some complications may occur after the first year, studies with longer follow-up periods are needed to prove the safety of the implantation at a 250-μm depth.

We observed no statistically significant difference in variables (refractive and visual improvements, aberrometric, keratometric, and corneal biomechanical changes) between the 2 implantation depths of 250 and 300 μm. This finding is especially valuable in the case of a thin cornea (which is not a rare finding in keratoconic patients) where the surgeon wants to maintain a safe distance from the endothelium to avoid presumed harmful effects of the laser to endothelial cells.

Strict inclusion criteria (which were planned to make the 2 groups more comparable) make this study population not a good representative of all keratoconic patients that undergo MyoRing implantation. Further studies in larger populations with different subgroups and longer follow-ups are recommended to compare implantation of the MyoRing at different depths.

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