Management of Keratoconus Using Myoring

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ABSTRACT

Background: keratoconus (KC) is an ectatic condition of the cornea which is usually progressive and non-inflammatory, affecting both eyes asymmetrically. It is characterized by stromal thinning that leads to corneal surface irregularity. Vision affection is due to irregular astigmatism and corneal scarring.

Aim of the Work: assessment of the effectiveness of Myoring intreating patients with keratoconus.

Patients and Methods: prospective non-randomized non-comparative clinically controlled study, Myoring was implanted for (20) eyes of 20 patients with progressive keratoconus.

Results: visual acuity and corneal parameters improved significantly in all patients after one year postoperatively.

Conclusion: Myoring when used in suitable patients has the potential to produce excellent long-term vision results in mild, moderate and advanced keratoconus cases, regardless of cone position and disease progression.

Keywords: keratoconus, intracorneal rings, Myoring.

INTRODUCTION

Keratoconus (KC) is an ectatic condition of the cornea which is usually progressive and noninflammatory, affecting both eyes asymmetrically. It is characterized by stromal thinning that leads to corneal surface irregularity. Vision affection is due to irregular astigmatism and corneal scarring⁽¹⁾.

All layers of the cornea are affected by KC, especially thinning of the corneal stroma and rupture in Bowman's layer. Descemet's membranebreaks and folds lead to acute hydrops and striae⁽²⁾.

Intracorneal ring segments were designed to achieve refractive adjustment by flattening the cornea. Intracorneal rings have several distinct and important advantages. New thicknesses and different ring sizes and the use of femtosecond lasers to dissect channels inside the cornea will likely improve the surgical outcome⁽³⁾.

The Myoring (DIOPTEX) is a complete, flexible, continuous, PMMAringdesigned to correct moderate and high myopia. The diameter ranges from 5.0 to 8.0 mm, the thicknesses from 150 to 350 µm and the width of the ring is 0.5mm. The anterior surface is convex and the posterior surface concave, with aradius of curvature of 6.0 mm. It can be considered a permanent contact lens, which is squeezed underneath the corneal surface⁽³⁾.

AIM OF THE WORK

Assessment of the effectiveness of Myoring in treating patients with keratoconus as regard changes in visual acuity, error of refraction and corneal topography.

PATIENTS AND METHODS

In this prospective non-randomized noncomparative clinically controlled study, Myoring was implanted for (20) eyes of 20 patients (11 males & 9 females) with progressive keratoconus. All cases were performed and followed up in Al-Azhar University hospitals at the period from October 2015 to September 2018.

Ethical consideration: A signed informed consent was obtained from all participants and the study was approved by the Ethics Board of Al-Azhar University. The following inclusion and exclusion criteria were used:

Inclusion criteria: All patients were between 16-40 years with thinnest corneal pachymetry higher than 390 microns, corneal curvature more than 48D, scotopic pupil less than 6mm and no central scarring.

Exclusion criteria: Age: <16 or >40 years, thinnest corneal pachymetry less than 390 microns, corneal curvature less than 48D, scotopic pupil more than 6mm or central scarring.

Preoperative evaluation:

All patients were undergone slit-lamp examination of anterior segment, assessment of uncorrected visual acuity (UCVA) and best spectacle corrected visual acuity (BSCVA), pachymetry and corneal topography with anterior and posterior elevations.

The procedure:

The procedure for placement of Myoring can be performed with topical or local anesthesia. The operative field is prepared, and the patient is prepared and draped in the usual sterile fashion for ophthalmic surgery.

a- A lid speculum is used for globe exposure.

b- The corneal center is identified and marked with a Sinskey hook.

c- A 5.5mm long epithelial impression is created at the 12-o'clock position where the Myoring is placed at 6mm diameter optical zone.

d- A diamond blade, set at 75% of the peripheral corneal depth, is used to perform a circumferential incision along this mark.

e- Small crescent knife (1.25mm) is used to make a special pocket within corneal stroma.

f-Myoring is then inserted by being compressed by the edges of the incision.

g- Contact lens is then applied.

Postoperative follow-up

The patients were followed up for one year (at 1st day, 1st month, 3rd month, 6th month and 12th month) by slit-lamp examination of anterior segment, assessment of uncorrected visual acuity (UCVA) and best spectacle corrected visual acuity (BSCVA), pachymetry and corneal topography with anterior and posterior elevations.

STATISTICAL ANALYSIS OF DATA

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations and ranges when their distribution found parametric. Also qualitative data were presented as number and percentages. The comparison between two paired groups with quantitative data and parametric distribution was done by using *paired t-test* while the comparison between non-parametric data was done by using *Wilcoxon test*. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:

P > 0.05: Non significant, P < 0.05: Significant and P < 0.01: Highly significant.

 Table (2): Change in mean of UCVA over one year

Paired t-test: test which compare between pre and post values of parametric data.

Wilcoxon test: test which compare between pre and post values of non-parametric data.

RESULTS

Table 1 and Fig. 1 show the mean preoperative parameters of all patients.

 Table (1): Demographic data of the studied cases

Variable		No. = 20
Gender	Male	11 (55.0%)
	Female	9 (45.0%)
Age	Mean±SD	27.85 ± 6.12
	Range	17 – 39



Fig (1): Sex difference among patients

• Uncorrected visual acuity (UCVA):

UCVA was measured using the decimal format for statistical analysis. Table 2 and Fig. 2 provide the mean of UCVA for all patients at the preoperative and 12 months postoperatively.

UCVA	Pre	Post	Mean difference	Paired t-test		
				t	P-value	Sig.
Mean \pm SD	0.07 ± 0.02	0.23 ± 0.11	0.17	7 571	<0.001	цс
Range	0.05 - 0.1	0.1 - 0.5		-7.371	<0.001	пз

P-value < 0.01: Highly significant

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Fig (2): mean difference in UCVA pre and postoperative

Spherical error:

Table 3 and Fig. 3 provide the mean of spherical error for all patients at the preoperative and 12 months postoperatively.

Table (3):	Change	in mean	of sphere	over one	e year
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Sph./D	Pre	Post	Mean difference	Wilcoxon test		
				Z	P-value	Sig.
Mean \pm SD	-7.26 ± 4.45	-1.45 ± 1.68	5.91	2 0 2 2	<0.001	цс
Range	-201	-4 - 2.75	5.81	-3.922	<0.001	пэ

P-value < 0.01: Highly significant



Fig (3): mean difference in spherical error pre and postoperative

Cylindrical error:

Table 4 and Fig. 4 provide the mean cylindrical error for all patients at the preoperative and 12 months postoperatively.

Table (4):	Change	in mean	of cylinder	over one year
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Cyl./D	Pre	Post	Mean difference	Wilcoxon test		
				Z	P-value	Sig.
Mean \pm SD	-4.86 ± 2.25	-1.98 ± 1.83	2.89	2760	-0.001	IIC
Range	-10 - 0	-6.5 - 2.5		-3.700	<0.001	пз

P-value < 0.01: Highly significant



Fig (4): mean difference in cylindrical error pre and postoperative

The maximum keratometry:

Table 5 and Fig. 5 provide the mean of K-max for all patients at preoperative and 12 months postoperatively.

Table (5): Change in mean of K-max over one year

Kmov/D	Pro Paired t-test				d t-test	
Killax/D	rie	rost	Wean unter ence	t	P-value	Sig.
Mean \pm SD	55.29 ± 4.03	49.15 ± 3.41	-6.14	6 254	<0.001	це
Range	47.94 - 63.2	42.2 - 52.7		0.234	<0.001	115

P-value < 0.01: Highly significant

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Fig (5): mean difference in Kmax pre and postoperative

DISCUSSION

Implantation of the Myoring permits customized treatment of keratoconus through control of the ring position, diameter and thickness. The pocket technique allows postoperative adjustment of the Myoring to achieve the best result⁽⁴⁾.

In this study, we evaluated the visual and refractive outcomes after Myoring implantation in eyes with keratoconus. At 1 year after surgery, we observed statistically significant reductions in myopia and cylinder. The changes were of large magnitude, with a mean change in sphere of 5.81 D and a mean change in refractive cylinder of 2.89 D. These levels of refractive change were consistent with those reported by **Alio** *et al.*⁽⁵⁾ who analyzed 12 eyes following Myoring implantation using femtosecond laser, and reported a mean change in sphere of 4.62 D and a mean change in cylinder of 3.17 D.

The significant level of refractive correction achieved with Myoring implants in our study was accompanied with a significant improvement in UCVA. The mean change UCVA improvement was 5 lines of logMAR from 0.05 to 0.5. With regard to BSCVA, we observed an improvement by 4 lines of logMAR from 0.2 to 0.6.

With regard to corneal topography, we observed a significant central flattening after surgery, which was consistent with the refractive change induced. The mean change in Kmax was 6.14 D from 55.29D to 49.15D.

This flattening effect is comparable to those reported by **Mahmood** *et al.*⁽⁶⁾, **Daxer** *et al.*⁽⁷⁾ *and Alio et al.*⁽⁵⁾ who also used the Myoring in keratoconus.

Bikbova *et al.*⁽⁸⁾ carried a retrospective cohort study in 41 eyes to estimate the effect of Myoring implantation using Pocket Maker in patients with grade II-III keratoconus for 3 years follow up.

The results show there was a statistically significant improvement in the UCVA, BSCVA, K readings and spherical equivalent (P<0.001). The mean UCVA improved by almost 6 lines, mean BSCVA improved by almost 2 lines and SE decreased by 7.72D (from -9.03D to -1.31D). The mean change in Kmax was 8.45 D from 51.56 D to 43.11D⁽⁸⁾.

In another study carried out by daxer and his colleagues fourteen eyes suffering from keratoconus were treated by Myoring implantation into a corneal pocket and according to different techniques for corneal pocket creation. The cases divided in two groups. In the first group (7eyes) the corneal pocket for Myoring placement was created using the DIOPTEX PocketMaker microkeratome.

In the second group (seven eyes) the corneal pocket were created using LDV femtosecond laser (Zeimer AG, Switzerland). Both groups consisted of moderate and advanced keratoconus cases with comparable severity of the disease measured in preoperative average Kmax of 52.06 + 6.51 D in the PocketMaker group and 51.65 + 3.18 D in the LDV group, respectively.

Both groups showed no statistically significant difference in the severity of the disease measured in preoperative central k-readings. Both groups had also comparable age and sex distribution⁽⁹⁾.

LIMITATIONS OF OUR STUDY

There was no evaluation of aberrations, the small group size and non-uniformity of patients at each stage of keratoconus.

CONCLUSION

At the end of the study we conclude that Myoring treatment is a safe, effective and fully reversible refractive surgery procedure which gives excellent results in a particular group of myopic patients suffering from moderate and high myopia.

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