Comparative Study between Myoring and Ferrara Ring Intracorneal Implantation Using Femtosecond Laser for Treatment of Keratoconus

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ABSTRACT

Background: Keratoconus is a bilateral progressive, non-inflammatory ectatic corneal disease characterized by changes in corneal collagen structure and organization. Though the etiology remains unknown, novel techniques are continuously emerging for the diagnosis and management of the disease. Intracorneal rings are an effective way for treating keratoconus; the surgery is safe and has an adequate biocompatibility. The procedure is adjustable and reversible and, most importantly, effective in improving unaided visual acuity (UAVA), best corrected visual acuity (BCVA).

Aim of the Work: To compare the efficacy of MyoRing versus Ferrara ring using femtosecond laser for treatment of keratoconus as regards the visual outcome, refractive changes, keratometery reading (K-max), proper depth tilt and haze by anterior segment OCT and complications.

Patients and Methods: This study included forty eyes of patients with keratoconus. They were divided into two groups. Group (A) included twenty eyes of patients with keratoconus subjected to femtosecond laser assisted MyoRing implantation, while Group (B) included twenty eyes of patients with keratoconus subjected to femtosecond laser assisted Ferrara ring implantation.

Results: In group (A) MyoRing all patients showed improvement in UAVA, BCVA, refraction and K-max except 4 patients (20%) who showed no visual improvement despite the refractive and topographic improvement. Using the anterior segment OCT in interpretation of visual, refractive and topographic findings showed that those 4 patients had their MyoRings implanted at shallower depth with presence of intracorneal ring tilt. In group (B) Ferrara ring all patients showed no visual improvement despite the refractive and topographic improvement. Using the anterior segment OCT in interpretation of visual, refractive the refractive and topographic findings showed that those 2 patients (10%) who showed no visual improvement despite the refractive and topographic improvement. Using the anterior segment OCT in interpretation of visual, refractive and topographic findings showed that those 2 patients had their Ferrara rings implanted at shallower depth with presence of intracorneal ring tilt.

Conclusion: In comparison between two rings, there were no differences in different parameters except that the Ferrara ring showed more improvement in BCVA and spherical component. Using the anterior segment OCT in assessment of implanted rings, helped us to explain the non-improvement in visual outcomes despite the refractive and topographic improvements.

Keywords: keratoconus, Anterior segment OCT, MyoRing, Ferrara ring, femtosecond laser.

INTRODUCTION Keratoconus is a bilateral progressive, non-inflammatory ectatic corneal disease characterized by changes in corneal collagen structure and organization. Though the etiology remains unknown, novel techniques are continuously emerging for the diagnosis and management of the disease ¹.

Common methods of vision correction for keratoconus range from spectacles and rigid gas permeable contact lenses to other specialized lenses. Corneal collagen cross linking is effective in stabilizing theprogression of the disease. Intracorneal ring segments can improve vision by flattening the cornea in patients with mild to moderate keratoconus. Topography guided customized ablation treatment betters the quality of vision by correcting the refractive error and improving the contact lens fit. In advanced keratoconus with corneal scarring, lamellar or full thickness penetrating keratoplasty will be the treatment of choice ¹.

Intracorneal rings are an effective way for treating keratoconus; the surgery is safe and has an adequate biocompatibility. The procedure is adjustable and reversible and, most importantly, effective in improving unaided visual acuity (UAVA), best corrected visual acuity (BCVA). It reduces the manifest refractive spherical equivalent (MRSE) and keratometry readings, improves contact lens tolerance, and reduces the anisometropia between the two eyes. Intracorneal rings have a positive impact on the quality of life in keratoconic patients².

The Myoring (DIOPTEX) is a complete, flexible, continuous, PMMA ring designed to correct moderate and high myopia. The diameter ranges from 5.0 to 8.0 mm, the thicknesses ranges from 150 to 350 µm and the width of the ring is 0.5mm. The anterior surface

is convex and the posterior surface is flat, with a radius of curvature of 6.0 mm. It can be considered a permanent contact lens, which, rather than being placed on top of the cornea, is squeezed into the cornea slightly underneath the corneal surface ³.

The Ferrara ICRS are made of polymethylmetacrilate (PMMA) Perspex CQ acrylic segments. They vary in thickness, and are available in 0.15, 0.20, 0.25 and 0.30mm. The segment cross-section is triangular, and the base for every thickness and diameter is 0.60mm. The segments have 90, 120, 160 or 210 degrees of arc 4 .

The femtosecond laser can be programmed to create tunnels for segment placement at predictable corneal depth. Studies show that tunnel creation with femtosecond laser is easier, faster, more precise and more comfortable for the patient over the mechanical technique 5,6 .

Anterior segment OCT quantitative imaging allows comprehensive 3-D quantitative analysis of the keratoconic cornea and the changes produced by ICRS treatment, as well as monitoring of the ICRS three-dimensional location ⁷.

AIM OF THE WORK

To compare the efficacy of MyoRing versus Ferrara ring using femtosecond laser for treatment of keratoconus as regards the visual outcome, refractive changes, keratometery reading (K-max), proper depth tilt and haze by anterior segment OCT and complications.

PATIENTS AND METHODS

Forty eyes of patients with keratoconus were subjected to this study and were divided into two groups. Group (A) included twenty eyes of patients with keratoconus subjected to femtosecond MyoRing laser assisted implantation, while Group (B) included twenty eyes of patients with keratoconus subjected to femtosecond laser assisted Ferrara ring implantation.

Study design

A comparative interventional therapeutic study from May 2015 till May 2017.

It was approved by the ethical board of Al-Azhar University and an informed written constent was taken from each participant in the study

Patient's selection Inclusion criteria:

- Age: 16 40 years.
- Both gender

- Thinnest corneal pachymetry higher than 390 um.
- Maximum keratometery between 48 to 60 D.
- Refraction: Patients with myopic component > astigmatic component where included in group (A) MyoRing and patients with astigmatic component > myopic component where included in group (B) Ferrara ring.
 - Clear central cornea
 - **B)** Exclusion criteria:
- Age: <16 or > 40 years.
- Thinnest pachymetry less than 390micron.
- Evidence of subepithelial or mid anterior stromal scar or opacities.
- Maximum Keratometery readings 60 D or more.
- Pregnancy, diabetes or autoimmune disease.

Preoperative evaluation:

A complete ocular examination included: visual acuity, refraction, slit-lamp examination, indirect Ophthalmoscopy, Keratometry and corneal topography.

-Visual Acuity:

Uncorrected (UCVA) and best corrected visual acuity (BCVA).

-Refraction:

Manifest and cycloplegic refraction were done, cycloplegic refraction is done one hour after instillation of 1% cyclopentolate eye drops.

-Slit Lamp Examination:

Anterior segment examination using the slit lamp was performed.

-Indirect ophthalmoscopy:

Fundus examination was done to assess the periphery as well as the central part of the retina.

-Keratometry and Corneal Topography:

Using corneal topography (Orbscan II and Orbscan III) with the curvature map, corneal thickness map, anterior and posterior elevation maps were done.

Nomogram used:

MyoRing diameter and thickness selection were based on manufacturer's nomogram, which is based on central average keratometery reading (average Sim K) (*table 1*)⁸.

Ferrara ring selection was based on manufacturer's nomogram table (*table 2*) (*Figure 1*), which is based on the manifest refraction (subjective) versus centration of the cone 4 .

In our study we preferred to put the incision on the flat meridian guided by the preoperative topography.

Keratometery	Mesopic pupil (mm)	Diameter (mm)	Thickness (um)
$K \le 44$	< 5.5	6	240
	< 4.5	5	240
$44 < K \leq 48$	≥4.5	6	280
	< 4.5	5	280
$48 < K \le 52$	\leq 4.5	6	320
K ≥ 52	< 4.5	5	320

 Table (1): Nomogram for MyoRing implantation

Table (?	2):	Nomogram	for	Ferrara	rino	impl	antation
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SE (D)	Cone	Cone	Cone	Cone
	Type I	Type II	Туре	Туре
			III	IV
>-10.00	250/350	250/350	300/350	350/350
-8.25 to	200/300	200/300	250/300	300/300
-10.00				
-6.25 to	150/250	150/250	200/250	250/250
-8.00				
-4.25 to	0/200	0/200	150/200	200/200
-6.00				
<-4.00	0/150	0/150	150/150	150/150

Мар	Distribution of Ectasia	Description
	0 %/100%	All the ectatic area is located at one side of the cornea.
	25%/75%	75% of the ectatic area is located at one side of the cornea.
Ó	33%/66%	66% of the ectatic area is located at one side of the cornea.
Ø	50%/50%	The ectatic area is symmetrically distributed on the cornea.

Figure (1): Nomogram selection for Ferrara ring.

The procedure:

- The procedure was performed under topical anesthesia using benoxinate hydrochloride 0.4%.
- Povidone iodine (Betadine) 5% was used to sterilize the eye, and povidone iodine 10% to sterilize the eyelids and surrounding skin.
- A plastic sterile drape (Opsite) was applied to draw away the lashes, followed by the application of a wire speculum to separate the eyelids.
- Placement of a suction ring to the eye followed by docking of the cone (*Figure 2*), centering and adjusting cone with Intraoperative guided anterior segment OCT (*Figure 3*).
- A tunnel for Ferrara ring (*Ferrara, AJL, Spain*) (*Figure 4*) and a pocket for Myoring (*Keratex, ITM, USA*) implantation were performed at 80% of the corneal thickness with the aid of femtosecond laser (*Figure 5*).
- After clearance of the gas bubbles, a spatula was passed gently (*Figure 6*) and the intracorneal rings were implanted under full aseptic conditions with a special forceps and placed in the final position with a Sinskey hook (*Figure 7*).
- Contact lens was then applied.



Figure (2): Docking of the cone.

Comparative Study between Myoring and Ferrara Ring Intracorneal...



Figure (3): Centering and adjusting cone.



Figure (4): Tunnel creation for Ferrara ring.



Figure (5): Pocket creation for MyoRing.



Figure (6): Passing a spatula gently.



Figure (7): MyoRing insertion into the pocket.

Post-operative medication:

-Topical Antibiotic eye drops (e.g. Gatifloxacin 0.3%, 5times/day for one week).

-Topical steroid eye drops (e.g. Prednisolone acetate 1%, 5times/day for one week).

-Lubricant eye drops.

Postoperative follow-up:

All patients were followed up for one year $(1^{st} \text{ month}, 3^{rd} \text{ month}, 6^{th} \text{ month} \text{ and } 12^{th} \text{ month})$, with corneal topography was done at 3^{rd} , 6^{th} month and anterior segment OCT at 3^{rd} month.

Both groups were compared as regards to: -Uncorrected visual acuity improvement.

-Best corrected visual acuity improvement.

-Astigmatism reduction.

-Spherical reduction.

-Keratometry reading (K-max).

-Postoperative complications (e.g. extrusion, deposits, infection).

Anterior segment OCT was done at 3rd month to assess intracorneal ring depth, tilt and haze

The depth of the intracorneal ring was measured from the apex of the ring perpendicular to the anterior corneal surface.

Tilt was measured by drawing a straight line (using anterior segment OCT software) between the inner edges of the intracorneal ring in both the vertical and horizontal cut scans passing through the apex of the cornea.

The anterior segment OCT was also used to assess the corneal haze which was defined as hyperreflective area along the site of insertion of intracorneal rings.

The study was done after approval of ethical board of al-Azhar university and an informed written consent was taken from each participant in the study. Data were analyzed using Statistical Program for Social Science (SPSS) version 20.0. Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

The following tests were done:

- Independent-samples t-test of significance was used when comparing between two means.
- Paired sample t-test of significance was used when comparing between related samples.
- Chi-square (X2) test of significance was used in order to compare proportions between two qualitative parameters.
- Probability (P-value)
- P-value < 0.05 was considered significant.
- P-value <0.001 was considered as highly significant.
- P-value >0.05 was considered insignificant.

RESULTS Demographic Data:

In Group (*A*) twenty eyes of 12 patients had Femtosecond laser assisted MyoRing implantation. There were 7 females (58.33%) from which 5 had a bilateral MyoRing implantation and 5 males (41.67%) from which 3 had a bilateral MyoRing implantation. The mean age was 27.75 ± 5.46 SD years (range: 17-38 years).

In Group (B) twenty eyes of 13 patients had Femtosecond laser assisted Ferrara ring implantation. There were 6 females (46.15%) from which 4 had a bilateral Ferrara ring implantation and 7 males (53.85%) from which 3 had a bilateral Ferrara ring implantation. The mean age was 24.75 ± 5.56 years (range: 17-35 years).

Comparison between Groups there were no statistically significant difference between groups according to demographic data.

Statistical analysis

 Table (3): Comparison between groups according to demographic data.

Demographic Data	Group (A) MyoRing	Group (B) Ferrara	t/x2*	p-value
Age (years)				
Mean±SD	27.75±5.46	24.75±5.56	2 065	0.003
Range	17_38	17_35	2.903	0.093
Gender				
Female	7(58.33%)	6(64.15%)	0.404*	0.525
Male	5(41.67%)	7(53.85%)	0.404	0.323

Mean Sphere readings:

In Group (*A*) mean preoperative sphere was -10.96 ± 5.31 D which shows a highly statistically significant difference along the periods of follow up postoperatively p-value was <0.001

Comparative Study between Myoring and Ferrara Ring Intracorneal...

Tuble (4). Dijjerence beiwe	(4) . Difference between preoperative and follow-up postoperatively according to sphere in group (A).					
Sphere	Group (A) MyoRing	Mean Diff.	t-test	p-value		
Preoperative	-10.96 ± 5.31					
At 1st month	-4.50±5.94	-6.46	-10.95	< 0.001		
At 3rd month	-4.33±5.64	-6.64	-11.72	< 0.001		
At 6th month	-4.23 ± 5.51	-6.74	-12.00	< 0.001		
At 12 month	-4.00±4.97	-6.96	-12.73	< 0.001		

Table (4): Difference between preoperative and follow-up postoperatively according to sphere in group (A).

In group (B) mean preoperative sphere was -3.79 ± 3.47 D which shows a highly statistically significant difference along the periods of follow up postoperatively p-value was <0.001.

Table (5): Difference between preoperative and follow up postoperatively according to sphere in group (B).

Sphere	Group (B) Ferrara	Mean Diff.	t-test	p-value
Preoperative	-3.79±3.47			
At 1st month	$0.19{\pm}2.42$	-3.98	-5.99	< 0.001
At 3rd month	0.13±1.86	-3.91	-6.02	< 0.001
At 6th month	-0.19±1.43	-3.60	-5.43	< 0.001
At 12 month	-0.11±1.24	-3.68	-5.83	< 0.001

In Comparison between Groups there was a statistically significant difference between two groups throughout the follow up period as regard the spherical reading.

Sphere	Group (A) MyoRing	Group (B) Ferrara	t-test	p-value
Preoperative				
Mean±SD	-10.96 ± 5.31	-3.79 ± 3.47	25 561	<0.001
Range	-215	-11.75_2	23.301	<0.001
At 1st month				
Mean±SD	-4.50±5.94	0.19 ± 2.42	10 692	0.002
Range	-17.5_3	-4_4	10.085	0.002
At 3rd month				
Mean±SD	-4.33±5.64	0.13±1.86	11 241	0.002
Range	-16.75_2	-3_3	11.241	0.002
At 6th month				
Mean±SD	-4.23 ± 5.51	-0.19±1.43	10.050	0.002
Range	-15.5_2	-3_2.5	10.039	0.005
At 12 month				
Mean±SD	-4.00±4.97	-0.11±1.24	11 520	0.002
Range	-14.5_1	-2.75_2	11.539	0.002

Table (6): Comparison between groups according to sphere.

Mean Cylinder reading:

In Group (A) mean preoperative cylinder was -3.85 ± 3.23 D which shows a statistically significant difference along the periods of follow up postoperatively.

Table (7): Difference between preoperative and follow up postoperatively according to cylinder in group (A).

Cylinder	Group (A) MyoRing	Mean Diff.	t-test	p-value
Preoperative	-3.85±3.23			
At 1st month	-2.40±1.67	-1.45	-2.89	0.009
At 3rd month	-2.24±1.67	-1.61	-3.33	0.003
At 6th month	-1.99±1.59	-1.86	-3.72	0.002
At 12month	-1.50±1.54	-2.35	-4.13	0.002

In group (B) mean preoperative sphere was -6.13±2.52 D which shows a highly statistically significant difference along the periods of follow up postoperatively p-value was <0.001.

Hany Sammour et al.

Cylinder	Group (B) Ferrara	Mean Diff.	t-test	p-value
Preoperative	-6.13±2.52			
At 1st month	-1.96 ± 2.00	-4.16	-8.46	< 0.001
At 3rd month	-1.56 ± 2.00	-4.56	-8.64	< 0.001
At 6th month	-1.25 ± 1.61	-4.88	-9.52	< 0.001
At 12month	-1.24 ± 1.60	-4.89	-9.58	< 0.001

Table (8): Difference between preoperative and follow up postoperatively according to cylinder in group (B).

In Comparison between Groups there was a no statistically significant difference between two groups throughout the follow ups as regard the cylinder reading.

Table (9): Comparison	between groups	according to c	hange of cylinder.
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Cylinder	Group (A) MyoRing	Group (B) Ferrara	t-test	p-value
Preoperative				
Mean±SD	-3.85 ± 3.23	-6.13±2.52	6 172	0.017
Range	-110.25	-100.25	0.175	0.017
At 1st month				
Mean±SD	$-2.40{\pm}1.67$	-1.96 ± 2.00	0 563	0.457
Range	-5_0	-8_1.75	0.303	0.437
At 3rd month				
Mean±SD	-2.24 ± 1.67	-1.56 ± 2.00	1 227	0.255
Range	-5_0	-8_1.75	1.557	0.233
At 6th month				
Mean±SD	-1.99 ± 1.59	-1.25 ± 1.61	2 1 2 7	0 152
Range	-5_0	-7_1	2.127	0.155
At 12month				
Mean±SD	-1.50 ± 1.54	-1.24 ± 1.60	0.270	0.600
Range	-4.5_2	-7_1	0.279	0.000

Mean UAVA:

In Group (A) mean preoperative UAVA was 1.20±0.030 LogMAR (range 0.1-1.4 Log MAR)

In group (B) mean preoperative UAVA was 1.04±0.33 LogMAR (range0.2-1.4 LogMAR).

In Comparison between Groups there was a no statistically significant difference between two groups throughout the follow up postoperatively.

Table (.	10):	Comparison	between	groups	according	to unaided	visual ac	cuity.
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UAVA (LogMAR)	MyoRing	Ferrara ring	t-test	p-value
Preoperative				
Mean±SD	1.20 ± 0.30	1.04 ± 0.33	2 600	0.115
Range	0.1-1.4	0.2-1.4	2.009	0.115
At 1st month				
Mean±SD	0.65 ± 0.33	0.71±0.25	0.504	0.482
Range	0.2-1.3	0.3-1	0.304	0.482
At 3rd month				
Mean±SD	0.64 ± 0.33	0.71±0.25	0.574	0.453
Range	0.2-1.3	0.3-1	0.374	0.433
At 6th month				
Mean±SD	0.62 ± 0.32	0.67 ± 0.25	0.200	0.591
Range	0.2-1	0.3-1	0.309	0.381
At 12 month				
Mean±SD	0.61 ± 0.32	0.65 ± 0.24	0.156	0.605
Range	0.2-1	0.3-1	0.150	0.093

Mean BCVA:

In Group (*A*) mean preoperative BCVA was 0.92±0.29 LogMAR (range 0.4-1.3 LogMAR)

In group (B) mean preoperative BCVA was 0.75±0.33 LogMAR (range 0.3-1.3 LogMAR).

In Comparison between Groups there was a statistically significant difference between two groups at the end of follow up.

Comparative Study between Myoring and Ferrara Ring Intracorneal...

BCVA (LogMAR)	MyoRing	Ferrara ring	t-test	p-value
Preoperative				
Mean±SD	0.92±0.29	0.75±0.33	2 11	0.096
Range	0.4-1.3	0.3-1.3	5.11	0.080
At 1st month				
Mean±SD	0.50±0.29	0.31±0.16	6 412	0.016
Range	0.1-1	0.1-0.7	0.415	0.010
At 3rd month				
Mean±SD	0.45±0.29	0.42 ± 0.28	0.11	0.742
Range	0.1-1	0.2-1	0.11	0.742
At 6th month				
Mean±SD	0.42 ± 0.31	0.47 ± 0.34	0.104	0.662
Range	0.1-1	0.2-1	0.194	0.002
At 12 month				
Mean±SD	0.39±0.31	0.67 ± 0.36	6 700	0.014
Range	0.1-1	0.2-1	0.709	0.014

Table (11): Comparison between groups according to best corrected visual acuity.

Mean K-max Readings:

In Group (*A*) mean preoperative K-max was 52.56±4.44 SD (range 47.4_59.8 D)

In group (B) mean preoperative K-max was 52.90±3.93 SD (range 46.4_59 D).

In Comparison between Groups there was a no statistically significant difference between two groups throughout the follow up postoperatively.

<i>Table (12):</i>	Comparison	between groups	s according to	K-max.
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Kmax	Group (A) MyoRing	Group (B) Ferrara	t-test	p-value
Preoperative				
Mean±SD	52.56 ± 4.44	52.90±3.93	0.069	0 705
Range	47.4_59.8	46.4_59	0.008	0.795
At 3rd months				
Mean±SD	46.48±5.25	45.97±4.70	0.102	0.750
Range	39.6_56.9	37.7_55.2	0.105	0.750
At 6th months				
Mean±SD	46.68±6.07	44.82 ± 4.77	1 1 / 9	0.201
Range	39.2_64.4	35.42_53.3	1.140	0.291

Complications:

No intraoperative complications had occurred during surgeries.

Postoperative complication included only the presence of intrastromal deposits which was observed at first month and lasted throughout the follow up period, *In Group* (A) 4 eyes (20%) had intrastromal deposits, and *In Group* (B) 7 eyes (35%) had intrastromal deposits.

In Comparison between Groups there was no statistically significant difference between two groups. *Table (13): Comparison between groups according to intrastromal deposits.*

Intrastromal deposits	Group (A) MyoRing	Group (B) Ferrara	x2	p-value
At 1st day	0(0.0%)	0(0.0%)	-	-
At 1st month	4(20.0%)	7(35.0%)	1.129	0.288
At 3rd month	4(20.0%)	7(35.0%)	1.129	0.288
At 6th month	4(20.0%)	7(35.0%)	1.129	0.288
At 12 month	4(20.0%)	7(35.0%)	1.129	0.288

Anterior segment OCT:

Ant OCT done at the 3^{rd} month of follow up to assess the proper depth of intracorneal rings which was defined as $80\% \pm 3\%$ of initial corneal thinnest location, presence of intracorneal ring tilt and corneal haze showed:

In Group (*A*) mean depth of implanted rings was 74.43 ± 12.54 % (range $37.9_82.5$ %) with 16 rings (80%) were within the proper depth, 6 rings (30.0%) were tilted, and one ring (5.0%) showed corneal haze.

In Group (*B*) mean depth of implanted rings was 78.35 ± 3.66 % (range $65_82.5$ %) with 18 rings (90.0%) were within the proper depth, 4 rings (20.0%) were tilted, and one ring (5.0%) showed corneal haze.

In Comparison between Groups there was a no statistically significant difference between two groups.

Ant OCT	Group (A) MyoRing	Group (B) Ferrara	t/x2*	p-value
Depth				
Mean±SD (%)	74.43±12.54	78.35 ± 3.66	1 802	0 197
Range (%)	37.9-82.5	65-82.5	1.602	0.187
Depth%				
More shallow	4(20.0%)	2(10.0%)	0 794*	0.276
Within proper depth	16(80.0%)	18(90.0%)	0.784*	0.570
Tilt				
No tilt	14(70.0%)	16(80.0%)	0 522*	0 465
Tilted	6(30.0%)	4(20.0%)	0.355*	0.465
Haze				
Corneal haze	1(5.0%)	1(5.0%)	0.000*	1 000
No corneal hzae	19(95.0%)	19(95.0%)	0.000*	1.000

Table (14): Comparison between groups according to Ant OCT.

DISCUSSION

Our study included 40 eyes with keratoconus, twenty eyes were subjected to Femtosecond laser assisted MyoRing implantation (Group A), and the other twenty were subjected to Femtosecond laser assisted Ferrara ring implantation (Group B). Preoperative visual acuity, refraction and topography were done, followed by twelve month of follow up of visual acuity, refraction, topography and anterior segment OCT.

To our knowledge this study is the first one to compare between the MyoRing and Ferrara ring intracorneal implantation in keratoconic patients by means of Femtosecond laser technology.

Also unique to our study is the use of Anterior segment OCT in assessment of Femtosecond laser assisted MyoRing implantation.

Group (A) MyoRing:

In our study *mean preoperative sphere* was - 10.96 ± 5.31 D which showed a highly statistically significant difference along the periods of follow up postoperatively, being - 4.50 ± 5.94 D at 1st month, - 4.33 ± 5.64 D at 3rdmonth, - 4.23 ± 5.51 D at 6th month and - 4.00 ± 4.97 D at 12th month.

This goes with a study done by *Hosney et al.*⁹ who investigates 15 femtosecond-assisted MyoRing implantation with mean change in sphere postoperatively was 4.45 ± 2.18 D.

*Jabbarvand et al.*¹⁰ in a study done on 98 keratoconic eyes of 98 patients had worst

results, where mean preoperative sphere was -5.48 \pm 4.30 D with postoperative mean change in sphere was 0.08 \pm 2.81 D at 1stmonth, 0.08 \pm 2.90 D at 3rdmonth, 0.10 \pm 2.90 D at 6thmonth and 0.09 \pm 2.91 D at 12thmonth. We owe this to the large pool of patients in his study which included keratoconic patients of grade I (15.3%), II (37.7%), III (24.5%) and IV (22.4%).

In our study *mean preoperative cylinder* was -3.85 ± 3.23 D which showed a statistically significant difference along the periods of follow up postoperatively, being -2.40 ± 1.67 D at 1st month, -2.24 ± 1.67 D at 3rd month, -1.99 ± 1.59 D at 6th month, -1.50 ± 1.54 D at 12th month.

This goes with a study done by *Alio et al.*¹¹ who evaluated the clinical outcome after implantation of the MyoRing by means of femtosecond laser technology on 12 eyes of 11 patients and reported mean preoperative cylinder -6.75 ± 2.99 D which changed postoperatively to -2.07 ± 1.20 D at 1st month, -2.07 ± 1.30 D at 3rd month and -2.45 ± 1.35 D at 6thmonth.

In comparison to our study **Daxer et al.**¹² performed a study on 15 eyes of 11 patients with keratoconus to assess the results of implantation of MyoRing with mean preoperative cylinder -3.50 ± 1.20 D and reported a statistical significant reduction in cylinder P= .0007 postoperatively, however the mean change was less than our study being-

 1.27 ± 0.75 D postoperatively. We owe this due to wide range of age included in his study 22 to 60 years old.

In our study mean preoperative UAVA was 1.20 ± 0.030 LogMAR which changed postoperatively to 0.65 ± 0.33 at 1^{st} month, 0.64 ± 0.33 at 3^{rd} month, 0.62 ± 0.32 at 6^{th} month and 0.61 ± 0.32 at 12^{th} month.

This goes with the study done by *Alio et al.*¹¹ who reported mean preoperative UAVA 1.36 ± 0.33 LogMAR which changed postoperatively to 0.69 ± 0.32 at 1^{st} month, 0.60 ± 0.30 at 3^{rd} month and 0.61 ± 0.25 at 6^{th} month.

This was also consistent with *Jabbarvand et al.*¹⁰ who reported mean preoperative UAVA 1.17 \pm 0.36 LogMAR which changed postoperatively to 0.66 \pm 0.31 at 1stmonth, 0.60 \pm 0.25 at 3rdmonth, 0.61 \pm 0.27 at 6thmonth and 0.62 \pm 0.28 at 12thmonth.

In our study the mean preoperative BCVA was 0.92 ± 0.29 LogMAR which changed postoperatively to 0.50 ± 0.29 at 1^{st} month, 0.45 ± 0.29 at 3^{rd} month, 0.42 ± 0.31 at 6^{th} month and 0.39 ± 0.31 at 12^{th} month.

This goes with the study done by *Alio et al.*¹¹ who reported mean preoperative BCVA 0.43 ± 0.24 LogMAR which changed postoperatively to 0.44 ± 0.26 at 1st month, 0.33 ± 0.22 at 3rd month and 0.32 ± 0.18 at 6thmonth.

Also *Jabbarvand et al.*¹⁰ in his study reported preoperative mean BCVA 0.85 ± 0.26 LogMAR and changed postoperatively to 0.51 ± 0.24 at 1^{st} month, 0.48 ± 0.21 at 3^{rd} month, 0.47 ± 0.23 at 6^{th} month and 0.52 ± 0.22 at 12^{th} month.

In our study *mean preoperative K-max* was 52.56 ± 4.44 D, which changed postoperatively to 46.48 ± 5.25 D at 3rd month and 46.68 ± 6.07 D at 6th month.

This correlates with the 18 month study done by *Mohebbi et al.*¹³ on 47 eyes of 46 patients with keratoconus and reported preoperative mean K-max 53.57 ± 3.72 D which changed postoperatively to 46.20 ± 4.34 D at 3rd month and 47.08 ± 3.84 D at 6th month.

Our results was also consistent with a study done by *Al-Tuwairqui et al.*¹⁴ who investigates 18 eyes with femtosecond laser-assisted MyoRing implantation with mean preoperative K-max 51.46±4.38 D which changed postoperatively to 45.10±3.37 D in 3rd month and 43.71±1.57 D in 6thmonth.

This also goes with a study done by *Janani et al.*¹⁵ who investigates 40 eyes MyoRing implantation with mean preoperative K-max 52.73 ± 4.14 D which changed postoperatively to 49 ± 24 D with 3 years of follow up.

In our study no *intraoperative complication* had occurred, this is consistent with the studies done by *Daxer et al.*⁸, *Alio et al.*¹⁰, *Jabbarvand et al.*¹¹ *and Janani et al.*¹⁵. Postoperative included the presence of intrastromal deposits in 4 eyes (20%) ^{8,10,11,15}.

In our study *the Anterior segment OCT showed mean* depth of implanted rings 74.43 ± 12.54 % with 16 rings (80%) within the proper depth, 6 rings (30.0%) tilted, and one ring (5.0%) showed corneal haze.

Using the anterior segment OCT in interpretation of our results helped us to explain the non-improvement in BCVA in 4 patients (20%) despite the improvement in their refractive and topographic results, as it showed that the MyoRing implanted in those patient were placed at a shallower depth than the preoperative planned one, being implanted at a depth 37.90%, 60.30%, 54.30% and 52.50% of the initial thinnest corneal location.

Also using the anterior segment OCT showed that the MyoRings implanted in those 4 eyes were tilted, which can explain the nonimprovement in BCVA despite the refractive and topographic improvement, mostly through induction of high order aberrations.

Group (B) Ferrara ring:

The refractive results in our study were a little bit different from other studies published.

In our study *mean preoperative sphere* was - 3.79 ± 3.47 D which shows a highly statistically significant difference along the periods of follow up postoperatively, being 0.19 ± 2.42 D at 1st month, 0.13 ± 1.86 D at 3rd month, -0.19 ± 1.43 D at 6th month and -0.11 ± 1.24 D at 12th month.

In a retrospective study done by *Kaya et al.*¹⁶ on 17 eyes with keratoconus implanted Ferrara ring using femtosecond Laser technology, he reported mean preoperative sphere -3.95 ± 1.41 D which changed to -1.81 ± 2.11 D at one year postoperative.

Also Ancèle et al.¹⁷ studied the effect of Ferrara ring implantation in 25 eyes of 25 patients with keratoconus and showed a mean preoperative sphere -4.39 ± 5.18 D which changed postoperatively to -2.34 ± 4.99 D at 1st month, -3.21 ± 4.98 D at 3rd month and -1.83 ± 3.16 D at 6thmonth.

In our study *mean preoperative cylinder* was -6.13 ± 2.52 D which shows a statistically significant difference along the periods of follow up postoperatively, being -1.96 ± 2.00 D at 1st month, -1.56 ± 2.00 D at 3rd month, -1.25 ± 1.61 D at 6th month and -1.24 ± 1.60 D at 12th month.

Kwitko and Severo ¹⁸ in retrospective study with mean follow up 13.0 month assessed the outcome of Ferrara intracorneal ring segment for 51 keratoconus eyes of 47 patients and reported mean preoperative cylinder -3.82 ± 2.13 D which changed postoperatively to -2.16 ± 2.07 D.

Kaya et al. ¹⁶ also showed a mean preoperative cylinder -3.54 ± 1.26 D which changed to -2.31 ± 1.03 at one year postoperative.

Ancèle et al. ¹⁷ showed a mean preoperative cylinder -4.19 ± 2.06 D which changed postoperatively to -2.77 ± 1.72 at 1st month, -2.75 ± 1.62 at 3thmonth and -2.57 ± 1.47 at 6thmonth.

Hamdi ¹⁹ also studied the effect of Ferrara intrastromal corneal ring segment implantation in 100 cases of keratoconus and reported mean preoperative cylinder 5.18 ± 2.10 D which changed postoperatively to -2.90 ± 2.50 D at 6th month.

Unlike the refractive results, the change in UAVA and BCVA were greater in our study compared to other studies.

In our study the *mean preoperative UAVA* was 1.04 ± 0.33 LogMAR which changed postoperatively to 0.71 ± 0.25 at 1^{st} month, 0.71 ± 0.25 at 3^{rd} month, 0.67 ± 0.25 at 6^{th} month and 0.65 ± 0.24 at 12^{th} month, with 19 patients (95%) had improvement in UAVA.

*Kwitko and Severo*¹⁸ in their retrospective study with mean follow up 13.0 month showed improvement in UCVA in 86.4% of eyes.

Kaya et al. ¹⁶ in his study showed improvement in UAVA in 88.2% of patients.

In our study the *mean preoperative BCVA* was 0.75 ± 0.33 LogMAR which changed postoperatively to 0.31 ± 0.16 at 1^{st} month, 0.42 ± 0.28 at 3^{rd} month, 0.47 ± 0.34 at 6^{th} month and 0.67 ± 0.36 at 12^{th} month, with 18 patients (90%) had improvement in BCVA.

*Kwitko and Severo*¹⁸ in their retrospective study with mean follow up 13.0 month showed improvement in BCVA in 86.4% of eyes.Also *Ancèle et al.*¹⁷ showed an improvement in BCVA in 72.8% of his patients.*Hamdi*¹⁹ reported in his prospective study 64% improvement in BCVA.

Also the mean change in K-max in our study was greater than other studies.

In our study the mean *preoperative K-max* was 52.90 ± 3.93 D, which changed postoperatively to 45.97 ± 4.70 D at 3rd month and 44.82 ± 4.77 D at 6th month.

Kaya et al. ¹⁶ showed a mean preoperative K-max 51.95±3.78 D which changed

postoperatively to 48.67 ± 3.00 at one year postoperative.

Ancèle et al.¹⁷ showed a mean preoperative K-max 54.27 ± 6.52 D which changed postoperatively to 51.42 ± 5.75 at 3thmonth and 50.39 ± 4.88 at 6thmonth.

In our study no *intraoperative complication* had occur which was consisting with *Kaya et al.*¹⁶ and Ancèle et al.¹⁷.

Postoperative complications included the presence of intrastromal deposits in 7 eyes (35%). **Ruckhofer et al.**²⁰ reported the presence of intrastromal deposits in the lamellar channels with incidence up to 60% with severity of the deposits increased with segment thickness.

In our study *the Anterior segment OCT showed* that the mean depth of implanted rings was 78.35 ± 3.66 % with 18 rings (90.0%) were within the proper depth, 4 rings (20.0%) were tilted, and one ring (5.0%) showed corneal haze.

In 2012 Ortiz et al.⁷ conducted a study on ten keratoconic eyes to characterize the geometrical properties of keratoconic corneas upon intracorneal ring segments implantation using anterior segment OCT, and reported that the 3D ICRS depth correlated with the ICR planned depth which was higher for femtosecond technique (15 ± 20 um between the planned and achieved depth), and showed a small tilt of the ICR between 7 and 90 days postoperative.

We can claim that the overall results of our study were better than other studies published about the Ferrara ring implantation in keratoconic patients, however our refractive results were less than other studies, the improvement in UAVA and BCVA were greater, which was confirmed also by improvement in topographic findings.

Using the anterior segment OCT in interpretation of our results helped us to explain the non-improvement in BCVA in 2 patients (10%) despite the improvement in their refractive results, as it showed that the Ferrara rings segments implanted in those patients were placed at a shallower depth than the preoperative planned one, being implanted at a depth 72.9% and 65% of the initial thinnest corneal location.

Also using the anterior segment OCT showed that the Ferrara rings implanted in those 2 eyes were tilted, which can explain the nonimprovement in BCVA despite the refractive improvement, mostly through induction of high order aberrations.

*Lyra et al.*²¹ in a recent retrospective study done on 241 eyes in 182 patients with keratoconus analyzed the topographic findings

after Ferrara intracorneal ring segment implantation and compared those changes with visual outcomes and reported that the implantation of the Ferrara ICRS changes the corneal tomographic parameters in both anterior and posterior surfaces but despite the changes in corneal parameters a poor correlation was found with the visual outcomes with further study to be done. We claim that the use of anterior segment OCT in interpretation of visual and topographic findings can explain the outcomes after intracorneal ring implantation.

In Comparison between the two Groups:

There was a statistical significant difference between two groups throughout the follow up periods postoperatively as regard the *mean spherical reading* being more in group(B) Ferrara ring with p=0.002 at 1st month, p=0.002 at3rd month , p=0.003 at 6th month and p=0.002 at 12th month.

The mean cylinder reading showed no statistical significant difference between two groups throughout the follow up periods postoperatively.

As regard the mean change in UAVA there was a no statistical significant difference between two groups throughout the follow up periods postoperatively.

The mean change in BCVA showed a statistical significant difference between two groups throughout the follow up periods postoperatively being more in group (B) Ferrara ring with p=0.019 at 1^{st} month, p=0.033 at 3^{rd} month , p=0.027 at 6^{th} month and p=0.028 at 12^{th} month.

There was no statistical significant difference between two groups throughout the follow up periods postoperatively as regard the *K-max readings*.

The postoperative complications and anterior segment OCT findings showed also no statistical difference between two groups.

CONCLUSION

Intracorneal rings are one of the most effective treatments in the management of keratoconic patients. It is a safe and reversible technique, which can regularize the irregular corneal surface resulting in improvement of visual function in non-progressive patients.

Using the femtosecond laser technology has allowed us to implant the intracorneal rings at the desired depth which minimize to a great extent the intraoperative complication.

Using the anterior segment OCT in assessment of implanted rings, helped us to explain the non-improvement in visual outcomes despite the refractive and topographic improvements.

In comparison between two rings, there were no differences in different parameters except that the Ferrara ring showed more improvement in BCVA and spherical component.

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