Impact of MyoRing Femtosecond-Assisted Intracorneal MyoRing Implantation in Management of Post Lasik

Mohamed I. EL-Kasaby, MD

Ophthalmology Department Al-Azhar University Cairo, Egypt
shahdmsaleh@hotmail.com

Abstract: Purpose: To evaluate long term follow‑up data on implantation of a full‑ring intra‑corneal implant (Myoring) for management of post lasikectasia and keratoconus with no cross linking postoperatively done. **Methods:** In this prospective, randomized, interventional clinical study, 40 eyes of 20 patients with postlasikectasia and keratoconus grade 2 to 4 entered the study. For all patients, a MyoRing (Dioptex, GmbH, Austria) was implanted using a femtosecond laser (Victus Femto Second Laser SW version 3.2 Technolas Perfect Vision GmbH. Munich, Germany). **Results**: The study evaluated 40 eyes of 20 patients 5 males (25%) and 15 female (75%) with keratoconus grade 2 to 4 entered the study with a mean age of 24.6 ± 7.92 years. Preoperatively, the mean central corneal thickness was 440.25±44.49 µm in the right eye and the mean central corneal central thickness 441.35±43.02 in the left eye, while mean keratometry (K) readings, 52.57±5.24 diopters (D) in the right eyes and 50.16±3.59 D in the left eyes. Postoperatively, there was a statistically significant improvement in the UDVA, CDVA, K readings, manifest spherical and cylindrical refractive errors, and spherical equivalent ($P<0.05$). The mean K reading decreased by 6.8 D, from52.57±5.24D to 45.77±2.16D in the right eyes and by 4.56D from 50.16±3.59 D to 45.60±3.63D in the left eyes. No serious intraoperative complications occurred. **Conclusions**: Myoring had the capability in halting the progression of the disease, Insert it whatever the site of lesion and no need for cross linking done postoperatively.

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1. Introduction:

keratoconus is a rare (prevalence of 1in 2000) chronic corneal disease affecting a young population. The cornea assumes a conical shape as a result of progressive, non-inflammatory thinning. Nonsurgical therapeutic options for keratoconus are spectacles and contact lenses. In more advanced cases and in cases of deformed or opaque cornea, corneal grafts, either lamellar or penetrating keratoplasty are the main treatment options. Although keratoplasty has acceptable results, ongoing research seeks less invasive methods including corneal collagen cross-linking and intrastromal corneal rings to treat keratoconus. Intrastromal corneal ring segment implantation has been proved to be safe approach to reinforce corneal structure in mild to moderate keratoconus and other ectatic disorders. However, they are not as effective in more advanced cases. The recently proposed MyoRing (Dioptex GmbH, Linz, Austria) is a complete intrastromal ring designed to be placed into a corneal pocket. A potential advantage of the MyoRing over ring segments is its effectiveness on advanced keratoconus and also its ability to reduce keratometric power of the cornea much more. [(1)] Satisfactory 6-month results of vision, refraction, keratometry, and corneal biomechanical properties following femtosecond-assisted MyoRingim plantation in a pilot study. [(2)]

2. Material and methods

Informed consent was taken after explanation of the procedure. Ethical committee approval from the Faculty of Medicine, Al –Azhar University, was obtained. In this prospective, randomized, interventional clinical study, patients with bilaterally keratoconus grade 2 to 4, or post-lasikkeratoectasia entered the study from march2014 to march 2017. A continuous (360°) intrastromal ring 6mm (MyoRing) was implanted in 40 eyes of 20 patients. No cross linking was done for all patients postoperatively. The inclusion criteria was based on slit-lamp observation and corneal topography, age between 20 and 35 years (24.6±7.92), akeratometry between 44.69±2.51 and 52.57±5.24 diopters (D), and a central corneal thickness (CCT) of at least 370 µm ranged between 421.50±44.28 and 462.70±42.47D. Patients who had any concomitant ocular disease or any history of ocular surgery were excluded from the study.

Surgical Technique

Topical and systemic antibiotics were prescribed 2 days before the surgery. After topical anesthesia by 0.5 % propacaine hydrochloride eye drops. A corneal pocket was created with a femtosecond laser (VictusFemto Second Laser SW version 3.2 Technolas Perfect Vision GmbH. Munich, Germany)) at a depth of 80% of corneal thickness with a pocket diameter 8.0 mm, frequency 80KHz, energy 0.95 micro Jules,

spot spacing and line spacing of 5.2 micrometer. First, the pupil center was marked with a Sinskeyhook before applanation. This mark was used as a reference point to locate the incision and to center the MyoRing after implantation. A temporal upper corneal incision of 90 degrees of arc length was made, and afterwards an intrastromal pocket was created. Once the pocket was created, a continuous 360° intrastromal ring (MyoRing) DIOPTEX GmBH, Linz, Austria with a diameter of 6 mm and thickness of 350 µ in all cases. A MyoRing was implanted without any complications. After the procedure, the same preoperatively local and systemic antibiotics were described for one week and lubricant prescribed for two months, not corticosteroid was prescribed at all. Slit lamp examination was performed for all patients on the first postoperative day. The patients received ophthalmic examinations and paraclinical evaluations before (at baseline) and 1, 3, 6, 18 and 36 months after the operation. Tests included uncorrected distance visual acuity (UDVA) and best-corrected distance visual acuity (CDVA) assessed using the 'automated chart projector' Topcon ACP.8, Tokyo Japan, Corneal indices, were evaluated with the Pentacame (Oculus pentacame, Optikgerate GmbH, D-35582Wetzlar, type70700, SN 34822150. Germany).

Statistical Methods Of Data Analysis

We calculate sample size according to Raosoft and All statistical calculations were done using SPSS (statistical package for the social science version 20.00) statistical program at 0.05, 0.01 and 0.001 level of probability (Snedecor and Cochran, 1982). Quantitative data with parametric distribution were done using Analysis of variance t test. The confidence interval was set to 95% and the margin of error accepted was set to 5%. The p-value was considered non-significant (NS) at the level of > 0.05, significant at the level of < 0.05, 0.01 and highly significant at the level of < 0.001. Pearson linear correlation coefficient (r) was estimated to show the relationship between quantitative parameters [(3)].

3. Results

Forty- eyes of 20 patients 5 males (25%) and 15 female (75%) with keratoconus grade 2 to 4 entered the study. The mean age of the participants was 24.6 ± 7.92 years. At the end of 36 months, 40 eyes were analyzed. No eyes were lost to follow-up.22 (55%) eyes presented with keratoconus2 (kc), 9 (45%) out of 22 eyes were right eyes and 13 (65%) were left eyes. 14(35%) patients presented with kc3, 8 right eyes (40.0%) and 6 (30.0%) left eyes.2 (5%) patients presented with kc4 and 5 (12.5%) were post lasikectasia. rh was 7.01±0.79, rv 6.53±0.68 and the mean rm was 6.77±0.71 improved post operatively to 7.90±0.59, 7.45±0.57 and 7.72±0.51, respectively with (P 0.000 HS) and in the left eye rh was 7.32±0.65, rv 6.85±0.67 and the mean rm was 7.11±0.63 improved post operatively to 7.81±0.34, 7.54±0.59 and 7.71±0.56 respectively with (T test 2.955 P 0.005s) (Ttest 3.437 P0.001S) (Ttest 3.207 P0.003S).

The k1 47.37±4.64 with axis 52.02±59.32, the k2 52.57±5.24 with axis 97.31±29.33, the k reading improved to 41.32±3.84 (T test 4.492) (P0.000 HS) with axis 38.93±29.79 (Ttest 0.882 p:0.383 NS), and 45.77±2.16 (Ttest 5.365 P 0.000 HS) with axis 121.30±23.62 (Ttest 2.849 P 0.000 HS) respectively. The mean k reading (km) preoperatively 50.19±4.83 improved to 42.94±2.93 (T test 5.739 P 0.000 HS) with astigmatism -198±4.72 changed to 1.81±1.73(T test 0.153 P 0.879 NS) and in the left eye The k1 44.69±2.51 with axis 132.00±40.26, the k2 50.16±3.59 with axis 70.57±21.88, the k1 reading improved to 42.06±2.28 (T test 3.477) (P0.001 S) with axis 132.00±40.26 changed to130.30 ±37.68 (Ttest0.139 p:0.890 NS), and K2 Was 50.16±3.59 with axis 70.57±21.88 changed to 45.60±3.63 (T test 45.60±3.63 P0.000 HS) with axis 67.07±32.02 (Ttest 0.404 P 0.688 NS) respectively. The mean k reading (km) preoperatively 47.53±2.88 improved to 43.53±2.56 (T test 4.639 P 0.000 HS) with astigmatism changed from -2.31± 3.69 preoperatively to -2.77± 1.23 (T test 0.523 P 0.604 NS). The corneal eccentricity preoperatively -0.35±1.17 changed to -0.84±2.23 (t test 0.859 P 0.396 NS, the pupil center was 440.25±44.49 improved to 476.57±41.36 (Ttest 2.674 P0.011 S). Also the thinnest location of the cornea preoperatively was 421.50±44.28 improved to 452.20±37.50 (Ttest 2.366 P 0.023S). Also the left eye showed the corneal eccentricity preoperatively -0.73±0.78 changed to-0.42±0.79 (t test 1.249 P 0.219 NS), the pupil center was 441.35±43.02 improved to 470.63±41.96 (Ttest 2.719 P0.036N S). The center of the pupil was 441.35±43.02 improved to 470.63±41.96 (t test 2.719 P0.036 NS. Also the thinnest location of the cornea preoperatively was 462.70±42.47 changed to 445.66±43.50 (t test1.394 P0. 1710NS). The anterior chamber depth (AC) 3.38±0.30 changed to (improved) 3.11±0.20 (t test 3.259 P0.002 S). The angle of AC was 35.48±4.48 improve to 28.81±5.59 (Ttest 4.165 P 0.000 HS, the pupil diameter was 3.29±0.55 changed to 3.43±0.51(T test 0.813 P 0.421NS). In the left eye the anterior chamber depth (AC) 3.32±0.24 changed to (improved) 3.23±0.30 (t test 1.068 P0.292 NS). The angle of AC was 38.47±6.33 improve to 31.22±7.58 (Ttest 3.284 P 0.002S, the pupil diameter was 3.25±0.49 changed to 3.00±0.42 (T test 1.713 P 0.095NS). Also the ART max was 122.23 ±34.04 changed to 138.80±37.64 (Ttest 1.460 P 0.153Ns), the back elevation was 51.63±10.64 improved to 47.51±10.46 (Ttest 1.233 P 0225NS). The ART max in the left eye was 126.26

±33.35 changed to 144.44±30.82 (Ttest 1.790 P 0.081 NS), the back elevation was 44.39±9.39 improved to 41.32±10.10 (Ttest 0.995 P 0.326NS). The refraction preoperatively was ranged between-4.87± 3.06 and -6.25±2.18 with axis 77.80 ±45.77 Improved postoperatively 0.44 ±1.64 and -1.75±1.94 with axis 90.95± 26.99 (Ttest 6.848, 6.889 and 4.896 respectively) with Pvalue (0.000 HS, 0.000 HS and 0.036S respectively). Also the refraction preoperatively in the left eye was ranged between-3.40± 3.48 and -4.02±3.42 with axis 122.50± 32.83 improved postoperatively 0.51 ±1.84 and -1.81±2.03 with axis 112.00± 17.50 (Ttest 3.285, 2.488 and 1.942 respectively) with Pvalue (0.002 S,0.017S and 0.031S respectively). The visual acuity was improved from (0.06 ±0.11) to (0.31± 0.11) (Ttest 10.212, P 0.000 HS) in the right eye and was improved from (0.11 ±0.09) to 0.34 ±0.11) (T test 6.933, P 0.000 HS) in the left eye.

Table (1): Results of Comparison between groups as regards the mean of right eye before, right eye after and their statistical significance.

		Groups		T test	P value
		right eye before	right eye after		
Rh		7.01±0.79	7.90±0.59	4.011	0.000 HS
Rv		6.53±0.68	7.45±0.57	4.601	0.000 HS
Rm		6.77±0.71	7.72±0.51	4.817	0.000 HS
K1	D	47.37±4.64	41.32±3.84	4.492	0.000 HS
	axis	52.02±59.32	38.93 ±29.79	0.882	0.383 NS
K2	D	52.57±5.24	45.77±2.16	5.365	0.000 HS
	axis	97.31±29.33	121.30±23.62	2.849	0.000 HS
Km		50.19±4.83	42.94±2.93	5.739	0.000 HS
Astigmatism		-1.98± 4.72	1.81± 1.73	0.153	0.879 NS
Ecc		-0.35±1.17	-0.84±2.23	0.859	0.396 NS
Pupil center		440.25±44.49	476.57±41.36	2.674	0.011 S
Thinnest location		421.50±44.28	452.20±37.50	2.366	0.023 S
A.C depth		3.38±0.30	3.11±0.20	3.259	0.002 S
Angle		35.48±4.48	28.81±5.59	4.165	0.000 HS
Pupil diameter		3.29±0.55	3.43±0.51	0.813	0.421 NS
ART max		122.23 ±34.04	138.80±37.64	1.460	0.153 Ns
Back elevation		51.63±10.64	47.51±10.46	1.233	0225 NS
Refraction		-4.87± 3.06	0.44 ±1.64	6.848	0.000 HS
		-6.25±2.18	-1.75±1.94	6.889	0.000 HS
		77.80 ±45.77	90.95± 26.99	4.896	0.036 S
VA		0.06 ±0.11	0.31± 0.11	10.212	0.000 HS

NS = Non significant level is considered at p value < 0.05.
S, HS = significant level is considered at p value < 0.001.

Table (2): Results of Comparison between groups as regards the mean of left eye before, left eye after and their statistical significance.

		Groups		T test	P value
		LEFT eye before	LEFT eye after		
Rh		7.32±0.65	7.81±0.34	2.955	0.005 s
Rv		6.85±0.67	7.54±0.59	3.437	0.001 s
Rm		7.11±0.63	7.71±0.56	3.207	0.003 S
K1	D	44.69±2.51	42.06±2.28	3.477	0.001 S
	axis	132.00±40.26	130.30 ±37.68	0.139	0.890 Ns
K2	D	50.16±3.59	45.60±3.63	3.994	0.000 HS
	axis	70.57±21.88	67.07±32.02	0.404	0.688 NS
Km		47.53±2.88	43.53±2.56	4.639	0.000 HS
Astigmatism		-2.31± 3.69	-2.77± 1.23	0.523	0.604 NS
Ecc		-0.73±0.78	-0.42±0.79	1.249	0.219 NS
Pupil center		441.35±43.02	470.63±41.96	2.719	0.036 NS
Thinnest location		462.70±42.47	445.66±43.50	1.394	0.171 NS
A.C depth		3.32±0.24	3.23±0.30	1.068	0.292 NS
Angle		38.47±6.33	31.22±7.58	3.284	0.002 S
Pupil diameter		3.25±0.49	3.00±0.42	1.713	0.095 NS
ART max		126.26 ±33.35	144.44±30.82	1.790	0.081 NS
Back elevation		44.39±9.39	41.32±10.10	0.995	0.326 NS
REFRACTION		-3.40± 3.48	0.51 ±1.84	3.285	0.002 S
		-4.02±3.42	-1.81±2.03	2.488	0.017 S
		122.50± 32.83	112.00± 17.50	1.942	0.031 S
VA		0.11 ±0.09	0.34 ±0.11	6.933	0.000 HS

NS = Non significant level is considered at p value < 0.05.
S, HS = significant level is considered at p value < 0.001.

Table (3): The correlation between Rh and items (RV, Rm, K1(D, axis), K2(D, axis), Km among the studied patients

Item	Person correlation coefficient (r)	P. value	Significance
Rv	0.797	0.000	significant
Rm	0.906	0.000	significant
K1D	-0.666	0.000	significant
K1axix	-0.078	0.489	Non significant
k2D	-0.729	0.000	Significant
k2axix	0.099	0.381	Non significant
Km	-0.786	0.000	significant

The study showed that there is statistically significant negative correlation between K1 (D, axis), K 2(D), Km with Rh, while statistically significant postive correlation between Rv, Rm with Rh ($p \leq 0.05$).

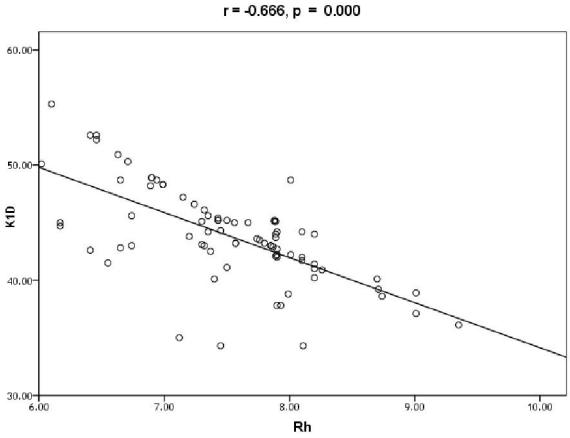
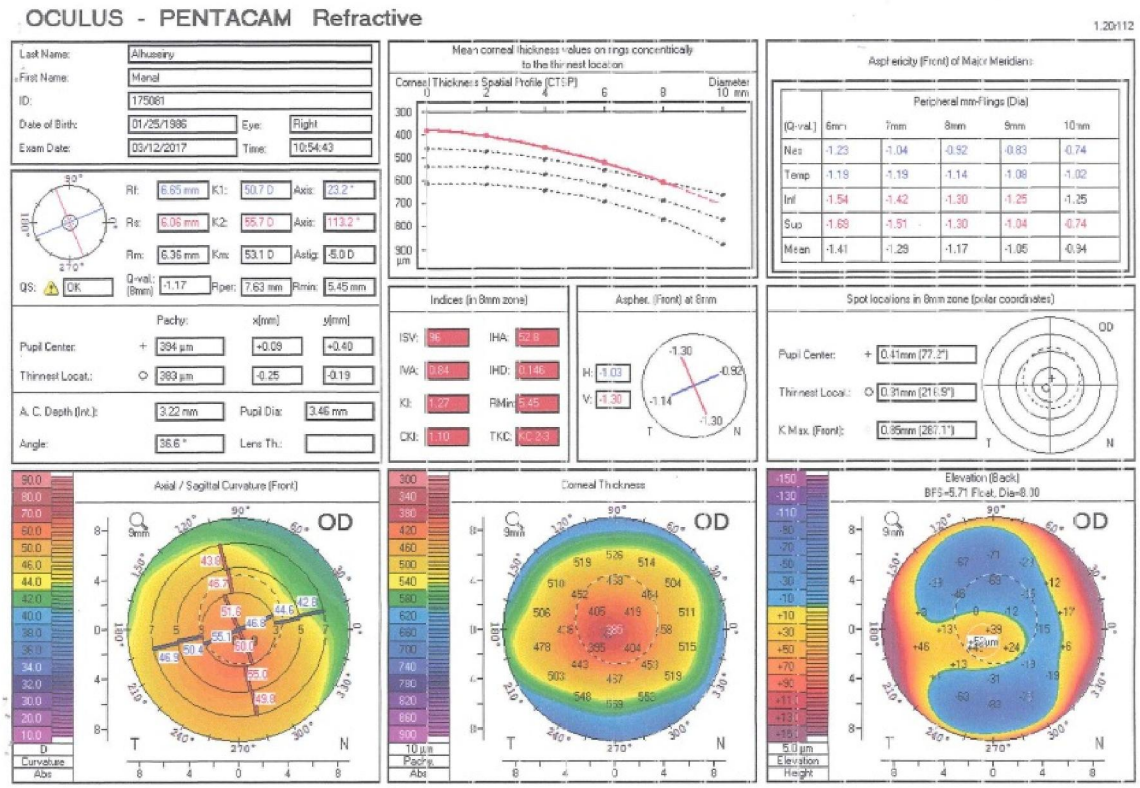


Fig (5): Linear correlation between Rh, K1(D) and their statistical significance statistical significance.



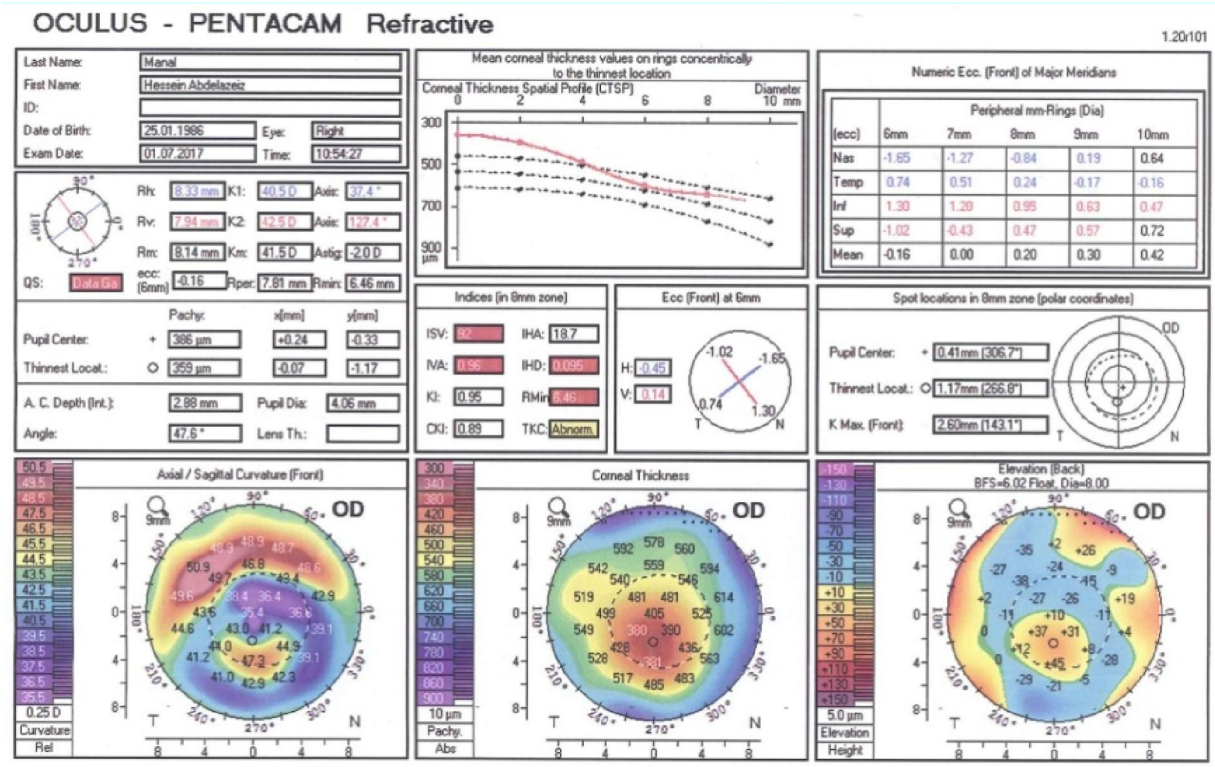


Fig (2): postoperatively difference map with improvement in k1 and k2 with decrease thinnest location

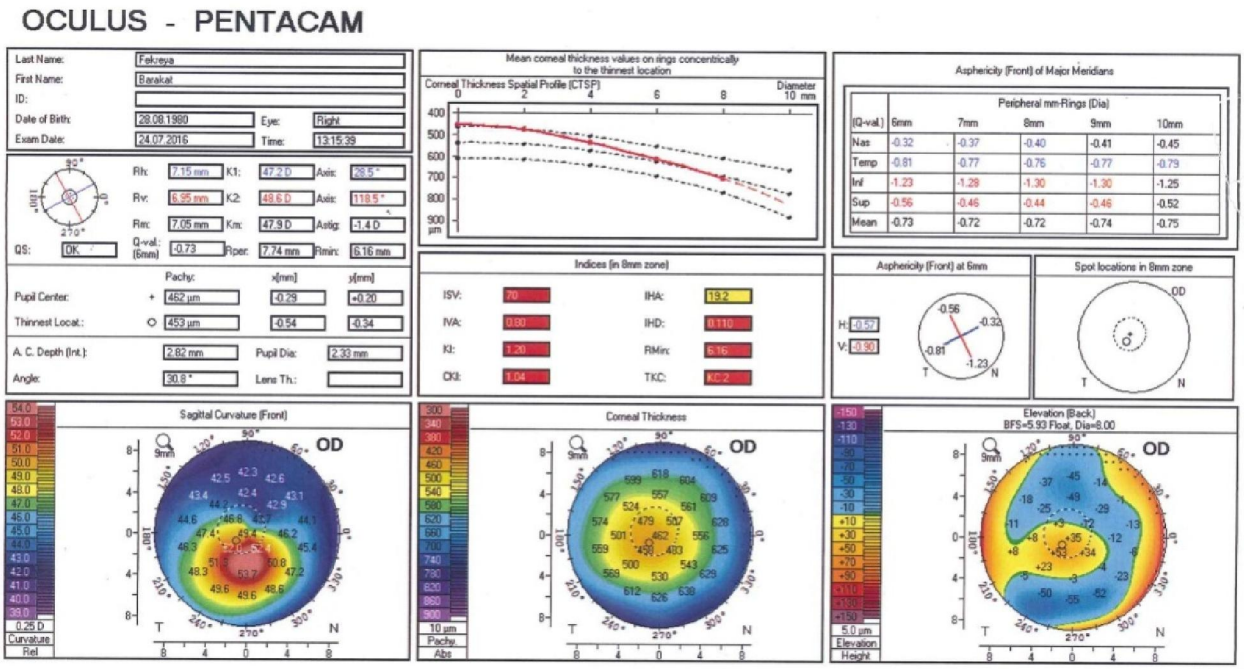


Fig (3): preoperatively k 147.2 and k 248.6 D with thinnest location 453µ

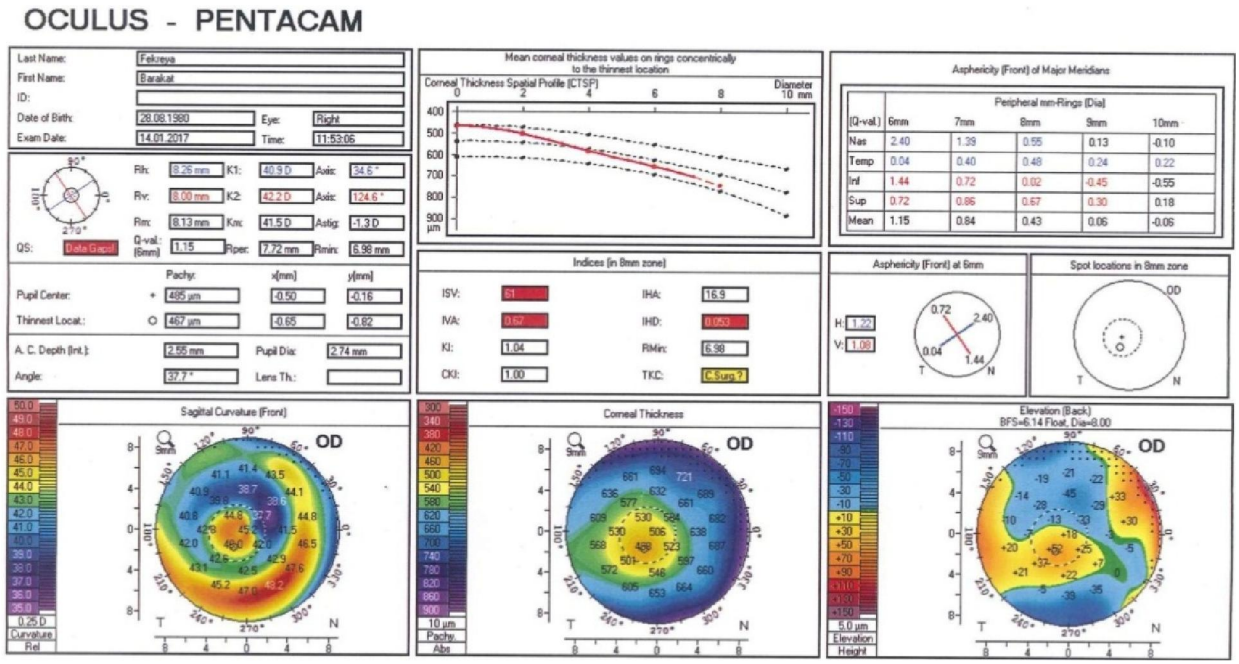


Fig (4): postoperatively (k1) 413 and (k2) 42.2D with thinnest location 467µ

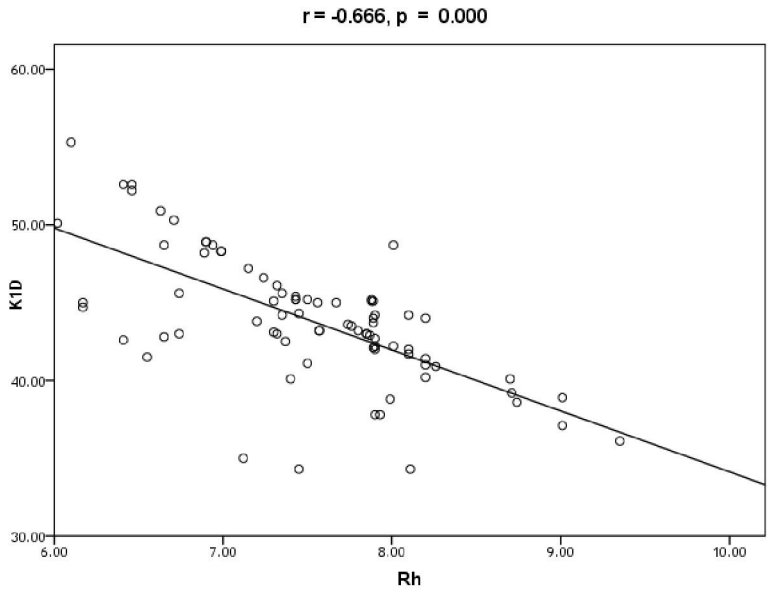


Fig (5): Linear correlation between Rh, K1(D) and their statistical significance statistical significance

4. Discussion:

The results of the present study show a significant improvement of K-reading, sphere and cylinder as well as uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) after MyoRing implantation in keratoconusatthe first follow-up approximately 3 months after surgery. (Table 1, 2,).

The present study showed that femtosecond-assisted intracorneal Myoring implantation improved visual acuity and refraction, and decreased keratometry 18 months after the procedure in patients with different grades of keratoconus. The results show a significant improvement of K-reading, sphere and cylinder as well as UDVA and CDVA. The safety, efficacy, and predictability of the procedure are acceptable and in line with other studies [4,5]. The rate of improvement of visual indices and refraction in our study was very similar to a study conducted by Jabbarv and et al. and another study performed by Alio et al. [1,2] In our study, the rate of Myoring exchange and removal was zero and disagreement

with study reported by others [6, 7, 8]. The explanation may be due to no postoperative corticosteroid was prescribed at all during the post-operative follow up, so the pocket healed faster. The status of preoperative visual acuity and refraction and the severity of keratoconus can affect the results of the operation. The reason for the apparent changes in the refraction and visual acuity of the patients could be the changes in the corneal surface due to the arc-shortening effect of MyoRing implantation, especially during the early weeks after the operation. The flexible nature of the MyoRing, its ability to touch the center of the cornea, and its central effect of flattening in the inferior and superior parts of the cornea can be the reason for this improvement [9]. In our study, (fig,1-4) we demonstrated a reduction in corneal power and astigmatism after MyoRing placement. The reduction in the mean corneal keratometry (7.25 D) and spherical power (4.5 D) in the right eye and km in the left eye (4.0D) and spherical power (2.21D) (fig: 5) was more significant than the cylindrical power reduction this study is agree with study by Alio et al. [1,2] Therefore, it can be concluded that MyoRing can reduce spherical power than astigmatic power. The correction levels of refractive and keratometric changes were larger than previous reports for Intacs (Addition Technology Inc, Des Plaines, Illinois, USA) segments in keratoconus. [1] The level of keratometry change in our study was closely related to vision improvement. The mean change in keratometry in this study was comparable only with that of previous studies on MyoRing and a study by Miranda and associates after Ferrara ring placement. [10]

Central corneal thickness and MCT had increased significantly by about 476.57±41.36 from 440.25±44.49 and 36.32µm in the right eye, and the mean central corneal thickness was 441.35±43.02 in the left increased by 470.63±41.96 and 29.28 µm this study with agree with study by Alio and associates reported significant thickening of the central cornea after MyoRing implantation [2]. The increase in the corneal thickness following MyoRing implantation a study performed by Alio et al., an increase of about 11.5 µm was observed in the CCT 6 months after the operation. The difference could have resulted from the difference in the thickness of the rings that were used in the two studies, the difference in the severity of keratoconus, variability of Pentacam CCT measurement, or the difference in the follow-up period. [9] While ACD showed a significant decrease from 3.38±0.30 to3.11±0.20 (0.27 mm in the right eye and the angle decreased 7.25 mm while in the left eye the ACD decreased up to 9mm and the angle 7.25mm, The significant decrease in ACD can be secondary to the flattening of the anterior surface and also the increase in the corneal thickness following MyoRing implantation. In the present study, CCT and MCT had increased significantly by about 10.0µm, while ACD showed a significant decrease of 0.27 mm. The significant decrease in ACD can be secondary to the flattening of the anterior surface and also the increase in the corneal thickness following MyoRing implantation this study disagree with study reported by Mohebbietal., [8] but agree with study reported by Alio et al., an increase of about 11.5 µm was observed in the CCT 6 months after the operation [2].

In the our study higher-order aberrations and coma and trophile aberrations were reduced significantly after surgery this study is agree with previous studies reported reduction of aberrations after ring segment implantation in keratoconus. [10] In a previous study by Alio and associates, higher-order aberrations did not change significantly and also coma-like aberrations were reduced non-significantly and reported a 2-m increase in spherical aberration. The increase was expectable because of flattening of the central part of the cornea and changing the shape of the cornea from prolate to oblate. [2] This study is disagree with my study because we used Myoring with a diameter 6-mm optical zone for mesopic pupil size 4.5 mm or less this explains the significant reduction of higher-order aberrations and coma-like aberrations in our study. After the MyoRing implantation, significant improvement of UDVA was obtained after 1 month, whereas significant improvement in CDVA was achieved after 3 months. There were no significant changes in CDVA values between the 6-month and 1-year follow-up visits. We observed that CDVA improved more slowly compared to UDVA. This may be due to the fact that MyoRing reduces the myopic refractive error significantly and improves UDVA earlier. But improvement in CDVA needs reduction of higher-order aberrations and coma that improves after 1 month along with improvement in CDVA. [11] Contrary to our results, Alio et al. and associates reported a non-significant increase in CDVA after 5-mm MyoRing implantation. [2] However, Daxer and Mahmoud and associates reported a significant increase that is consistent with our study. [4] We believe that poor results of CDVA in Alio and associates' study may have been caused by small ring size in proportion to the patient's pupil. In our study we reported a reduction in cylindrical value astigmatism changed from -2.31± 3.69 preoperatively to -2.77± 1.23 for MyoRing implantation in keratoconus the full ring implant has more arc shortening effect compared to ring segments this result is with agree with study reported by other. [2,4] The mean k reading (km) preoperatively 47.53±2.88 improved to 43.53±2.56 (T test 4.639 P 0.000 HS) (table:3). The level of keratometric changes was significant after 3 months in our study with no

significant changes afterward. The change is comparable to previous reports of MyoRing implantation in keratoconic patients. [12] It is greater than the result of ICRS in the patients with ectasia after lasik. [13] Alio et al. reported a small regression of keratometry at the 6-month follow-up visit, which was not observed in our results [2]. Our study showed improved visual acuity and refraction, and decreased keratometry 3 months after the procedure in patients with different grades of keratoconus. The safety, efficacy, and predictability of the procedure are acceptable and in line with other studies [14,15] The rate of improvement of visual indices and refraction in our study was very similar to a study conducted by Jabbarv and et al. and another study performed by Alio et al. [1, 2]

Compliance

with ethical standards.

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Conflict of interest:

The author certifies that they have no affiliations with or involvement in any organization or entity with any financial interest in the subject matter or materials discussed in this manuscript.

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