

Myoring Femtosecond-Assisted Intracorneal in Management of Keratoconus Mohamed I. EL-Kasaby

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Abstract

Purpose: To evaluate long term follow-up data on implantation of a full-ring intra-corneal implant (Myoring) for management of keratoconus with no cross linking postoperatively done. **Patients and methods:** A prospective non-randomized interventional clinical study was carried out at Nour- EL-Hayaha Eye Center (Cairo) between July, 2015 and July, 2017. 40 eyes of 20 patients with symptomatic marked diminution of vision and keratoconus grade 2 to 4 were enrolled in this 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). Inclusion criteria; age was between 18 and 35 years, maximum K reading less than 60D (based on pentacam examination), and a central corneal thickness (CCT) was at least 380 μm . Patients who had corneal scarring, any concomitant ocular disease or any history of ocular surgery were excluded from the study. Patients who failed to complete follow-up examinations one month after the surgery were also excluded. **Results:** 40 eyes of 20 patients 5 males (25%) and 15 females (75%) with keratoconus grade 2 to 4 enrolled in this study with a mean age of 24.6 ± 7.92 years. Preoperatively, mean central corneal thickness (CCT) was $440.25 \pm 44.49 \mu\text{m}$ in the right eye and mean CCT 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 uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), K readings, manifest spherical and cylindrical refractive errors, and spherical equivalent ($P < 0.05$). Mean K reading decreased by 6.8 D, from 52.57 ± 5.24 D to 45.77 ± 2.16 D. No serious intraoperative complications were occurred. **Conclusion:** Myoring had the capability in halting the progression of the disease, Insert it whatever the site of lesion and it was noticed that no need for cross linking done postoperatively. **Keywords:** Keratoconus, Femtosecond laser, MyoRing, Cross linking.

Introduction:

Keratoconus is a rare (prevalence of 1 in 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. 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 MyoRing implantation in a pilot study⁽²⁾.

Patients and methods:

In this prospective, randomized, interventional clinical study, 40 eyes of 20 patients with post lasik ectasia and keratoconus grade 2 to 4 entered the study. The study protocol was adhered to the tenets of declaration of Helisinki and was approved by the ethics board of AL- Azhar university .An informed written consent was taken from each participant in the study after a detailed explanation of the procedure and possible benefits and risks. Patients with a history of previous ocular surgery and coexisting ocular diseases other than keratoconus were excluded. Patients

who failed to complete follow-up examinations one month after surgery were also excluded. The demographic data, material and position of ICR, and ocular examinations results, including measurements of uncorrected distance visual acuity (UDVA) and best-corrected distance visual acuity (CDVA) at a distance using a logarithm of the minimum angle of resolution (logMAR) scale, refractive were assessed using status an autorefractometer (KR-8100; Topcon corporation, Tokyo, Japan) and 'automated chart projector' (Topcon ACP.8, Tokyo Japan), IOP measured by Goldman applanation tonometry (CT-80; Topcon corporation, Tokyo, Japan), slit lamp examination and fundus evaluation using an indirect ophthalmoscope were obtained. Corneal indices were evaluated using the Pentacam (Oculus pentacam, Optikgerate GmbH, Germany). Inclusion criteria included were; age is between 18 and 35 years, maximum K reading is less than 60D (based on pentacam examination), and a central corneal thickness (CCT) is at least 370 μ m. Patients who had corneal scarring, any concomitant ocular disease or any history of ocular surgery were excluded from the study. Patients who failed to complete follow-up examinations one month after the surgery were also excluded. 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).

Surgical procedure:

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 (Victus Femto 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 0.95micro Jules, spot spacing and line spacing of 5.2 micrometer. First, the pupil center was marked with a Sinsky hook 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 a lubricant was prescribed for two months, corticosteroid was prescribed only when corneal haze was present. Slit lamp examination was performed for all patients on the first postoperative day. The patients received ophthalmic examinations and 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

The sample size was calculated according to Raosoft and all statistical calculations were done using SPSS (Statistical Package for the Social Science version 20.00; SPSS Inc., Chicago, Illinois, USA). Quantitative data with parametric distribution were done using Analysis of variance t test .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⁾.

Results

Forty- eyes of 20 patients 5 males (25%) and 15 females (75%) with keratoconus grade 2 to 4 enrolled in this study. Mean age of the participants was 24.6 ± 7.92 years ((Range: 19-33 years). At the end of 36 months, 40 eyes were analyzed. 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.7 (17.5%) patients presented with kc4 (Fig.1,3). Horizontal radius of curvature (rh) was 7.01 ± 0.79 , verticle radius of curvature (rv) 6.53 ± 0.68 and mean radius of

curvature (rm) was 6.77 ± 0.71 improved post operatively as shown in(table,1) with (P 0.000 HS) (table :3).

K1 (Fig. 4,5) was 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 (T test 5.365 P0.000 HS) with axis 121.30 ± 23.62 (Ttest 2.849 P 0.000 HS) respectively. 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). 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 (T test 2.674 P0.011 S). Also the thinnest location of the

cornea preoperatively was 421.50 ± 44.28 improved to 452.20 ± 37.50 (T test 2.366 P 0.023S) .The anterior chamber depth(AC) 3.38 ± 0.30 was improved to 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 (T test 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). Also the ART(table 1,2) max was 122.23 ± 34.04 changed to 138.80 ± 37.64 (T test 1.460 P 0.153Ns), the back elevation was 51.63 ± 10.64 and was improved to 47.51 ± 10.46 (T test 1.233 P 0.225NS) . The refraction preoperatively (tables 1,2) 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 (T test 6.848, 6.889 and 4.896 respectively) with P value (0.000 HS, 0.000HS and 0.036S respectively). The visual acuity was improved from (0.06 ± 0.11) to (0.31 ± 0.11) (T test 10.212, P 0.000 HS) (tables 1,2). Higher order aberration was markedly improved significantly after operation.

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
Rms		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	0.225 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	0.001 HS

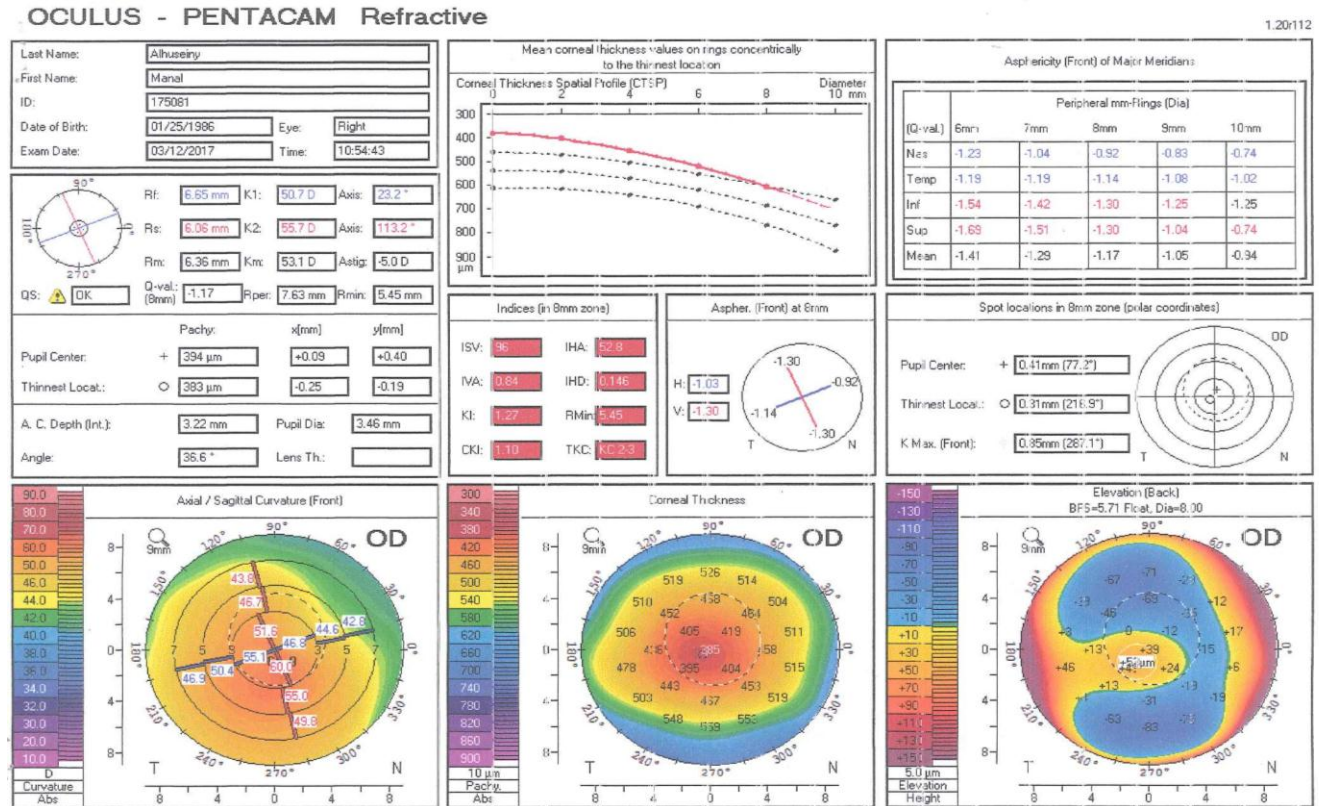
NS = Non significant level is considered at p value < 0.05.

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	0.001	significant
Rm	0.906	0.001	significant
K1D	-0.666	0.001	significant
K1axis	-0.078	0.489	Non significant
k2D	-0.729	0.001	Significant
k2axis	0.099	0.381	Non significant
Km	-0.786	0.001	Significant

The study showed that there is statistically significant negative correlation between K1 (D, axis), K2(D), Km with Rh, while statistically significant positive correlation between Rv, Rm with Rh ($p < 0.05$).



OCULUS - PENTACAM

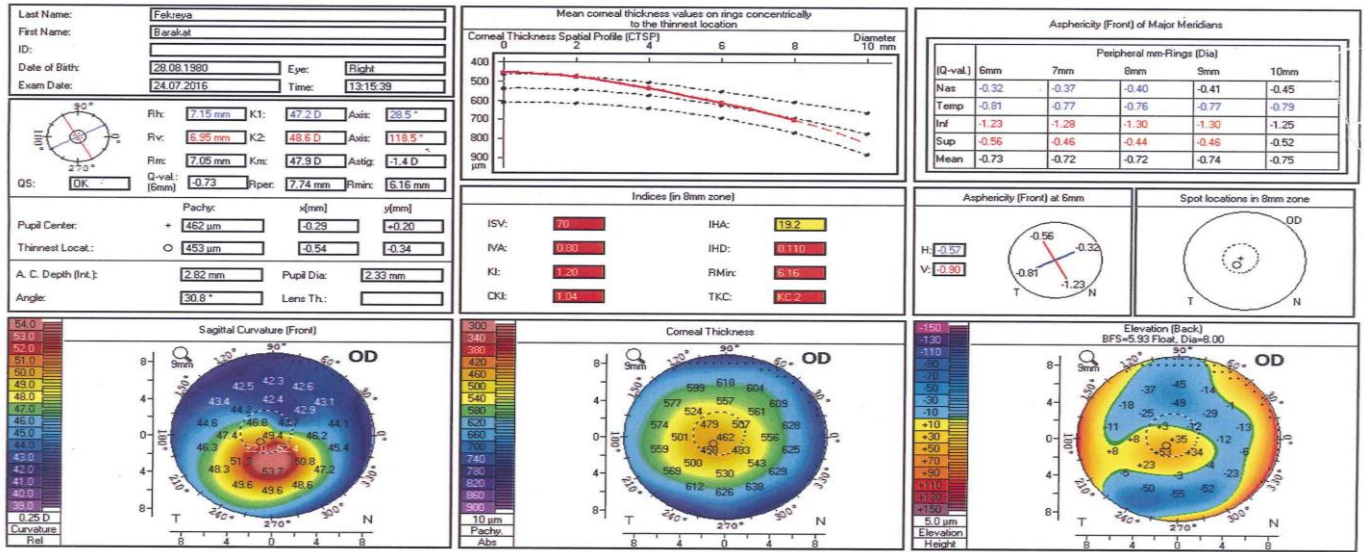


Fig.(2): Postoperative difference map with improvement in k1 and k2 with decrease thinnest location

OCULUS - PENTACAM Refractive

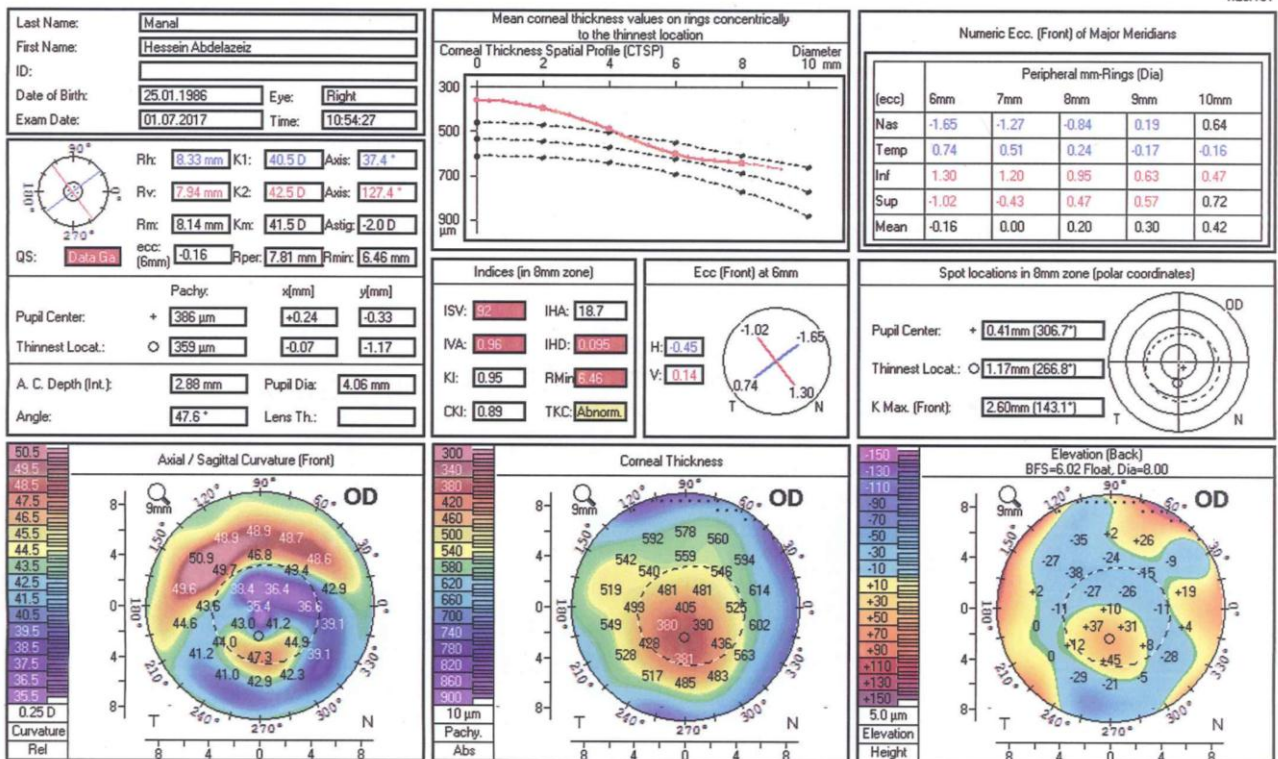


Fig.(3): Preoperative k147.2 and k248.6D with thinnest location 453µm

OCULUS - PENTACAM

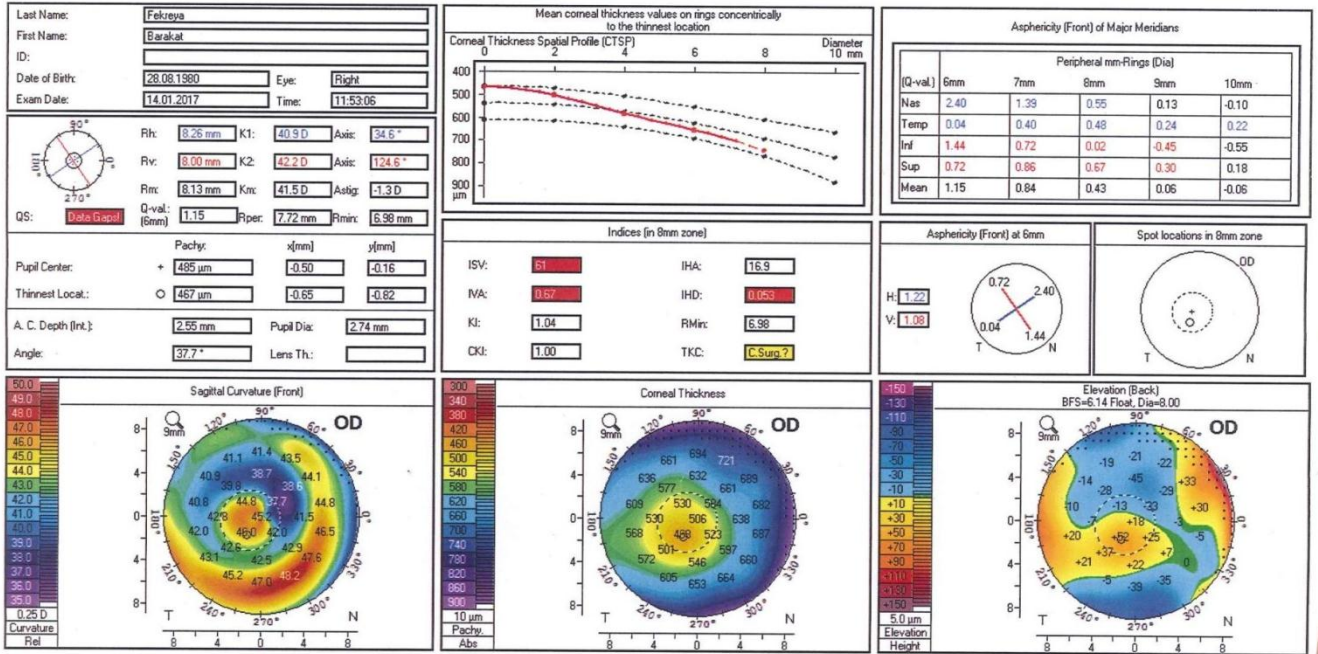


Fig.(4):Postoperative (k1)413and (k2)42.2D with thinnest location467µ

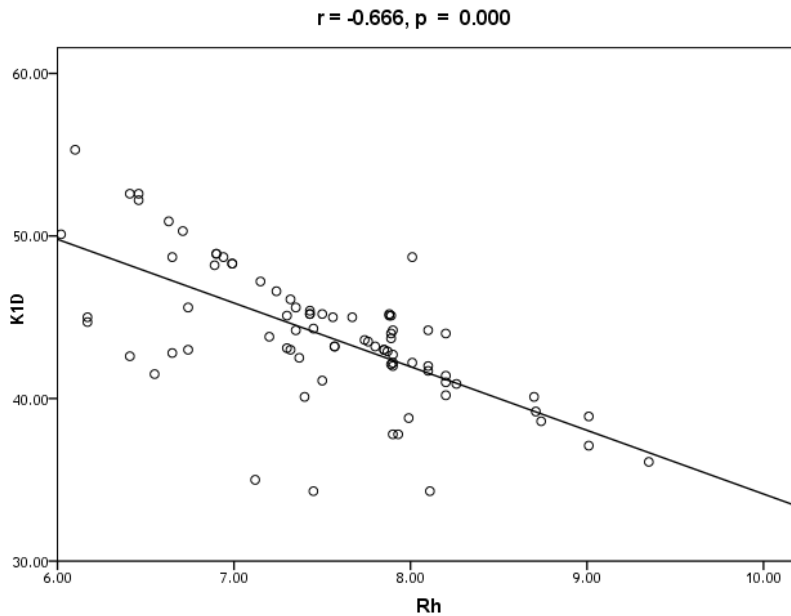


Fig.(5): Linear correlation between Rh, K1(D) and their statistical significance
statistical significance

Discussion:

Results of the present study showed a significant improvement of K-readings, spherical errors, cylindrical errors, uncorrected distance visual acuity as well as best corrected distance visual acuity after MyoRing implantation in keratoconus early at the first follow-up visits and continued to be maximally manifested approximately 3 months after surgery. The present study showed that femtosecond-assisted intracorneal Myoring implantation improved visual acuity and refraction, and decreased keratometric readings after the procedure in patients with different grades of keratoconus. The results showed a significant improvement of K-readings, spherical errors, cylindrical errors 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 et al.**⁽¹¹⁾. and another study performed by **Alio et al.**⁽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) (Fig.5) was more significant than the cylindrical power reduction this study was agree with study by **Alio et al.**⁽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 et al.**⁽¹⁰⁾ after Ferrara ring placement.

Central corneal thickness and MCT had increased significantly by about 476.57 ± 41.36 from 440.25 ± 44.49 and $36.32 \mu\text{m}$, this study with related with study by **Alio et al.**⁽²⁾ who reported significant thickening of the central cornea after MyoRing implantation. The increase in the corneal thickness following MyoRing implantation a study reported by **Alio et al.**⁽²⁾ an increase of about $11.5 \mu\text{m}$ 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 to 3.11 ± 0.20 (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. In the present study, CCT and MCT had increased significantly by about $10.0 \mu\text{m}$, while ACD showed a significant decrease of 0.27 mm. This study was disagree with study reported by **Mohebbi et al.**⁽⁸⁾. This study was closely related to study reported by **Alio et al.**⁽²⁾ who reported increasing about $11.5 \mu\text{m}$ was observed in the CCT 6 months after the operation⁽²⁾. In the presenting study, high-order aberrations (coma and trophile) were reduced significantly after surgery this presenting study was closely related with previous studies reported reduction of aberrations after ring segment implantation in keratoconus⁽¹⁰⁾. In a previous study by **Alio et al.**⁽²⁾ 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. This study was disagree with presenting study, because we used Myoring with a diameter 6-mm optical zone for mesopic pupil size 4.5 mm or less and 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.⁽²⁾ who reported a non-significant increase in CDVA after 5-mm MyoRing implantation. However, Daxer et al.⁽⁴⁾ reported a significant increase that was consistent with our study. We believe that poor results of CDVA in Alio et al.⁽²⁾ 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 in keratoconus, the full ring implant has more arc shortening effect compared to ring segments this result was closely related with study reported by others^(2,4). Mean k reading (km) preoperatively improved with highly significant value. The level of keratometric changes was significant after 3 months in presenting study with no significant changes afterward. The change was comparable to previous reports of MyoRing implantation in keratoconic patients⁽¹¹⁾. It was greater than the result of ICRS in the patients with ectasia after lasik⁽¹²⁾. Alio et al.⁽²⁾ reported a small regression of keratometry at the 6-month follow-up visit, which was not observed in our results. In our study showed improved visual acuity, 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^(13,14). The rate of improvement of visual indices and refraction in our study was very similar to a study conducted

by Jabbarv et al.⁽¹⁾ and another study performed by Alio et al.⁽²⁾.

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Conflict of interest : certifies that he has 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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