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Outcome of intrastromal corneal ring segment relative to depth of insertion evaluated with scheimpflug image

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Abstract

Purpose: To report the results of intrastromal corneal ring segment (KeraRing; Mediphcose, Belo Horizonte, Brazil) implantation relative to depth of insertion in keratoconic patients.

Methods: In this retrospective, observational study, we evaluated 29 eyes of 27 patients with keratoconus who underwent implantation of KeraRing SI-5 with mechanical tunnel creation. In the mean follow-up of 8.8 months, all eyes underwent scheimpfluge image of pentacam (Oculus, Germany) to determine insertion depth. Based on the measured implantation depth, cases were categorized into: 40–59% thickness group, 60–79% thickness group, and $\geq 80\%$ thickness group. Visual, refractive, and shape outcomes were evaluated relative to implantation depth.

Results: The mean insertion depth was 61.7%.We had 41.4% of cases were in the 40–59% thickness group, 51.7% in the 60–79% group, and 6.9% in the $> 80\%$ group. Results were similar in 40–59% and 60–79% thickness groups: uncorrected visual acuity (UCVA) and best spectacle corrected VA (BSCVA) improved 3 and 2 lines, respectively, maximum keratometry (Kmax) decreased 2.6 D, refractive cylinder improved 2.04 D, and Q value 8 mm anterior changed by 0.35. In the $\geq 80\%$ thickness group, UCVA and BSCVA improved less than 1 lines, Kmax change was less than 0.5 D, and RC decreased less than 0.25 D.

Conclusion: Implantation of KeraRing with mechanical tunnel creation in 40–80% of stromal thickness despite the variable insertion depth is effective.

Keywords: KeraRing; Keratoconus; Scheimpflug; Pentacam

Introduction

Keratoconus is a noninflammatory, bilateral, asymmetric disease of the cornea. The localized thinning and protrusion induce irregular astigmatism and decrease visual acuity. In mild form, glasses or hard contact lens may be effective, but in more advanced stages of keratoconus or contact lens intolerance, surgery will be the only viable option.[1–6]

Deep lamellar keratoplasty and penetrating keratoplasty can be effective methods in advanced keratoconus, but with the risk of graft rejection, endothelial cell loss, corneal vascularization, the long postoperative recovery period, and the need for medication several months after surgery, planning must be considered very carefully.[7–10]

Barraquer[11] suggests the application of intrastromal implants for the correction of myopia and astigmatism. Studies have demonstrated that the implantation of intrastromal corneal ring segment (ICRS) is a safe and effective treatment of keratoconus. The main advantages of ICRS are reversibility, stability, and safety.[12–17]

KeraRing, (Mediphacos, Belo Horizonte, Brazil) made of PMMA, is a minimally invasive surgical option for keratoconus that is characterized by a triangular cross-section segment that induces prismatic effect and flattening of the cornea. The optical zone provided by KeraRing SI-5 is 5.0 mm in diameter. Their apical diameter is 5 mm with variable arc length (90°, 160°, and 210°) and thickness (0.15–0.35 mm thickness with 0.05 mm step).[18]

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However to the best of our knowledge, there are no reports on the effect of insertion depth of KeraRing on the outcome. In this study, we evaluated the outcome of KeraRing implantation relative to insertion depth as measured with scheimpflug image of pentacam.

Methods

In this retrospective study, keratoconus patients who had KeraRing implantation between April 2013 and January 2014 at Nikookari Eye Hospital in Tabriz, Iran were evaluated. Informed consent was obtained from all patients.

Inclusion criteria included all patients with keratoconus who underwent KeraRing implantation. Exclusion criteria included history of cross linking, post LASIK ectasia, or intraoperative or postoperative complicationsly.

The KeraRing SI-5 (Mediphacos, Brazil) was implanted in each eye according to the manufacturer's nomogram (KeraRing Calculation Guidelines 2009), segment distribution, and thickness according to the area of ectasia and refraction.

Surgical technique

All surgical procedures were performed using general anesthesia by one surgeon. The geometric center of the cornea was marked. A 5 mm marker was used to locate the ring channel. The incision was performed on the steepest topographic axis using a diamond blade. The tunnel depth was set at 80% of the thinnest corneal thickness on the tunnel location using a pachymetric map of pentacam. The tunnel was created using a counterclockwise and clockwise spatula. The KeraRing was inserted in the tunnel using forceps, and spatulas were provided by the respective manufactures. Finally, the incision was closed with a 10-0 Nylon suture. A bandage contact lens was placed on all eyes and removed after 24 h. Postoperative antibiotic and steroid eye drops were prescribed 4 times daily, and the suture was removed after four weeks.

Patient evaluation

The following preoperative and post operative data were evaluated: uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BSCVA), refractive cylinder (RC), and maximum keratometry reading (Kmax) from the Auto Kerato-Refractometer (Tomy); Q value 8 mm Anterior from the 4 refractive maps Pentacam (Oculus, Germany). UCVA and BSCVA were converted to LogMAR for statistical analysis. Scheimpflug image was performed postoperatively using the Pentacam to determine the depth at which KeraRing were implanted into the cornea. All measurements were performed by one surgeon. The depth of implanted segment was measured at the middle of its length. The stromal thickness was measured over (t1) and under (t2) the segment. KeraRing depth was calculated as $t1/(t1 + t2)$, and the result was multiplied by 100 to determine the percent of stromal depth in which the KeraRing had been inserted. If the two segments had been implanted, the result of the superior and inferior segment were then averaged. The cases were categorized into 3 groups based on measured implantation depth: 40–59%, 60–79%, and $\geq 80\%$ thickness (Figs. 4–6).

Statistical analysis

Data were analyzed using SPSS version 20 (SPSS, Inc.). The paired-samples T test was used to compare the preoperative and postoperative values of UCVA, BSCVA, RC, Kmax, and Q value. A p value less than 0.05 was statistically significant. The regression linear test was used to assess the relation between the study parameters.

Results

The study enrolled 29 eyes of 27 patients. The mean age of the patients was 27.24 $\pm$ 7.6 years (range, 16–45 years). Seven patients (24.1%) were women, and 22 patients (75.9%) were men. One segment was inserted in 17 eyes, and 2 segments were inserted in 12 eyes. The mean follow-up time was 8.8 months (range, 4–12 months).

Visual acuity

The mean preoperative UCVA for all eyes (n = 29) was 0.8 $\pm$ 0.28 logMAR (range, 0.18–1.3 logMAR). The postoperative mean of UCVA was 0.5 $\pm$ 0.32 logMAR (range, 0.1–1.3 logMAR; $p < 0.001$). The mean preoperative BSCVA was 0.41 $\pm$ 0.22 logMAR (range, 0.1–1.00 logMAR). Postoperatively, the mean BSCVA was 0.18 $\pm$ 0.16 logMAR (range, 0.0–0.7 logMAR; $P < 0.001$) (Table 1).

Refractive and shape results

The mean preoperative maximum keratometry (Kmax) was 51.05 $\pm$ 5.25D (range, 45–64 D) and decreased to 48.58 $\pm$ 4.17D (range, 43–59 D; $p < 0.001$). There was a statistically significant reduction in refractive cylinder from 5.1 $\pm$ 1.72 D (range, 8.00–1.75 D) preoperatively to 3.17 $\pm$ 1.68 D (range, 6.00–0.50 D; $p < 0.001$) postoperatively. The mean preoperative Q value was 0.84 $\pm$ 0.42 (range, 0.07–1.80) postoperatively decreased to 0.53 $\pm$ 0.38 (range, 0.06–1.46; $p < 0.001$) (Table 1).

Results and depth of insertion

Based on scheimpflug image of Pentacam, the mean depth of insertion was 61.78% (range, 41.20–88.80%). There were 12 cases (41.4%) in 40–59% thickness group, 15 cases (51.7%) in the 60–79% group, and 2 cases (6.9%) in the $\geq 80\%$ group. Overall, UCVA changed by 0.30 $\pm$ 0.05 logMAR, and BSCVA increased by 0.23 $\pm$ 0.03 logMAR, which is approximately a gain of 3 and 2 Snellen lines, respectively. Kmax decreased by 2.47 $\pm$ 0.39 D, RC improved 1.92 $\pm$ 0.26 D, and Q value decreased by 0.31 $\pm$ 0.27.

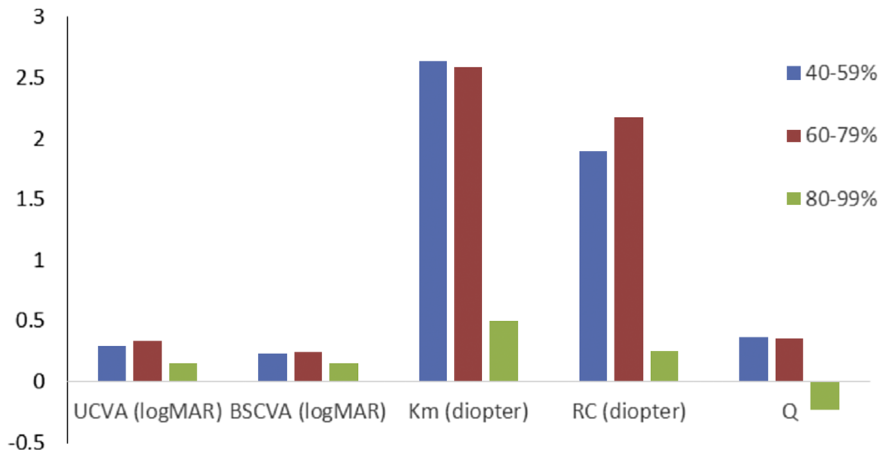

Fig. 1. Bar graph demonstrating changes in uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BSCVA), maximum keratometry (Km), refractive cylander (RC) and Q value 8 mm anterior (Q) by corneal thickness depth of Keraring insertion group.

This result is similar in the 40–59% and 60–79% thickness group (Table 2, Fig. 1).

There was no statistically significant correlation between the depth of KeraRing insertion and changes in UCVA, BCVA, Kmax, RC, and Q Value (Table 3, Figs. 2 and 3).

Discussion

Several studies[19–21] show that ICRS implantation is a safe and effective method of managing keratoconus, KeraRing by shortening the arc length and flattening the corneal surface induced significant improvement in UCVA, BSCVA, and keratometry. In the current study, we evaluated the effect of implantation depth in the corneal stroma on the postoperative outcome after KeraRing. There was a significant improvement in the visual acuity result of UCVA and BSCVA. Shabayek and Alio,[15] report the 6-month results of Keraring ICRS: the mean increase was 0.06–0.30 (decimal scale) in UCVA and 0.54 to 0.71 in BSCVA. Coskunseven et al,[18] reported a mean gain in UCVA 1.7 line and 1.3 line in BSCVA. In our results, there was a UCVA gain of 3 lines and BSCVA of 2 lines in the mean follow-up of 8.8 months. We also found a significant decrease in Kmax and RC. Coskunseven et al,[18] report a decrease in K power of 3.07 D. In a study by Shabayek and

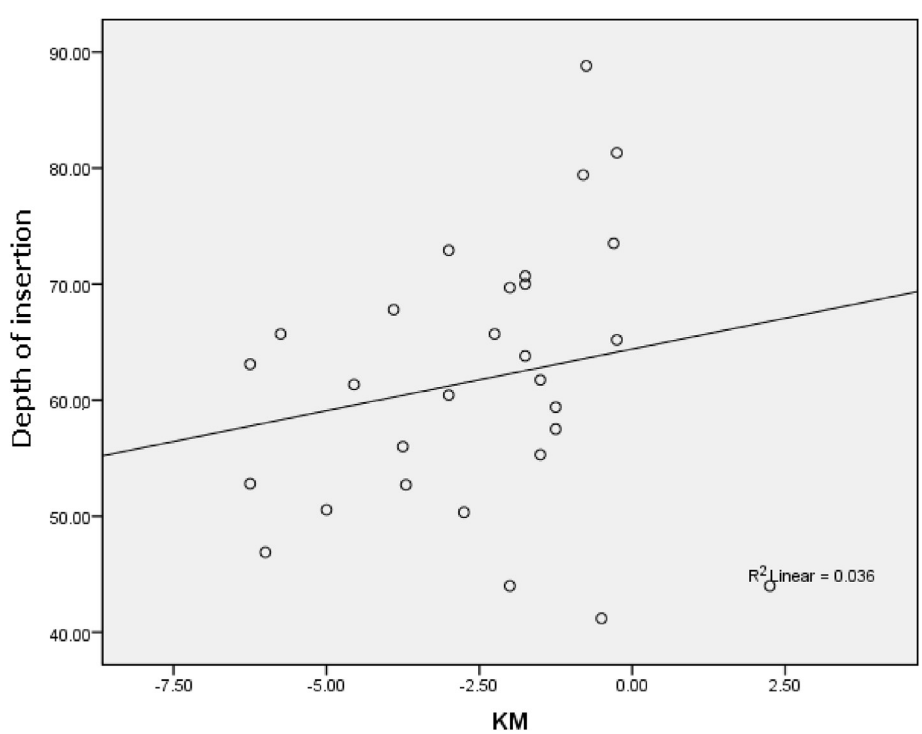

Fig. 2. Changes (preoperative vs. postoperative) of Kma relative to depth of KeraRing insertion.

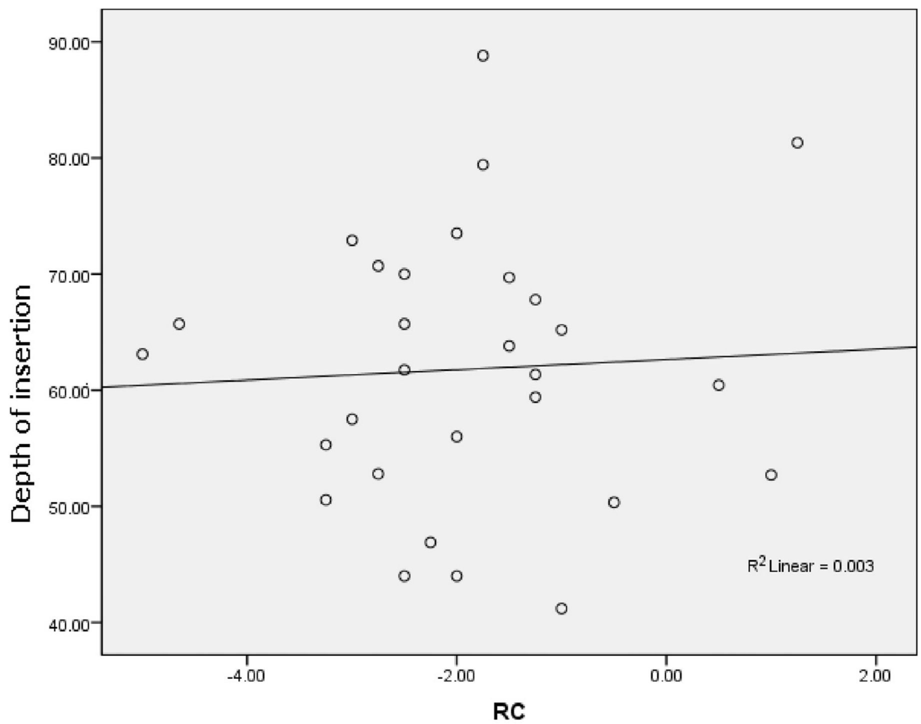

Fig. 3. Changes (preoperative vs postoperative) of refractive cylinder relative to depth of KeraRing insertion.

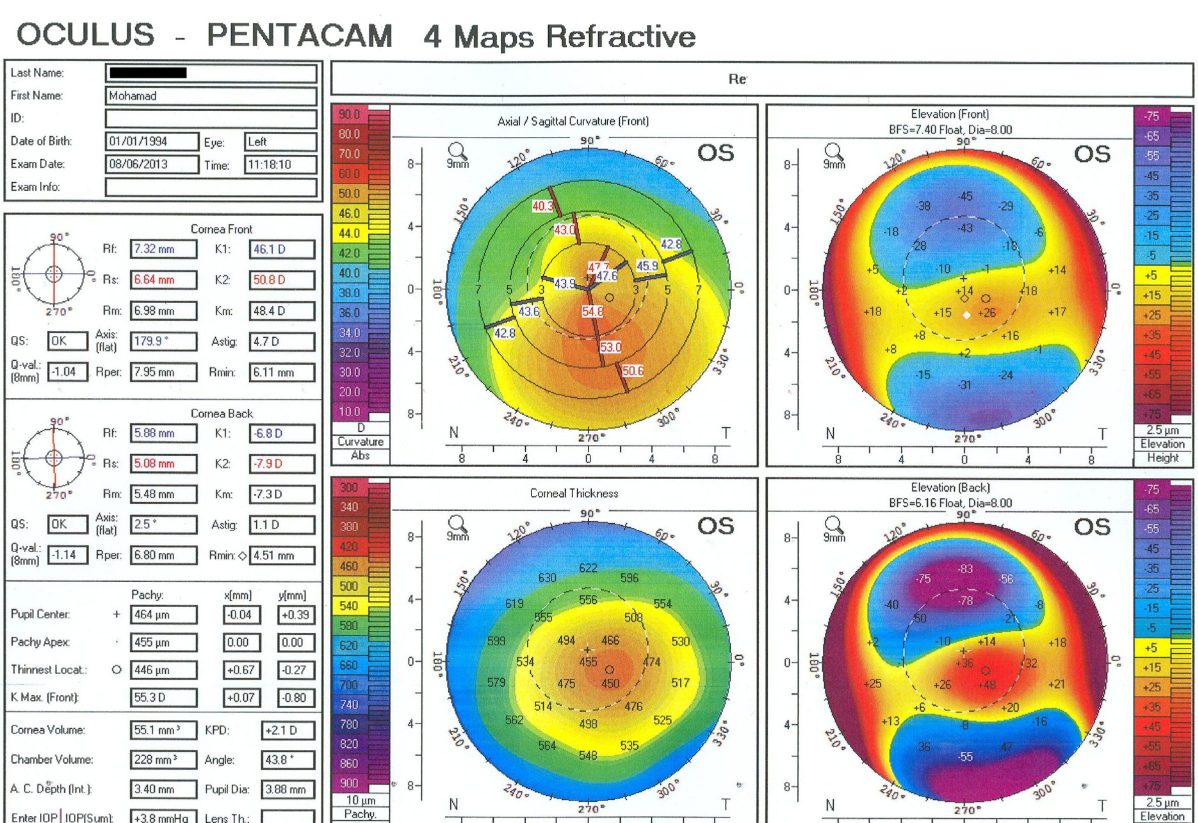

Fig. 4. Preoperative Pentacam 4 map refractive of a patient with keratoconus who planned for 2 segment Keraring implantation.

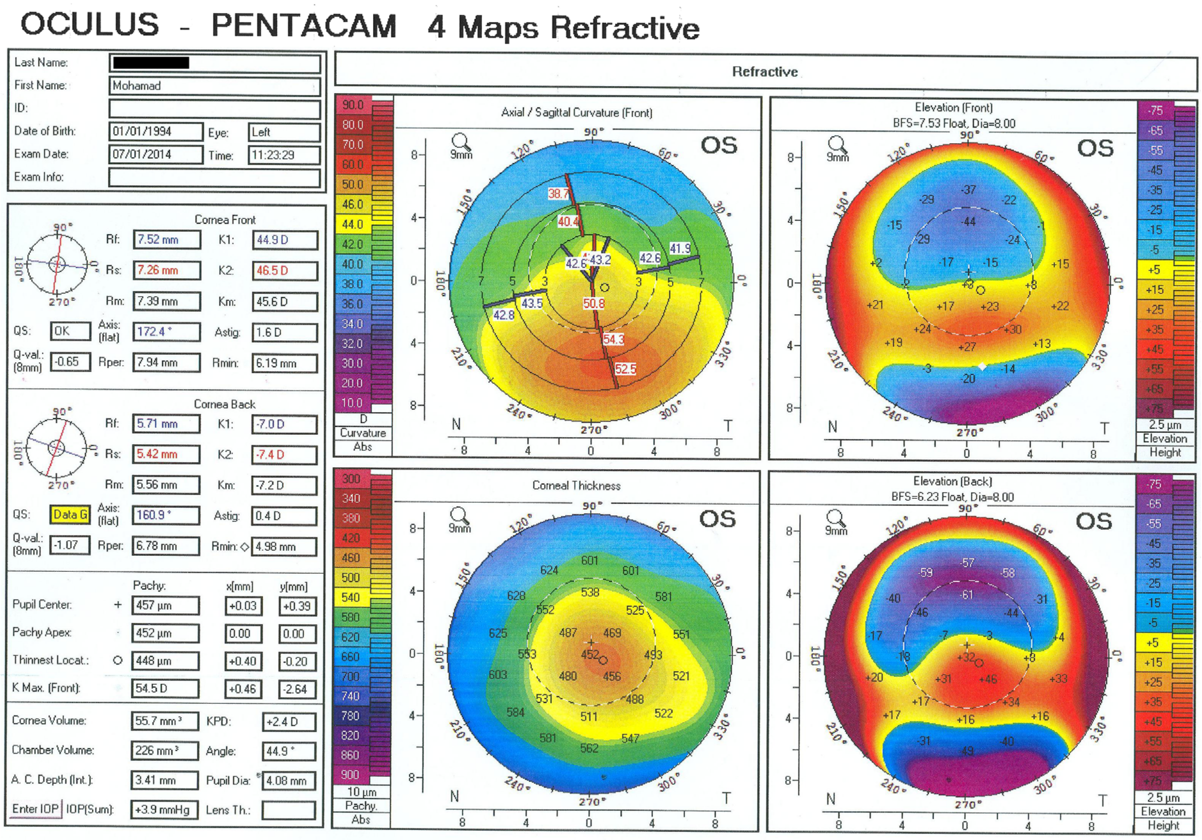

Fig. 5. 4-map refractive map of the same patient 11 months postoperatively, showing a significant reduction in Q value 8 mm anterior.

Alio,[15] the main difference was 3.37 D and 2.23 D in K power and SE, respectively. In our study, Kmax decreased 2.47D, and RC improved 1.92 D. Q value (8 mm) anterior decreased significantly with respect to flattening of the cornea. Corneal tunnel creation can be done with mechanical method or femtosecond laser. Mechanical method is cost-effective, but

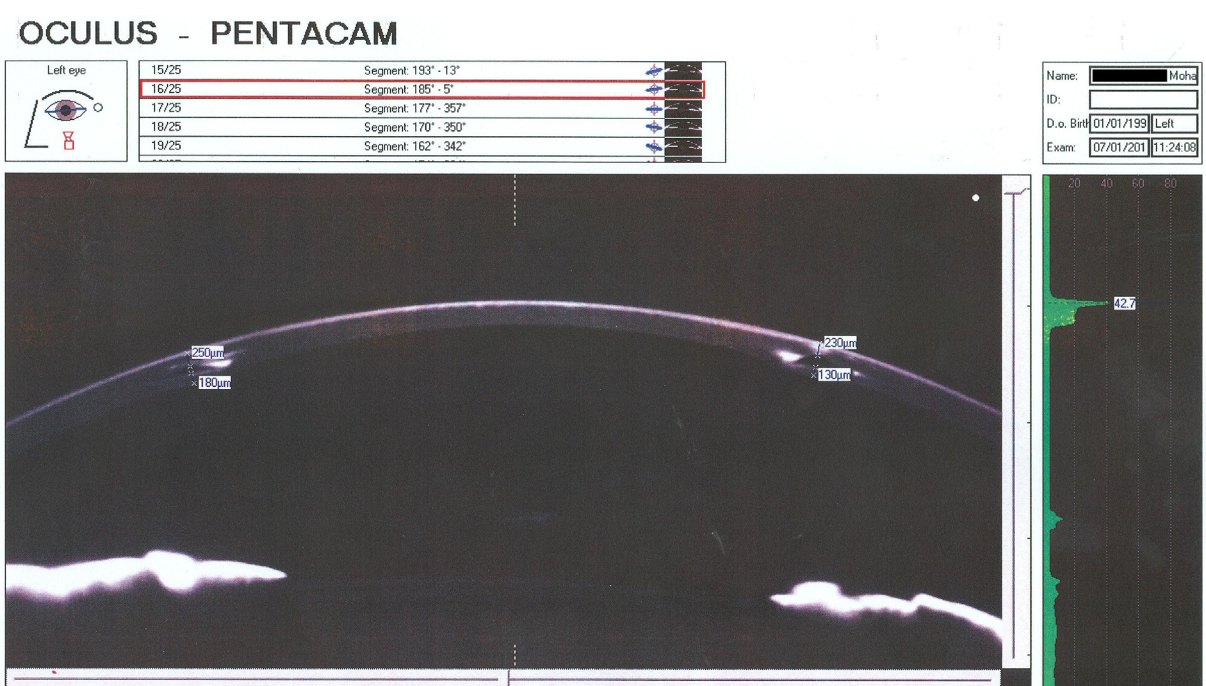

Fig. 6. Scheimpflug image obtained by Pentacam system in the same patient, 2 segment Kerarings were implanted in 60.75% of corneal stromal depth.

Table 1
Mean (±standard deviation) values and changes of visual, refractive, and shape variables before and after surgery.

	Preoperative	Postoperative	Change	p value
UCVA (logMAR)	0.80(0.05)	0.50(0.06)	0.30(0.05)	0.001* <
BSCVA (logMAR)	0.41(0.04)	0.18(0.03)	0.23(0.03)	0.001* <
Km (diopter)	51.05(0.98)	48.58(0.78)	2.47(0.39)	0.001* <
RC (diopter)	5.10(0.32)	3.17(0.31)	1.92(0.26)	0.001* <
Q value	0.85(0.08)	0.53(0.07)	0.31(0.27)	0.001* <

UCVA: Uncorrected Visual Acuity; BSCVA: Best Spectacle Corrected Visual Acuity; RC: Refractive Cylinder; Km: maximum keratometry; Q: Qvalue 8 mm anterior.
*Paired Samples Test.

Table 2
Mean (±standard deviation) change (preoperative versus postoperative) in visual, refractive and shape variables relative to the depth of Keraring insertion.

	Keraring depth			
	40–59%	60–79%	80–99%	Total
UCVA (logMAR)	0.29(0.10)	0.33(0.06)	0.15(0.15)	0.30(0.05)
BSCVA (logMAR)	0.23(0.03)	0.24(0.04)	0.15(0.07)	0.23(0.03)
Km (diopter)	2.64(0.71)	2.59(0.47)	0.50(0.25)	2.47(0.39)
RC (diopter)	1.90(0.37)	2.18(0.36)	0.25(1.09)	1.92(0.26)
Q value	0.36(0.09)	0.35(0.04)	−0.23(0.12)	0.31(0.27)

UCVA: Uncorrected Visual Acuity; BSCVA: Best Spectacle Corrected Visual Acuity; RC: Refractive Cylinder; Km: maximum keratometry; Q: Q value 8 mm anterior.

the main advantage of femtosecond laser tunnel creation over this method is its precision of implantation depth.[18] Several studies[22,23] compared femtosecond and mechanical tunnel creation in ICRS implantation and found no statistically significant difference in visual and refractive outcomes between the two methods. Hashemi et al,[24] report results of INTACS relative to depth of insertion with mechanical tunnel creation. They found 18.8% of cases in the 40–59% thickness group, 56.2% in the 60–79% thickness group, and 25% in the ≥80% group, despite the initial incision depth set at 70% of the corneal thickness at the insertion location. In our study, the mean depth of insertion was 61.78%, despite the initial incision depth set at 80%. We had 41.4% in the 40–59% thickness group, 51.7% in the 60–79% group, and 6.9% in the ≥80% group. Hashemi et al also report that the best stromal depth is 60–79%, and insertion in the stromal depth of 40–59% has a lesser effect. In contrast with Hashemi et al.'s study, we found similar results in the 40–59% and 60–79% insertion thickness groups. The smaller optical zone of KeraRing compared to INTACS is the most likely cause of this difference. Implantation of ICRS deeper than 80% stromal depth may have little effect on the corneal curvature and central flattening. Similar to Hashemi et al, our study found little effect in visual and refractive outcomes when ICRS was implantated at ≥80% stromal depth. Limitations of this study were using scheimpflug image in the detection of KeraRing insertion depth, retrospective observational design of study, and a small sample size of treated eyes.

Table 3
Correlation between depth of KeraRing insertion and changes in UCVA (logMAR), BSCVA (logMAR), Km, RC, and Q Value.

	Depth of KeraRing implantation	
	R	p value
UCVA (logMAR)	0.002	0.84
BSCVA (logMAR)	0.003	0.77
Km (diopter)	0.04	0.32
RC (diopter)	0.003	0.78
Q	0.08	0.14

UCVA: Uncorrected Visual Acuity; BSCVA: Best Spectacle Corrected Visual Acuity; RC: Refractive Cylinder; Km: maximum keratometry; Q Value 8 mm cornea front.
*Regression linear test.

Despite the variable depth of insertion, KeraRing with mechanical tunnel creation seems to be an effective treatment with good visual and refractive outcomes. Implantation of KeraRing deeper than 80% lower its effect. Shallow ring segment placement may cause complications such as corneal thinning over ring and ring extrusion. We recommend a larger, comparative study with femtosecond laser tunnel creation or using anterior segment optical coherence tomography for the detection of depth of KeraRing implantation in mechanical tunnel creation method to determine the best stromal depth of KeraRing implantation.

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