Efficacy of topography-guided femtosecond laser-assisted intrastromal corneal rings implantation in patients with keratoconus

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Purpose
The aim was to evaluate the efficacy of intrastromal corneal rings using femtosecond laser depending on the patient's topography for the correction of keratoconus.
Patients and methods
This was a prospective interventional study. A total of 33 eyes of thirty-one patients with keratoconus, with mean age 26.85±6.59 years, were included in the study. Fourteen cases were male and 19 were female. Intrastromal corneal ring segments, Kerarings, were implanted for keratoconus correction after corneal tunnel creation with the aid of femtosecond laser (Fs200).
Full ophthalmologic examination, including slit lamp biomicroscopy was done. Uncorrected visual acuity, manifest refraction, and best spectacle corrected visual acuity were also recorded. Pentacam and corneal topography were also done before and after the surgery.
Results
The mean age of the studied patients was 26.85±6.59 years. The mean uncorrected visual acuity before and after the procedure was 0.78±0.38 and 0.24±0.19, respectively. The mean BCVA before and after the procedure was 0.19±0.12 and 0.12±0.10, respectively. There was statistically significant difference between preoperative and postoperative mean sphere, cylinder, and spherical equivalent ($P<0.001$). There was significant decrease in the maximum k value and an increase in the center k value leading to a decrease in the mean maximum k–center k value from −6.05±3.42 preoperatively to −2.23±2.38 postoperatively. There was also significant decrease in the aberration coefficient value.
Conclusion
Kerarings in eyes with keratoconus improved postoperative topographic characteristics and visual acuity. Nomograms for intrastromal corneal ring segment insertion based on preoperative topography in addition to refraction are suggested, rather than relying primarily on refraction.

Keywords:
cornea, femtosecond, ICR, keratoconus, laser, rings

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Keratoconus is a progressive degenerative non-inflammatory ectatic disease. It compromises the integrity of collagen matrix in the corneal stroma. Keratoconus usually affects both eyes, although only one eye may be affected initially. Its hallmark characteristic is localized cone-shaped bulging with thinning at the site of the cone. This condition leads to the development of irregular astigmatism and steepening of corneal curvature that can cause myopia, which decreases visual acuity and visual quality [1].

Recently, intrastromal corneal ring segments have been designed to achieve refractive adjustment by flattening the cornea. The intrastromal corneal ring segments (ICRS) act by an arc-shortening effect, as they flatten the center of the cornea and provide a biomechanical support for the thin ectatic cornea. The changes in corneal structure induced by the rings can be roughly predicted by the Barraquer thickness law, that is, when a material is added to the periphery of the cornea or an equal amount of material is removed from the central area, a flattening effect is achieved. In contrast, when a material is added to the center or removed from the corneal periphery, the surface curvature is steepened. The corrective result varies according to the thickness and the diameter of the segment [2–4].

Currently, Kerarings can change the surface shape of the cornea not by pushing out on the edge of the cornea like Intacs but simply by flattening the cornea like putting a pillow under the bed covers and changing the shape of the covers. Its apex acts like a pivot for corneal stromal tissue [5].

The traditional mechanical technique of tunnel creation led to many complications. However, the femtosecond laser offers less complications owing to more precise localization of the channel by manipulation of its dimensions, depth, diameter, and width.

Patients and methods

A prospective interventional study including 33 keratoconic eyes of 31 patients who had femtosecond laser-assisted Kerating implantation was conducted. The corneal irregularity was high preoperatively with the ring segments flattening the topography and affecting spherical equivalent (SE). All had complete data up to 3 months. Eleven eyes were excluded as nine eyes were lost to follow-up, one eye had high keratometric reading (K_{max} was 80 D), and one eye had corneal thickness of 340 μm at the thinnest location.

Full ophthalmologic examination, including slit lamp biomicroscopy including dilated fundus examination was done. Uncorrected visual acuity (UCVA), manifest refraction, best spectacle corrected visual acuity were also recorded. Pentacam and corneal topography were also done.

All patients were appropriately informed before their participation in the study and gave their written informed consent in accordance with institutional guidelines and according to the Declaration of Helsinki.

Surgical technique

The manufacturer nomogram was checked to choose the proper ring segments to be used. The procedure was done under topical anesthesia (Benoxinate eye drops, benox, Eipico, Egypt). Sterilization of both eyes was done with povidone iodine followed by draping, and then a speculum was applied to the eye to be treated.

Once the patient was in place, the suction ring was placed on the surface of the eye and suction was then activated using a foot-pedal, and then the joy stick was used to rest the applanation cone into the suction ring, where pressure sensors were detected when the cone was properly seated automatically stopping the downward motion of the cone. The treatment was then centered on the pupil.

The ultrafast laser (10^{-15} of a second), Femtosecond laser (Fs200, Wavelight, Germany), was used to create the tunnel and the incision with a wavelength of about 1030±5 nm. The laser spot size is 5 μm, spot separation is 6.5 μm, and line separation is 6.5 μm. Laser pulse repetition rate is 200 kHz. Tunnels were set to be at 80% of corneal thickness at their sites. Energy used was less than 1.7 mJ with procedure time of about 5 s for femtolaser to create all tunnels and incisions. The tunnel was created and the suction was released. The incision was made on the steepest corneal topographic axis or on the coma axis. Inner diameter of the tunnel was about 6.0 mm, whereas outer diameter was 7.0 mm. The access incision and the tunnel were tested to ensure their patency and then implantation of ring segments was done.

The Keraring (Mediphacos, Belo Horizonte, Brazil) according to the chosen nomogram was carried out after channel creation under full aseptic technique with the aid of KeraRing forceps and Sinsky hook through a dialing holes at both ends of the segment. The segment was centered in the middle of its tunnel at equal distance from the line bisecting the cornea at the incision site.

Postoperative treatment included topical moxifloxacin (Vigamox Alcon, Fort Worth, Texas, United States) and steroids in the form of tobramycin dexamethasone (Tobradex; tpbradex Alcon, Fort Worth, Texas, United States) every 6 h for 1 week. Artificial tears were used every 4 h for 6 weeks. Follow-up schedule was done immediately, 1 day after the surgery and 1 week later. At 3 months, complete ophthalmic examination, UCVA, best spectacle corrected visual acuity, autorefraction, manifest refraction, and pentacam were assessed.

Results

The mean age of the studied patients was 26.85±6.59 years. A total of 14 patients were male and 19 were female.

The mean value of preoperative UCVA was 0.78±0.38, whereas the mean values of postoperative UCVA on the same day of the surgery and 3 months were 0.25±0.18 and 0.24±0.19, respectively. There was a statistically significant difference between the mean UCVA at the three visits ($P<0.001$). All eyes showed progressive significant improvement of UCVA.

Regarding the BCVA, the mean value of preoperative BCVA was 0.19±0.12 whereas the mean value postoperatively at the same day and 3 months were 0.14±0.11 and 0.12±0.10, respectively. There was a statistically significant difference between the mean BCVA preoperatively and after 3 months ($P<0.001$). There was a progressive significant improvement of BCVA in most of the patients.

The mean value of preoperative sphere was −1.27±1.82 D whereas the mean value of postoperative sphere at the same day and 3 months were −0.42±0.53 and −0.35±0.58 D, respectively. There was a statistically significant difference between preoperative and postoperative mean sphere. All eyes showed significant reduction of the sphere.

Regarding the cylinder, results show that the mean value of preoperative cylinder was −3.72±1.72 D, whereas the mean values of postoperative cylinder at the same day and 3 months were −1.11±0.35 and −1.23 ±0.53 D, respectively. There was a statistically significant difference between preoperative and postoperative mean cylinder values ($P<0.001$).

The mean value of preoperative SE was −3.13±2.15 D, whereas the mean values of postoperative SE at the same day and 3 months were −0.98±0.60 and −0.97 ±0.67 D, respectively. There was a statistically significant difference between preoperative period and postoperative SE ($P<0.001$).

Concerning maximum K at different periods, the mean value of K_{max} preoperatively was 51.89±6.33 D, whereas postoperatively, the mean values at the same day and 3 months were 52.52±6.20 and 51.75±5.83 D, respectively, as shown in Table 1. There was a statistically significant difference between preoperative and postoperative values of K_{max} ($P<0.001$).

The statistical analysis of center K data showed that the mean value of K_{center} was 48.84±4.90 D in the preoperative period, whereas the mean values of K_{center} postoperatively at the same day and 3 months were 49.59± 4.53 and 49.52±4.79 D, respectively. There was a statistically significant difference between K_{center} values at different periods.

The difference between center K and maximum K was −6.05±3.42 D in the preoperative period whereas postoperative mean values of K_{center}–K_{max} at the same day and 3 months were −2.93±3.95 and −2.23±2.38 D, respectively. There was a statistically significant difference between preoperative and postoperative values at different periods ($P\leq0.001$).

The mean value of aberration coefficient (AC) preoperatively was 3.0±1.02, whereas postoperatively at the same day and 3 months, the mean values of AC were 2.44±0.68 and 2.28±0.48 D, respectively. There was a statistically significant difference between preoperative and postoperative values of K_m ($P<0.001$).

The study showed that there was no correlation between change of UCVA with change of manifest refraction (SE), center K–max K, and AC.

Discussion

Keratoconus is a bilateral noninflammatory degenerative disease of the cornea. It is characterized by progressive thinning and steepening of the corneal apex, which achieves a conical shape in advanced stages. The resultant irregular astigmatism and myopia induce significant visual complaints. The insertion of ICRS is one of the treatment options that has been gaining popularity during the past decade. First evaluated as a treatment for mild to moderate myopia, these polymethyl methacrylate segments modify the corneal curvature by an arc-shortening, flattening effect and have proven especially effective in reducing the irregular astigmatism caused by keratoconus [6].

The aim of our study was to evaluate the effect ICRS (Keraring) has on corneal topography and visual acuity. We present 33 eyes of 31 patent with keratoconus. All patients had mixed astigmatism. The corneal asymmetry was high preoperatively with the ring segments flattening the topography and affecting SE. All had complete data up to 3 months. Eleven

Table 1 Comparison between the three studied periods according to center *K*–max *K*

	Preoperative (n=33)	Postoperative (n=33)	3-month follow-up (n=32)
Center K–maximum K			
Minimum–maximum	−13.90 to −2.10	−9.40 to 8.10	−8.70 to 3.40
Mean±SD	−6.05±3.42	−2.93±3.95	−2.23±2.38
Median	−5.10	−3.30	−2.30
Significance between periods		$^*P_1<0.001$, $^*P_2<0.001$, $P_3=0.178$	

*Statistically significant.

eyes were excluded as nine eyes were lost to follow-up, one eye had high keratometric reading (K_{max} was 80 D) and one eye had corneal thickness of 340 μm at the thinnest location. The results were analyzed and correlated with a number of preoperative and postoperative clinical parameters.

Regarding the visual acuity in the current study, the mean UCVA and BCVA showed significant improvement at first day postoperatively (0.25±0.18 and 0.14±0.11 logMAR, respectively) in comparison with preoperative measurements (0.78±0.38 and 0.19±0.12 logMAR, respectively). This was found to be statistically significant ($P<0.001$ and 0.001, respectively). However, the mean UCVA and BCVA results 3 months after ICRS insertion were found to be similar to first day after surgery. The reason behind the improvement in vision could be the corneal tissue redistribution from the inferior cornea (area of cone) toward the center after ring segment insertion.

Long-term outcomes of ICRS implantation for the treatment of keratoconus have always been a topic of debate. It was observed that long-term stability of ICRS implantation depended on the progression pattern of keratoconus at the time of surgery. Thus, in those cases with the stable form of the disease, ICRS implantation does not cause significant changes after a long period of follow-up [7]. Hence, we observed most changes of UCVA and BCVA during the first day postoperatively but stabilized afterward in 3 months.

Similarly, Fahd *et al.* [8] conducted a retrospective case series on 30 eyes with moderate to severe keratoconus and found significant improvement of preoperative UCVA and BCVA (0.633±0.303 and 0.322±0.156 logMAR, respectively) to that measured after 6 months (0.202±0.135 and 0.134±0.131 logMAR, respectively). The first-day and 3-month follow-ups were not recorded in their article; therefore, it was not noted if these improvements were found earlier on. He stated that the reason behind the improvement in BCVA could be the upward shifting of the cone toward the center.

None of our patients experienced deterioration of UCVA and BCVA. However, one case showed no difference of BCVA owing to high preoperative *K* readings but he was still satisfied after the surgery.

Shabayek and Alió [9] had one case with decreased BCVA of one line and three cases with no improvement in BCVA. They also found a significant negative correlation between keratconus grades and postoperative BCVA. The higher the keratoconus grade or the average *K* value, the lower the postoperative BCVA achieved after ICRS insertion.

Regarding the manifest refraction in the current study, it was noted that the SE has been significantly reduced from −3.13±2.15 D preoperatively to −0.98±0.60 D on the first day of the surgery, which was statistically significant ($P<0.001$). This decline is owing to the reduction in both the spherical and cylindrical components. They dropped significantly from −1.27 ±1.82 and −3.72±1.72 D, respectively, preoperatively to −0.42±0.53 and −0.42±0.53 D, respectively on the first day of the surgery.

This was also reported in Shabayek and Alió [9] when they noted that the mean decrease in spherical power was 0.96 D ($P=0.04$), in cylindrical power 2.67 D ($P=0.0004$), and in SE 2.23 D ($P=0.0004$). Other studies reported similar decrease in SE [10–12].

Flattening of the cornea was observed, with mean K_{max} value declined by 3 D at the third month ($P=0.001$). This flattening coincides with the expected change in curvature considering the mechanism of action of ring segments.

There are two ways to effectively flatten the central cornea and reduce the K_{max}. The first one is to implant the ICRS more centrally which has been demonstrated by Shabayek and Alió [9] where he assumed that implantation of the intrastromal corneal ring segment (Keraring) more centrally at a 5 mm diameter theoretically will achieve a greater flattening of the central cornea. Implanting a central ICRS at 5 mm has its disadvantages which includes higher order aberration and increased glare at night when the pupil becomes dilated [13].

Another method in effectively reducing the K_{max} is by insertion of a thicker intracorneal segment. Patel *et al.* [14] studied different mathematical models to predict the effect of intracorneal ring segments for myopia correction in relation to corneal asphericity and the spherical aberration of the eye. They correlated the thickness of the ICRS with the change in the keratometric readings and found that there was a negative correlation between the segment thickness and the change in mean keratometry and positive one with the change in the root mean square (RMS) value corresponding to the corneal higher order aberrations. In other words, the thinner rings have less effect on corneal asphericity, thus less flattening of the cornea.

In our study, the intracorneal rings were implanted at 6 mm from the center of the cornea to reduce the adverse effects of glare, haloes at night, and higher order aberrations. The thickness of the Kerarings was ranging from 150 to 300 μm, reserving thicker segments for higher preoperative K_{max}. This explains significant reduction of *K* readings which is comparable to other papers mentioned previously.

The mean value of *K* center increased by 0.68 D after 3 months could be related to shifting of the cone to the corneal center from the lower part of the cornea. Similarly, Fahd *et al.* [8] reported that in some cases, there was a significant decrease of the mean K_{max} with a minimal effect on the center *K* (dropped from 49.14±4.39 preoperatively to 47.43±1.95 postoperatively) and that is why the SE was almost constant in those cases. The results cannot be accurately compared with ours, as they used the average corneal power of all measured points within the central 4.0 mm zone, instead we used the value of *K* center at the corneal vertex [8].

The *K* reading at the center of the cornea (center *K*) is not the best reflection of the corneal status in keratoconus as the cone is displaced inferiorly. The maximum *K* reading (K_{max}) that is found at the steepest point in the cone correlates better with the severity of the keratoconus. Therefore, it was better to calculate corneal irregularity based on the difference between the central corneal power (center *K*) and the corneal power at the cone apex (maximum *K*) (center *K*–maximum *K*) and check the amount of change postoperatively. This measurement represents corneal irregularity in a concrete way and is a practical means to extrapolate topographic information.

We found that the mean value of this difference decreased by 3.82 D postoperatively, indicating that the corneal contour has become more regular. Similarly Fahd *et al.* [8] noted a decrease in this value (from 7.45±5.61 preoperatively to 4.92± 4.36 postoperatively) which is comparable to our results.

Concerning corneal aberrations, there was significant decrease in corneal aberrations after ICRs implantation. The mean value of the AC decreased by 0.72 by the third month ($P \leq 0.001$).

These results are similar to other studies that have assessed the optical quality by analyzing the changes in anterior corneal higher order aberrations and have found a reduction in these parameters after ICRS implantation, specifically in the asymmetric aberrations (coma and coma-like). These changes observed in the aberrometric coefficient are expected to occur owing to the capability of the implants in regularizing the geometry of the corneal tissue [9,12].

As we only measured the coefficient variation in our study to evaluate the higher order aberration preoperatively and postoperatively, we cannot accurately compare our results with other papers that have published RMS values.

Femtosecond laser allows accurate calculations and correct placement of the intracorneal rings at a precise depth and precise tunnel dimensions, width, and diameter. This reduces the incidence of decentration, perforation, and extrusion of the intracorneal rings. This is the reason why there is reduced complications in our study, which was comparable to other studies that used the femtosecond technique. The same was reported in another study where there were no intraoperative or postoperative complications [15].However, one complication noticed with femtosecond technique was incomplete tunnel creation, not allowing insertion of the intracorneal ring. This happened in only one of the cases owing to superior pannus, and the surgery was aborted. Its result was not included in our statistical analysis.

In 2011, Coskunseven *et al.* [16] described the occurrence of intraoperative complications during Keraring implantation in 850 eyes using femtosecond laser, including incomplete tunnel formation (2.6%), endothelial perforation (0.6%), incorrect entry into the tunnel (0.2%), and loss of vacuum (0.1%) as well as postoperative complications, such as ring migration (0.8%), corneal melting (0.2%), and infection (0.1%).

Other surgical complications such as anterior chamber perforation, stromal necrosis superficial to the segment or infective keratitis were not encountered. All eyes showed excellent corneal tolerance to the segments with no extrusion, or vascularization around the incision or the tunnels. One patient had intracorneal ring removal as he was not satisfied because of intolerable glare and haloes although the intracorneal ring was correctly placed at 6 mm away from the center. This could be explained when further examining him, as his metopic pupil was 6 mm.

One of the main advantages that ICRS implantation has is its reversibility. Even when some of the aforementioned complications might appear, some studies have shown that segment explanation can be safely performed, with visual, refractive, and topographic variables coming to preoperative levels

[7]. Our patient who had the intracorneal ring removed has reverted back to the preoperative status with no added complications.

Glare and haloes are expected complications after intracorneal rings insertion depending on placement of the intracorneal ring away from the center of the cornea. We had only eye with glare and haloes, and this was owing to placement of the intracorneal ring at 6-mm diameter. However, other papers have reported more incidence of glare and haloes owing to placement of the intracorneal rings nearer to the center.

In conclusion, we found that implantation of ICRS in eyes with keratoconus improved postoperative topographic characteristics and visual acuity as the cornea becomes more regular. The shape of the cornea is corrected to a physiologic aspheric shape because astigmatism, keratometry, and vertical asymmetry of the cornea decreased. Furthermore, protrusion of the cornea moves from inferior to the central part, and the corneal shape becomes prelate, which improves the quality of vision and reduces spherical aberrations. We suggest basing monograms for ICRS insertion on preoperative topography, in addition to refraction, rather than relying primarily on refraction while using cone location as guidance. However, further studies are necessary to complete such a nomogram as it is recommended to to encompass other types of ring segments and also evaluate the stability of the results of using rings in long-term follow-ups.

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Conflicts of interest
There are no conflicts of interest.

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