Evaluation of intrastromal corneal rings (two segments vs. keraring 355) in central keratoconus using femtosecond laser

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Purpose
The aim was to compare visual acuity, refraction of intrastromal segment 355, and two, 160° symmetrical segments in central keratoconus.
Setting
Al-Fath Eye Hospital, Zagazig, Egypt.
Design
Prospective case series.
Patients and methods
Surgeries were performed using a femtosecond laser for tunnel creation for the 355° near-total ring (group 1) and the 160° two-segment device (group 2). The preoperative and 6-month postoperative uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA) distance visual acuities were acquired.
Results
The study included 40 eyes. No statistically significant differences were found in the preoperative parameters between groups ($P>0.05$). The postoperative UCVA and CDVA were statistically better than the preoperative parameters in all study groups ($P<0.001$). A statistically significant increase in the median UCVA and BCVA occurred in group 2 compared with group 1 ($P<0.01$).
Conclusions
All devices were effective in improving UCVA and BCVA. The UCVA results in the two separated 160° segment better than the 355 segment. Patients with high spherical than cylindrical power had better vision and satisfaction with the 355 segment, while the two separated segments had better vision in high cylindrical patients than spherical power patients.

Keywords:
keratoconus, ectasia, cornea, rings, astigmatism

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Background

Keratoconus is a bilateral, progressive, noninflammatory disease of the cornea which often leads to cone-like steeping of the cornea leading to severe astigmatism and myopia [1] with an estimated prevalence of ~1 in 2000. In the general population, the incidence of keratoconus is estimated to be between 50 and 230 per 100 000 [2–4].

It seems to be a multifactorial disease with an unknown exact etiology which increases sensitivity to light and visual distortion. This results in an irregular astigmatism with or without myopia [5–7]. Despite the fact that only one eye may be affected initially, keratoconus ultimately affects both eyes [8].

The management of keratoconus in early stages consists of spectacle correction or hard contact lenses, corneal crosslinking (CXL), intrastromal corneal ring segment (ICRS) implantation, and lamellar and penetrating keratoplasty [9–13].

ICRSs represent a substantial evolution in the management of keratoconus. Moreover, long-term data on ICRS procedures demonstrated promising results in topographic regularity and uncorrected visual acuity (UCVA), indicating the 'possibility of putting back or even replacing keratoplasty in keratoconus patients' [14].

Different types of ICRSs are currently on the market, including Intacs (Addition Technology Inc., Sunnyvale, California), Ferrara (Ferrara Ophthalmics Ltd, Belo Horizonte, Brazil), and Keraring (Mediphacos Ltd, Belo Horizonte, Brazil). Kerarings are made of medical-grade polymethyl methacrylate with a ultraviolet blocker. They are characterized by a

triangular cross-section with variable thickness and an arc length that induces a flattening effect on the cornea.

Keraring 355° intrastromal corneal ring (ICR; Mediphacos, MinasGerais, Brazil) is a new unique intracorneal segment design especially for nipple-type keratoconus. It is available in a diameter of 5.7 mm and a thickness range of 200 and 300 μm [15].

There are several therapeutic choices for the management of keratoconus, such as hard contact lens use, corneal crosslinking (CXL), ICRS implantation, and lamellar and penetrating keratoplasty.

In general, ICRs act by an arc-shortening effect, which flattens the center of the cornea and provides 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. The final position of the segment taking angle α the center of the cornea, the better the flattening effect will be (i.e. myopic correction). Therefore, segments implanted on the 5 mm circle (like Ferrara and Keraring) have better effect on astigmatism, and those implanted on the 7 mm (such as INTACS) have better effect on myopia.

Since getting closer to the center of the cornea carries the problem of night glare, new designs of the segments were developed to be implanted on the 6 mm circle, such as Kera-6 and INTACS-SK. In general, by using the 6 mm segments, less night glare (if any) is encountered, and better effect on both myopia and astigmatism is achieved.

In summary, if a case requires correcting myopia more than astigmatism, longer and thicker arcs are needed and vice versa. However, each company has its own nomogram and guidelines to choose the segments. The surgeon thereafter may modify the nomogram according to his/her accumulative experience

A central cone is defined when 50% or more of the cone is within the 3.0 mm zone on the posterior elevation map of the Pentacam rotating Scheimpflug device, wavelight, Germany.

The development of new technologies, new designs of intracorneal implants, and new surgical approaches, such as a femtosecond laser corneal tunnel creation, made the procedure faster, easier, more safe, and more comfortable for patients and surgeons. The main advantages of this method over mechanical tunnel creation are that the depth of implantation is more precise with lesser complications.

Patients and methods

A comparative prospective nonrandomized study for corneal changes in keratoconus patients with central cone.

Patients were recruited from a private practice and Menoufia University cornea clinics from March 2015 to March 2017, and all provided written informed consent to enroll in the study. All surgeries were performed and followed at a private ophthalmic hospital.

Inclusion and exclusion

Inclusion criteria will include the following:

(1) Both sex (male and female).
(2) Presence of keratoconus.
(3) Corneal thickness greater than 400.
(4) Stages 2 and 3 of KC according to the Amsler–Krumeich classification.

Exclusion criteria will include the following:

(1) Thickness of cornea less than 400 at implantation site.
(2) Other types of KC than central.
(3) Corneal scarring.
(4) History of LASIK.
(5) History of pregnancy and lactation during the course of study.
(6) History of any disease affecting vision other than KC like cataract or glaucoma or retinal or optic nerve disease.

Preoperative assessment

(1) Medical, ocular, and family histories.
(2) Visual acuity:
    (a) UCVA using Snellen's projected chart.
    (b) Best spectacle corrected visual acuity.

Refraction

(1) Keratometric changes.
(2) Slit lamp examination of the anterior segment.
(3) Dilated fundus examination: using indirect ophthalmoscopy and lens VOLK90.
(4) Investigation: Pentacam and topography.

Surgical procedure

Preoperative preparation

Topical antibiotics were instilled to the eye to be operated five times per day 1 day before the surgery and hourly at the day of surgery.

Operative procedure

All patients in this study were operated under topical anesthesia.

Skin sterilization around the eye was done by Betadine 10% solution. Wire speculum was placed for widening of the palpebral fissure. Ocular irrigation with Betadine 5% solution. The surgical procedures were performed using topical anesthesia and a femtosecond laser (Wavelight-FS 200; Alcon Surgical Inc., fort worth, Texas) for tunnel creation in eyes that had 355 near-total ring segment (group 1) or two symmetrical 160° kera segments (group 2).

Postoperatively all patients were prescribed topical gatifloxacin and dexamethasone eye drops five times daily for 2 weeks.

Postoperative assessment

The patients' follow-up was at 1 day, 1 week, and 1, 3, and 6 months. Postoperative evaluation 1 month after UCVA and best corrected visual acuity (BCVA) manifest and cycloplegic refractions, slit lamp examination, and corneal topography were performed.

Table 1 Comparison of demographic data among the studied groups

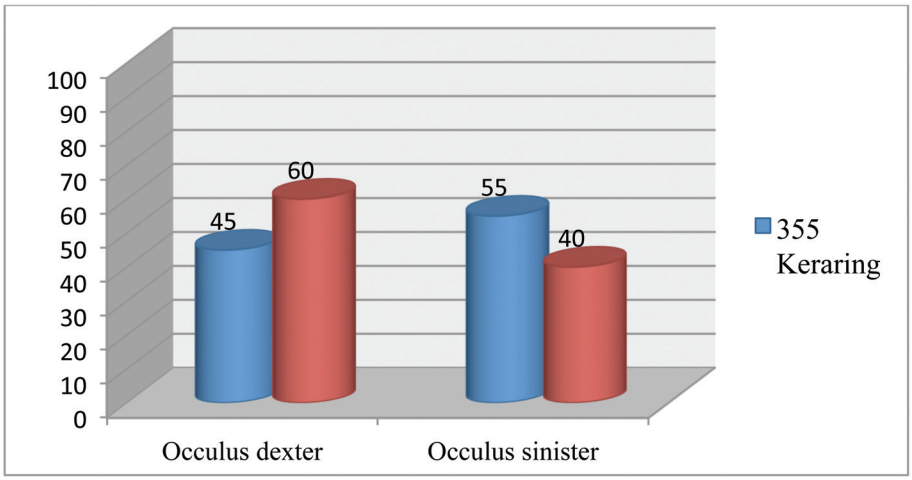
Variables	355 keraring group (*n*=20) [*n* (%)]	Two segment group (*n*=20) [*n* (%)]	Test	*P* value
Age (years)				
Mean±SD	27.8±6.50	28.2±5.36	–0.212	0.833 (NS)
Range	16–40	18-43		
Sex				
Female	11 (55)	0 (0)	χ^2=**15.17**	<**0.001 (HS)**
Male	9 (45)	20 (100)		

HS, highly significant.

Table 2 Comparison of side among the studied groups

Variable	355 keraring group (*n*=20) [*n* (%)]	Two-segment group (*n*=20) [*n* (%)]	χ^2	*P*
Side				
OD	9 (45)	12 (60)	0.902	0.342 (NS)
OS	11 (55)	8 (40)		

Fig. 1



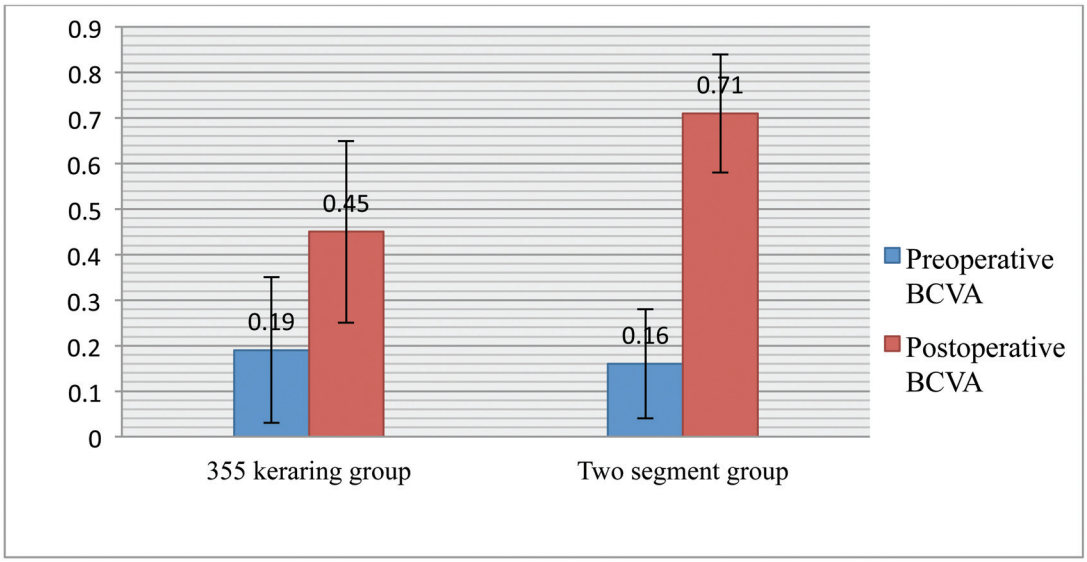
Bar chart showing frequency distribution of the side of keratoconus among the studied groups.

Table 3 Comparison of best corrected visual acuity among the studied groups

Variables	355 keraring group (*n*=20)	Two segment group (*n*=20)	Test	*P* value
Preoperative BCVA				
Mean±SD	0.19±0.16	0.16±0.12	−0.125	0.900 (NS)
Median	0.10	0.1		
Range	0.0–0.5	0.05–0.5		
Postoperative BCVA				
Mean±SD	0.45±0.20	0.71±0.13		
Median	0.45	0.70		
Range	0.1-1	0.4–0.9	**−4.022**	<**0.001****
P	<**0.001****	<**0.001****		

BCVA, best corrected visual acuity. **statistically significant difference.

Fig. 2



Bar chart showing best corrected visual acuity preoperatively and postoperatively among the studied groups.

Results

Table 1 shows that there was nonsignificant difference between the studied groups as regards age; however, the difference was significant between them in six.

Table 2 shows that there was nonsignificant difference between the studied groups as regards the side of keratoconus (Fig. 1).

Table 3 shows that there was nonsignificant difference between the studied groups as regards preoperative best corrected visual acuity ($P>0.05$); however, postoperative BCVA in the two segment groups was significantly higher than in the 355 ring group. Postoperative BCVA was found to be significantly higher in both groups when compared with the preoperative one (0.45, 0.71 vs. 0.19 and 0.16 in 355 keraring and two segment groups, respectively) (Fig. 2).

Discussion

This is the first paper to compare between 355 segment and two separated segments.

In this study, implantaion of the 355 segment and two separated segments using a femtosecond laser improved UCVA and BCVA, and K reading and refractive segment.

The efficiency of ICRS was reported by several studies [9,16,17].

The concept of inserting segments as corneal inserts was first introduced by Fleming and Schanzlin in 1987; the aim at that time was myopia correction.

A study by Hellstedt *et al.* [18] demonstrated a 35% rate of postoperative complications such as corneal melt, segment movement, and exposure with the mechanical tunnel dissection method. These complications could be

reduced with a femtosecond laser due to the more precise localization, dimensions, diameter, depth, and width of the channel.In addition, there is excellent corneal tolerance to polymethyl methacrylate rings with only short-term, low-grade inflammatory stromal reaction consisting of a discrete concentration of inflammatory cells adjacent to the ring.

A total of 40 eyes of 23 patients participated in this study; all were diagnosed with keratoconus and had ICRS (keraring) implantation either one or two segments according to the nomogram

Our goal of treatment of keratoconus is to improve the vision and its quality with corneal flattening and stabilization of the disease [19].

At the end of the follow-up period after 6 months, there was a nonsignificant difference between the studied groups as regards preoperative best corrected visual acuity ($P>0.05$); however, postoperative BCVA in the two segment groups was significantly higher than in the 355 ring group.

Postoperative BCVA was found to be significantly higher in both groups when compared with the preoperative one (0.45, 0.71 vs. 0.19 and 0.16 in 355 keraring and two segment groups, respectively).

The uncorrected visual acuity improved in 90% of eyes, did not change in 10%, and none worsened (0%), while the BCVA improved in 94% of eyes, did not change in 6%, and none worsened (0%).

Ten eyes in this study suffered from postoperative complications: segment displacement in one eye in each group, segment extrusion in one eye in the 355 group, keratitis in four eyes in the 355 group and in one eye in the other group, and corneal vascularization in one eye in each group.

Recommendation

Using 355 ring in cases with central keratoconus with more spherical error than cylindrical and two separated segments in patients with more cylinder error than spherical error.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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