ARTICLE

Comparative study of 3 intracorneal implant types to manage central keratoconus

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Purpose: To compare the visual acuity, refraction, corneal topography, and corneal asphericity of intrastromal corneal implantation of Keratacx 160-degree 2 symmetrical ring segment, the Keratacx 320-degree near-total ring, and the Myoring continuous intracorneal ring (ICR) in central keratoconus.

Setting: Ophthalmology Department, Ain Shams University, Cairo, Egypt.

Design: Prospective case series.

Methods: Surgeries were performed using a femtosecond laser for tunnel creation for the 160-degree 2-segment device (Group 1) and the 320-degree near-total ring (Group 2), and for pocket creation for the ICR (Group 3). The preoperative and 6-month postoperative uncorrected (UDVA) and corrected (CDVA) distance visual acuities, spherical equivalent (SE), corneal and refractive astigmatism, keratometry (K) readings, and Q value using topography images were acquired.

Results: The study included 73 eyes. No statistically significant differences were found in the preoperative parameters between groups ($P > .05$). The postoperative UDVA, CDVA, SE, corneal and refractive astigmatisms, K readings, and Q value were statistically better than the preoperative parameters in all study groups ($P < .01$). A statistically significant increase in the median UDVA and CDVA occurred in Group 2 compared with Group 1 ($P < .01$). Groups 2 and 3 had a more effective reduction in SE ($P < .01$). No statistically significant difference was found in the postoperative changes in the corneal and refractive cylinders, mean and maximum K readings, and corneal asphericity between the study groups ($P > .05$).

Conclusions: All devices were effective in improving UDVA, CDVA, refraction, K readings, and corneal asphericity. The 320-degree segment and ICR improved UDVA and SE more than the 2-segment device.

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Keratoconus is an ectatic corneal disorder characterized by cone-like steepening of the cornea. The progressive thinning and subsequent anterior bulging of the cornea lead to severe astigmatism and central scarring, producing visual distortion, increased sensitivity to light, and an associated reduction in corrected visual acuity.[1]

There are several therapeutic choices for management of this condition, such as contact lens use, thermokeratoplasty procedures, corneal crosslinking (CXL), intrastromal corneal ring segment (ICRS) implantation, and lamellar and penetrating keratoplasty.[2]

Intrastromal corneal ring segments are small devices made of rigid poly(methyl methacrylate) (PMMA) that are implanted within the corneal stroma to induce a change in the geometry and the refractive power of the tissue. The concept of inserting segments as corneal inserts was first introduced by Fleming and Schanzlin in 1987[3]; the aim at that time was myopia correction.

Intacs (Addition Technology, Inc.), one of the first ICRS, received Conformité Européenne certification in 1996 and U.S. Food and Drug Administration approval in 1999 for the correction of low to moderate myopia.[4]

Colin at al.[2] found that ICRS could flatten the central cornea and regularize the asymmetry of tissue, leading to a reduction in keratometry (K) readings and an improvement in the refraction and vision of patients with keratoconus. Since then, several authors have reported the benefit of implanting ICRS in keratoconic eyes and in delaying or avoiding more complex interventions, such as keratoplasty procedures.[4]

Four types of ICRS are available, and various reports in the ophthalmic literature describe their effectiveness in treating keratoconus[2] In addition is the newly developed Keratacx Plus rings (Imperial Medical Technologies Europe GmbH), and there is only 1 report of their effectiveness in management of keratoconus.[5]

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Keratacx Plus rings have a smaller visual zone than and dimensions similar to those of Kerarings ICRS (Mediphacos Ltda.) and Ferrara ICRS (Ferrara Ophthalmics Ltd.). The design is meant to prevent the visual aberrations, halos, glare, sparkles, and field defects sometimes encountered with the other 2 designs. The decrease in visual problems is the result of the rings' domed edges. Also, smooth borders were incorporated to help protect the corneal stroma from erosion over time (Figure 1). Keratacx Plus rings are more affordable than other types of ICRS[6] and are available in several radii (45 degrees, 90 degrees, 120 degrees, 160 degrees, 210 degrees, 320 degrees, 355 degrees) to allow for precise diopter (D) corrections in eyes with all types of corneal topography. Table 1 shows the basic characteristics of different ring segments.[5,6]

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 (Oculus Optikgeräte GmbH).[7] Eccentric cones tend to have larger higher-order aberrations and astigmatism, and central cones produce higher refractive errors.[8]

The decision to implant symmetric ICRS versus asymmetric ICRS is based on the cone location. Symmetric segments are typically used to manage central ectatic conditions, whereas asymmetric segments are used for eccentric ectatic conditions.[7] The results of the first experiments with intracorneal continuous rings in the early 1980s were unacceptable.[9]

The development of new technologies, new designs of intracorneal implants, and new surgical approaches, such as femtosecond laser corneal tunnel creation, made the procedure faster, easier, 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 and there are fewer complications.[10]

The Myoring intracorneal implant, a continuous intracorneal ring (ICR) (Dioptex GmbH), is another surgical option in which a flexible 360-degree, full-ring PMMA implant is inserted into a corneal pocket for treatment of keratoconus, keratectasia after laser in situ keratomileusis (LASIK), and moderate to high myopia. This ICR is available in diameters ranging from 5.0 to 6.0 mm and thickness ranging from 200 to 400 µm in 20 µm increments. The anterior surface is convex, and the posterior surface is concave.[11]

Because the Myoring ICR is a continuous, full-ring implant with no disruption of continuity along its circumference, it acts in the cornea as a second (artificial) limbus and supports the cornea biomechanically in the same way as a ceiling beam supports the ceiling of a room under load by separating the ceiling (cornea) into 2 compartments and reducing the load on each compartment. Specifically, the ICR takes up a significant amount of the load acting on the cornea.[12]

Another difference between ring segments and the Myoring ICR is that the latter provides all 3 possible degrees of freedom (implant thickness, implant diameter, and implant position) with the goal of achieving the optimum result in any given case, whereas ring segments provide 1 degree of freedom (implant thickness).[12] Daxer et al.[13] concluded that the ICR has the potential to produce excellent long-term vision results in cases of mild, moderate, and advanced keratoconus, regardless of the cone position and disease progression.

The aim of this study was to compare the efficacy (visual acuity, refraction, corneal topography, corneal asphericity) of intrastromal corneal implantation of Keratacx 160-degree 2 symmetrical ring segments, the Keratacx 320-degree near-total ring, and the Myoring ICR in central keratoconus. To our knowledge, this is the first study to do such a comparison.

PATIENTS AND METHODS

This prospective nonrandomized comparative interventional case study included eyes with a diagnosis of keratoconus of the central cone or symmetric bowtie type. All patients were not contact lens wearers. Patients were recruited from a private practice and Ain Shams University cornea clinics from March 2015 to November 2016, and all provided written informed consent to enroll in the study. All surgeries were performed and followed at a private ophthalmic subspecialty center by same surgeon (M.O.Y.). Approval of the Ethical Committee of Ain Shams University was obtained before the patients' enrollment.

Inclusion and Exclusion Criteria

Inclusion criteria were a diagnosis of moderate to severe keratoconus according to keratoconus study classification using the steepest K reading[14] with a history of progression over the previous 12 months in the form of a change in the steepest K reading of 1.0 D or more,[15] age between 18 years and 40 years, maximum K reading less than 65.0 D, minimum corneal thickness at the proposed tunnel or pocket site of greater than 400 µm, presence if central cone (≥50% of cone within 3.0 mm zone on the rotating Scheimpflug posterior elevation map), and ability to complete a follow-up of 6 months postoperatively. Exclusion criteria were previous corneal surgery; evidence of infectious corneal disease in the study eye; unclear visual axis resulting from corneal opacity,

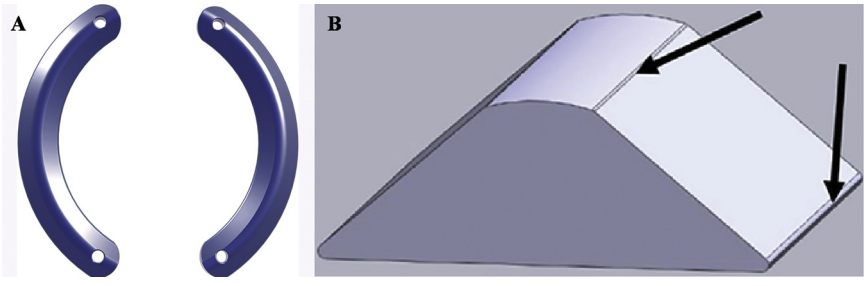

Figure 1. *A*: Cesign of the 160-degree 2-ring segment. *B*: Dome edges and smooth borders of the segments.