Outcomes of a Single-Segment Intrastromal Corneal Ring in Early Keratoconus and Early Pellucid Marginal Degeneration

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Abstract

Purpose To determine the effect of a single-segment intrastromal corneal ring segment (ICRS; Intacs SK) on early keratoconus (KCN) and pellucid marginal degeneration (PMD).

Methods It is a prospective interventional study. One hundred twenty-four eyes (99 patients) with KCN and 36 eyes (26 patients) with PMD at early stage (the maximum keratometric reading less than 55 diopters) were included in ICRS implantation using femtosecond laser at a tertiary university-based hospital and a private outpatient center. The uncorrected distance and spectacle-corrected visual acuity (UDVA and SCDVA), manifest spherical and cylindrical refractions, and keratometry indices were measured preoperatively and postoperatively, 1 week, 2 and 6 months.

Results One week after surgery, significant improvements were observed in UDVA, SCDVA, cylinder and keratometry readings of both KCN and PMD groups (all $P<0.05$) with no significant changes afterward. No significant change occurred in the sphere refraction of PMD group ($P=0.10$) in contrast to KCN group ($P<0.001$). Corneal irregularity of KCN group in central 3 and 5 mm zones increased at 1 week (both $P<0.001$) and then started to decrease up to 6 months. However, the corneal irregularity of PMD group had significant reduction only at 1 week in 5-mm zone ($P=0.02$) and 2 months in 3-mm zone ($P=0.01$) postoperatively. The final efficacy indexes were $1.44\pm0.71$ and $0.87\pm0.40$ in KCN and PMD groups, respectively.

Conclusion Visual acuity, refractive errors and keratometry values have been improved after one-segment Intacs SK implantation in early KCN and PMD patients.

Keywords Femtosecond laser · Intacs · SK · Intracorneal ring · Keratoconus · Pellucid marginal degeneration

Introduction

Keratoconus (KCN) and pellucid marginal degeneration (PMD) are the most common forms of non-inflammatory corneal ectatic disorders in which progressive corneal steepening causes increasing myopia and high irregular astigmatism. The diagnosis of PMD and its distinction from KCN have been an ongoing discussion. For most, this is nothing more than an academic exercise with little clinical
significance, because most view these two entities as different points on a clinical continuum [1]. Although the ectasia of both KCN and PMD usually affects the inferior part of the cornea, the corneal protrusion of PMD is located above the area of thinning [2].

Different methods of visual rehabilitation in KCN and PMD, including spectacles, contact lenses and corneal transplantation, have been introduced. Intrastromal corneal ring segment (ICRS) implantation is considered a minimally invasive surgical procedure in the management of KCN and PMD that may defer the need for keratoplasty and restore contact lens tolerance [3].

The ICRSs are polymethylmethacrylate segments that generate an immediate response by reshaping the cornea. The ICRSs act as a spacer in corneal lamella, induce an arc-shortening effect and decrease the steepness of the curvature of the central cornea by creating a second limbus of smaller diameter in the middle of the cornea [4]. It minimizes the spherocylindrical error and flattens the topographic analysis with a subsequent improvement of the visual acuities. The main advantages of ICRS are safety, stability, and individualized treatment of ectatic cornea depending on ring thickness, diameter, and centration [5, 6]. Additionally, the ICRS implantation is partially reversible and with its removal the topographic and refractive values return to its preoperative state. [4] Therefore, dealing with its complication is less dreadful although some patients may suffer glare and halo after ICRS removal due to scarring [4].

Different types of intracorneal rings are available in the market that have variable curvatures, widths and zones of implantation. Modern ICRSs are incomplete rings. Intacs (Addition Technology, Fremont, California, USA) have a crescent-shaped arc length of different degrees and subdivided into two models: standard Intacs and Intacs SK [7]. Standard Intacs have external and inner diameters of 8.10 mm and 6.8 mm, respectively, with a hexagonal transverse shape. Intacs SK has an inner diameter of 6.0 mm and two thicknesses with a round cross section to minimize glare [8]. It is positioned closer to the visual axis and central cornea, consequently being more effective than standard Intacs in severe ectatic cases [5].

Previous studies have shown the promising results of single-segment and double-segment implantation of Intacs in corneal ectasia [6, 9–11]. However, these studies have focused on the moderate KCN and no previous study evaluated the outcomes of femtosecond-assisted implantation of single-segment Intacs SK in the early KCN. Therefore, this study aimed to assess the femtosecond laser-assisted implantation of single-segment Intrastral corneal ring (ICRS; Intacs® SK) in eyes with early stages of KCN and PMD.

Methods

This is a prospective interventional study on patients with diagnosis of KCN or PMD who underwent femtosecond-assisted single-segment Intacs® SK ICRS (Addition Technology Inc., Sunnyvale, USA) implantation at Rassoul Akram Hospital and Iranian Eye Clinic, Tehran, Iran, from 2015 to 2019. The Ethics committee of Iran University of Medical Sciences approved the study (IR.IUMS.1398.544) and informed consent was obtained from all patients and the study adhered to the tenets of Declaration of Helsinki.

Included were patients with clear cornea who did not tolerate contact lens, the mean central keratometry reading less than 53.00 diopters (D), and the corneal thickness more than 400 μm at the incision site, keratoconus of stage I and II according to Amsler–Krumeich classification and mesopic pupil of less than 6.5 mm in diameter. Patients with severe dry eye, corneal scar, severe allergic conjunctivitis, previous ocular surgery, glaucoma, cataract, a history of herpes simplex keratitis, pregnancy, breast-feeding, and use of Accutane (Isotretinoin, Accutane™ Roche®) or Amiodarone hydrochloride (Cordarone®) were excluded.

The diagnosis of PMD was made on the basis of slit lamp findings (ectasia above the area of maximum thinning in the inferior cornea). The diagnosis was confirmed by corneal topography (‘butterfly’ keratometry pattern, very steep peripheral inferior cornea, and high keratometric powers radiating from the center to the inferior oblique meridians), and refractive findings (against-the-rule astigmatism with loss of spectacle corrected distance visual acuity (SCDVA). Diagnosis of KCN was established by the combination of computed videokeratography for the anterior and posterior corneal surface (Orbscan IIz; Bausch & Lomb, Rochester, NY), keratometry readings, and corneal pachymetry. All eyes showed an
inferior–superior corneal shape index > 1.40 Diopter (from an average of five points at 30 degree intervals located 3 mm from center).

Each study participant underwent a comprehensive ophthalmic evaluation, including subjective refraction, uncorrected Snellen distance visual acuity (UDVA), SCDVA, IOP measurement with a calibrated Goldmann applanation tonometer and slit-lamp biomicroscopy at preoperative and postoperative visits. Corneal thickness at the incision site was measured using Orbscan pachymetry with Intracal software. Topographical indices were measured by Orbscan II (Bausch & Lomb, Rochester, New York, USA) which include corneal dioptic power in the flattest meridian for the 3-mm central zone (flat keratometry), corneal dioptic power in the steepest meridian for the 3-mm central zone (steep keratometry), mean corneal power in the 3-mm central zone (mean keratometry), Simulated keratometry (Sim-K), irregularity in the 3 and 5 mm zones, anterior chamber depth, anterior best fit sphere (BFS) and posterior BFS, preoperatively and 1 week, 2 and 6 months postoperatively. Furthermore, the efficacy index was defined as the ratio of the postoperative UDVA to the preoperative SCDVA. Safety index was calculated as the ratio of the postoperative SCDVA to the preoperative SCDVA. Snellen Visual acuities were used to calculate safety and efficacy.

Surgical technique

All surgical procedures were performed by the first author (SJH) under topical anesthesia using% 0.5 tetraacaine eye drop (Anestocaine; Sina Darou, Tehran, Iran). Intacs SK segment implantation was performed using a femtosecond laser LDV Z6 (Ziemer Ophthalmic Systems, Port, Switzerland). All intrastromal rings that were used in this study had 150-degree arcs with various thicknesses including 300, 350, 400 and 450 µm. The manufacture nomogram was used to select the ring based on corneal thickness at the incision site, SCDVA, sphere, spherical equivalent (SE), astigmatic power, and location of the cone. Patients were placed under the laser system, and the femtosecond suction ring was centered at the pupil center. Suction was applied and the femtosecond laser was used to create a channel at the selected corneal depth (75% of the corneal thickness at the incision site), with an inner diameter of 6.0 mm and an outer diameter of 7.2 mm. The femtosecond laser was also used to create an incision to insert the Intacs SK segment, preferably on the steepest axis. If the patient’s SCDVA was better than 0.5 logarithm of the minimum angle resolution (LogMar), the axis of manifest refraction was used for this purpose [12]. Under microscopic guidance, the Intacs SK segments were implanted inside the channels using forceps and Sin-skey hooks placed through dialing holes at the ends of the segment, which was centered in the middle of its tunnel, equidistant from the incision. The incision site was not sutured. A bandage contact lens (AIR optix AQUA; Base Curve: 8.6, Diameter: 14.2; CIBA VISION) was fitted for 24 h. Levofloxacin eye drop was administered four times a day for one week. Betamethasone eye drop (Betasonit %0.1, betamethasone disodium phosphate; Sina Darou, Tehran, Iran) was given twice daily for 3 weeks, and artificial tears (Artelac™, Hypromellose; Bausch and Lomb, Montpellier, France) were administered every 4 h for 4 weeks.

Power vector analysis

Power vector analysis was performed to compare astigmatism between pre- and post-operative measurements. The results of sphero-cylindrical refraction were converted to vectors expressed by three dioptic powers (M, J₀, J₄₅). M equals to the spherical equivalent of the refractive error. J₀ is Jackson cross-cylinder power axes at 0 or 180 degrees. J₄₅ is Jackson cross-cylinder power axes at 45 and 135 degrees. The Pythagorean length of the power vector is called B. It represents the overall blurring strength of the refractive error. Manifest refraction was recorded in the conventional manner (S[sphere], C[cylinder], α[axis]) and converted to the power vector coordinates using the following formulas [13]:

\[ M = S + \left(C/2\right) \]

\[ J₀ = -C/2 \cos (2\alpha) \]

\[ J₄₅ = -C/2 \sin (2\alpha) \]

\[ B = \sqrt{J₀^2 + J₄₅^2 + M^2} \]
Statistical analysis

Statistical analyses were performed with SPSS for Windows software version 22.0 (SPSS Inc., Chicago IL, USA). Quantitative data were described with means (standard deviation) and percentage in continuous and numerical data, respectively. Snellen visual acuity was converted into logarithm of the minimum angle of resolution [LogMAR] for statistical analysis. Shapiro–Wilk test was used to assess whether variables had a normal distribution. Mixed model analysis was used to account for the inclusion of both eyes from some of the patients, which was performed to evaluate the changes of the main outcome measures including visual acuity, refraction and topographic indices after Intacs SK implantation. P values less than 0.05 were considered statistically significant.

Results

One hundred sixty eyes of 125 patients with mean age of 31.15 ± 7.81 years (range = 19–67) were enrolled. According to the Amsler–Krumeich classification, four-fifths of subjects (79.2%, 99/125 patients or 77.5%, 124/160 eyes) were assembled in early KCN groups, including 77/124 eyes (62.1%) as stage 1 and 47/124 eyes (37.9%) as stage 2. One-fifth of (20.8%, 26/125 patients or 22.5%, 36/160 eyes) patients had PMD. Table 1 shows the baseline features of patients in each group (Table 1). Intacs SK ring segment with 450μ thickness were implanted in 66.3% (104/160) of eyes, 400μ thickness in 23.8% (38/160) of eyes, 350μ thickness in 7.5% (12/160) of eyes and 300μ in 2.5% (4/160) of eyes.

| Variables          | KCN Patient = 99 | PMD Patient = 26 |
|--------------------|------------------|------------------|
| Age                | 30.49 ± 65.66    | 34.38 ± 7.99     |
| Sex (female %)     | 32.3% (32/99)    | 30.8% (8/26)     |
| Corneal thickness  | 537.66 ± 38.39   | 531.60 ± 36.98   |
| Ring thickness     | 428.63 ± 36.74   | 432.86 ± 26.96   |
| Depth of insertion | 402.38 ± 21.24   | 399.29 ± 17.66   |

Table 1 Baseline characteristics of 160 eyes from 125 patients with early keratoconus (KCN) or pellucid marginal degeneration (PMD) underwent single-segment Intacs SK implantation

Keratoconus group

Visual and refractive outcome

There were significant reductions in SE, spherical refraction and cylindrical refraction (all \( P < 0.001 \)) at the first week. The changes were not statistically significant at months 2 and 6 (Table 2). Vector analysis also showed significant reduction of astigmatism (Table 3). Visual acuity results at the preoperative and postoperative examinations are summarized in Table 2. The mean UDVA of KCN group showed statistically significant improvement, at the first postoperative week (\( P < 0.001 \)) which continued to increase at month 2 while they remained stable at month 6 (\( P = 0.62 \)). The mean SCDVA of KCN group had also similar pattern of changes following Intacs SK implantation (Table 2). The efficacy index after 6 months was 1.44 ± 0.71, proposing that Intacs SK alone achieved 144% of baseline SCDVA of KCN group. The safety index was 2.15 ± 0.83 after 6 months indicating 115% increase in visual acuity in KCN group. The UDVA increased one line and more (up to 8 lines) in % 93.6% (116/124) of eyes, remained at the preoperative level in 5.6% (7/124) of eyes (all of these were grade 2 KCN), and decreased 1 line in 0.8% (1/124) of eyes (which was KCN of the grade 2). Furthermore, the SCDVA increased one line and more (up to 6 lines) in 96% (119/124) of eyes, remained at the preoperative level in 4% (5/124) of eyes (three and two of them belonged to KCN grade 1 and 2, respectively).

Topographic outcome

The steep keratometry, flat keratometry, mean keratometry, BFS, Sim-K, and anterior chamber depth (ACD) decreased significantly after surgery and reached stability at postoperative week 1 (Table 2). Although anterior BFS of KCN group decreased significantly at 1 week (\( P < 0.001 \)), it rose again at month 2 (\( P = 0.001 \)) and then remained stable at month 6 (\( P = 0.38 \)) (Table 2). The corneal irregularity of KCN group had a trend of reduction up to months 6 after surgery in 3 mm zone (Table 2). However, the irregularity had a statistically significantly transient increase at week 1 in 5 mm zone (\( P < 0.001 \)) and then decreased (Table 2). The corneal irregularity of 5 mm zone at month 6 was
Table 2  Visual acuity, refractive and keratometry outcomes in 124 eyes of 99 patients with keratoconus (KCN) underwent single-segment Intacs SK implementation

| Variables                      | Preoperative  | 1 week | 2 months | 6 months | Total  | 1 week vs. preop | 6 months vs. preop |
|-------------------------------|---------------|--------|----------|----------|--------|------------------|-------------------|
| UDVA (LogMar)                 | 0.77±0.21     | 0.46±0.23 | 0.42±0.22 | 0.39±0.20 | <0.001* | <0.001*         | <0.001*          |
| SCDVA (LogMar)                | 0.47±0.17     | 0.26±0.15 | 0.21±0.14 | 0.19±0.14 | <0.001* | <0.001*         | <0.001*          |
| Spherical Equivalent (D)      | -4.22±2.99    | -2.47±2.76 | -2.30±2.65 | -2.31±2.73 | <0.001* | <0.001*         | <0.001*          |
| Sphere (D)                    | -2.34±2.88    | -1.19±2.70 | -1.06±2.59 | -0.98±2.53 | <0.001* | <0.001*         | 0.009*           |
| Cylinder (D)                  | -3.76±1.61    | -2.55±1.63 | -2.49±1.62 | -2.65±1.47 | <0.001* | <0.001*         | <0.001*          |
| Steep keratometry (D)         | 49.65±3.14    | 46.97±2.73 | 47.06±2.80 | 47.32±2.85 | <0.001* | <0.001*         | <0.001*          |
| Flat keratometry (D)          | 45.32±2.74    | 44.14±2.71 | 44.08±2.57 | 44.25±2.69 | <0.001* | <0.001*         | <0.001*          |
| Mean keratometry (D)          | 47.48±2.83    | 45.56±2.61 | 45.57±2.58 | 45.78±2.69 | <0.001* | <0.001*         | <0.001*          |
| Anterior BFS (D)              | 43.96±1.45    | 42.86±1.42 | 43.03±1.41 | 43.25±1.43 | <0.001* | <0.001*         | <0.001*          |
| Posterior BFS (D)             | 54.56±2.27    | 53.09±2.23 | 53.27±2.20 | 53.39±2.16 | <0.001* | <0.001*         | <0.001*          |
| Sim-K (D)                     | -4.33±1.61    | -2.83±1.57 | -3.02±1.42 | -3.07±1.30 | <0.001* | <0.001*         | <0.001*          |
| Irregularity in central 3 mm  | 4.97±1.68     | 4.81±1.46 | 4.36±1.36 | 4.21±1.44 | <0.001* | >0.99          | <0.001*          |
| Irregularity in central 5 mm  | 5.11±1.53     | 6.02±1.42 | 5.38±1.34 | 5.05±1.29 | <0.001* | <0.001*         | 0.99             |
| Anterior chamber depth (mm)   | 3.21±0.31     | 3.09±0.32 | 3.11±0.32 | 3.11±0.32 | <0.001* | <0.001*         | <0.001*          |

SD Standard deviation, UDVA uncorrected distance visual acuity, SCDVA spectacle corrected distance visual acuity, LogMar logarithm of the minimum angle of resolution, D diopter, BFS best fit sphere, Sim-K simulated keratometry astigmatism

*statistically significant
*aEstimated marginal means by Mixed model linear analysis with Bonferroni correction for comparing with previous time point
bMixed model linear analysis

Table 3  Statistical summary of the vector analysis 6 months after single-segment Intacs SK implementation referenced to spectacle plane

| Variables                  | Keratoconus Preoperative Mean±SD | Postoperative Mean±SD | P-value | Pellucid marginal degeneration Preoperative Mean±SD | Postoperative Mean±SD | P-value |
|----------------------------|----------------------------------|-----------------------|---------|--------------------------------------------------|-----------------------|---------|
| J₀                         | -0.19±1.12                       | 0.38±0.96             | 0.003*  | -1.40±1.01                                       | -0.87±1.00            | <0.001* |
| J₄₅                       | -0.15±1.97                       | -0.02±1.29            | 0.16    | -0.18±2.16                                       | -0.16±1.43            | 0.94    |
| M                         | -2.44±1.78                       | -1.33±1.62            | <0.001* | -2.50±1.49                                       | -1.40±1.15            | <0.001* |
| B                         | 3.40±1.59                        | 2.27±1.33             | <0.001* | 3.82±1.44                                        | 2.39±1.30             | <0.001* |

M, the spherical equivalent; J₀, Jackson cross-cylinder power axes at 0 and 180 degrees; J₄₅, Jackson cross-cylinder power axes at 45 and 135 degrees; B, Pythagorean length of the power vector; SD, Standard deviation

*Statistically significant

not statistically different from preoperative values (P > 0.99) in contrast to its significant reduction at 3 mm zone (P < 0.001).

Pellucid marginal degeneration group

Visual and refractive outcome
The SE and cylindrical refraction decreased after 1 week in PMD group (all \( P < 0.001 \)) while they remained stable at months 2 and 6 (Table 4). Spherical refraction of PMD group did not have a statistically significant change after surgery (\( P = 0.1 \)). Vector analysis also showed significant reduction of astigmatism at 6 months (Table 3). Preoperative UDVA and SCDVA of PMD group increased significantly at the first week while they did not experience further improvement at 2 and 6 months after surgery (Table 4).

The efficacy and safety indices after 6 months were 0.87 ± 0.40 and 1.52 ± 0.45, respectively. It means that Intacs SK caused 52% increase in visual acuity and it alone achieved 87% of baseline SCDVA in eyes with PMD. The UDVA increased one line and more in 94% (34/36) of eyes and remained at the preoperative level in 6% (2/36) of eyes. Furthermore, the SCDVA increased one line and more in 92% (33/36) of eyes, remained at the preoperative level in 6% (2/36) of eyes, and decreased 1 line in one eye (1/36, 2%).

**Topographic outcome**

The keratometry values (flat, steep, and mean), BFS, Sim-K, and ACD decreased significantly 1 week after surgery and did not change afterward (Table 4). Anterior BFS of PMD group decreased after 1 week (\( P < 0.001 \)) which remained stable at 2 and 6 months (\( P > 0.99 \)) (Table 4). The overall pattern of corneal irregularity after Intacs SK implantation was a decreasing pattern up to months 6 after surgery in 3 mm zone (Table 4). The changes were statistically significant only between week 1 and month 2 (\( P = 0.01 \)). At 5 mm zone, the irregularity had a

**Table 4** Visual acuity, refractive and keratometry outcomes in 36 eyes of 26 patients with pellucid marginal degeneration (PMD) underwent single-segment Intacs SK implementation

| Variables                        | Preoperative Mean ± SD | 1 week Mean ± SD | 2 months Mean ± SD | 6 months Mean ± SD | Total P-value | 1 week vs. preop P-value | 6 months vs. preop P-value |
|----------------------------------|------------------------|------------------|-------------------|-------------------|---------------|--------------------------|---------------------------|
| UDVA (LogMar)                    | 0.85 ± 0.17            | 0.46 ± 0.29      | 0.44 ± 0.26       | 0.42 ± 0.25       | < 0.001*      | < 0.001*                 | < 0.001*                  |
| SCDVA (LogMar)                   | 0.42 ± 0.23            | 0.24 ± 0.22      | 0.21 ± 0.19       | 0.16 ± 0.17       | 0.001*        | 0.002*                   | 0.001*                    |
| Spherical Equivalent (D)         | − 2.96 ± 2.06          | − 1.37 ± 1.71    | − 1.27 ± 1.52     | − 0.99 ± 1.23     | < 0.001*      | < 0.001*                 | < 0.001*                  |
| Sphere (D)                       | − 0.72 ± 1.93          | − 0.13 ± 1.86    | 0.13 ± 1.55       | 0.25 ± 1.42       | 0.10          | 0.52                     | 0.20                      |
| Cylinder (D)                     | − 4.47 ± 1.69          | − 2.47 ± 1.62    | − 2.79 ± 1.69     | − 2.47 ± 1.18     | < 0.001*      | < 0.001*                 | < 0.001*                  |
| Steep keratometry (D)            | 48.57 ± 2.60           | 45.89 ± 2.47     | 46.19 ± 2.33      | 46.18 ± 1.62      | < 0.001*      | < 0.001*                 | < 0.001*                  |
| Flat keratometry (D)             | 43.38 ± 2.22           | 43.02 ± 2.12     | 42.87 ± 2.15      | 43.35 ± 1.75      | 0.001*        | 0.004*                   | 0.17                      |
| Mean keratometry (D)             | 46.06 ± 2.14           | 44.45 ± 2.07     | 44.53 ± 1.99      | 44.77 ± 1.53      | < 0.001*      | < 0.001*                 | < 0.001*                  |
| Anterior BFS (D)                 | 48.57 ± 2.60           | 45.89 ± 2.47     | 46.19 ± 2.33      | 46.18 ± 1.62      | < 0.001*      | < 0.001*                 | < 0.001*                  |
| Posterior BFS (D)                | 53.94 ± 2.24           | 52.25 ± 2.08     | 52.79 ± 2.25      | 53.27 ± 2.16      | < 0.001*      | < 0.001*                 | < 0.001*                  |
| Sim-K (D)                        | − 5.01 ± 2.27          | − 2.88 ± 2.02    | − 3.31 ± 2.06     | − 2.82 ± 1.42     | < 0.001*      | < 0.001*                 | < 0.001*                  |
| Irregularity in central 3 mm     | 4.43 ± 1.94            | 4.08 ± 1.30      | 3.79 ± 1.43       | 3.07 ± 0.83       | 0.003*        | 0.86                     | 0.009*                    |
| Irregularity in central 5 mm     | 5.77 ± 5.38            | 5.95 ± 1.87      | 5.37 ± 1.70       | 4.99 ± 1.61       | 0.01*         | 0.02*                    | 0.26                      |
| Anterior chamber depth (mm)      | 3.20 ± 0.41            | 3.16 ± 0.43      | 3.15 ± 0.42       | 3.03 ± 0.75       | < 0.001*      | < 0.001*                 | 0.003*                    |

*a Estimated marginal means by Mixed model linear analysis with Bonferroni correction for comparing with previous time point

*b Mixed model linear analysis

*Statistically significant

SD Standard deviation, UDVA uncorrected distance visual acuity, SCDVA spectacle corrected distance visual acuity, LogMar logarithm of the minimum angle of resolution, D diopter, BFS best fit sphere, Sim-K simulated keratometry astigmatism
statistically significantly transient increase at week and then decreased (Table 3). After 6 months of ICRS implantation, the corneal irregularity of 3 mm zone has decreased significantly although the irregularity of 5 mm zone did not have.

Adverse events and complication

No surgical complications, such as anterior chamber perforation, extrusion, migration, or visualization, around the incision or the tunnels occurred. In addition, neither corneal ulcers nor stromal necrosis superficial to the segment were observed.

Discussion

In this study, we assessed the outcomes of femtosecond laser-assisted single-segment Intacs SK implantation in early stages of KCN and PMD. The current study showed that implantation of single-segment Intacs SK could significantly improve the UCVA and SCDVA of eyes with mild KCN and PMD by decreasing the cylindrical refraction and keratometry (mean, steep and flat) values 1 week after surgery which remained stable afterward. The reduction of spherical refraction was significant only in eyes with KCN. Furthermore, the corneal irregularity at central 3 mm and 5 mm had a trend of increase at 1 week postoperatively and then decrease up to 6 months. The current study showed that the single-segment Intacs SK was safe and efficacious in early KCN and early PMD.

Previous studies demonstrated that Intacs implantation with femtosecond laser was an effective method in the management of patients with either KCN or PMD to reduce the SE and consequently improve the UCVA and SCDVA although some studies reported regression in the long term following short-term improvement [14, 15]. Changes of refractive and visual outcomes over time after ICRS implantation have rarely been reported [5, 16]. All of them reported immediate improvement of visual and refractive outcome remaining unchanged in short period [5, 16]. Our results showed similar trend in which immediate significant improvement of visual acuity, refraction and keratometry values at first week followed by Plateau status in both PMD and KCN groups.

The comparison of effects of single-segment and double-segment implantation of Intacs have been explored in some studies [6, 9, 10, 17]. Abad et al. [18] showed that the implantation of 150-degree single-segment Intacs SK could decrease the steepness of the cornea as much the asymmetric double-segment Intacs SK implantation did. The impact of single-segment implantation on ectatic cornea may return to the asymmetric changes in such patients, which usually happens in the inferior part of the cornea. In other words, implantation of single-segment ICRS induces inferior flattening and superior steepening in contrast to double-segment ICRS which flattens the cornea both inferiorly and superiorly. Therefore, single-segment rings result in greater change in inferior-superior ratio, and thus, more favorable outcomes compared with double-segment implantation, especially for cases of peripheral steepening [11]. Implantation of single-segment ICRS accompanies with less corneal trauma which decreases the risk of infection, segment extrusion, glare, and halos. Our results were in agreement with Amanzadeh’s [12] prospective case series of keratoconic eyes. Despite the fact that they used single-segment conventional Intacs in their study, the results of visual outcome of our study with Intacs SK are comparable to those results. Fahd et al. [19] evaluated the efficacy and safety of a single-segment Intacs SK in 30 eyes with moderate to severe KCN up to 6 months. Although they reported significant improvement of visual and refractive outcomes after 1 month, no significant change was observed afterward [19]. Fahd and association [20] calculated corneal irregularity based on the topography differences between apex and steepest point to implement single-segment Intacs SK and proposed the development of a topographically driven nomogram rather than a primarily refraction-based nomogram for single-segment rings implementation [20]. The flattening effect of single-segment Intacs SK was more pronounced in eyes with the steeper keratometry [20]. This can explain the subtle discrepancies between our study and others’ in terms of the amount of postoperative refractive and visual changes. Hence, customizing the ring segment size based on these measures might be a better option than relying purely on the preoperative manifest refraction [20]. Single-segment rings also maximize the reduction in lower-order astigmatism and corneal coma-like aberrations [20, 21].

The ICRS implantation is also effective and safe for patients with PMD [21–24]. Some case studies
have explored the use of Intacs in PMD patients and the results have been promising [22–24]. Ertan et al. [22] assessed the 6-month outcomes of two-segment Intacs using femtosecond laser in 9 eyes with PMD. In this study, there was statistically significant improvement in UDVA, SCDVA, keratometry readings and cylindrical refractions [22]. However, no significant decrease was observed in sphere refraction [22]. More favorable outcomes were reported by one-segment 210 degree keraring and Myoring in patients with PMD that probably due to extended arc length and higher arc-shortening effect [16, 21]. Jabbarvand et al. [16] proposed that Myoring could be used in more advanced cases with higher myopia. Kubaloglu et al. [21] reported the mean reduction of 1 logMar of UDVA, 0.5 logMar of SCDVA, 2.5 diopter of steep keratometry and 2 diopter cylindrical refraction in 16 eyes with PMD, 3 years after single-segment 210-degree arc length Keraring implantation. However, they did not evaluate the early postoperative results earlier before 1 year [21]. Single-segment ICRS provide a localized flattening in a wide field of steep area and steepening in the superior cornea, instead of flattening seen with the implantation of double segments. Therefore, single-segment ICRS induces a more regular optical zone and a greater improvement in SCDVA. Our results with single-segment Intacs are comparable with those by Kubaloglu et al. [21] with single-segment Keraring in terms of reduction of steep keratometry and cylindrical refraction although the decrease in flat keratometry and spherical refraction were much higher than our study. Moreover, our results were in agreement with Jabbarvand’s study [16] in which no significant change was observed 1 month after surgery.

The effect of ICRS on visual, refractive and topographic outcomes depends on the severity of corneal ectasia. However, there continues to be controversy over which stage of KCN and PMD has the best outcomes after the ICRS. The contradictory results may be explained by fundamental differences including the type of ICRS used, the technique of tunnel creation and the nomograms for ring selection. Some studies reported that in patients with more pronounced KCN, the mean reduction in keratometric values after Intacs or Keraring was higher compared with the mean reduction in patients with early stages [25, 26]. Boxer Wachler et al. [27] observed a greater reduction in SE in those with more advanced KCN following Intacs implantation. It contradicts Ertan’s study, in which higher stage of the KCN was associated with less improvement of UCVA despite flatter postoperative keratometry after Intacs implantation using femtosecond [26]. Different stages were similar in terms of change in SCDVA, manifest spherical refraction, or manifest cylindrical refraction [26]. In the stage II group, the mean UCVA (1.15 to 0.63) and BCVA (0.48 to 0.28) improved significantly from preoperatively to postoperatively [26]. The mean preoperative spherical refraction (-5.94 to -3.29), cylindrical (-3.98 to -2.31) refraction, and mean K (50.26 to 47.49) values were statistically significantly lower postoperatively [26]. Similarly, Wild et al. [28] found out that patients with mild KCN are more likely to have a favorable outcome following Keraring implantation while the changes were more prominent in advanced groups. In the mild KCN group with maximum keratometry less than 48 D, the increase in SCDVA was 0.16 logMar while the sphere, cylinder and maximum keratometry decreased nearly 2 D [28]. They mentioned that patients with severe KCN failed to achieve significance in sphere or cylinder [28].

This article has several potential limitations including the small sample of eyes with PMD, the relatively short period of follow-up, and the lack of analysis of corneal aberrations. Moreover, absence of data regarding contrast sensitivity, contact lens intolerance, or qualitative outcomes can be other reservations in concluding sufficient results.

In conclusion, the implantation of single-segment Intacs SK using femtosecond laser is safe and effective to address early stages of KCN and PMD with significant improvement in UDVA, SCDVA and topography profile of cornea.

Authors’ contributions SJH conceptualized the study; LG, PA, FNS, and MEJ contributed to methodology; PA, FNS, and MEJ contributed to formal analysis and investigation; PA, FNS, SMH, and MSH involved in writing—original draft preparation; SJH, LG, AH, PA, and HA involved in writing—review and editing; SJH, LG, HA, and AH contributed to resources; SJH involved in supervision; All authors read and approved the final manuscript.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval Approval was obtained from the ethics committee of Iran University of Medical Sciences approved the study (IR.IUMS.1398.544). The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

Consent to participate Informed consent was obtained from all individual participants included in the study.

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