Intacs SK for Management of keratoconus


Purpose: To Evaluate Intacs SK (Addition technology) for management of keratoconus.

Patients and Methods: Twenty two eyes of 17 patients with keratoconus (12 males, 5 Females, ages 19 to 42 years), who completed 6 months follow up were included. Two Intacs SK segments of 0.45 mm thickness were inserted in the cornea of each eye at steepest axis, aiming at embracing the keratoconus area in order to achieve maximal flattening.

Results: The mean UCVA significantly improved from 0.12±0.13 (range, CF -0.5) to 0.38± 0.26 (range CF -0.8). Of 22 eyes, one eye lost one line of UCVA and 4 eyes maintained the preoperative UCVA whereas the rest (17 eyes) gained form 1-5 lines.

The mean BCVA also improved from 0.38±0.28 (range CF -0.7) to 0.62± 0.22 (range 0.2 – 0.9) from 22 eyes, 7 eyes maintained the preoperative BCVA while 15 eyes experienced a 1-6 lines gain. SE improved from -5.42± 3.62D to -3.92± 1.44D. Mean K reading improved from 51.32± 4.12 to 48.44± 3.92.

Conclusion: Intacs SK implantation improved UCVA, BCVA and K readings in keratoconic patients.

Keratoconus is an ectatic corneal disorder characterized by a progressive corneal thinning that results in corneal protrusion irregular astigmatism, and decreased vision\(^{(1)}\). In early stages, treatment consists of spectacles or rigid contact lenses. However some patients can become intolerant to contact lenses or achieve an unacceptable visual performance.\(^{(2)}\)
In advanced stages, the accepted approach is penetrating keratoplasty (PKP). Despite the good result of PKP complications such as graft rejection, irregular astigmatism and side effects from long use of topical steroids still present\(^3\). Corneal collagen cross linking primary gain to stop ectasia\(^4\).

Intacs SK (Addition technology) were designed to achieve a refractive adjustment by flattening the central corneal curvature while maintaining clarity in the central optical zone, aiming at delaying and preventing corneal graft in patients with keratoconus.\(^5\) The aim of this study is to evaluate, visual, corneal changes, and complications after mechanical implantation of these rings in keratoconus.

**Patients and Methods**

Twenty two eyes of 17 patients, 12 males (70.6%) and 5 females (29.4%). The mean age 26.24± 4.76 years (range 19 to 42 years) were included in our study. All patients had clear central corneas, contact lens intolerance, \(K < 60\) D and minimum pachymetry of 400 \(\mu\)m along the track of insertion. All of them have no herpetic keratitis, no autoimmune or systemic connective tissue disease, and no previous corneal surgery. A complete ophthalmologic examination was performed preoperatively to exclude other ocular disease and the preoperative and postoperative follow up evaluation included uncorrected visual activity (UCVA), best corrected visual acuity (BCVA); (decimal scale), manifest refraction, kerotometric data and corneal topography (PENTACAM) the follow up visits were 1 week, 1, 3, 6 months ranged from 6 m to 11 m for all patients (7.75± 1.25m). The determination of which thickness of the Intacs SK segments to implant is dependent upon a number of variables; spherical equivalent and the location of the cone "Nomogram". All eyes in our study had central cones and implanted with 0.45 mm two Intacs segments.
Patients were asked to sign an informed consent before implantation and for further follow up examinations in Egyptian Eye Academy.

**Surgical Procedure:**

The surgical procedure was done under topical anesthesia under sterile conditions. A diamond knife set at 70% of the thinnest corneal measurement (Pentacam), a 0.9 mm radial incision was formed at steepest axis; corneal pockets were created using two Sinskey hooks and a Saurez spreader. Two corneal tunnels were then formed using clockwise and counter clockwise dissectors under suction created by a vacuum-centering guide. The polymethyl methacrylate segments (0.45 mm thickness) were implanted in the respective corneal tunnels with 2.0 mm space between their ends and 1.5 mm between each segment edge and the incision site was closed with a single 10/0 nylon stitch. All eyes received antibiotic-steroid combination eye drops four times per day for two weeks tapered to once daily for one month in addition to artificial tears.

**Statistical analysis:**

Group differences for continuous variables were tested using the paired student t test. Results are presented as mean± standard deviation (SD). P value of less than 0.05 was considered statistically significant.

**Results**

Intacs SK were successfully implanted in all eyes, although in one eye the tension is low and perforation occurred and we readjust its position again.

**Refractive outcome:**

Preoperative and 6 m follow up mean values for spherical equivalent refraction revealed a statistically significant reduction from
-5.42D± 3.62 D (range, -14.36 to 1.68 D) to -3.9D± 1.44 D (range, -8.34 to 2.12D).

**Visual acuity:**

The mean UCVA significantly improved after Intacs SK implantation from 0.12± 0.13 (range, CF -0.50) to 0.38± 0.26 (range CF -0.80), at 6 m follow up from 22 eyes, 1 eye lost 1 line of UCVA, 4 eyes maintained UCVA, 17 eyes gained 1-5 lines (77%) the mean difference between preoperative and 6 m follow up UCVA was a gain of 2 lines (range loss of 1 line to gain 5 lines). Fig. (1).

![Figure (1): Changes in UCVA after Intacs SK (Gain +, Lost -).](image1)

![Figure (2): Changes in BCVA after Intacs SK.](image2)
Best corrected visual acuity significantly improved from 0.38±0.28 (range, CF -0.7) to 0.62±0.22 (range, 0.2-0.9). 15 eyes gained 1-6 line (68%). The mean difference between preoperative and 6 m follow up BCVA was again of 1.7 lines (range 0 to gain 6 lines) fig. (2).

**Keratometric Values:**

A significant reduction in keratometric values was found postoperative. Mean preoperative keratometry was 51.32±4.12D (range, 43.16 to 58.86 D) changed at 6 m follow up to 48.44±3.92D (range 40.68 to 56.6D) fig. (3). Similarly, mean preoperative keratometric astigmatism was 4.57±2.86 D (range 1.14 to 11.44D), at 6 m follow up it changed to 3.86±2.64D (range, 1.02 to 8.14D) fig. (4).

**Complication:**

No post operative complications occurred in this short study (range 6-11 m). Although in one eye there was perforation. Because of low tension which was managed with reposition of Intacs SK.

**Discussion**

In keratoconus patients have a progressive deterioration in UCVA and BCVA resulting from irregular astigmatism induced by the corneal thinning, irregular shape. Intacs SK have crescent-shaped arc length of 150 degrees. Their inner diameter is 6 mm and the outer diameter is 7mm when placed in the cornea, they flatten the central cornea and maintain its clarity. Colin and associates reported their preliminary results regarding the management of keratoconus with Intacs SK\(^6\).

In our study 6m after Intacs SK implantation UCVA was improved in 17 eyes (77%), BCVA was improved in 15 eyes (68%).
Compared with the preoperative levels, we agree with Siganos et al that Intacs SK improve UCVA, BCVA, refraction and topographic findings in keratoconic patients.

George et al (7) found that UCVA was improved (in 77%), BCVA was improved (in 59%), and also they observed that the major changes in refraction and topographic findings took place during the early postoperative period (the first postoperative months). In our short term study we agree with them because we observed stability between 3-6 m although they have five years follow up.