·Clinical Research·

Treatment of moderate to severe keratoconus with 6-mm Intacs SK

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Abstract

• AIM: To evaluate the effect of Intacs SK corneal ring segment implant for treatment of patients with moderate to severe keratoconus, who have clear central cornea and cannot tolerate contact lens.

• METHODS: In this prospective, non-comparative, interventional case series study performed in Dena Hospital, Shiraz, Iran, thirty-seven eyes of thirty-six patients with moderate to severe keratoconus, clear central cornea, and contact lens intolerance were enrolled and underwent Intacs SK corneal ring segment implantation. Preoperatively, uncorrected distance visual acuity (UCDVA), best-corrected distance visual acuity (BCDVA), central corneal thickness(CCT) and average keratometry (Av-K) were measured and compared with post-operative results at one week, one month, three months, and six months.

• RESULTS: Mean preoperative UCDVA and BCDVA were (1.32±0.31) logMAR and (1.07±0.27) logMAR, respectively. Av-K was (52.13±0.39)D, and the CCT was (432±39.5)μm. Post-operative examinations showed a clinically significant improvement in both UCDVA and BCDVA (P<0.001). There was also a significant effect based on the time of assessment on both UCDVA and BCDVA and both parameters had a continuous improvement during the follow-up period. Three months after operation there was a statistical significant reduction of Av-K (P=0.0001), but there were no significant changes in CCT (P=0.149).

• CONCLUSION: Intacs SK corneal ring segment implants seem to be a safe and effective treatment option for patients who have keratoconus, clear central cornea, and contact lens intolerance.

• KEYWORDS: keratoconus; Intacs; myopia
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INTRODUCTION

Keratoconus is a noninflamatory progressive corneal thinning in which the cornea assumes a conical shape. It is frequently associated with irregular astigmatism with or without myopia, resulting in mild to severe visual impairment[1-3].

Spectacles and contact lens are usual treatment options in mild cases of keratoconus. In more advanced cases, with contact lens intolerance and corneal scar, penetrating keratoplasty (PKP) is necessary to restore visual function[4]. However, PKP is irreversible and contains risks including graft rejection, progressive endothelial cell loss, and suture-related problems such as increased astigmatism and wound dehiscence. Thus, finding another option to avoid or at least postpone PKP in these young patients is desirable.

Intrastromal corneal ring segments (INTACS, Addition technology) were first tried for the correction of mild to moderate myopia [5]. Intacs improve myopia by an arc-shortening effect on the corneal lamella, thus flattening the central cornea [6], neutralizing or minimizing topographic abnormalities and consequently improving visual acuity. Furthermore, Intacs usually improve corneal astigmatism by a mechanism that is not well understood[7]. It is considered a safe and minimal invasive procedure because there is no tissue removed or manipulation of the central optical zone. They have also been reported to be an effective modality for the treatment of mild keratoconus and to stabilize ectasia resulting from keratorefractive surgery [8-10]. The

biomechanical effect of the rings seems to be greater in keratoconic eyes, which have thinner corneas[4].

Standard Intacs are delivered in boxes containing 2 segments of the same thickness. In Europe, Intacs corneal rings are available in 11 sizes ranging from 210μm to 450μm. In the United States, the rings are available in 5 sizes from 250μm-350μm [4]. However, they are less effective in patients with more advanced keratoconus. So, a new design, Intacs SK was introduced for use in cases of advanced keratoconus.

Intacs SK is a new design of intrastromal corneal ring segments with a smaller 6-mm optical zone to correct higher grades of keratectasia and a proprietary elliptical cross-section to minimize glare usually associated with smaller optical zones. The acronym"SK" denotes severe keratoconus or steep keratometry. In comparison, standard Intacs segments have optical zones of 6.8mm and a hexagonal cross-section [11]. Results from preliminary studies indicate that Intacs seem to allow a better quality of vision in patients with advanced keratoconus, may permit refitting these patients with contact lenses, and may delay or eliminate the need for a corneal transplantation[12].

In this study, an attempt was made to evaluate the effect of Intacs SK corneal ring segment implant for treatment of patients with moderate to severe keratoconus, who have clear central cornea and cannot tolerate contact lens.

SUBJECTS AND METHODS

Subjects

Patients´ recruitment and evaluation The study design was a prospective, non-comparative, interventional case series study in which thirty-seven eyes of thirty-six patients were included. All patients had moderate to severe keratoconus corresponding to stages 2 and 3 of the Krumeich classification [13]. They were all contact lens intolerant and had clear central cornea. Preoperative assessment included uncorrected distant visual acuity (UCDVA), best-corrected distant visual acuity (BCDVA), scotopic pupil measurement with the Colvard pupillometer, slit-lamp examination, dilated fundus examination, and topography. Optical pachymetry and keratometry were done with the Orbscan II (Bausch and Lomb). To qualify for enrollment in the study, all patients had to have a mesopic pupil size less than 5.5mm and corneal thickness at the 6-mm optical zone of >400μm. Post-operatively, UCDVA and BSCDVA were measured one week, one month, three months, and six months later. Orbscan II topography was also done after 3 months, postoperatively. The study was performed according to the principles of the Declaration of Helsinki and after informing patients about the experimental nature of the study, informed consent was taken.

Methods

Surgical techniques All eyes were implanted with symmetrical ring segments. The selection of the segment size was based on manufacturer recommendations. For eyes having an average keratometry reading between 55-60 diopters (D) and corneal astigmatism less than 5D, the 400μm ring segments were selected. Eyes which had either an average keratometry of more than 60D or more than 5D of corneal astigmatism were implanted with a 450μm ring segment. Standard Intacs surgical technique was used for the implantation of Intacs corneal implants, except for a specially designed 6-mm stromal dissector for Intacs SK, and a 6-mm corneal marker was used. All surgeries were done under general anesthesia.

The diamond blade was set to achieve 75% depth of corneal thickness at the site of incision. In cases that had rather symmetrical bow-tie in the topography image, incisions were made on the steepest corneal meridian. In patients who had severe inferior steepening, incisions were made on the horizontal axis. Intrastromal corneal tunnels were then created with the 1.2mm especially blunt corneal dissector, aided by use of the suction centering device. The PMMA ring segments were then implanted and the incision was tightly closed with a single 10-0 nylon suture. The suture was removed 2 months postoperatively. All patients received prednisolone 1% drops (predfort, allergan) and moxifloxacin 0.5% drops (vigamox, Alcon) 4 times a day for one week.

Patients were seen for follow-up visits on the first day, first week, first month, third month, sixth month, and then every six months.

The outcome of the procedure was evaluated in terms of improvement in UCDVA and BCDVA in all follow-up visits. Changes in average keratometry and pachymetry were evaluated 3 months postoperatively as well.

Statistical Analysis Statistical analysis was performed by SPSS software version 16. UCDVA and BSCDVA were analyzed by repeated measurement designs. Time of evaluation was considered as within subject factor. Assumption of sphericity was violated in Muchly test (P= 0.01) for UCDVA. Therefore, after adjustment of degree of freedom by correlation coefficient of Greenhouse-Gisser and Huynh-Feldt, the average P-value of those assumptions were reported, but assumption of sphericity for BCDVA was met (P=0.27). Differences between amounts of pachymetry and average keratometry before and 3 months after surgery were analyzed with paired t-test.

RESULTS

Thirty-seven eyes of 36 patients (21 men, 15 women) were evaluated. The mean age was 24.5 ±7.35 (range: 12-42) years. Patients were followed for 6 months. The outcomes of UCDVA, BCDVA, CCT and average keratometry were shown in Table 1. There was a statistically significant improvement in both UCDVA and BCDVA postoperatively (P=0.0001). UCDVA and BCDVA were (1.32±0.31) and

Table 1 Clinical characteristics of patients before surgery and within follow ups

Parameter	Pre-op	1 week post-op	1 month post-op	3 months post-op	6 months post-op	*P*
BCDVA(logMAR)	1.07±0.27	0.67±0.21	0.41±0.13	0.3±0.1	0.28±0.8	[1]0.0001
UCDVA(LogMAR)	1.32±0.31	0.24±0.11	0.4±0.12	0.51±0.11	0.41±0.12	[1]0.0001
Pachymetry(μm)	432.1±39.5	-	-	434.6±41.5	-	[2]0.149
Mean Av-K(D)	52.13±0.39	-	-	47.65±3.49	-	[2]0.0001

[1]Repeated measurement ANOVA test, [2]Paired *t*-test; BCDVA: Best-corrected distance visual acuity; UCDVA: Uncorrected distance visual acuity; Av-K: Average keratometry.

(1.07±0.27) LogMAR preoperatively, which improved to (0.41 ± 0.12) and (0.28 ±0.8) LogMAR, respectively 6 months after operation. Time of assessment also had a significant effect on both UCDVA (P=0.0001) and BCDVA (P=0.0001). Changes in average keratometry, both before and 3 months after surgery were shown in Table 1. There was a significant flattening effect after surgery (P=0.0001). Mean keratometry was (52.13±0.39)D preoperatively, which decreased to (47.65 ±3.49)D post-operatively. Pachymetry was also evaluated before and 3 months after surgery, but there was no statistically significant change (P=0.149). No intraoperative complications occurred. In one eye, the inferior segment was explanted 3 months postoperatively due to implant exposure. The segment was removed easily under topical anesthesia.

DISCUSSION

The main goal of implanting intracorneal ring segments is not to treat or eliminate the existing disease, but to decrease the corneal abnormality and thus increase the visual acuity to acceptable limits as a way of delaying, if not eliminating the need for corneal transplantation.

Intacs implantations can reduce corneal steepening and astigmatism associated with keratoconus. The effect of Intacs on soft keratoconic tissue is much greater than on normal corneas. In our study a mean keratometric reduction of 5D was achieved, which was similar to the results of Colin *et al* [8]. There was also a progressive increase in both UCDVA and BSCDVA over time which became stable 3-6 months after operation.

In the present study, 6 months after operation, 41% of eyes had UCDVA of equal to or better than 20/40 and 74% had BSCDVA of 20/40 or better. The mean BCDVA and UCDVA 6 months after operation were (0.28 ±0.8) SD (-20/40) and (0.41±0.12) SD (-20/50), respectively. Various authors have used traditional Intacs with a 7-mm optical zone for the treatment of mild to moderate keratoconus and post-operative LASIK ectasia [8,14]. Colin *et al* [8] reported roughly similar results (UCDVA: 0.30±0.19 and BSCDVA: 0.63±0.29) six months after operation. Although, they used standard Intacs, the mean keratometry reduced about 5D, which was quite similar to our results. Ertan and Kamburoglu[15] found that standard Intacs in eyes with severe keratoconus improves BCDVA significantly, but UCDVA did not change. Sansanayudh *et al* [16], on the other hand, reported that Intacs SK improves both UCDVA and BCDVA, but mean keratometry reduction was about 3.2D, which was less than our results. Kanellopoulos *et al* [11] used a modified technique in which standard Intacs ring segments were centered on the cone center instead of the geometrical corneal center. In their study, six months after operation UCDVA and BSCDVA were 20/28 (SD±0.21) and 20/22 (SD±0.13), which was much better than our results, but their patients had rather mild keratoconus and the mean preoperative UCDVA was 20/154, which was much higher than in our patients.

Alio *et al* [4] studied the outcomes of standard Intacs implantation and concluded that patients with mean k-reading ≥55D are not good candidates for ring segment implantation and the surgical outcome is usually poor, however Ertan *et al* [15] showed that patients with cornea steeper than 57D would also benefit from standard intacs. In our study, patients with steeper cornea had greater improvement in both UCDVA and BCDVA. It seems that Intacs ring segments induce an exaggerated flattening effect in steeper cornea.

Alio *et al* [12] also studied the long-term effects of intacts and concluded that between 6-36 months postoperatively, although there was a significant increase in average keratometry, BCDVA remained stable. In our study, both UCDVA and BCDVA were rather stable 6 months postoperatively and there were only small changes in both parameters afterward, if at all. Colin *et al* [13], for the first time used Intacs to treat patients with keratoconus. They used an asymmetrical segment implantation, a 450μm segment inferiorly and 250μm segment superiorly. In 2007, Colin and Malet [17] changed their nomogram and used symmetrical segments, either 400μm or 450μm according to preoperative spherical equivalent refraction.

In other studies reported by Boxer Wachler *et al* [10] and Kanellopoulos *et al* [11], asymmetrical ring segments with thicker segment inferiorly and thinner segment superiorly were implanted. Their rationale was that a thicker segment inferiorly would have a better flattening effect on inferiorly displaced cone. Swanson also reported asymmetrical

implantation in patients with pellucid marginal degeneration, but he placed the thicker segment superiorly and the thinner segment inferiorly. In our study, symmetrical ring segment implantation was used according to manufacturer recommendations. In 2005, Alio *et al*[18] evaluated the effect of implanting 1 or 2 Intacs segments oriented by preoperative corneal topography. In group 1, a single 450μm segment inferiorly was used and in group 2, a 250μm segment superiorly and a 450μm segment inferiorly. After the 1 year follow-up, there were no statistically significant differences in UCVA and BCVA between the two groups.

Rabinowitz *et al* [19] analyzed patients who had a single Intacs inserted and a group that had 2 Intacs inserted and reported no statistically significant difference between the two groups in any outcome measures. Several studies recommend inserting a single inferior Intact in patients with post-LASIK ectasia[14,20-22].

In one of our patients, it became necessary to explant the inferior segment 3 months postoperatively due to implant exposure, interestingly, there was no visual consequence after implant removal and UCDVA and BSCDVA remained stable during the 15 month follow-ups. No significant change in pachymetry was noted during the 6 month follow-up. One case (2.7%) developed implant exposure and the inferior segment was explanted 3 months after operation. In summary, Intacs SK intracorneal ring segments are a safe and effective option for treatment of patients with moderate to advanced keratoconus. Easy removability, adjustability and allowance for future surgical procedure (if necessary) make intacts SK implantation an important alternative to keratoplasty in advanced keratoconus.

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