Visual and Refractive Outcomes and Tomographic Changes after Femtosecond Laser-assisted Intrastromal Corneal Ring Segment Implantation in Patients with Keratoconus

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Abstract

Purpose: To evaluate the visual, refractive, and tomography changes after femtosecond laser-assisted intrastromal corneal ring segment (ICRS; Intacs[®] SK) implantation in patients with keratoconus. **Methods:** In this prospective interventional case series, Intacs SK ICRSs were inserted using a femtosecond

laser into eyes with stage I–IV keratoconus. Visual, refractive, and corneal tomography changes, along with surgical complications, were analyzed 1 week, 2 months, and 6 months postoperatively.

Results: The study evaluated 71 eyes of 52 patients (mean age: 27.5 years). Six months postoperatively, the spherical equivalent, mean sphere, and mean cylinder were decreased by 2.07, 1.47, and 1.13 diopters (D), respectively. The mean preoperative uncorrected distance visual acuity (UDVA) increased from 0.87 ± 0.26 to 0.46 ± 0.19 LogMAR and the mean preoperative corrected distance visual acuity (CDVA) increased from 0.55 ± 0.21 to 0.28 ± 0.17 LogMAR (P < 0.001). Flat and steep keratometry decreased by a mean corneal power in the 3-mm zone, and mean anterior elevation decreased by 0.91 D, 2.52 D, and 1.03 microns (P < 0.001), respectively. Among all eyes, 93.0% gained one or more lines of CDVA. Mean internal anterior chamber depth decreased from 3.25 ± 0.33 to 3.14 ± 0.45 mm (P = 0.001), and mean irregularity in the 3-mm zone decreased from 5.63 ± 1.71 to 5.24 ± 1.82 (P = 0.006). However, mean posterior elevation and irregularity in the 5-mm zone did not change significantly.

Conclusion: Implantation of one or two Intacs SK segments is safe and effective to treat keratoconus, leading to significant improvement in UDVA, CDVA, and refractive error.

Keywords: Icrs; Intacs-SK; Intrastromal Corneal Ring Segment; Keratoconus

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INTRODUCTION

Keratoconus is a progressive bilateral, though asymmetric, corneal disease which is characterized

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by corneal thining and bulging.^[1,2] The diseasse leads to reduced visual acuity due to myopia, irregular astigmatism, and corneal scar.^[1,2] Treatment of the early stage of keratoconus includes glasses and contact lenses. However, with keratoconus progression, spectacles or contact lenses can no longer improve visual acuity, and other treatment modalities are needed,^[3,4] namely intrastromal corneal ring segments (ICRSs) and corneal transplantation (lamellar or penetrating).^[5] However, keratoplasty is irreversible and may be associated with several complications, including graft rejection, endothelial cell loss, and suture-related problems.^[2] Thus, it is advisable to seek other options to avoid or delay the need for keratoplasty. The Intacs® SK ICRS (Addition Technology Inc., Sunnyvale, USA) was introduced in 2000 and subsequently became the mainstay of refractive management in keratoconus-affected patients who are contact lens-intolerant and have no central cornea scars.^[4,6-14]

Sansanayudh et al^[12] evaluated the outcomes of Intacs SK ICRS implantation in 10 eyes with advanced keratoconus and found a significant improvement in visual outcomes and aberrometric conditions after 6 months. However, no significant improvement in refractive parameters was observed. Furthermore, several studies have evaluated Intacs SK implantation to treat moderate to severe keratoconus.^[15,16]

To our knowledge, no previous studies have evaluated femtosecond laser-assisted Intacs SK implantation with regard to its safety, efficacy, stability, refractive and visual outcomes, or topographic changes in all Amsler– Krumeich grades of keratoconus. The present study aimed to do so.

METHODS

This prospective, interventional, case series evaluated 101 eyes of 74 kertoconus patients (47 men, 27 women) diagnosed on the basis of Orbscan[™] IIz indexes (Bausch and Lomb, NY). All patients had non-progressive disease-that is, the topography and refraction data were stable—and all were aged between 19 and 47 years (mean \pm standard deviation [SD]: 27.9 \pm 6.9 years). They had been referred to Rassoul Akram Hospital and Iranian Eye Clinic in Tehran. Because of incomplete follow-up of 22 patients, the final data of 71 eyes of 52 patients were analyzed. The tenets of the Declaration of Helsinki were followed, and Iran University Health Network Research Ethics Board approved the study. Intacs SK implantation was performed using a femtosecond laser (FEMTEC; Perfect Vision 20/10, Heidelberg, Germany). All eyes had a corneal thickness of more than 450 µm at the incision site, and all were subjected to preoperative evaluation, including systemic and ophthalmological history, uncorrected (UDVA) and corrected (CDVA) distance visual acuity measurement,

subjective refraction, slit-lamp examination, applanation tonometry, indirect ophthalmoscopy, and corneal topography by OrbscanII_ZTM (Bausch and Lomb, NY). Postoperative visits were scheduled after 1 week, 2 months, and 6 months; they included UDVA and CDVA measurement, slit-lamp examination, applanation tonometry, corneal topography, and subjective refraction.

Inclusion criteria were as follows: keratoconus of stage I–IV according to Amsler–Krumeich classification, mean keratometry reading (K) of less than 60 D, mesopic pupil of less than 6.5 mm in diameter, and contact lens intolerance.

Exclusion criteria were as follows: severe dry eye, corneal scar, severe allergic conjunctivitis, a history of intraocular surgery, glaucoma, cataract, a history of herpes simplex keratitis, pregnancy, breast-feeding, and use of certain medications, such as Accutane (Isotretinoin, AccutaneTM Roche[®], Canada).

Recently, a new Intacs design (Intacs SK; Addition Technology Inc., Sunnyvale, USA) has been introduced. It has an inner diameter of 6.0 mm and an oval cross section,^[17] whereas the standard Intacs has a 6.8-mm inner diameter and a hexagonal cross section.^[12,18]

Due to its smaller diameter, the Intacs-SK is more effective in advanced keratoconus cases and in early cases with low corneal thickness.^[19] It is now available in thicknesses of 0.21, 0.25, 0.30, 0.35, 0.40, and 0.45 mm.

Surgical Technique

Implantation was performed on the basis of cone location, mean refractive sphere, astigmatism, and keratometric data. In eyes with central cones, symmetric segments were implanted, while in those with eccentric cones, single segments were implanted.

The thickness of the ring was selected on the basis of either corneal thickness at the incision site or spherical equivalent (SE) in patients with a central cone. In patients with an eccentric cone, it was selected based on astigmatic power.

We followed the company nomogram and used symmetric pair rings in cases of central conus, asymmetric pairs in cases of keratoconus with myopic spherical refraction and asymmetric conus, and single segments in cases of eccentric conus with astigmatism.

Corneal thickness at the incision site was measured using Orbscan pachymetry with Intracalc software. All surgical procedures were performed by the same surgeon (SJH) under topical anesthesia by 0.5% tetracaine eye drop (Anestocaine; Sina Darou, Tehran, Iran). "Prep and drape" were performed using povidone-iodine (BacterBye 10% povidone iodine; Kishmedipharm, Kish, Iran), blepharostat placement, and conjuctival sac irrigation with normal saline.

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 360-degree 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 BCVA was better than 0.5 logarithm of the minimum angle resolution (LogMAR), the axis of manifest refraction was used for this purpose.

Under microscopic guidance, the Intacs SK segments were implanted inside the channels using forceps and Sinskey hooks placed through dialing holes at the ends of every segment. Each part was centered in the middle of its tunnel, equidistant from the incision. If a single segment was used, it was implanted inferiorly; if two were used, the largest was implanted inferiorly. The incision site was not sutured.

Postoperative Medication

Postoperatively, a bandage contact lens (AIR optix AQUA; Base Curve: 8.6, Diameter: 14.2; CIBA VISION) was fitted for 24 hours. Ciprofloxacin eye drops (Ciplex; Sina Darou, Tehran, Iran) were administered four times a day for one week. Betamethasone eye drops (Betasonate, 0.1% betamethasone disodium phosphate; Sina Darou, Tehran, Iran) were given every 12 hours for 3 weeks, and artificial tears (Artelac[™], Hypromellose; Bausch and Lomb, Montpellier, France) were given every 4 hours for 4 weeks.

Statistical Analysis

Data were analyzed using SPSS software (version 20, IBM SPSS statistics, SPSS Inc., USA). After 6 months, preoperative and postoperative parameters were compared using the paired *t*-test, *P* values less than 0.05 were considered statistically significant.

RESULTS

The mean age of the patients was 27.5 years (SD: 7.1 years, range: 19–47). According to the Amsler–Krumeich classification, 25 eyes (35.2%) were grade 1, 28 (39.4%) were grade 2, six (8.5%) were grade 3, and 12 (16.9%) were grade 4.

The mean thinnest pachymetry in the 6-mm zone was $528.2 \,\mu\text{m}$ (SD: $40.5 \,\mu\text{m}$, range: $450-615 \,\mu\text{m}$). Thirty-five of the eyes received two ring segments (49.3%), while the remaining 36 eyes (50.7%) received one ring segment. All patients completed the 6-month follow up.

Visual Acuity

The preoperative UDVA ranged from 0.3 to 1.00 LogMAR,(20/40tocountingfingers). The mean UDVA was

significantly better 6 months postoperatively (0.46 ± 0.19) than before surgery $(0.87 \pm 0.26; P < 0.001)$.

Six months after surgery, 68 eyes (95.8%) gained one or more lines of UDVA, and none lost any lines, although three eyes (4.2%) showed no change in the Snellen test.

The preoperative CDVA ranged from 0.1 to 1.00 LogMAR (20/25 to 20/200) and the mean postoperative CDVA (0.28 \pm 0.17) was significantly better than the preoperative value [0.55 \pm 0.21; *P* < 0.001; Table 1].

By 6 months, 66 eyes (93.0%) gained ≥ 1 line of CDVA, while five (7.0%) showed no change.

The mean subjective refractive astigmatism after 6 months of follow-up changed from a preoperative mean of -3.72 ± 1.51 D to a postoperative mean of -2.59 ± 1.16 D. Moreover, the mean subjective sphere changed from a preoperative mean of -2.11 ± 2.85 to a postoperative mean of -0.60 ± 2.15 D 6 months after surgery.

The mean subjective defocus improved from a preoperative mean of -5.83 \pm 3.30D to a postoperative mean of -3.19 \pm 2.36D.

The mean subjective SE changed from- 3.97 ± 2.99 D before surgery to -1.90 ± 2.18 D after surgery [Table 1].

Changes in Keratometric and Elevation Parameters

Steep keratometry

The mean preoperative steep K (52.39 ± 4.48 D) changed to 49.53 ± 4.49 D (P<0.001) after 1 week, 49.68 ± 4.19 D (P = <0.001) after 2 months, and 49.40 ± 4.02 D (P < 0.001) after 6 months [Table 2].

Flat keratometry

The mean preoperative flat K (46.95 \pm 3.74 D) had changed to 46.30 \pm 13.01 D (*P* = 0.67) after 1 week, 45.05 \pm 3.45 D (*P* < 0.001) after 2 months, and 44.91 \pm 3.33 D (*P* < 0.001) after 6 months.

Simulated keratometric astigmatism

The mean preoperative simulated K astigmatism (5.41 ± 2.14 D) had changed to 4.02 ± 7.01 D (P = 0.11) after 1 week, 4.63 ± 2.09 D (P < 0.001) after 2 months, and 4.49 ± 1.82 D (P < 0.001) after 6 months.

Mean keratometry

The mean preoperative mean K (49.67 \pm 3.98 D) had changed to 47.22 \pm 3.91 D (*P* < 0.001) after 1 week, 47.37 \pm 3.69 D (*P* < 0.001) after 2 months, and 47.16 \pm 3.58 D (*P* < 0.001) after 6 months.

Irregularity in the 3-mm zone

The mean preoperative irregularity in the 3-mm zone (5.63 \pm 1.71) changed to postoperative values

Table 1. Mean visual and refractive values before, and6 months after the surgery					
Refractive Values	Preoperative	6 months postoperative	Р		
UDVA (logMAR)	0.8659 ± 0.25983	0.4600 ± 0.18759	< 0.001		
CDVA (logMAR)	0.5538 ± 0.20501	0.2780±0.16890	< 0.001		
Sphere (D)	-2.1078 ± 2.84779	-0.6034 ± 2.15009	< 0.001		
Cylinder (D)	-3.7241 ± 1.50634	-2.5905 ± 1.16387	< 0.001		
SE (D)	-3.9698 ± 2.98831	-1.8987±2.18353	< 0.001		
Defocus (D)	-5.8319±3.29919	-3.1940±2.36432	< 0.001		

UCVA, uncorrected distance visual acuity; logMAR, Logarithm of the minimum angle of resolution; CDVA, corrected distance visual acuity; SE, spherical equivalent; D, diopter

Table 2. Mean topographic values before, and 6 mor	nths
after the surgery	

Orbscan Values	Preoperative	Postoperative	Р
Sim K Astig	-5.406	-4.492	< 0.001
Steep K	52.385	49.403	< 0.001
Flat K	46.948	44.913	< 0.001
Mean K	49.674	47.158	< 0.001
Irregularity 3 mm	5.634	5.239	0.006
Irregularity 5 mm	5.893	6.061	0.267
Ant. BFS	44.587	43.562	< 0.001
Post. BFS	54.758	54.262	0.472
ACD	3.251	3.142	0.001

Sim K Astig, simulated keratometric astigmatism; K, keratometry; Ant. BFS, anterior best fit sphere; Post. BFS, posterior best fit sphere; ACD, anterior chamber depth

of 6.03 ± 1.82 (P = 0.02), 5.57 ± 1.80 (P = 0.67), and 5.24 ± 1.82 (P = 0.006), respectively, after 1 week, 2 months, and 6 months.

Irregularity in the 5-mm zone

The mean preoperative irregularity of $5.89 \pm 1.57D$ changed to $7.24 \pm 2.44D$ (P < 0.001), 6.71 ± 2.30 (P < 0.001), and 6.06 ± 1.88 (P = 0.27), respectively, after 1 week, 2 months, and 6 months.

Anterior chamber depth

The mean preoperative ACD of 3.25 ± 0.33 mm changed to 3.16 ± 0.34 mm (P = 0.40), 3.17 ± 0.34 mm (P < 0.001), and 3.11 ± 0.45 mm (P = 0.001), respectively, at the 1-week, 2-month, and 6-month follow-up visits.

The changes in anterior elevation (anterior best fit sphere [BFS]) and posterior elevation (posterior BFS) at the 6-month follow-up are shown in Table 1. In terms of stability, during 6 months of follow-up, there were no statistically significant changes in any parameters (P = 0.006) except for irregularities (P < 0.05; [Table 2]).

Safety and Efficacy Indexes

The mean safety index, (the mean postoperative CDVA divided by the mean preoperative CDVA) was 2.04 \pm 0.93, while the efficacy index (the mean postoperative UCVA/the mean preoperative CDVA) was 1.38 \pm 0.69 after 6 months of follow-up.

No intraoperative complications occurred, such as corneal perforation or incomplete tunnel creation, and there were no postoperative complications, such as segment migration, in the present study.

DISCUSSION

It has been demonstrated that Intacs SK implantation is safe and effective in the treatment of advanced keratoconus.^[20] We found that the mean postoperative UDVA and CDVA were significantly improved over the preoperative values. At the 6-month postoperative visit, the mean defocus had decreased by about 2.50 D compared to the preoperative value. The mean subjective refractive astigmatism (cylinder) had decreased by 1.134 D, corroborating the results of a study by Sansanayudh et al who reported a decrease of 1.1 D.^[15]

The mean subjective SE had decreased by 2.07 D, while Sansanayudh et al reported a greater reduction (3.02 D). The mean subjective sphere in the present study had decreased by about 1.50 D.

Our study assessed the earliest effect of ring segment implantation and evaluated the topographic and refractive outcome changes during 6 months of follow-up. In most patients, the outcomes were stable after 1 week. Similarly, Kotb and Hantera reported that the implantation of Intacs SK insertion in grade II or III keratoconus was safe and effective.^[20] The mean UDVA, spherical equivalent (SE), and average K showed significant improvement after 6 months, but there were no significant improvements in mean CDVA and manifest cylinder.^[20]

Ibrahim and Elmor reported outcomes in 114 patients,^[21] finding that CDVA, UDVA, and mean K were significantly improved after 3 years. Sánchez-Thorin and Navarro reported the results of femtosecond laser-assisted Intacs SK insertion in 18 eyes with a 9-month follow-up. They noted a significant change in manifest cylinder (3.00 \pm 2.00 D) and sphere in 14 eyes (78%).^[22]

Sansanayudh et al reported that the mean UDVA had significantly improved 6 months after femtosecond laser-assisted ring segment implantation. The mean preoperative UDVA was 1.19 ± 0.57 LogMAR, compared to 0.66 ± 0.21 LogMAR postoperatively (P = 0.004), while the mean preoperative CDVA was 0.51 ± 0.20 LogMAR, compared to 0.25 ± 0.15 LogMAR postoperatively (P = 0.018). The mean spherical equivalent refractive error was -8.08 D preoperatively

and -5.03 D after 6 months (P = 0.65). The mean preoperative refractive astigmatism of -5.05 D had reduced to -3.90 D postoperatively (P = 0.22), and the mean sim K value had decreased from 5.794 D to 5.007 D (P = 0.15).^[15]

Other researchers have shown that femtosecond laser-assisted implantation of the Intacs SK ring segment is effective and safe in patients with severe keratoconus, while our results showed that the procedure is effective and safe in patients with mild keratoconus, as 74.6% of the eyes in the present study had grade I or II keratoconus. In fact, more than 90% of the eyes that received a single segment implantation in the present study were of grade I or II. After 6 months of follow-up, the mean steep K and mean flat K had significantly decreased. Postoperatively, the mean simulated K astigmatism had decreased (0.9–1.4 D), although this reduction was smaller than that in similar studies.^[15] The preoperative mean K had decreased significantly (by 2.5 D) after 1 week, 2 months, and 6 months; this reduction was less than that seen in other studies by Kotb and Hantera^[20] and Ibrahim and Elmor,^[21] which reported decreases of 4.10 D and 4.00 D, respectively [Table 3]. These differences are probably related to the severity of keratoconus which was less in our patients and resulted in the implantation of one segment instead of two. Our study showed that both one-and two-segment implantation of Intacs SK was effective and significantly reduced the mean K, flat K, and steep K in all grades of keratoconus [Table 4]. Moreover, the postoperative results showed a significant reduction in spherical equivalent error, a decrease in refractive astigmatism, and an improvement in visual acuity in all patients [Table 5].

All patients with grade I keratoconus gained one or more lines of CDVA, and none of the treated eyes lost any lines of CDVA [Table 6].

We found a significant increase in mean irregularity in the 3-mm zone 1 week postoperatively; this had improved 2 months after the operation. We could not find any justification for increasing irregularity despite the improvement of visual acuity.

The mean postoperative anterior elevation had improved significantly 1 week, 2 months, and 6 months after surgery, while the mean postoperative posterior elevation had improved significantly after 1 week, but not after 2 or 6 months, indicating that the Intacs SK had a greater effect on the anterior surface of the cornea than on the posterior surface.

We found that the internal (endothelial) ACD had decreased significantly at all postoperative visits.

Use of the femtosecond laser leads to a more uniform depth of stromal tunnel and thus to a safer procedure, faster surgery, and a patient-and surgeon-friendly procedure.^[23-27]

There were no intraoperative or postoperative complications, but peri-segment deposits were seen

Table 3. Visual and refractive outcomes after femtosecond laser assisted implantation of Intacs SK in keratoconic eyes										
Authors	Year	Number of Eyes/Patient	Mea	Mean SE Mean Cylinder		Cylinder	Mean KM		Mean SimK astig.	
			PreOp	PostOp	PreOp	PostOp	PreOp	PostOp	PreOp	PostOp
Sansanayudh, et al	2010	10/8	-8.08	-5.03	-5.05	3.9	57.94	50.07		
EI-Moatassem Kotb, et al	2013	37/24			-3.24	-2.8	48.50	44.40	3.40	3.05
Ibrahim et al	2013	114/71					52.53	49.17		
Thorin et al	2014	18/15			-5.60	-2.50				
Current Study	2017	71/52	-2.11	-0.60	-3.72	-2.59	49.67	47.16	5.41	4.49

SE, spherical equivalent; KM, mean corneal dioptric power; SimK astig: simulated keratometric astigmatism; Op, operation

Table 4. Keratometric changes after intracorneal ring segment implantation (Intacs SK) classified according to thepreoperative keratoconus severity									
Keratoconus Grade	K1 Pre	K1 6M	Р	K2 Pre	K2 6M	Р	KM Pre	KM 6M	Р
Ι	43.33±1.89	42.29±1.58	< 0.001	47.72±1.90	45.70±1.58	< 0.001	45.52±1.71	44.00 ± 1.46	< 0.001
	(38.8 - 46.3)	(39.0 - 45.0)		(44.2 - 51.3)	(43.0 - 49.1)		(42.3 - 48.0)	(41.3 - 47.1)	
II	46.98 ± 1.56	44.64 ± 1.84	< 0.001	52.81±2.21	49.54 ± 2.28	< 0.001	49.89 ± 1.42	47.09 ± 1.78	< 0.001
	(43.9 - 50.2)	(40.1 - 47.7)		(49.9 - 58.4)	(45.5 - 55.9)		(48.1 - 52.6)	(43.1 - 51.6)	
III	49.98±0.72	46.57±1.53	< 0.001	57.68±1.15	52.3±1.51	< 0.001	53.83±0.57	49.43 ± 1.40	< 0.001
	(48.8 - 50.6)	(44.3 - 48.6)		(55.6 - 59.0)	(51.0 - 55.2)		(53.1 - 54.8)	(47.6 - 51.6)	
IV	52.91±1.06	50.18 ± 2.91	< 0.001	58.47±1.19	55.43 ± 2.91	< 0.001	55.74±0.69	52.80 ± 2.82	< 0.001
	(51.3 - 54.6)	(45.1 - 56.0)		(55.8 - 60.0)	(49.9 - 61.4)		(55.1 - 57.2)	(48.7 - 58.7)	

K1, corneal dioptric power in flattest meridian; K2, corneal dioptric power in steepest meridian; KM, mean corneal dioptric power; Pre, preoperative period; 6M, 6 months postoperative period

Table 5. Preoperative and 6 months postoperative refractive characteristics by single versus paired segments							
Parameter, mean±SD	Single ICRS (preoperative)	Single ICRS (6 months postoperative)	Р	Paired ICRS (preoperative)	Paired ICRS (6 months postoperative)	Р	
Sphere (D)	-0.62 ± 1.71	0.008 ± 1.45	0.008	-3.58 ± 3.00	-1.21±2.55	< 0.001	
Cylinder (D)	-3.15 ± 1.10	-2.12 ± 0.90	< 0.001	-4.29 ± 1.65	-3.06 ± 1.21	< 0.001	
SE (D)	-2.20 ± 1.55	-1.05 ± 1.42	< 0.001	-5.73 ± 3.05	-2.74 ± 2.48	< 0.001	
Steep K (D)	49.57 ± 3.57	47.42±3.26	< 0.001	55.27 ± 3.34	51.43±3.72	< 0.001	
Flat K (D)	44.97 ± 3.11	43.88±2.89	< 0.001	48.98±3.22	45.97±3.44	< 0.001	
Mean K (D)	47.28±3.27	45.65±3.02	< 0.001	52.13 ± 3.04	48.70±3.47	< 0.001	

ICRS, intrastromal corneal ring segment; K, keratometry; SE, spherical equivalent; SD, standard deviation; D, diopter

Table 6. Percentage of cases that gained or lost lines of corrected distance visual acuity 6 months after Intacs se- vere keratoconus intracorneal ring segment implantation, classified according to preoperative keratoconus severity						
Keratoconus grade	Gained ≥1 line CDVA (%)					
I	100.0	0.0	0.0			
II	89.3	10.7	0.0			
III	83.3	16.7	0.0			
IV	91.7	8.3	0.0			

CDVA, corrected distance visual acuity

in two patients. The limitations of our study were its short-term follow-up and our neglect to measure corneal aberrometric changes.

In conclusion; implantation of one or two Intacs SK segments using a femtosecond laser to create the channels is safe and effective to treat stage I–IV keratoconus, leading to significant improvement in UDVA, CDVA, and refractive error.

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Conflicts of Interest

There are no conflicts of interest.

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