

**TREATMENT OF KERATOCONUS WITH INTACS INTRASTROMAL RINGS ICI  
(7 MM) AND ISK (6 MM). UP TO 3 YEARS IN 72 EYES.**

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**The authors do not have commercial interest.**

## **SUMMARY**

**Treatment Keratoconus with INTACS Intrastromal Rings ici (7 mm) and ISK (6 mm). up to 3 years in 72 eyes.**

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**OBJECTIVE:** Describe and compare the clinical and surgical experience in 72 eyes diagnosed with keratoconus treated with INTACS Intrastromal rings of 7 and 6 mm.

**MATERIALS AND METHODS:** A case series of 72 eyes treated with Intacs. We evaluated corrected visual acuity, topography, pachymetry and astigmatism before and after the procedure, measured by Pentacam and anterior chamber of OCT.

**RESULTS:** 20 eyes with ICI and 52 segments with segments ISK.

Track average of 28.4 months in ICI segments (group 1) and 21.2 months in ISK segments (group 2). The corrected visual acuity improved 1.78 sightlines, in group 1 and 3.01 sightlines at 2. The astigmatism measured by keratometry (differences between meridian plane and curved) showed a flattening of -1.24 to 5.23 (average 1.46) diopters in segments 7 mm and a change of -2.00 to 6.34 (average 2.19) diopters in segments of 6 mm, Keratometry average decreased 2.45 diopter in rings of 7 mm and 3.50 mm in rings of 6 mm. Keratometry average decreased in 2.45 diopter ring of 7 mm and 3.50 mm in rings 6. On average, there was an

increase in pachymetry of 23.8 in ICI segments of 27.11 in ISK segments. All rings were implanted over 70% of total thickness in both groups.

**CONCLUSIONS:** Intacs intrastromal rings produce a significant improvement in visual acuity and a significant change in keratometrias, pachymetry and corneal thickness in patients with keratoconus. These changes are more marked in ISK segments of 6 mm.

### **ABSTRACT**

#### **ICI (7 mm) and ISK (6 mm) INTACS Intrastromal Rings for Keratoconus. Three Year Follow-up of 72 Eyes**

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**PURPOSE:** To describe and compare clinical and surgical experience of 72 eyes that underwent ICI (7 mm) and ISK (6 mm) INTACS placement for the treatment of keratoconus.

**METHODS:** Case series of 72 eyes treated with INTACS. Corrected visual acuity, corneal astigmatism, topography and pachymetry were evaluated before surgery and at last follow-up.

**RESULTS:** 20 eyes with 7 mm and 52 with 6 mm segments. 28.4 months follow-up for 7 mm and 21.2 for 6 mm. Corrected visual acuity improved 1.78 lines in group 1 and 3.01 lines in group 2. Corneal astigmatism decreased -1.24 to 5.23 (1.46) diopters in 7 mm and -2.00 to 6.34 (2.19) diopters in 6 mm. Median keratometry decreased an average of 2.45 d in 7 mm and 3.5 in 6 mm. Corneal pachymetry

increased 23.8 microns in 7 mm and 27.11 microns in 6 mm. All segments were implanted in the 30% of the corneal posterior lamellae.

**CONCLUSIONS:** INTACS intrastromal rings placed in patients with keratoconus produce a significant change in corrected visual acuity, corneal keratometry, pachimetry and thickness. These changes are more prominent in 6 mm segments.

## **Treatment of Keratoconus with INTACS Intrastromal Rings of 7 and 6 mm.**

**Follow up to three years in 72 eyes.**

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### **INTRODUCTION:**

Keratoconus is a degenerative disease of unknown origin in which the cornea has a progressive thinning and distortion (cone) resulting in blurred vision secondary to irregular astigmatism, myopia and walle formation <sup>1</sup>. Until recently, the only surgical treatment for this condition was penetrating keratoplasty, although with a high success rate, is at risk of intraoperative and postoperative<sup>2</sup>. The implantation of Intacs intrastromal rings (Addition Technology, Inc.) is a refractive procedure that originally was used to correct mild to moderate degrees of myopia, and for some time it has been used for the surgical treatment of keratoconus and ectasia postoperative iatrogenic<sup>3</sup>. The INTACS implantation is a safe and reversible which aims to postpone or prevent the need for corneal transplantation in these patients.<sup>4</sup>. Currently INTACS rings come in two forms, ICI (7 mm) and ISK (6 mm), the main difference is given by its diameter and the distance between each other at the time of implantation.

The aim of our study is to describe, evaluate and compare the clinical and surgical experience in patients treated with INTACS intrastromal rings of 7 and 6 mm for the management of keratoconus.

**MATERIALS Y METHODS:**

An retrospective and comparative study of a case series comprised 72 eyes of 42 patients with keratoconus who were implanted with INTACS intrastromal rings. Patients who were implanted ICI segments corresponded of 7 mm correspond to Group 1 and which were implanted ISK segments of 6 mm to group 2. We evaluated visual acuity, topography, pachymetry and astigmatism before the procedure and in the latest review measured by Pentacam (Oculus, Optikgeräte GMBH, Wetzlar, Germany). Table 1 shows the nomogram used to choose the type of rings and depth. This nomogram was the same for patients with lower and central cones.

Two rings were implanted in all cases. The procedures were performed by the senior author using topical anesthesia. Initially identified geometric center of the cornea using a marker 11 mm, and the incision was marked and performed on the meridian of 12:00 in all cases. After path and formation of top pocket a guide was implanted with vacuum and intrastromal tunnel was created on both sides of the pocket, guide to vacuum was released and the rings were implanted in the tunnels. The wound was sutured with 10-0 nylon and placed a bandage contact lens. The depth of implantation was performed in the posterior third of the cornea in all patients.

We excluded patients with presence of central opacities of the cornea and less than 12 months follow-up. In the first week withdrew the contact lens and the third week the upper suture, After withdrawing the suture was sent to patients to service of contactology for contact lenses adaptation or frame. The checks were

made on the first day, first week, third week, third month and every 3 months after surgery. In each control after the third week was making visual acuity, examination. oftalmológico completo y evaluación de topografía, paquimetría y astigmatismo queratométrico.

Differences between groups were determined by means of the "t tests" paired and unpaired. A p less than 0.5 was considered statistically significant.

## **RESULTS:**

Tables 2 and 3 show the results of both groups. Average age of 32.6 years in group 1 and 34.4 years in the 2. Track average of 28.4 months in group 1 and 21.2 months in the 2 group. Twelve right eyes in group 1 and 44 in group 2. Twenty eyes with ICI segments and 52 with segments ISK. Comparing the initial assessment and final corrected visual acuity improved 1.78 sightlines in group 1 and 3.01 sightlines at 2 group ( $p < 0.5$ ). The astigmatism measured by keratometry (differences between meridian plane and curved) presented a flattening of -1.24 to 5.23 (average 1.46) diopters in segments in group 1 and a change of -2.00 to 6.34 (average 2.19) diopters in group segments 2 ( $p < 0.5$ ). Keratometry mean decreased 2.45 diopters in rings of 7 mm and 3.50 mm into rings of 6 mm ( $p < 0.5$ ). On average, there was an increase of 23.8 pachymetry in ICI segments and in segments ISK 27.11 ( $p > 0.5$ ). All rings were implanted over 70% of the total thickness in both groups and this was confirmed in the control of the three months through anterior chamber of OCT (Carl Zeiss Meditec, Dublin, CA, USA).

Any intraoperative complication occurred In group 1, postoperative complications in one case consisted in the wound neovaso,requiring the application of antiangiogenic therapy, intravitreal and a case of superficial punctate keratitis (QPS) which improved with the application of lubricants. In group 2, postoperative complications included two cases of extrusion of a ring, the first was handled with the removal of the segment while in the second segment extruded moved towards the lower, a case of QPS that was managed with lubricants and applying punctal plugs, and a case of dry eye that was handled in the same manner as that of QPS.

### **CONCLUSIONS:**

Requiring the application of antiangiogenic therapy, intravitreal and a case of superficial punctate keratitis (QPS) which improved with the application of lubricants. In group 2, postoperative complications included two cases of extrusion of a ring, the first was handled with the removal of the segment while in the second segment extruded moved towards the lower, a case of QPS that was managed with lubricants and applying punctal plugs, and a case of dry eye that was handled in the same manner as that of QPS, This effect, being greater on the cornea of the subjects who were implanted segments of 6 mm, and better visual acuity at the last follow-up, these results were statistically significant. To our knowledge, this is the first study to evaluate and compare the effects of ICI and ISK rings objectively. Although some studies evaluate the effects of intrastromal rings, by measuring the spherical equivalent 5-6, we evaluated these effects using topography, keratometry mean and keratometric astigmatism, since our concept



these parameters evidence of more clearly way, the changes in the curvature of the cornea. The improvement in visual acuity that we observed in our study corresponds with previous reports<sup>5</sup>, and is more pronounced in rings of 6 mm possibly by the fact that the effect of these segments is greater because they are closer to each another. It is important to note that the implementation of INTACS produce secondary astigmatism, and should be evaluated in future studies to determine their clinical relevance. Our study has several limitations such as the retrospective character and nonrandomized, as the no categorization of cases according to the keratometry or degree of keratoconus, as it is documented that the effect of the rings is not equal in all keratoconus cases.<sup>6</sup>

Complications occurred in both groups did not differ significantly. The incidence of extrusion in our series was less than 10%, and is comparable with previous reports<sup>5</sup>. We believe that this complication occurring only in rings of 6 mm, has to do only with the fact that the sample was higher in this group. In conclusion, the implantation of Intacs intrastromal segments is a safe and effective procedure for the management of patients with keratoconus. These segments produce a significant change in visual acuity, queratometrías, pachymetry and corneal thickness, being more marked changes in these ISK segments of 6 mm. New prospective studies with larger numbers of patients, longer follow-up and proper categorization of degrees of keratoconus are needed to determine whether these effects and benefits are long-term clinical relevance.

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<b>Spherical equivalent</b>	<b>Depth</b>	<b>Type</b>
< a -5.00	450	ICI
-5.00 a -7.00	400	SK
> a -7.00	450	SK

Table 1. INTACS nomogram. Always in queratometrías under 50. If greater than 50 using ISK (400 if equivalent less than -5.00, 450 if greater).

	Age	Change in A.V	Change in A.Q	Change Q.M	Change Pachymetry	Thickness	Intraoperative Complications	Complications POP
1	25	0	0.45	1.01	10	400	(-)	(-)
2	25	0	-1.22	0.87	24	400	(-)	(-)
3	27	2	1.98	1.52	136	450	(-)	(-)
4	27	1	4.03	2.46	97	400	(-)	(-)
5	29	3	3.98	4.52	9	450	(-)	(-)
6	29	5	0.9	0.23	36	450	(-)	(-)
7	43	5	-0.34	-0.49	21	400	(-)	(-)
8	38	3	2.76	1.52	71	400	(-)	(-)
9	26	8	2.1	3.06	22	450	(-)	Neovaso in wound
10	26	1	5.23	3.98	36	450	(-)	QPS
11	40	-2	1.61	1.08	77	450	(-)	(-)
12	40	-2	-0.22	1.32	35	400	(-)	(-)
13	46	6	-0.79	4.06	24	400	(-)	(-)
14	17	1	0.3	5.02	-18	450	(-)	(-)
15	17	2	-0.27	4.23	-27	450	(-)	(-)
16	35	-3	4.98	2.73	-11	450	(-)	(-)
17	21	3	0.89	4.45	34	450	(-)	(-)
18	21	1	2.75	3.63	41	450	(-)	(-)
19	35	0	-1.24	1.52	-4	450	(-)	(-)

Table 2. Results Group 1.

A.V visual acuity. A.Q: keratometric astigmatism. Q.M: Keratometry mean. POP:

Postoperative. QPS: superficial punctate keratitis.

	Age	Change en A.V	Change en A.Q	Change Q.M	Change Pachymetry	Thickn ess	intraoperative Complications	Complications POP
1	35	3	4.24	2.22	23	450	(-)	
2	35	0	3.06	2.63	30	400		
3	18	7	0.65	3.5	28	450		
4	19	2	6.01	12.2	80	450		
5	19	8	5.13	4.03	34	450		
6	20	2	0.3	0.97	21	400		extrusion
7	43	4	-0.46	0.4	32	450		
8	43	5	-1.83	1.02	18	450		
9	33	3	3.2	5.4	24	400		
10	33	1	0.33	3.03	16	400		
11	21	-1	0.54	-2.01	42	450		
12	21	1	1.01	9.71	67	450		
13	27	-4	-0.26	-1.3	-41	450		
14	38	2	0.73	6.5	36	450		
15	38	1	0.79	4.66	71	450		
16	72	0	3.22	5.31	22	450		
17	51	3	1.83	4.43	16	450		
18	51	5	2.2	7.03	41	450		
19	27	6	-2	7.65	33	450		
20	27	6	-0.71	5.51	50	450		
21	22	3	-2.5	4.82	21	450		
22	22	2	-4.2	2.09	13	450		
23	31	3	0.72	-4.22	23	450		QPS
24	31	4	0.36	4.06	-2	450		
25	19	0	1.8	6.06	36	450		
26	19	1	1.78	3.95	74	450		
27	28	8	4.41	1.4	11	450		
28	49	-1	-0.74	4.34	7	450		
29	49	5	3.89	1.5	18	450		
30	32	-1	1.51	2.57	4	450		
31	32	0	3.2	3.51	15	450		
32	34	1	1.3	4.8	39	450		
33	34	0	4.45	4.61	52	450		
34	26	1	-5.02	-3.43	12	450		
35	26	5	1.73	4.21	16	450		
36	16	5	0.7	1.41	21	450		
37	16	8	-2.23	-2.92	6	450		
38	22	8	2	1.65	34	450		
39	22	8	0.9	5.2	18	450		
40	33	4	1.75	5.56	12	450		
41	27	8	2.8	4.9	44	450		
42	27	0	4.24	0.5	41	450		Eye dry
43	22	4	0.94	2	12	450		
44	22	4	1.78	4.3	8	450		
45	31	1	1.22	5.4	-12	450		
46	31	1	1.45	7.05	-57	450		
47	33	2	2.24	7.5	15	450		extrusion
48	31	2	-56	1.7	39	450		
49	31	8	-1.1	4.51	-86	450		
50	29	6	-0.71	6.02	-5	450		
51	29	0	1.82	1	15	450		
52	25	3	-1.45	3.56	10	450		

Table 3. Results group 2.

A.V visual acuity. A.Q: keratometric astigmatism. Q.M: Keratometry media. POP:

Postoperative. QPS: superficial punctate keratitis.