Incidence and associations of intracorneal ring segment explantation

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Purpose: To assess the incidence and motivating determinants of explantation of intracorneal ring segments (ICRS) (Intacs) used for the treatment of keratoconus and corneal ectasia.

Setting: Cornea and refractive surgery subspecialty practice.

Design: Retrospective case series.

Methods: Consecutive cases of ICRS implantation performed to treat keratoconus or corneal ectasia were reviewed to determine the number that were eventually explanted and the motivating factors for explantation. Cases were assigned to 1 of 2 groups: (1) medical complications requiring removal and (2) refractive/topographic problem, with the explantation being elective. The corrected distance visual acuity, uncorrected distance visual acuity, maximum keratometry, and inferior–superior topography power difference before and after ICRS removal were also evaluated.

Results: The ICRS were explanted from 35 eyes of 31 patients from a total cohort of 572 eyes (6.1%). Of these, 15 ICRS (2.6%) were removed for medical complications and 20 (3.5%) for refractive/topographic considerations.

Conclusions: A large proportion of ICRS were generally well tolerated on a long-term basis. The incidence of explantation secondary to medical complications was low, with the most frequent complication being infiltration around the segment. Explantation was effective in ameliorating medical complications and can be effective in improving corneal topography and clinical outcomes in some cases.

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Keratoconus is a noninflammatory process in which the cornea thins and weakens. This biomechanical instability leads to progressive deformation of the corneal optics with consequent visual impairment. Intracorneal ring segments (ICRS), such as Intacs (Addition Technology, Inc.) are one modality to improve the corneal shape in eyes with keratoconus.[1] They are used to reshape and flatten the corneal curvature to improve symmetry of the corneal optical contours. The clinical goal of implantation is to improve contact lens tolerance, improve corrected distance visual acuity (CDVA), and ultimately, avoid or delay the need for corneal transplantation.

In this retrospective report, we analyzed the prevalence and proximate causation of segment explantation and categorized segment explantation as motivated by a medical complication or a refractive/optical consideration.

PATIENTS AND METHODS

A clinical study of consecutive ICRS implantations from 2006 to 2017 was performed by record review. Informed consent was obtained before all procedures. The study included only eyes with channels created by a femtosecond laser (iFS, Johnson & Johnson). All patients had 1 or 2 Intacs segments placed for the treatment of keratoconus or corneal ectasia. All surgery was performed by the same surgeon (P.S.H.), and the dataset included explantations in these cases only, with patients who had explantation on a referral basis excluded.

The cause of explantation was identified as being a medical complication requiring segment removal or elective explantation for a refractive/topographic problem with a goal of improvement in vision. For each procedure, the specific militating cause of explantation was assessed.

Clinical measures of CDVA, uncorrected distance visual acuity (UDVA), manifest refraction, maximum keratometry (K) value, and inferior–superior (I–S) value were analyzed where applicable. The I–S value was measured using the anterior sagittal curvature map of a rotating Scheimpflug camera (Pentacam HR, Oculus Optikgeräte GmbH). For this measurement, the angle of the maximum K value was identified first. Then, taking values at a 3.0 mm radius on the topography map at this angle, the inferior topographic K value was obtained and the superior K was taken 180 degrees away. The difference between the inferior and superior K values was noted as the I–S value.

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Table 1. Patient characteristics and explantation rates.

Group	Number (%)	Mean Age (Y) ± SD	Sex (n)		Number (%)	
			Male	Female	ICRS Alone	ICRS/CXL
Total population	572	35 ± 11	423	149	122 (21)	450 (85)
Total explants	35 (6.1)	41 ± 11	25	10	9 (7)	26 (6)
Medical explants	15 (2.6)	45 ± 14	11	4	5 (4)	10 (2)
Refractive explants	20 (3.5)	40 ± 10	14	6	4 (3)	16 (4)

CXL = corneal crosslinking; ICRS = intracorneal ring segments

Surgical Technique

The ICRS size, symmetry, and placement angle were determined based on analysis of individual patient topographic and refractive data. Typically, a symmetric pair was chosen for a central cone (within a 1.0 mm zone), an asymmetric size pair for a paracentral elevation (1.0 to 3.0 mm), and a single segment for a more peripheral cone (outside 3.0 mm). The ICRS thickness was chosen based on the degree of topographic elevation and distortion (as seen on Placido-disk imagery). In general, the entry incision was made 90 degrees from the axis of the maximum K on the topography map. Direct examination of the Placido-disk image (Eyesys Vision, Inc.) was used as well to guide placement.

After the patient received topical anesthesia, a lid speculum was placed. With a 3.0 mm gentian violet optical zone marker, the cornea was marked centered on the pupil. A 5.0 mm marker was then used to place another concentric mark. The limbus was marked with a tissue-marking pen. A femtosecond laser was used to prepare the corneal channel. Typical settings were an inner diameter of 6.8 mm and an outer diameter of 7.8 mm, with depth set at approximately 75% of the thinnest affected area of the cornea as determined by optical and ultrasound pachymetry. After the dissection was completed, the ICRS were placed at the desired axis. A single 10-0 nylon suture was placed in some cases, whereas no suture was used for others.

Postoperatively, antibiotic and corticosteroid drops were administered and the eye was examined by slitlamp examination to ensure proper ICRS depth and position. Antibiotics and corticosteroid drops were continued 4 times daily for 1 week, and the corticosteroid was tapered over 1 month.

For explantation, access to the corneal ring segments was achieved in 1 of 2 ways. If the original surgery was proximate to revision, the previous entry site was opened with a Sinskey hook. If the surgery site had fully healed, a diamond blade set to the depth of the original ring placement was used to make an incision adjacent to the end of the ring segment. In these cases, the depth of the ring first was confirmed by ocular coherence tomography examination. A circumferential dissector was used to open a channel beneath the segment. A Sinskey hook was then used anterior to the segment to push it down gently to break adhesions of the ring with the stroma. The Sinskey hook was then used to gently extract the segment(s) after entering the positioning hole from below. A single 10-0 nylon suture was used if necessary to close the entry incision.

RESULTS

Population Characteristics and Explantation Rates

Five hundred ninety-three eyes with keratoconus or corneal ectasia had ICRS placement between 2004 and 2017. Twenty-one eyes (4%) had manual channel dissection and were excluded from the study. Five hundred seventy-two eyes (96%) had femtosecond laser–assisted channel dissection. Four hundred-fifty eyes (76%) had adjunctive corneal crosslinking (CXL); 281 had both procedures at the same setting, 145 had ICRS placement first and CXL thereafter (typically 3 months), and 24 had CXL first and ICRS placement thereafter.

Table 1 shows patient characteristics and the general explantation rates. Overall, 35 eyes (6.1%) of 31 patients had explanation of 1 or 2 segments, 15 (2.6%) for medical complications and 20 (3.8%) for optical/refractive considerations. Explantation rates were similar irrespective of adjunctive CXL.

Medical Explantation

Table 2 shows the causes of explantation for medical complications of the ICRS. Of the 15 explantations necessitated by medical complications, the most serious was microbial keratitis with segment extrusion and corneal perforation 6 weeks postoperatively (Figure 1). Emergency removal of the segment was performed, and the patient was treated with gatifloxacin and vancomycin drops every hour. Culture showed no growth. Resolution of the infection occurred over 2 months, at which time the CDVA was 20/25 and a corneal scar remained.

The most frequent medical complication requiring explantation was keratitis with signs of inflammation around the segment. Of the 11 eyes with inflammation, all had a sterile infiltrate around the ICRS (Figure 2, *right*) and 3 had stromal melting and thinning over the infiltrate (Figure 2, *left*).

Three eyes had recalcitrant subjective patient symptoms without gross clinical findings; of these, 2 had a chronic foreign-body sensation and 1 had chronic photophobia. All eyes had clinical improvement and resolution of symptoms after explantation. Table 3 shows the visual acuity and topographic data. Although the complications necessitating explantation resolved, topography indices worsened; such a finding would be expected because the beneficial topographic effect of the segments revert after their removal.

Table 2. Intracorneal ring segment explantation secondary to medical/subjective etiology.

Complication	Number (%)*
Microbial keratitis	1 (3)
Inflammation (keratitis/infiltrate around segment)	11 (31)
Persistent photophobia	1 (3)
Persistent foreign-body sensation	2 (6)

*Percentage of population having explantation

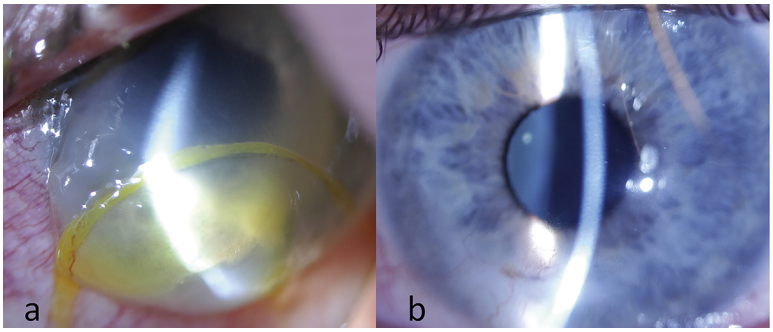

Figure 1. Corneal infection after intracorneal ring segment placement. *a*: On presentation. *b*: Healing after 2 months.

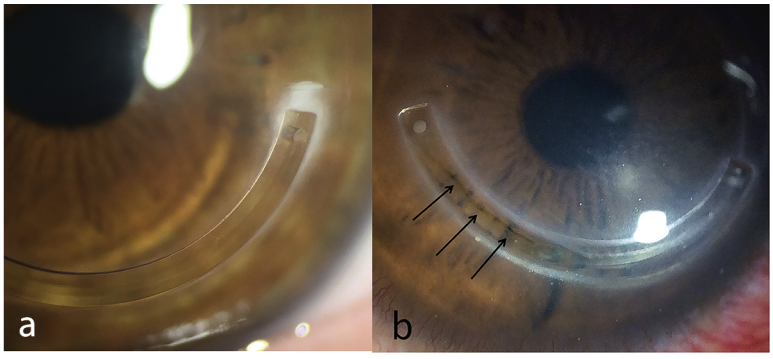

Figure 2. *a*: White milky infiltrate around proximal end of a segment. *b*: Linear corneal melt (*arrows*). Note milky infiltrate surrounding segment.

Table 3. Outcomes after ICRS explantation secondary to medical/subjective etiology.

Parameter	Mean ± SD		
	Preop	After Explantation	Difference
UDVA (logMAR)	0.87 ± 0.62	0.55 ± 0.27	−0.32 ± 0.78
CDVA (logMAR)	0.28 ± 0.18	0.31 ± 0.20	0.03 ± 0.18
Max K (D)	58.98 ± 8.96	59.35 ± 8.00	0.36 ± 6.17
I–S (D)	10.08 ± 5.88	13.87 ± 13.87	3.79 ± 9.82

CDVA = corrected distance visual acuity; ICRS = intracorneal ring segments; I–S = inferior–superior; logMAR = logarithm of the minimum angle of resolution; Max K = maximum keratometry; UDVA = uncorrected distance visual acuity

Table 5. Outcomes after ICRS explantation secondary to optical side effects.

Parameter	Mean ± SD		
	Preop	After Explantation	Difference
UDVA (logMAR)	0.76 ± 0.23	0.48 ± 0.30	−0.28 ± 0.26
CDVA (logMAR)	0.32 ± 0.19	0.24 ± 0.23	−0.08 ± 0.19
Max K (D)	51.02 ± 6.20	50.34 ± 6.68	−0.68 ± 1.25
I–S (D)	7.32 ± 4.27	4.56 ± 3.39	−2.76 ± 2.19

CDVA = corrected distance visual acuity; ICRS = intracorneal ring segments; I–S = inferior–superior; logMAR = logarithm of the minimum angle of resolution; Max K = maximum keratometry; UDVA = uncorrected distance visual acuity

Table 4. Intracorneal ring explantation secondary to optical/topographic etiology.

Complication	Number (%)*
Optical side effects (eg, halo, diplopia)	5 (14)
Lack of subjective improvement after initial surgery	8 (23)
Prepare for additional procedure	7 (20)
Penetrating or deep anterior lamellar keratoplasty	3 (9)
Conductive keratoplasty	3 (9)
Photorefractive keratectomy	1 (3)

*Percentage of population having explantation

Refractive Explantation

Table 4 shows the motivating factor for removal of ICRS for optical and topographic causes. Twelve of 20 total refractive explantations were necessitated by worsened subjective optical symptoms (eg, halo and monocular diplopia) or in an effort to further improve the corneal topography in circumstances in which the initial surgery did not achieve the desired optical outcome.

Table 5 shows the visual acuity and topography data for eyes with optical side effects. On average, improvement was seen in all outcomes evaluated. The most notable effect was improvement in corneal topographic symmetry measured by the difference in the I–S values (Figure 3). In contradistinction to the medically necessitated explantations, this improvement would be expected. In these cases, the corneal topography before explantation seemed to correspond to

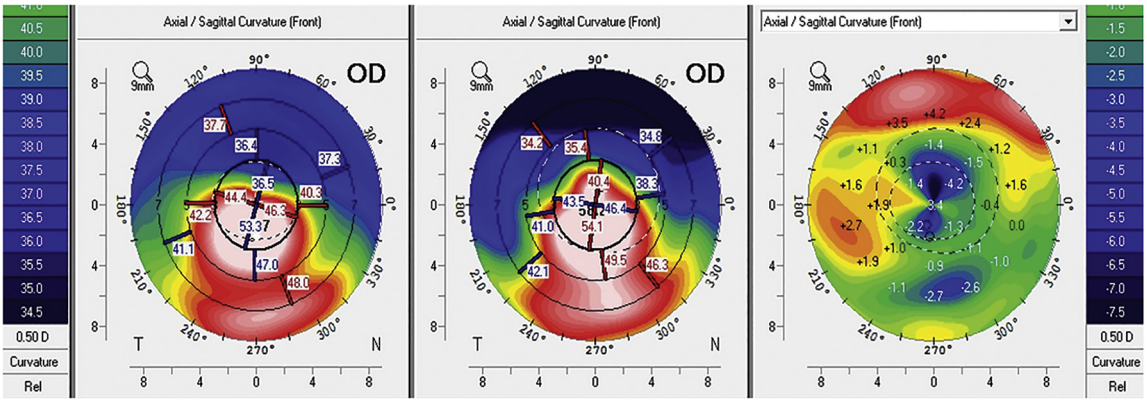

Figure 3. Corneal topography. *Left*: Postoperative explantation of superior segment. *Center*: Before segment explantation. *Right*: Difference map. Note improved symmetry of topography with superior steepening and inferior flattening.

patient reports and symptoms; thus, the treatment was directed specifically toward improving corneal optics.

Table 6 shows the visual acuity and topography data for the subset of explantations performed in patients who subjectively did not note the desired effect after initial surgery. In these patients, there was not necessarily a correspondence between specific patient complaints and topography characteristics. Rather, these were cases in which the patient simply did not note a beneficial effect. For these patients, there was little change in visual acuity outcomes and topography outcomes tended to worsen, likely as a result of segment removal.

Table 7 shows the visual acuity and topography data for eyes in which segments were explanted and had additional surgery, either conductive keratoplasty (CK) or photorefractive keratectomy (PRK). In these patients, corneal topography measured by I–S values improved substantially after explantation as well as after final surgery, with little change in visual acuity.

DISCUSSION

The goal of our study was to define the ultimate explantation rate of ICRS (specifically, Intacs) implantation as well as the motivating factors for the removal. Such information is invaluable in counseling patients with keratoconus and corneal ectasia. In general, we found that the Intacs were well retained over several years in most patients. In 572 total ICRS implantations surgeries, 35 segments were explanted (6.1%). Of these, 43% were necessitated by a medical complication or an untoward effect (2.6% of total population) and 57% were removed electively, motivated by refractive, topographic, or subjective outcomes.

Table 6. Outcomes after ICRS explantation in eyes with no subjective improvement after initial segment placement.

Parameter	Mean ± SD		
	Preop	After Explantation	Difference
UDVA (logMAR)	0.74 ± 0.28	0.73 ± 0.60	−0.01 ± 0.62
CDVA (logMAR)	0.35 ± 0.22	0.38 ± 0.26	0.03 ± 0.19
Max K (D)	55.18 ± 8.29	56.41 ± 9.05	1.24 ± 2.97
I–S (D)	8.43 ± 7.74	10.64 ± 7.23	2.21 ± 5.34

CDVA = corrected distance visual acuity; ICRS = intracorneal ring segments; I–S = inferior–superior; logMAR = logarithm of the minimum angle of resolution; Max K = maximum keratometry; UDVA = uncorrected distance visual acuity

Previous studies have evaluated ICRS complications and removal, but most did not concentrate on the Intacs device. Hofling-Lima et al.[2] retrospectively assessed the incidence of corneal infections after implantation of intracorneal ring segments and reported 8 cases of infectious keratitis among 499 eyes; 7 had received Ferrara inlays and 1 had Intacs implantation. These investigators reported other complications, including superficial implantation, asymmetric placement, persisting incisional gap, decentration, and stromal thinning. Ferrer et al.[3] performed a multicenter retrospective review of 250 ICRS implantations, again with variety of devices; of these, 58 were removed. Reasons for explantation included segment extrusion in 28 cases, poor refractive outcomes in 22, keratitis in 4, corneal melting in 3, and corneal perforation through the endothelium in 1. In a more comprehensive study of Ferrara rings, Ferrara et al.[4] presented a large cohort of 1073 eyes and found a low complication rate of 4%, consistent with the finding in our current study. Undercorrection was the most frequent reason for removal (16/1073), followed by overcorrection (11/1073), extrusion (6/1073), malpositioning (4/1073), progressive corneal steepening (2/1073), and neovascularization (2/1073).

In another large review, Coskunseven et al.[5] reviewed 850 eyes after Keraring implantation and found postoperative complications, including segment displacement in 11 eyes, segment migration in the channel in 7, superficial movement of a segment in 4, corneal melting in 2, and microbial keratitis in 1, a finding similar to ours. The overall complication rate was 6%; however, there were only 2 cases of explantation, both in patients with corneal melting. Piñero et al.[6] reviewed 146 eyes with Intacs or Kerarings. Explantation was performed in 18% of eyes when rings were implanted after a mechanical dissection technique

Table 7. Outcomes after ICRS explantation and subsequent CK or PRK.

Parameter	Preop	After Explantation	After Final Surgery	Difference
UDVA (logMAR)	0.53 ± 0.28	0.73 ± 0.51	0.73 ± 0.51	0.20 ± 0.24
CDVA (logMAR)	0.20 ± 0.14	0.20 ± 0.08	0.28 ± 0.15	0.08 ± 0.05
Max K (D)	54.23 ± 1.53	53.58 ± 0.41	54.20 ± 3.56	−0.02 ± 4.21
I–S (D)	12.93 ± 5.69	9.90 ± 3.24	7.55 ± 3.35	−5.38 ± 5.85

CDVA = corrected distance visual acuity; CK = conductive keratoplasty; CXL = corneal crosslinking; ICRS = intracorneal ring segments; I–S = inferior–superior; logMAR = logarithm of the minimum angle of resolution; Max K = maximum keratometry; UDVA = uncorrected distance visual acuity

and 13% when rings were implanted after femtosecond dissection. Explantation was performed for extrusion in 8 eyes, corneal melting in 3, and corneal neovascularization in 2. In another study of Intacs, Boxer Wachler et al.[7] reported 5 explantations in 74 eyes; segment migration was found in 1 eye and chronic foreign-body sensation in 4 eyes.

In our study, the explantations were stratified into those that were medically motivated and those that were electively removed for undesirable refractive outcomes or subjective symptoms. The most prevalent medical complication leading to inlay explanation was sterile inflammation around the Intacs segment. The area of most severe infiltrate typically surrounded the proximal end of the segment, nearer to the entry incision. Such inflammatory reactions can lead to stromal melting and thinning. These infiltrates should be differentiated from the typical white intrastromal deposits on or near the segments, as reported by Colin.[8] Segment removal invariably led to dissipation of the inflammatory reaction.

Many of the Intacs surgeries reviewed in this paper were combined with CXL, either simultaneously or consecutively over time. With the increasing use of CXL for the treatment of keratoconus and corneal ectasia,[9,10] it is important to know whether the addition of CXL to the Intacs procedure increases complications. In this study, we found no difference in the prevalence of medical complications with or without the use of adjunctive CXL (3% for ICRS alone; 2% for ICRS with CXL).

The main goal of ICRS implantation is to make the irregular keratoconic corneal more symmetric. In a previous report,[11] we described techniques for replacing and repositioning the segments to improve corneal topography in cases with suboptimum outcomes. Cases that can be considered for Intacs removal and/or repositioning typically include those with excess flattening, especially over the superior cornea. In these cases, removal of the superior segment leads to resteepening superiorly with an improvement in I–S topographic symmetry. Also, it may be beneficial to remove segments in preparation for additional corneal procedures such as CK or PRK, in which 1 or 2 segments might be detrimental to the final outcome.

Limitations of this retrospective analysis include the likelihood of patients lost to follow-up. This study included patients over a 13-year period; therefore, patients might have relocated or have other reasons for being lost to follow-up. However, patients with complications typically are motivated to return for examination or seek attention elsewhere, in which case the primary surgeon is frequently notified; thus, this effect might have been minimal. The ICRS, therefore, appear to be successfully retained by most patients over time. The explantation rates performed for medical or refractive reasons were modest. Furthermore, the success of explantation was good, with minimal adverse clinical sequelae.

WHAT WAS KNOWN

- Intracorneal ring segments are used to reshape and flatten the corneal curvature in eyes with keratoconus. This improves the symmetry of the corneal optical contours.
- ICRS can improve contact lens tolerance and corrected distance visual acuity (CDVA) and can avoid or delay the need for corneal transplantation.

WHAT THIS PAPER ADDS

- Of 572 eyes that had ICRS implantation, 35 (6.1%) of 31 patients had explanation of 1 or 2 segments for medical (2.6%) or optical/refractive (3.5%) considerations.
- Explantation rates were similar and successful in eyes that had adjunctive CXL and those that did not, with minimal adverse events.

REFERENCES

1. Colin J, Cochener B, Savary G, Malet F. Correcting keratoconus with intracorneal rings. J Cataract Refract Surg 2000; 26:1117–1122
2. Hofling-Lima AL, Castelo Branco B, Romano AC, Campos MQS, Moreira H, Miranda D, Kwitko S, de Freitas D, Casanova F, Sartori M, Schor P, Souza LB. Corneal infections after implantation of intracorneal ring segments. Cornea 2004; 23:547–549
3. Ferrer C, Alió JL, Montañés AU, Pérez-Santonja JJ, Diaz del Rio MA, Alvarez de Toledo J, Teus MA, Javaloy J. Causes of intrastromal corneal ring segment explantation: clinicopathologic correlation analysis. J Cataract Refract Surg 2010; 36:970–977
4. Ferrara G, Torquetti L, Ferrara P, Merayo-Lloves J. Intrastromal corneal ring segments: visual outcomes from a large case series. Clin Exp Ophthalmol 2012; 40:433–439
5. Coskunseven E, Kymionis GD, Tsiklis NS, Atun S, Arslan E, Siganos CS, Jankov M, Pallikaris IG. Complications of intrastromal corneal ring segment implantation using a femtosecond laser for channel creation: a survey of 850 eyes with keratoconus. Acta Ophthalmol 2011; 89:54–57
6. Piñero DP, Alio JL, El Kady B, Coskunseven E, Morbelli H, Uceda-Montanes A, Maldonado MJ, Cuevas D, Pascual I. Refractive and aberrometric outcomes of intracorneal ring segments for keratoconus: mechanical versus femtosecond-assisted procedures. Ophthalmology 2009; 116:1675–1687
7. Boxer Wachler BS, Chandra NS, Chou B, Korn TS, Nepomuceno R, Christie JP. Intacs for keratoconus. Ophthalmology 2003; 110:1031–1040; errata, 1475
8. Colin J. European clinical evaluation: use of Intacs for the treatment of keratoconus. J Cataract Refract Surg 2006; 32:747–755

9. Hersh PS, Stulting RD, Muller D, Durrie DS, Rajpal RK, on behalf of the United States Crosslinking Study Group. United States multicenter clinical trial of corneal collagen crosslinking for keratoconus treatment. Ophthalmology 2017; 124:1259–1270
10. Hersh PS, Stulting RD, Muller D, Durrie DS, Rajpal RK, for the U.S. Crosslinking Study Group. U.S. multicenter clinical trial of corneal collagen crosslinking for treatment of corneal ectasia after refractive surgery. Ophthalmology 2017; 124:1475–1484
11. Chan K, Hersh PS. Removal and repositioning of intracorneal ring segments: improving corneal topography and clinical outcomes in keratoconus and ectasia. Cornea 2017; 36:244–248

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