



Case report

Late extrusion of intrastromal corneal ring segments: A report of two cases

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ABSTRACT

Purpose: To report two cases of patients with late extrusion following uneventful implantation of intrastromal corneal ring segments (ICRS) for myopia.

Observations: Two patients with previously implanted ICRS for low myopia presented with spontaneous onset of extrusion of their ICRS, one at 7 years post-operatively and the other at 17 and 20 years. Both cases underwent explantation and maintained excellent best-corrected visual acuity. These cases represent the longest reported intervals between implantation of the ICRS and subsequent extrusion.

Conclusions and importance: Late extrusion can occur many years following implantation of ICRS, even in eyes without pre-existing thinning or ectasia. The technique for explantation described herein can result in favorable clinical outcomes in such cases. These cases demonstrate the importance of long-term follow up of eyes that have undergone ICRS implantation.

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1. Introduction

Intrastromal corneal ring segments (ICRS; Intacs, formerly Keravision Inc.; Fremont, CA; Addition Technology Inc., Sunnyvale CA) have been approved by the United States Food and Drug Administration (FDA) for correction of low myopia¹ and are also used for the treatment of keratoconus and corneal ectasia occurring after laser assisted in situ keratomileusis (LASIK). These polymethyl methacrylate implants, initially designed as complete rings and later revised as two separate 150° segments, work by shortening the arc length of the cornea, with thicker segments inducing more central corneal flattening.² The advantages of a corneal expanding technique, compared to a tissue eliminating technique such as LASIK, include maintenance of corneal asphericity, sparing the central visual axis, adjustability and the potential for removal.³ In general, late complications are rare.⁴ We report two cases of spontaneous late ICRS extrusion, occurring 7, 17, and 20 years after implantation. While spontaneous extrusion has been previously reported, this report documents the longest interval between

implantation and extrusion in the English literature to date, suggesting that long-term vigilance in such cases may be necessary.

2. Findings

2.1. Case 1

A 42-year-old man with low myopia presented with the desire to decrease dependence on spectacles for distance visual acuity and a willingness to accept the need for reading spectacles for presbyopic correction. In each eye, uncorrected visual acuity (UCVA) was 20/50, improving to 20/20 with a refraction of -1.00 sphere. Slit lamp examination was unremarkable, and central corneal thickness by ultrasonic pachymetry was 530 μm in each eye. At the time of presentation (mid-1990's), the patient was offered all available options for the treatment of low myopia and he elected to undergo placement of ICRS. The left eye underwent uncomplicated implantation of a 0.25 mm thick ICRS through a 1.8 mm superior radial corneal incision using a manual dissection technique as previously described.² Surgery and the postoperative course were uncomplicated and the patient's UCVA was 20/20. One year after surgery, the patient's UCVA remained 20/20 and best spectacle corrected visual acuity (BSCVA) of 20/12.5 with +0.50 + 1.25 × 090. The medial segment was at a depth of 40% and the temporal segment was at a

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depth of 35% as estimated by slit lamp examination. The patient also underwent an attempted ICRS placement in the right eye, however this procedure was aborted due to mechanical failure of the vacuum centering device and the patient elected not to proceed with a repeated attempt, noting that he had good distance and near vision with mini-monovision.

Six years later, the patient presented complaining of foreign-body sensation and moderate photophobia in the left, ICRS-implanted eye. His UCVA was 20/20. Examination showed full-thickness erosion and thinning of the stroma at 3 o'clock overlying the mid-point of the temporal corneal ring segment, with an overlying epithelial defect measuring 1 mm by 0.5 mm. The poles of the temporal segment were at 20% depth, which was more anterior than had been noted previously. The nasal segment remained at more than 50% depth and well positioned with no evidence of extrusion (Fig. 1A). After discussing treatment options, the patient elected for explantation.

For explantation, a 2 mm radial incision set at 68% of the ultrasonically measured corneal depth (or 360 μ m) was placed between the two segments inferiorly. Following intralamellar dissection from the radial incision to identify the lamellar plane containing the segment, a Sinsky hook was inserted into the positioning hole of each segment and used to extract each segment using a dialing maneuver. The radial incision was then sutured with a 10-0 nylon interrupted suture. On post-operative day 1, the

patient's BSCVA was 20/20 with a refraction of -1.50 sphere. At one month post-operatively, the corneal suture was removed and the epithelium was noted to have completely filled the previous stromal defect (Fig. 1B). The patient's topography and refraction returned to near pre-operative values within one month of explantation (Fig. 2) and remained stable over the ensuing months of follow up.

2.2. Case 2

A 24-year-old woman with moderate myopia presented with the desire to decrease dependence on spectacles. Her uncorrected visual acuity (UCVA) was 20/400 which improved to 20/20 with refraction -3.75 sphere in each eye. Slit lamp examination was unremarkable and central corneal thickness by pachymetry was 575 μ m in right eye and 558 μ m in the left eye. Again, the patient was offered all available options for the treatment of low myopia and also elected to undergo placement of ICRS sequentially, first in the right eye. Both eyes underwent uncomplicated implantation of 0.25 mm thick ICRS using a manual dissection technique. The patient reported good visual results from her procedure and did well thereafter with no ocular complaints. All segments were noted to be at more than 50% depth by slit lamp examination at her immediate post-operative visits. She presented 17 years following implantation with a history of 1 year of decreased vision in the right eye accompanied by intermittent foreign body sensation. Her BSCVA in the right eye was 20/20 with -1.25 + 1.00 \times 008. On slit lamp examination of the right eye, the nasal segment was intact and at 40% depth, but there was light epithelial punctate staining in an arcuate pattern just inside the inner border of the segment. The temporal segment showed a heavier pattern of fluorescein staining of the epithelium immediately adjacent and central to the inner segment border. The stroma overlying the temporal segment at 8 o'clock showed focal, severe stromal thinning with near-perforation (Fig. 1C). Anterior segment optical coherence tomography (ASOCT) imaging showed modest thinning of the stroma overlying the remainder of the temporal ICRS (Fig. 3).

After a discussion of the risks and benefits, the patient elected to proceed with explantation of both segments in the right eye using the same technique that was described in Case 1. On post-operative day 1, the patient's UCVA was 20/100 and BSCVA was 20/20 with a refraction of -4.25 + 1.50 \times 155. One year post-explantation, her BSCVA remained stable at 20/20 with a refraction of -4.75 + 1.25 \times 147. Compared to the pre-implantation refraction from 17 years previously, the spherical equivalent was within 0.62 diopters and there was a net 1.25 diopter increase in cylinder. Three years post-explantation of the ICRS in the right eye and 20 years following original ICRS implantation, the patient presented with foreign body sensation in her left eye and was found to have thinned cornea overlying the temporal ICRS with extrusion of the segment superiorly. The patient elected to proceed with explantation of both segments in the left eye as well.

3. Discussion

ICRS represent a treatment option for patients with myopia and keratoconus with the advantage of maintaining corneal asphericity, and generally, implantation is low risk. Eighty percent of patients were available for two-year follow-up in the FDA phase II and III studies, and outcomes were overall good. A small percentage of patients (2%) had intra-operative complications including anterior or posterior corneal surface perforation, anterior chamber perforation, or peri-limbal hemorrhage. Post-operative complications were rare but included one eye each with infectious keratitis, shallow segment placement, and loss of two lines of BSCVA, though

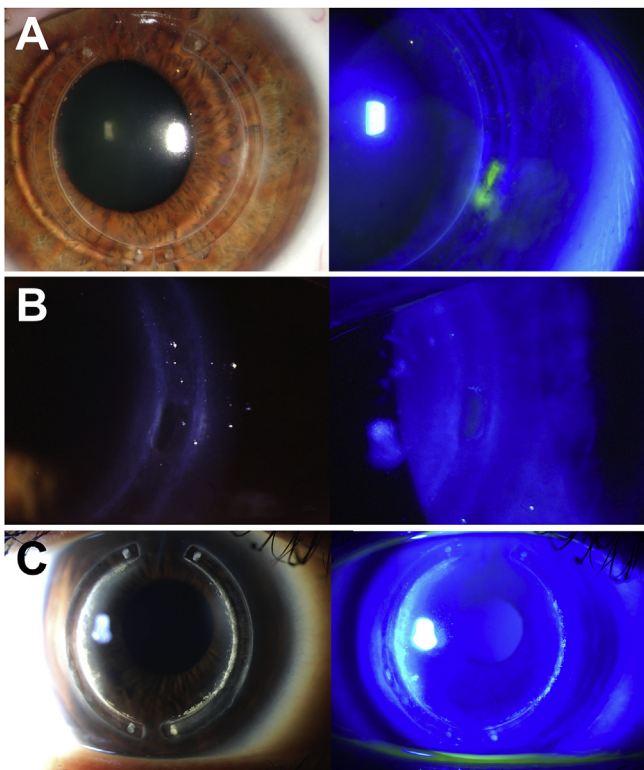


Fig. 1. A, Slit lamp photographs of left eye of patient 1 six years following implantation of intrastromal corneal ring segments (ICRS) with unremarkable nasal segment and 1 mm (height) by 0.5 mm (width) epithelial defect overlying temporal segment highlighted with cobalt blue filter. B, Slit lamp photographs of left eye of patient 1 one month following explantation of ICRS showing residual tracks from the explanted device, filling in of the stromal defect, and intact overlying epithelium. C, Slit lamp photographs of the right eye of patient 2 seventeen years following implantation of ICRS with epithelial staining just inside the nasal segment, diffuse epithelial staining and pooling central to the temporal segment, and pinpoint stromal melting at 8 o'clock. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

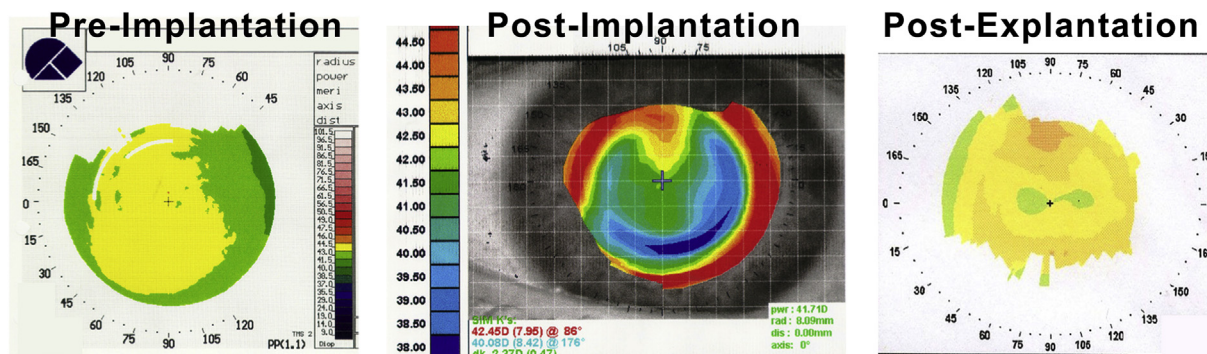


Fig. 2. Serial topographic images of the left eye of patient 1 one month prior to implantation of intrastromal corneal ring segments (ICRS), three months following ICRS implantation, and one month following ICRS explantation (7 years after original implantation).

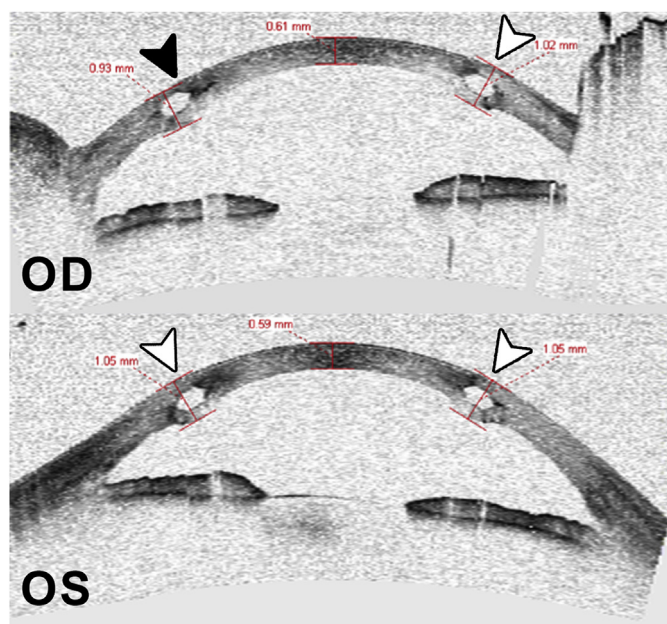


Fig. 3. Anterior segment optical coherence imaging (Visante; Carl Zeiss Meditec International; Dublin, CA, USA) of the right and left eyes of patient 2. The stroma overlying the temporal segment in the right eye in the areas outside the area of focal severe thinning appear mildly thinned (dark arrow) compared to the nasal segment of the right eye or the segments in the fellow, left eye (light arrows).

no patient suffered permanent visual loss attributable to these adverse events. There were no documented corneal erosions or extrusions observed in this group.⁴

There have been isolated reports of extrusion including one patient who developed anterior stromal necrosis 5 years following implantation⁵ and another patient 40 days after implantation associated with acute bacterial keratitis.⁶ Some have also described problems secondary to “shallow placement”⁷ or stromal thinning at one year⁸ without specific reference to extrusion. The two cases reported herein represent the longest interval between implantation and extrusion, at 7, 17, and 20 years postoperatively. Fortunately, no case developed additional complications, such as infection or epithelial ingrowth, and explantation of the intracorneal ring segments was accomplished without difficulty. In both cases, the refractive error post-explantation returned to a level approximating that of the preoperative refraction.

The mechanism of late extrusion in these and other reported cases remains unknown. In both cases, it appeared that spontaneous focal severe thinning without an obvious antecedent trigger

had occurred, but the corneal stroma overlying the remaining aspects of the segment was only modestly thinning. In Case 2, punctate staining at the inner border of the segments suggested the presence of an associated disturbance in the tear film and/or ocular surface integrity. All segments appeared at an appropriate depth post-operatively, though the cases reported here all employed a manual dissection technique intraoperatively to create channels for the ICRS. It is possible that this technique could lead to minor differences in channel depth. If this represents a risk factor for extrusion, this would be eliminated with the increasing use of femtosecond laser which provides a more precise stromal depth.

Potential triggers or contributing factors for late extrusion have yet to be established but could include biomechanical stresses on the stroma induced by the segment; ocular surface drying and dell formation in the region overlying the ICRS; alteration in the diffusion of metabolites to the stroma overlying the polymethylmethacrylate segment; and/or other biochemical changes favoring a balance toward increased matrix metalloproteinase activity and net stromal degradation. Understanding this pathophysiology is particularly important for cases in which the stroma may already be thinned, as in cases of keratoconus due to keratotomy or prior refractive surgery. Previous work has shown fair biocompatibility in rabbit eyes implanted with these devices, divided into an acute mild inflammatory response up to 3 months following implantation and a moderate fibrosis occurring between 3 and 8 months post-implantation.⁹ A more recent histologic study of humans with keratoconus who underwent penetrating keratoplasty after removal of ICRS demonstrated hypoplasia of the epithelium surrounding the channel with decreased keratocyte density above and below the tunnel, and collagen IV synthesis up to 27 months following implantation. Neither myofibroblasts, nor foreign-body granulomas were present.¹⁰ Interestingly, these histologic changes were absent at 6 months post-explantation, suggesting reversibility. Recently, preserved topographic changes have been reported following explantation of ICRS in patients with keratoconus who had previously undergone same-day corneal collagen crosslinking at the time of ICRS implantation.¹¹

We report two cases of late extrusion following implantation of ICRS for myopia, occurring more than five years post-implantation. Explantation of the extruded devices through a small inferior radial incision placed between the two segment ends was performed in a straightforward fashion with preservation of best corrected acuity and reversion of the refraction to a level similar to that of the preoperative level. The incidence of late extrusion of ICRS is not known, but ICRS are increasingly being placed for management of keratoconus and other corneal ectatic disorders. Further studies are needed to ascertain the risk of late extrusion in eyes with pre-existing corneal thinning. At a minimum, patients should be

informed of the possibility of late extrusion and advised to have regular follow-up examinations even years following implantation. Further work is needed to elucidate the mechanism of stromal remodeling and wound healing induced by ICRS implantation to characterize device success and long-term outcomes both in normal and ectatic corneas.

Patient consent

The patient provided written consent for publication of personal identifying information including medical record details and photographs.

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Conflict of interest

The following authors have no financial disclosures: JO, LS, DH.

Authorship

All authors attest that they meet the current ICMJE criteria for Authorship.

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