ARTICLE

Intrastromal corneal ring segment implantation for high astigmatism after penetrating keratoplasty

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PURPOSE: To evaluate the safety and efficacy of intracorneal ring segments (ICRS) for high astigmatism after penetrating keratoplasty (PKP).

SETTING: Department of Ocular Surface and Inflammation, Ophthalmology, Hospital Clínico San Carlos, Complutense University, Madrid, Spain.

METHODS: This retrospective noncomparative study comprised eyes with high post-PKP astigmatism (>4.00 diopters [D]), contact lens intolerance, and a minimum follow-up of 24 months who had ICRS (Kerarings) implantation by mechanical stromal dissection. Corrected distance visual acuity (CDVA), refractive astigmatism, spherical equivalent (SE), surgically induced astigmatism (SIA), central corneal curvature, topographic corneal astigmatism, average corneal power, and complications were assessed.

RESULTS: The mean CDVA was statistically significantly better postoperatively (0.23 $\pm$ 0.21) than preoperatively (0.98 $\pm$ 0.27) (P = .007); no eye lost CDVA. The mean refractive astigmatism decreased from 6.17 $\pm$ 1.12 D to 4.04 $\pm$ 1.67 D (P = .068) and the mean SE from $-$3.17 $\pm$ 5.48 D to $-$0.12 $\pm$ 2.40 D (P = .34). The mean SIA was 4.55 $\pm$ 2.83 D. The mean central corneal curvature decreased from 46.28 $\pm$ 1.73 D to 42.09 $\pm$ 3.20 D (P<.01); the mean topographic corneal astigmatism, from 7.07 $\pm$ 2.52 D to 4.48 $\pm$ 2.00 D (P<.05) and the mean average corneal power from 45.92 $\pm$ 1.59 D to 41.88 $\pm$ 3.37 D (P<.01); all decreases were statistically significant. One patient developed deep vascularization in the lower temporal stromal channel that resolved after ICRS removal. One patient reported significant night halos.

CONCLUSION: Implantation of ICRS for high post-PKP astigmatism reduced corneal curvature and topographic astigmatism, significantly improving CDVA.

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Astigmatism can significantly impede the visual rehabilitation of patients who have had corneal transplantation. After penetrating keratoplasty (PKP), the overall rate of high astigmatism (>5.00 diopters [D]) is reported to be 10% to 27%,[1,2] with higher rates reported for patients with keratoconus. Contact lenses are a better choice than spectacles to correct high astigmatism and may be effective in 80% of cases.[3] However, contact lenses are often difficult to fit and may cause peripheral neovascularization, increasing the risk for graft rejection. Moreover, eyes that have a corneal transplant may be contact lens intolerant because of ocular surface problems, such as dry eye.[4]

When optical methods fail to achieve satisfactory visual rehabilitation, surgical treatment may be necessary. Options for the surgical correction of post-PKP astigmatism include relaxing incisions, wedge resection, and astigmatic keratotomy; however, these procedures have a high incidence of recurrence of astigmatism and low predictability.[5] Furthermore, it has been argued that congenital astigmatism nomograms are not accurate for post-PKP astigmatism.[6] Excimer laser photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK) can be used to treat post-PKP astigmatism. However, PRK can cause significant haze in corneal grafts and may induce progression of the astigmatism.[7–9] Laser in situ

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keratomileusis can treat a wider range of post-PKP astigmatism[10,11]; however, corneal graft thickness and the amount of refractive error may limit the efficacy of the procedure.[12] In addition, severe complications, such as wound dehiscence and flap complications, have been reported.[13–15]

To improve outcomes, some authors propose performing the LASIK procedure in 2 steps (flap creation first followed by laser ablation 8 to 12 weeks later[16]) because of a hinged lamellar keratotomy effect.[17] Repeat PKP for the correction of high astigmatism in clear grafts after PKP has also been reported[18]; however, surgical outcomes worsen after suture removal. In a recent study of Artisan toric intraocular lens implantation to correct refractive errors after keratoplasty,[19] the authors found a 35% reduction in endothelial cells and 8.3% graft failure within 4 years of follow-up. Another possibility is the use of a toric intraocular Collamer lens (Staar Surgical Co.), which has good reported outcomes and endothelial safety.

Implantation of intrastromal corneal ring segments (ICRS) is being used to correct corneal ectasia with a clear cornea, and the results are reported to be good.[20] It is a safe and reversible procedure that does not affect the central visual axis of the cornea and has been used to treat keratoconus,[21,22] pellucid marginal degeneration,[23] post-LASIK ectasia,[24] and post-PRK ectasia.[25]

In the present study, we assessed visual, refractive, and topographic outcomes as well as postoperative complications of ICRS implantation to correct high astigmatism after PKP. To our knowledge, ours is the first study to evaluate ICRS implantation in these cases.

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PATIENTS AND METHODS

This retrospective noncomparative interventional case-series study comprised patients with contact lens intolerance and high post-PKP astigmatism (>4.00 D). Other inclusion criteria were a corrected distance visual acuity (CDVA) worse than 0.4, no history of corneal allograft rejection, PKP at least 2 years previously, a minimum follow-up after ICRS implantation of 24 months, and PKP graft suture removal at least 6 months before ICRS implantation.

The tenets of the Declaration of Helsinki and Spanish legislation were adhered to, and the local ethics committee approved the study protocol. All patients provided legally binding informed consent for ICRS implantation.

Preoperative and postoperative examinations included CDVA, slitlamp evaluation, applanation tonometry, manifest refraction (ARK-700, Nidek, Inc.), and corneal topography (TMS-2, Tomey Corp.).

Intrastromal Corneal Ring Segments

The Keraring ICRS (Mediphacos Ltd.) used in this study are made of acrylic Perspex CQ, are 150 to 300 μm thick, and have 160 degrees of arc length. This ICRS shares the original design and features of the Ferrara ring but is manufactured by another company. The ICRS thickness and the implantation site were selected according to the amount of astigmatism and axis of preoperative objective refraction following the nomogram for keratoconus surgery provided by the manufacturer. In 1 patient in whom preoperative refraction could not be determined, corneal topography was used to select ICRS thickness and the implantation site.

Surgical Technique

The ICRS were implanted using the mechanical technique described by Ferrara.[26] Surgery was performed using topical anesthesia of oxybuprocaine 0.40% and tetracaine 0.10%. No vacuum was used to create the tunnels, and no sutures were used to close the incision.

Postoperative treatment comprised tobramycin 0.3%–dexamethasone 0.1% eyedrops 3 times a day for 2 weeks, after which the dose was tapered over 3 weeks. Preservative-free lubricant tears were used 4 times a day for 2 months.

Outcome Measures

The outcome measures determined were CDVA, net astigmatism (refractive cylinder, topographic), spherical equivalent (SE), and central corneal power with topographic data (ie, mean, minimum, and maximum keratometry [K] values). In addition, average corneal power, a parameter provided by the corneal topography system, was assessed; this value is an area-corrected average of the local corneal power ahead of the entrance pupil.

Surgically induced astigmatism (SIA) was calculated using SIA-Soft software.[27] The software uses preoperative and postoperative keratometric data to calculate the changes in the magnitude and direction of the astigmatism by vector analysis.

Statistical Analysis

Preoperative and postoperative data were compared using the Wilcoxon nonparametric test. Statistical analysis was performed using SPSS for Windows software (version

Table 1. Preoperative and surgical data.

Pt	Age (Y)/ Sex	PKP Indication	Time from PKP to ICRS (Mo)	Follow-up (Mo)	Cyl (D)	SE (D)
1	77/M	PBK	70	34	−5.00	−0.50
2	80/F	PBK	44	34	−7.00	0.25
3	52/F	PLE	61	33	−6.00	−4.25
4	43/M	KC	34	33	−5.00	3.50
5	48/F	KC	54	29	−8.00	−12.00
6	29/F	KC	62	27	−4.00	−14.00
7	44/M	PMD	27	27	−6.50	−1.75
8	42/M	KC	52	25	ND	ND
9	46/F	KC	76	24	−6.00	−6.00

Cyl = refractive cylinder; ICRS = intracorneal ring segments; KC = keratoconus; ND = preoperative refraction could not be determined; PBK = pseudophakic bullous keratopathy; PKP = penetrating keratoplasty; PLE = post-LASIK ectasia; PMD = pellucid marginal degeneration; Pt = patient; SE = spherical equivalent

15.0, SPSS, Inc.). A P value less than 0.05 was considered statistically significant. Data are reported as the mean ± SD.

RESULTS

This study comprised 9 eyes of 9 patients (5 women, 4 men). The mean age of the patients was 51.22 years ± 16.7 (SD) (range 29 to 80 years). Table 1 shows the patients' preoperative and surgical data. The mean follow-up was 29.55 ± 4.15 months (range 24 to 34 months). The mean time between PKP and ICRS implantation was 53.33 ± 16.13 months (range 27 to 76 months).

Figure 1 shows a typical slitlamp photograph taken 1 week after surgery. Figure 2 shows an anterior segment optical coherence tomography (OCT) image of the same eye taken 2 years after surgery.

Visual and Refractive

The mean preoperative CDVA (logMAR) was 0.98 ± 0.27 (range 1.2 to 0.4) preoperatively and 0.23 ± 0.21 (range 0.6 to −0.1) at the last postoperative examination; the improvement was statistically significant (P = .007). The CDVA improved after surgery in all 9 eyes (Figure 3).

Preoperative refraction could be determined in 8 eyes and postoperative refraction in 7 eyes due to high astigmatism. Preoperative and postoperative refraction could be determined in 6 eyes (66%). The mean refractive astigmatism decreased from 6.17 ± 1.12 D (range 5.00 to 8.00 D) preoperatively to 4.04 ± 1.67 D postoperatively (range 2.50 to 7.00 D (P = .068) and the mean SE, from −3.17 ± 5.48 D to −0.12 ± 2.40 D (P = .34). Figure 4, *top*, shows the mean visual and refractive improvement.

The mean SIA after ICRS implantation was 4.55 ± 2.83 D.

Topographic

The decreases in topographic mean, minimum, and maximum keratometry K values from preoperatively to postoperatively were statistically significant. The maximum K value decreased from 49.81 D to 44.35 D (P = .008); the minimum K value, from 41.64 D to 38.96 D (P = .028); and the mean K value, from 46.28 D to 42.11 D (P = .008). The mean average corneal power decreased from 45.92 ± 1.59 D to 41.88 ± 3.37 D and the mean topographic astigmatism,

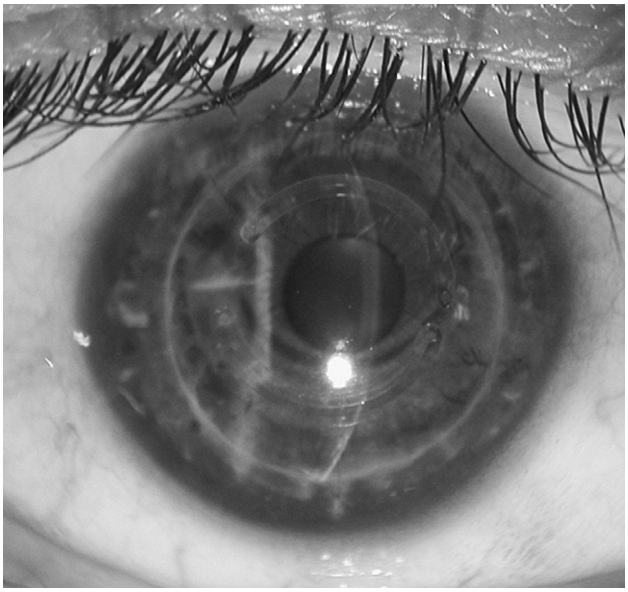

Figure 1. Slitlamp photograph taken 1 week after ICRS implantation.

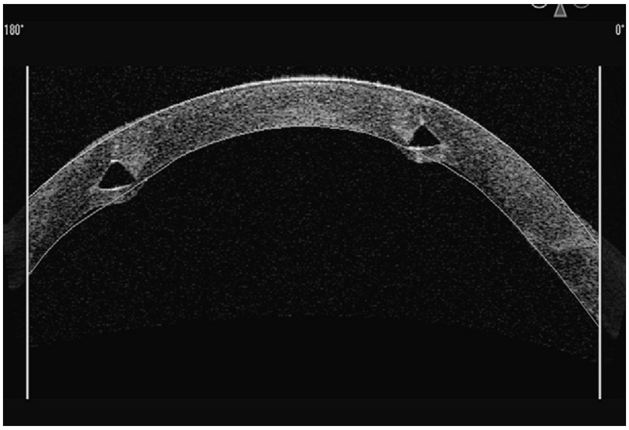

Figure 2. Anterior segment OCT of the eye in Figure 1 shows adequate ICRS depth and the graft–host interface.

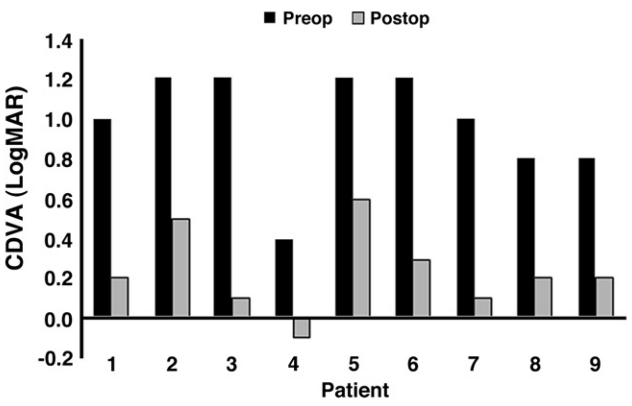

Figure 3. Improvement in CDVA after ICRS implantation (CDVA = corrected distance visual acuity).

from 7.07 ± 2.52 D to 4.48 ± 2.00 D; both decreases were statistically significant (P = .008 and P = .017, respectively). Figure 4, *bottom*, shows the mean topographic improvement.

Complications

Surgery was uneventful in 7 patients. In 2 patients, the upper ring segment was explanted during the same surgical session due to superficial implantation. This segment was not replaced subsequently because the outcome with a single ICRS was acceptable.

A 44-year-old man reported night halos, mainly when driving, beginning 1 month after surgery. The postoperative CDVA was 0.8. The slitlamp examination showed no corneal haze or migration of the rings. One drop of pilocarpine 0.5% at night was prescribed. The symptoms improved significantly, and after more than 2 years of treatment, the patient had no systemic or ocular secondary effects.

An 80-year-old woman developed vascularization in the lower temporal stromal tunnel 2 months after surgery (Figure 5, *A*). The vascularization was accompanied by a visual acuity decrease (from 0.2 to counting fingers) and topographic flattening. The ring segment was explanted 2 months later after ineffective topical steroid treatment. There were hematic deposits in the stromal channel in the immediate postoperative period (Figure 5, *B*). One month later, there were no vessels or hematic deposits in the stromal channel (Figure 5, *C*). Visual acuity improved to 0.3.

No corneal ulcers or stromal necrosis was noted after ICRS implantation. There were no cases of ICRS migration or extrusion during the follow-up.

DISCUSSION

In our study, implantation of ICRS to treat high astigmatism after PKP significantly reduced K values and significantly improved corneal topography and

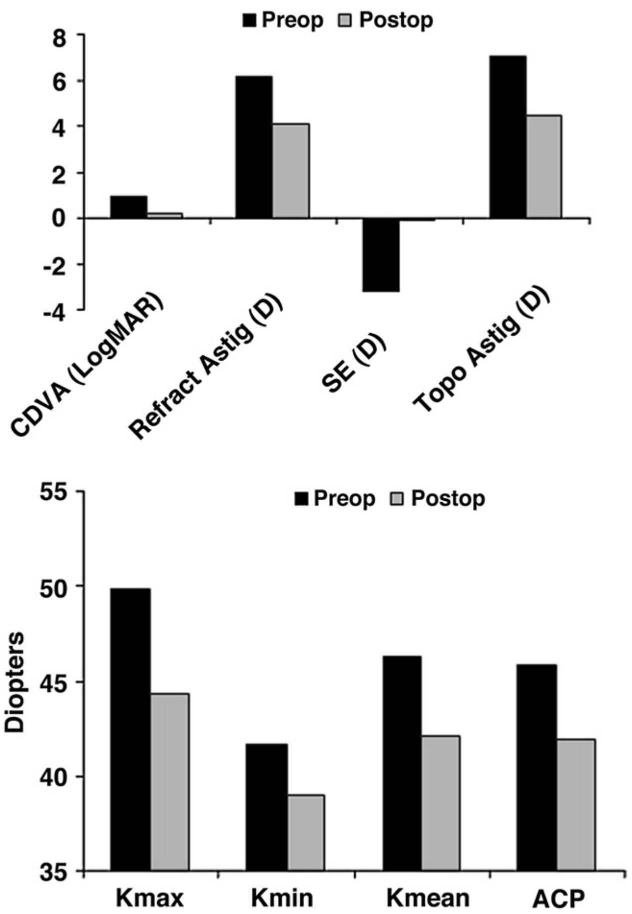

Figure 4. *Top*: Mean visual and refractive changes. *Bottom*: Mean topographic changes (ACP = average corneal power; CDVA = corrected distance visual acuity; Kmax = maximum keratometry value; Kmean = mean keratometry value; Kmin = minimum keratometry value; Refract Astig = refractive astigmatism; SE = spherical equivalent; Topo Astig = topographic astigmatism).

CDVA. The refractive astigmatism and SE also improved, although the changes were not statistically significant. At the end of follow-up, all patients had improved CDVA and there were no cases of graft rejection.

Postoperative complications included an inflammatory infiltrate around the upper segment 4 days after implantation in 1 eye, which was excluded from the statistical analysis; the segment was removed. One week later, the lower segment was explanted due to compulsive eye rubbing. The other 2 complications were night halos in 1 patient, in whom pharmacologic treatment yielded a good response, and stromal channel vascularization that improved after ring explantation in another patient. The last case highlights the need to position the rings as far as possible from the host–graft interface and to avoid ICRS implantation in patients with very eccentric corneal transplants or a vascularized donor cornea because it would increase

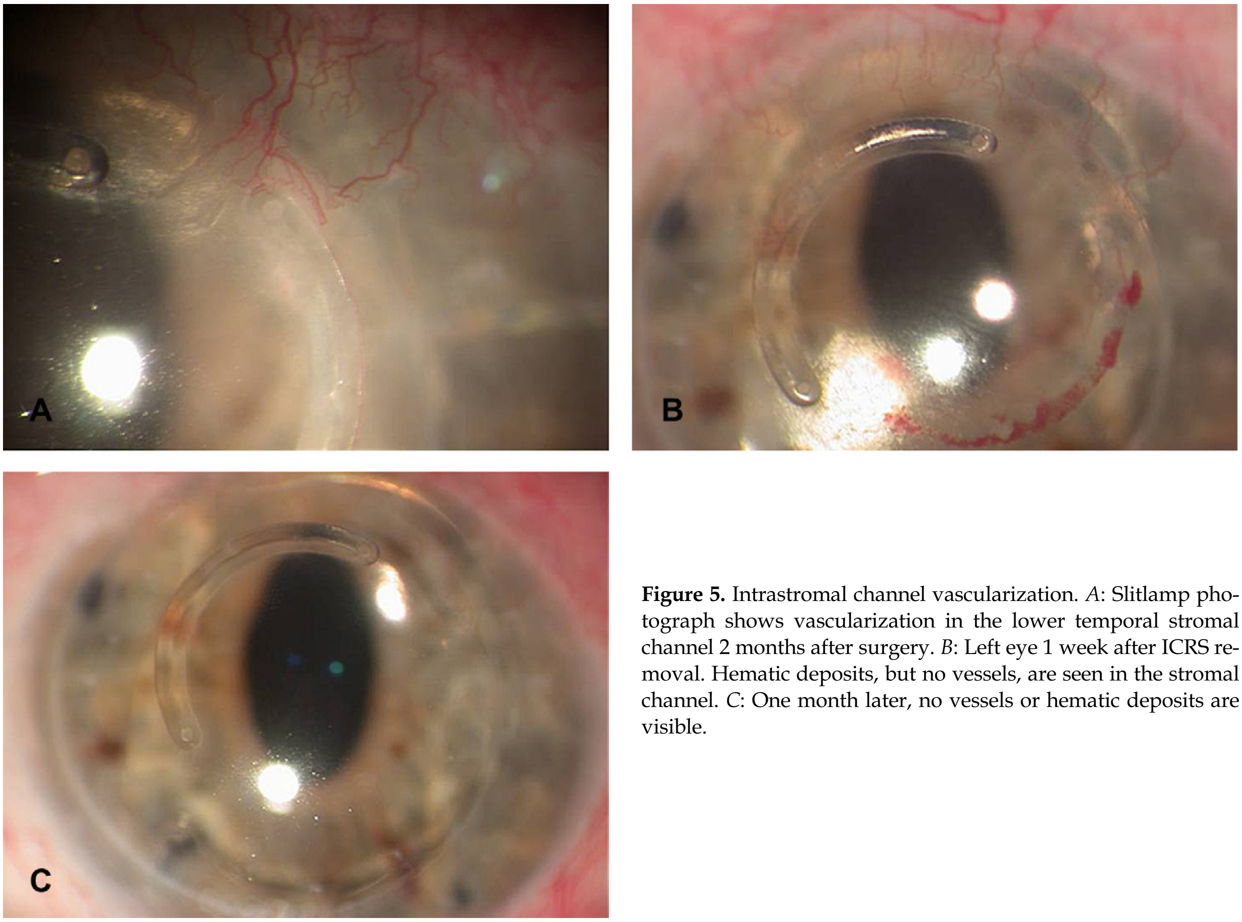

Figure 5. Intrastromal channel vascularization. *A*: Slitlamp photograph shows vascularization in the lower temporal stromal channel 2 months after surgery. *B*: Left eye 1 week after ICRS removal. Hematic deposits, but no vessels, are seen in the stromal channel. *C*: One month later, no vessels or hematic deposits are visible.

the risk for vascularization of the tunnel and for graft rejection.

The SIA was calculated using vector analysis, providing a measure of the change in the magnitude and axis of astigmatism. The astigmatism induced by ICRS implantation was slightly higher than 4.00 D.

The primary reason for previous PKP in 7 of 9 patients in our study was a primary ectatic disorder (ie, keratoconus or pellucid marginal degeneration). The periphery of the recipient cornea in these patients may have been abnormal (ie, thinned), which can affect the final corneal topography. However, to our knowledge, no study has evaluated differences in correction of post-PKP astigmatism based on the type of corneal disease before transplantation. Some studies do not mention the primary reason for PKP, and others include cases of bullous keratopathy and corneal dystrophy.[17,18]

The use of Kerarings with a 5.0 mm optical zone has 2 advantages over the use of Intacs (Addition Technology, Inc.), which have a 7.0 mm optical zone. First, the central cornea flattening is theoretically greater because the refractive outcome is inversely proportional to the diameter of the implant. The second benefit is that a small diameter ensures greater distance between the rings and the graft–host junction. This reduces the risk for interface dehiscence or vascularization of the stromal channel by vessels extending from the limbus and host cornea, as occurred in 1 of our patients. Thus, in patients with a corneal transplant with a diameter of 7.5 mm smaller, Intacs should not be used because the segments would be very close to the graft–host junction. Intacs-SK, which have a smaller implantation diameter, may be a good alternative. In contrast, the use of Kerarings has a greater risk for halos, as in 1 patient in our study.

The results of LASIK to treat astigmatism after keratoplasty are not as good as in nonoperated eyes. The predictability of LASIK in these eyes is lower, and loss of CDVA is not uncommon. In addition, LASIK after PKP has a higher complication rate than in eyes with normal corneas; complications include epithelial ingrowth, flap dislocation, dry eye, and graft failure.[10–15] Some authors suggest a 2-step LASIK procedure, which appears to improve the visual results but may increase adverse events such as epithelial ingrowth.[16] Implantation of ICRS has considerable theoretical benefits over LASIK. First, because material is added rather than tissue being removed, the mechanical strength of the cornea is not compromised and may be enhanced. Second, ICRS do not affect the central corneal zone, which minimizes the risk for opacification caused by scarring in the visual zone. Third, the technique is reversible; therefore, if the refractive outcomes are unsatisfactory, the ICRS can be explanted. Finally, ICRS can be replaced with thinner or thicker rings, as needed, to modify the amount of correction.

The disadvantages of incisional techniques include considerable instability in refractive outcomes with frequent regression.[5,6] In contrast, in the present study Kerarings provided stable refractive results in the midterm (29 months). In addition, arcuate incisions are usually more effective in eyes with an SE close to 0, while patients with PKP-induced astigmatism usually have myopic SE, for whom ICRS are more efficient. Effectively, in our series of patients, the SE was reduced from -3.17 ± 5.48 D to -0.12 ± 2.40 D.

Intrastromal corneal ring segment implantation has potential complications. Those associated with the mechanical technique of tunnel creation include epithelial defects, incisional gapping, anterior and posterior perforations, shallow or asymmetric placement, decentration, stromal thinning, corneal melting, and corneal stromal edema around the incision and channel from surgical manipulation.[20] Other reported complications include infectious keratitis,[28] sterile keratitis,[29] chronic pain,[30] corneal anterior stromal necrosis,[31] white intrastromal deposits (with no alteration in optical performance),[32] and stromal channel neovascularization,[33] similar to that in 1 of our patients.

Recommendations for the best time to perform ICRS surgery include waiting at least 1 year after PKP and at least 3 months after suture removal.[4] We waited at least 2 years after corneal transplantation and a minimum of 6 months after suture removal to avoid damaging the interface by the traction generated by the dissectors used during surgery in the manual technique. In 2 of our patients (excluded from the statistical analysis), small dehiscences formed at the interface during stromal tunnel dissection; the wounds had to be sutured and ICRS implantation postponed. Based on these 2 cases, we believe it is better to wait at least 1 year after suture removal, especially if the patient had prolonged topical corticosteroid treatment after PKP because use of this drug delays the wound-repair process at the host–graft interface. In our study, the dehiscence rate was low; however, the rate might be lower if the time between corneal transplantation and ICRS implantation is increased. Alternatively, ICRS implantation could be performed earlier using a femtosecond laser to create the stromal tunnels; this is the procedure of choice when the cornea is transparent.

The limitations of our study include the low number of patients and lack of a control group. It also has the limitations inherent to any retrospective study.

In cases of astigmatism after keratoplasty, rehabilitation with contact lenses is often preferred over surgical correction. However, contact lenses are not always effective in patients with high astigmatism after keratoplasty and fitting problems and complications (eg, corneal neovascularization, dry eye) can occur.[3,4] Incisional surgery and PRK are reported to have poor predictability and can lead to severe complications such as haze and graft failure; LASIK is more frequently used in these cases. We believe that ICRS implantation is a good alternative to LASIK in treating high post-PKP astigmatism, especially cases in which laser surgery is contraindicated because of insufficient corneal stroma thickness or unavailability of an excimer laser. In our study, ICRS implantation provided good refractive, visual, and topographic results that were stable over a follow-up longer than 2 years. Furthermore, the incidence of complications was acceptable, with no cases of graft rejection during the follow-up. To our knowledge, there is only 1 report in the literature of ICRS implantation in these cases, and it is of a single case with a follow-up of 10 months.[34]

In conclusion, our results indicate that ICRS implantation is a safe option to correct high astigmatism after PKP and that is yields good visual, refractive, and topographic outcomes. Future prospective studies with more patients and a longer follow-up are needed to confirm the safety and effectiveness of ICRS for high astigmatism after keratoplasty.

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