Scholastic Ophthalmology

Research Article

Volume 2 Issue 1 January 2026

Evidence of the Influence of Intra-stromal Ring Implant on Slowing the Progression of Keratoconus

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Received: December 05, 2025; **Published:** December 20, 2025

Abstract

Objective: To evaluate the evolution of topography, astigmatism, and visual acuity in eyes with keratoconus that underwent intra-stromal ring implant surgery, comparing them with the contralateral non-operated eyes, aiming to confirm if there is evidence that the intra-stromal ring may also help slow the progression of the disease.

Methods: Four cases of young and adult patients who underwent corneal ring implant surgery in one eye were analyzed, with clinical and topographic follow-up for up to 8 years. The results were compared with the contralateral non-operated eye.

Results: Significant improvement in visual acuity, and reduction in keratometry and astigmatism were observed in the operated eye with the corneal ring implant. Over time, these parameters remained relatively stable, while the contralateral eye showed progression of keratoconus, evidenced by increased keratometry, astigmatism, and worsening of visual acuity. At different follow-up times, the non- operated eyes began to show worse values than the treated ones.

Conclusion: The intra-stromal ring implant, in addition to optical correction, may contribute to slowing the progression of keratoconus in certain cases by exerting a biomechanical stabilizing effect on the cornea, functioning as a rigid structure that reduces stromal deformation. However, prospective studies with a larger number of patients and longer follow-up are needed to confirm this potential protective effect, and crosslinking remains the most accepted procedure for disease stabilization.

Keywords: Keratoconus, Intra-stromal ring; Ectasia; Keratometry.

Introduction

Keratoconus is a progressive ectatic corneal disease that usually begins in the second decade of life and is characterized by bilateral and asymmetrical corneal thinning, associated with a clinical picture of corneal protrusion, progressive irregular astigmatism and visual alterations. Its etiopathogenesis remains multifactorial, involving genetic predisposition, environmental factors and biomechanical changes in the cornea (1,2). Its prevalence is estimated at approximately 1 in 2,000 and its incidence varies between 50 and 230 per 100,000

(3).

The management of keratoconus should be aimed not only at visual rehabilitation, but also at stopping or slowing down its progression. In its early stages, keratoconus can be treated conservatively with glasses or rigid contact lenses. In advanced stages, deep lamellar keratoplasty and penetrating keratoplasty (PK) are considered. However, an excellent alternative has emerged, the intra-stromal corneal ring segment implant (ICRS), which was originally developed for myopia correction but has now been widely used in keratoconus patients (4). By achieving satisfactory visual rehabilitation, many patients are able to get out of the corneal transplant queue (5).

The aim of ICRS is to induce a change in the central curvature of the cornea, thereby reducing keratometry and refractive error. In addition, corneal remodeling results in a reduction in optical aberrations (6), improving visual acuity. Although the refractive and functional benefits of ICRS are well documented, its possible biomechanical effect on the structure of the cornea has been discussed, which could contribute to reducing the speed of progression of keratoconus.

In this context, this article presents case reports of patients undergoing ICRS in the eye with the most advanced disease, monitoring keratometric changes over time and comparing them with the evolution of the untreated contralateral eye. The aim is to review and critically analyze the clinical and experimental evidence available in the literature on the possible contribution of ICRS in slowing down the progression of keratoconus.

Material and Methods

Case 1

C. P. C. P., 30 years old, male.

He had allergic rhinitis and a habit of frequent eye rubbing.

At the age of 17, progression of the corneal ectasia was observed, with worsening of the topographic findings, and surgical intervention was indicated.

Pre-operative examinations:

Refraction: RE: -10.00 -5.00 x 40° (VA = 20/100)

LE: pl -2.50 x 130° (VA = 20/25)

Corneal topography: RE: 50.46 to 17° / 62.41 to 107°, astigmatism = 11.95 R

LE: 42.01 to 145° / 47.64 to 55°, astigmatism = 5.63 R Central pachymetry: RE= 516 µm, LE= 584 µm.

Biomicroscopy, tonometry and fundoscopy within normal standards.

Surgery data (right eye):

Tunneling technique: with Femtosecond Laser.

Two segments have been set up:

Temporal segment (Cornealring/Visiontech): Diameter 5mm / arc 155° / thickness: 300 µm

Nasal segment (Bioring/Biotech) Diameter 5mm / arc 160° / thickness: 250 µm.

Case 2

M. S. O., 17 years old, male.

History of allergy to dust and eye rubbing.

Pre-operative examinations:

Refraction: RE: -14.50 -6.00 x 20° (VA = 20/100)

LE: -0.50 -1.00 x 130° (VA = 20/25)

Corneal topography: RE: 54.51 to 32° / 62.55 to 122°, astigmatism = 8.04 R.

LE: 45.91 to 145° / 48.64 to 55°, astigmatism = 2.73 R. Central pachymetry: RE= 405 µm, LE= 496 µm.

Biomicroscopy, tonometry and fundoscopy within normal standards.

Surgery data (right eye):

Tunneling technique: with Femtosecond Laser.

1 segment was implanted: (Cornealring/Visiontech): Diameter 5mm / arc 300° / thickness: 300 µm

Case 3

L. M. S., 16 years old, male.

History of asthma and eye rubbing.

Pre-operative examinations:

Refraction: RE: -19.00 -4.50 x 40° (VA = 20/70 P)

LE: -1.50 -1.00 x 150° (VA =20/50P)

Corneal topography: RE: 56.42 to 40°/ 59.33 to 130°, astigmatism = 2.9 R

LE: 45.06 to 135° / 48.18 to 45°, astigmatism = 3.12 R Central pachymetry: RE= 489 µm, LE= 507 µm.

Biomicroscopy RE presence of discrete central vogt striae, LE without alterations.

Tonometry and fundoscopy within normal standards.

Surgery data (right eye):

Tunneling technique: manual.

1 segment was implanted: (Cornealring/Visiontech): Diameter 5mm / arc 300° / thickness: 250 µm

Case 4

E. A. R. C., 29 years old, female.

History of asthma and rhinitis, with frequent eye rubbing.

Pre-operative examinations:

RE refraction: -2.00 -6.00 x 5° (VA = 20/100)

LE: +0.50 -2.50 x 160° (VA =20/25).

Corneal topography: RE: 45.73 to 8° / 54.38 to 98°, astigmatism = 8.65 R

LE: 43.66 to 166° / 48.46 to 76°, astigmatism = 4.80 R. Central pachymetry: RE= 533 µm.

Biomicroscopy RE presence of central vogt striae, LE without alterations. Tonometry and fundoscopy within normal standards.

Surgery data: (right eye):

Tunneling technique: with Femtosecond Laser.

1 segment was implanted: (Cornealring/Visiontech): Diameter 5mm / arc 300° / thickness: 250 µm

Results

The following tables show information collected from serial examinations in the post-operative period. They show the evolution of the following variables:

- keratometry (K1 flattest meridian / K2 most curved meridian),
- corneal astigmatism (A) = difference between k2 and k1,
- Visual acuity with spectacle correction (VA KC).

In red, the moment when the unoperated eye starts registering higher values than the eye that received the corneal ring is highlighted:

CASE 1		Eye	Operated	-	RE	Non	operated	-	LE
Date	**Follow up**	**K1 (D)**	**K2 (D)**	**A (D)**	**VA KC**	**K1 (D)**	**K2 (D)**	**A (D)**	**VA KC**
03/05/13	Pre-op	50.46	62.41	11.95	20/100	42.01	47.64	5.63	20/25
04/25/13	1st month PO	47.78	55.42	7.64	20/80	41.62	47.39	5.77	20/50
07/16/13	3rd month PO	45.69	51.46	5.77	20/50	42.29	49.22	6.93	20/40
12/12/13	8th month PO	47.69	52.38	4.69	20/30	43.10	49.77	6.67	20/40
04/15/14	1st year PO	48.55	52.23	3.68	20/25	44.27	52.45	8.18	20/40

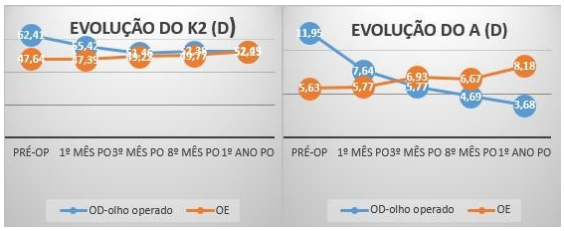
CASE 2		Eye	Operated	-	RE	Non	operated	-	LE
Date	**Follow up**	**K1 (D)**	**K2 (D)**	**A (D)**	**VA KC**	**K1 (D)**	**K2 (D)**	**A (D)**	**VA KC**
04/26/19	Pre-op	54.51	62.55	8.04	20/100	45.91	48.64	2.73	20/25
04/29/19	3rd day PO	46.61	49.28	2.67	20/70	45.35	47.17	1.82	20/25
01/08/20	8th month PO	46.66	50.38	3.17	20/40	45.75	49.10	3.35	20/25
10/06/23	4th year PO	46.69	51.22	4.53	20/25P	58.58	65.41	6.82	20/80

CASE 3		Eye	Operated	-	RE	Non	Operated	-	LE
Date	**Follow up**	**K1 (D)**	**K2 (D)**	**A (D)**	**VA KC**	**K1 (D)**	**K2 (D)**	**A (D)**	**VA KC**
10/01/20	Pre-op	56.42	59.33	2.91	20/70P	45.06	48.18	3.12	20/50P
12/21/20	2nd month PO	51.93	54.69	2.76	20/100	45.22	48.39	3.17	20/40
02/22/21	4th month PO	50.67	52.56	1.89	20/100	42.23	48.56	3.33	20/40
07/16/21	9th month PO	48.78	49.67	0.89	20/70	44.92	48.12	3.20	20/30
05/31/23	2a 7m PO	49.13	49.78	0.65	20/40	47.19	50.37	3.18	20/30
06/12/25	4a 8m PO	49.49	49.93	0.44	20/50	55.06	57.29	2.23	20/40

CASE 4		Eye	Operated	-	RE	Non	Operated	-	LE
Date	**Follow up**	**K1 (D)**	**K2 (D)**	**A (D)**	**VA KC**	**K1 (D)**	**K2 (D)**	**A (D)**	**VA KC**
05/05/17	Pre-op	45.73	54.38	8.65	20/100	43.66	48.46	4.80	20/25
07/21/17	2nd month PO	42.39	46.82	4.43	20/40	42.11	46.82	4.71	20/25
09/22/17	4th month PO	42.07	46.26	4.20	20/25	42.72	47.51	4.79	20/25
10/02/19	2a5m PO	44.47	50.23	5.76	20/25	42.49	47.11	4.62	20/25
08/05/21	4a 3m PO	42.50	47.07	4.57	20/40	43.23	48.36	5.13	20/25
08/25/22	5a 3m PO	42.39	47.36	4.97	20/25	42.40	47.46	5.06	20/25
01/25/24	6a8m PO	42.20	47.06	4.86	20/25	42.75	48.04	5.29	20/30
08/06/25	8a2m PO	42.26	46.93	4.67	20/25	43.02	48.28	5.26	20/30

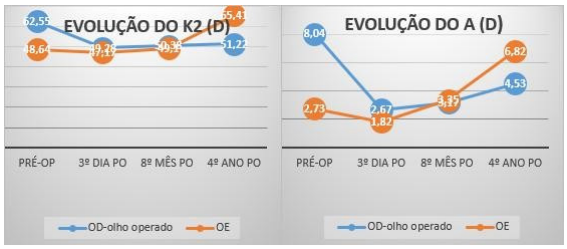
Figure 1 - Comparative evolution of keratoconus in the eye with the intrastromal ring implant compared to the contralateral unoperated eye. When the keratoconus in the non-operated eye progresses and shows worse values than the eye that received the ring, this value is marked in red.

To make the analysis comparing the speed of progression of keratoconus in the 2 groups (RE with corneal ring implant and LE without the ring) clearer, graphs were constructed showing the evolution of K2 and corneal astigmatism over time in the post-operative period.



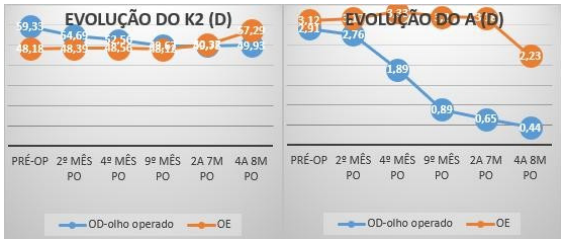
Graph 1: Representation of the variation in K2 values and corneal astigmatism

(D) throughout follow-up - Case 1.



Graph 2: Representation of the variation in K2 values and corneal astigmatism

(D) throughout follow-up - Case 2.



Graph 3: Representation of the variation in K2 values and corneal astigmatism

(D) throughout follow-up - Case 3 EVOLUTION OF A (D)

Graph 4: Representation of the variation in K2 values and corneal astigmatism

(D) during follow-up - Case 4.

Discussion

This study describes a series of cases of keratoconus patients who underwent corneal ring implantation, in which the surgery seems to have contributed to slowing down the progression of the disease. The results show that the ring implant was able to considerably improve VA and reduce corneal curvature and astigmatism. This result remained relatively stable over time, while the contralateral (non-operated) eye continued its natural evolution (getting worse). So, after a few months, the unoperated eye became worse than the eye that received the ring implant. This slowdown in the rate of progression of the ectasia was observed to a greater or lesser extent in the 4 cases reported.

The implantation of intra-stromal ring segments (ICRS) works by altering the distribution of forces in the cornea, which ultimately leads to a reduction in its curvature. They were introduced into the therapeutic approach to keratoconus with the The main objective is to reduce corneal irregularity and improve visual quality and acuity (6). However, there are indications that, in many cases, ICRS may also play a role in slowing down the progression of keratoconus. Some patients may even benefit to the point where corneal transplantation is not necessary (5).

Evidence that the corneal ring can help slow down the progression of keratoconus:

1) Reduction in the number of corneal transplant surgeries for keratoconus in hospitals that adopt corneal ring surgery.

2) Observation of the maintenance of the result obtained with the ring implant surgery over the years.

3) Observation that the rate of progression of keratoconus in the operated eye is slower than in the non-operated eye (demonstrating this is the aim of this study).

1) Reduction in the number of corneal transplant surgeries for keratoconus in hospitals that adopt corneal ring surgery:

There is often a reduction in the number of corneal transplant surgeries in hospitals that offer corneal ring implantation to their patients (a less invasive alternative with a lower risk of developing serious complications). It's also worth emphasizing that a tiny percentage of ophthalmologists are registered with eye banks, which makes transplantation available to only a few. This limiting factor is often even more significant away from large urban centers.

2) Observation of the maintenance of the result (visual acuity and keratometry) obtained with the ring implant surgery over the years:

Several publications describe that the keratometry values and/or corneal astigmatism and/or visual acuity of patients undergoing corneal ring implantation tend not to change significantly over the years (7, 8, 9, 10, 11, 12).

3) Observation that the speed of progression of keratoconus in the operated eye becomes slower than that observed in the unoperated eye (demonstrating this change in behavior is the aim of this study):

Keratoconus is an asymmetrical disease in which one eye ("worse eye") is more affected and has a faster rate of progression than the "better eye". This asymmetrical development may be related to the habit of scratching one eye more than the other. It's important to note that it's hard to find a patient in whom the eye that was the "better" one evolves more than the other, becoming the "worse eye". This means that, in a keratoconus patient, the "worse eye" will always be the worse of the two, while the "better eye" will always be the one that the patient can count on to give them the best possible vision. The difference between the vision

provided by the two eyes can be so great that it leads to an imbalance in binocular alignment (strabismus), with one eye not providing useful information to the brain.

Well, this study describes cases of keratoconus where the "better eye" progresses faster than the contralateral eye. The intervening factor that slowed down the evolution of the "worse eye" was the implantation of the corneal ring. Over time, the keratometry, corneal astigmatism and visual acuity values of the operated eye became better than those of the non-operated eye, which continued to evolve naturally. If it hadn't been for the corneal ring implant surgery, it would have been expected that the eye that was the worst preoperatively would have progressed faster and would have had keratometric measurements that were further away (worse) than those obtained in the contralateral eye.

The mechanism by which the corneal ring can contribute to reducing the rate of progression of keratoconus still needs to be elucidated. Among the hypotheses, we can mention:

1) Mechanical effect of the presence of the rigid structure of the ring in the middle of the cornea (soft structure and even more fragile in keratoconus). In this way, the ring acts as a "skeleton" implanted in the middle of the stroma, preventing any change in the morphology of the cornea. If the forces trying to bend the cornea are too powerful, the ring can even break in half (13).

2) Reduction of corneal inflammatory/allergic processes with a reduction in ocular pruritus. Patients often report that their eyes no longer itch so much after ring surgery. The rearrangement of forces that occurs with the implantation of the ring can reduce the buckling tension in certain meridians. This tension in the lamellae may be important in the pathophysiology of tissue inflammatory processes and its reduction may ultimately lead to a reduction in ocular allergy and pruritus. The enzymes from the inflammatory process can contribute to the deterioration of the corneal framework by affecting collagen fibers.

3) Reduction in ocular itching due to the fear that patients have of affecting the surgery and even dislocating the ring.

One topic worth discussing is the ability of each segment model to help slow down the progression of keratoconus. Common sense makes us think that a more robust segment of 320 degrees of arc should have greater power to stabilize the cornea than a short fragment of 90 degrees of arc. Long arc segments (300 degrees arc or greater) are able to form a rigid "new limbus", limiting the area where keratometric changes can occur due to keratoconus. If this premise is true, perhaps long arch segments should be indicated more often, even if they are not the models that can provide the best visual result. In other words, in the long term, ensuring the stabilization of the disease may be more important than improving visual acuity (especially in very young patients).

However, it is worth noting that the ability of ICRS to reduce the rate of progression of keratoconus is still the subject of debate in medical circles. Many colleagues believe that the evidence that exists today to support the idea of the ring's power to prevent the disease from progressing is still weak. More robust studies are still needed. Crosslinking has therefore emerged as an alternative that is more widely accepted by the scientific community as a procedure indicated to prevent the progression of the disease.

Conclusion

The data presented in this study suggest that the intra-stromal ring implant (ICRS), in addition to its well-known function in regularizing the cornea and improving visual acuity in patients with keratoconus, may also play a role in slowing down the progression of keratoconus. The longitudinal analysis of the cases showed topographic and refractional stability in the treated eyes, in contrast to the progression observed in the non-operated eyes. These findings reinforce the potential of the ICRS as a therapeutic tool in selected subgroups. However, future studies with larger samples, prolonged follow-up and rigorous methodological control are needed to validate these indications and elucidate the mechanisms involved.

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