Intracorneal Rings for Keratoconus Treatment

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Treatment scheme for keratoconus

- Spectacles
- Soft contact lenses
- Rigid contact lenses
- Collagen cross-linking with riboflavin
- Intra corneal ring segments (ICRS)
- Alternative methods
  - Thermal keratoplasty,
  - Epikeratoplasty,
  - Photorefractive keratectomy,
  - Laser in situ keratomileusis
  - Deep lamellar keratoplasty
- Penetran keratoplasty

Possible Penetran Keratoplasty Complications

- **allograft rejection (19,5 %),**
- **infection,**
- **significant endothelial cell loss,**
- **irregular astigmatism,**
- **side effects caused by long-term use of topical corticosteroids (eg, secondary glaucoma, cataract),**
- **recurrence of keratoconus.**

What is intracorneal rings?

- Intra-corneal rings are devices which shorten the arc length of the anterior corneal surface and therefore flatten the central cornea by spacing in the corneal stroma.
- They were first developed for myopia correction.
- But they have become a popular device with their therapeutic usage especially in keratoconus
- The major objective of this procedure is to reshape the keratoconic cornea, lifting the inferior ectasia and flattening the soft keratoconic cornea, to decrease the asymmetric astigmatism induced by keratoconus without removing any corneal tissue or touching the central cornea.
- The goal of using these devices to improve visual acuity and quality to satisfactory levels by regaining contact lens tolerence and to delay or eliminate the need for cornal graft.

How to work?

- Barraquer Thickness Law;
- When material is added to the periphery of the cornea or an equal amount of material is removed from the central area, a flattening effect is achieved.
- In contrast, when material is added to the center or removed from the corneal periphery, the surface curvature is steepened.
- The corrective result varies in direct proportion to the thickness of the implant and in inverse proportion to its diameter.
- The thicker and the smaller the device, the higher the corrective result.

•Barraquer JI. *Oftalmologicas* 1949; 2:10–30
•Barraquer JI. *Int Ophthalmol Clin* 1966; 6(1):53–78

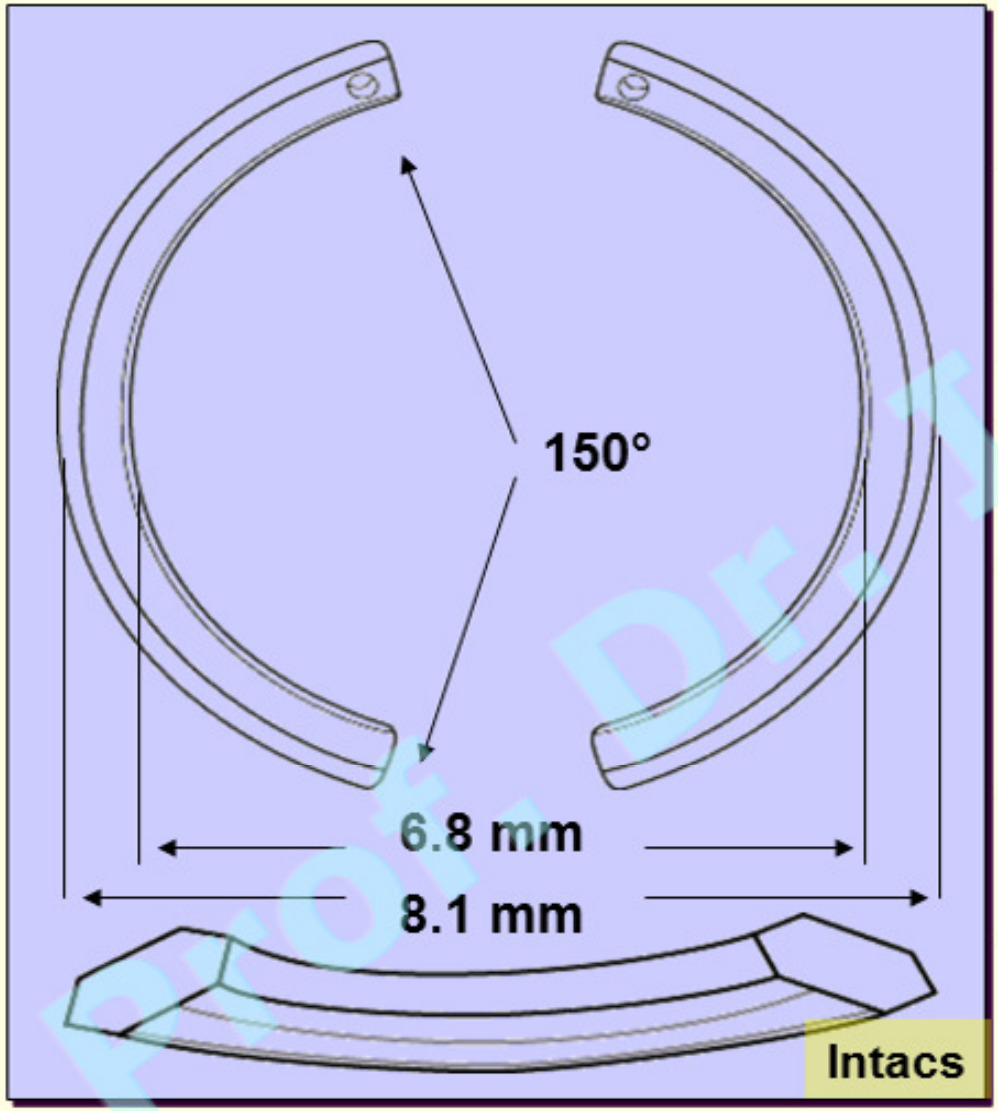
Brief History

- 1989: The concept of intracorneal ring segments (ICRS) to alter corneal curvature was first described by Fleming et al,
- 1990: Intacs were designed and approved by the U.S. FDA for the correction of low myopia (1.00 to 3.00 D).
- 1997: Colin performed the first implantation of Intacs for keratoconus
- 2004:Intacs were approved by the U.S. FDA for the keratoconus treatment.

Variables in the procedure

- Intra corneal ring models
  - Intacs
  - Ferrara rings
  - Bisantis rings
- Chanel dissection techniques
  - Manually
  - Femtosecond laser
- Incision places
  - Temporal
  - Superior
  - On steepest axis
  - Customised or other
- Placement locations
  - Horizontally
  - Vertically
- Segment numbers, thickness and symmetry
  - Single /inferior
  - Double / superior-inferior
    - Symmetric (same thickness)
    - Asymmetric (thinner superior, thicker inferior)
  - Three

Intra corneal ring segment models



Types (PMMA)	Intacs	Intacs SK	Ferrara rings	Bisantis rings
Arc length (degrees)	150		160	80 (4 segments)
Cross-section	Hexagonal	Oval	Triangular	Oval
Thickness (mm)	0.25 – 0.45 (0.05 incr.)	0,40 – 0,45	0.20–0.35 (0.05 incr.)	0.15
Radius (mm) Inner Outer	6.77 8.10	6.00	4.40 5.40 5.60 6.40	
Diameter optical zone (mm)	7.0		5.0 / 6.0	

- **Intacs;** *Addition Technology, Fremont, CA*
- **Ferrara rings;** *Ferrara Ophthalmics, Belo Horizonte, Brazil, / Mediphacos Inc.*
- **Bisantis segments;** *Opticon 2000 SpA and Soleko SpA*

ICRS Indications

- Refractive
  - Low myopia,
- Therapeutic
  - Keratoconus and other keratectatic disorders, (pellucid marginal corneal degeneration)
  - Post-LASIK ectasia,

Keratoconus patients with

- Clear central corneas,
- Contact lens intolerance,
- Corneal thickness of 400 µm or more at the location where Intacs segments are to be placed
- Inferior bulging with K readings are less than 56 D. and the refractive error is less than 5 D. of myopia

are the most suitable patients for this treatment.

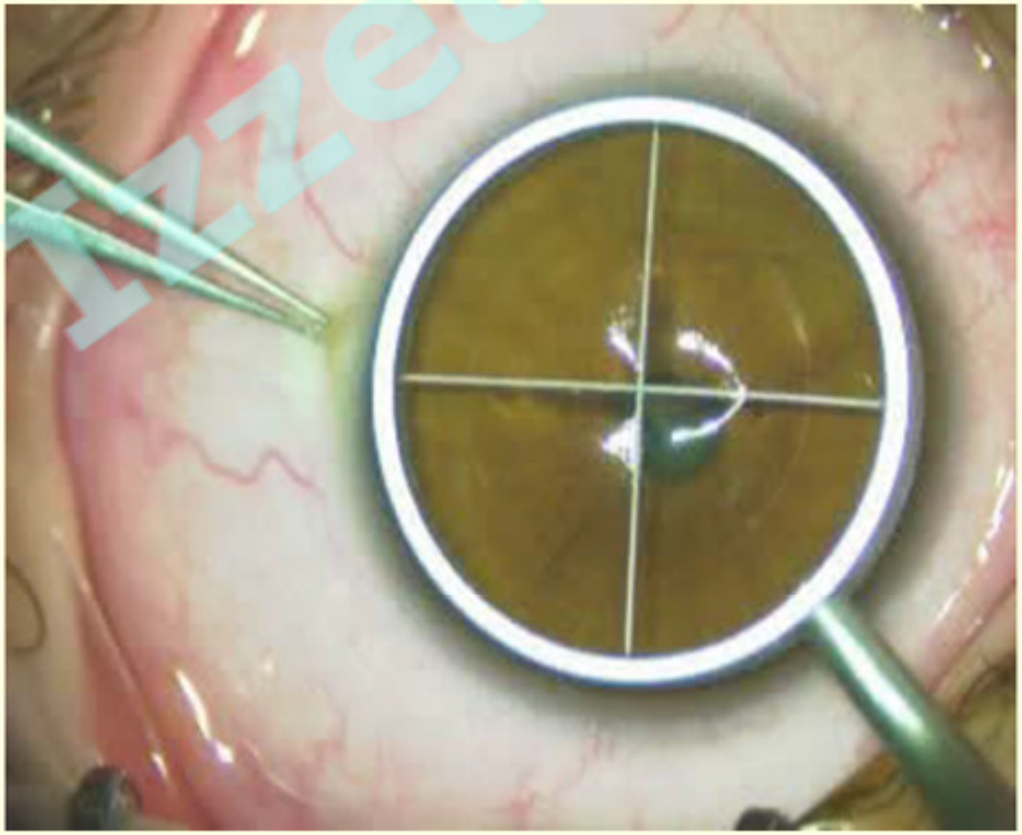
Bad candidates for ICRS

- BCVA 20/100 or worse
- Corneal scarring
- K readings greater than 57 D.
- Very young patients

Surgical technique / Channel Dissection Methods

Mechanical

- Pupil center identification
- Incision mark
- A calibrated diamond knife is used to create a temporal radial 1.0 mm incision approximately 70% of the cornea thickness on the flattest axis of the topographic map
- The intrastromal tunnels are initiated using a pocketing hook
- The KV 2000 vacuum system (Addition Technologies) is started on
- The counterclockwise and clockwise dissectors (corneal separators) are used to create the intrastromal tunnels in the desired directions
- the Intacs segments are implanted in the tunnels.

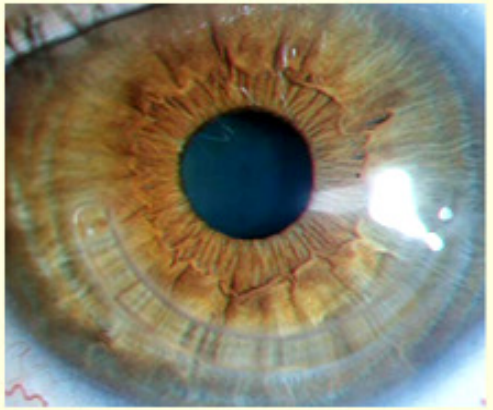


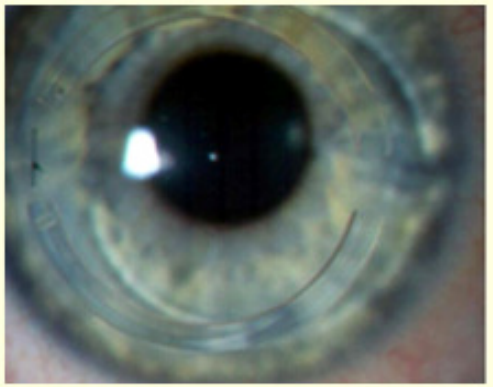
Advantages of preparation ring tunnels with femtosecond laser

- The femtosecond laser (FEMTEC)
- Infrared laser
- Wavelenght: 1052 nm.
- Ultrashort laser pulses diamater: 0,001 mm.
- A femtsecond is equivalent to a trillion seconds.
- With femtosecond laser tissue can be cut very precisely and nearly without any development of heat.
- Every laser pulse produces a micro gas bubble that seperates the tissue. (photodistruption)
- Thus microplasma is created, which evaporates corneal tissue of about 1 micrometer in diameter.
- Enables intrastromal cuts from inner parts to outer ones
- Different, depths, widths and diamaters, defined in advance, can be created resulting in different shapes of ring tunnels
- Centric as well as eccentric laser cuts can be performed
- Because of the patented patient interface, the cornea remains nearly in normal shape
- Corneal stress is minimal, because only moderate pressure is exerted on the eye during surgery
- Risk of infection is significantly reduced.

Implantation

- **Symmetric** / same thickness for both superior and inferior segments
  - Colin J, Cochener B, Savary G, et al. Ophthalmology 2001; 108:1409–1414
  - Colin J, Malet F. J Cataract Refract Surg 2007; 33:69–74
- **Asymmetric** / thinner for superior, thicker for inferior segments
  - Boxer Wachler BS, Chandra NS, Chou B, et al. Intacs Ophthalmology 2003; 110:1031–1040; errata, 1475
  - Kanellopoulos AJ, Pe LH, Perry HD, Donnenfeld ED. Cornea 2006; 25:29–33
  - Colin J. J Cataract Refract Surg 2006; 32:747–755
- **Single Segment** / only inferior segment
  - Alio´ JL, Artola A, Hassanein A, J Cataract Refract Surg 2005;31:943–953





Suggested Nomograms

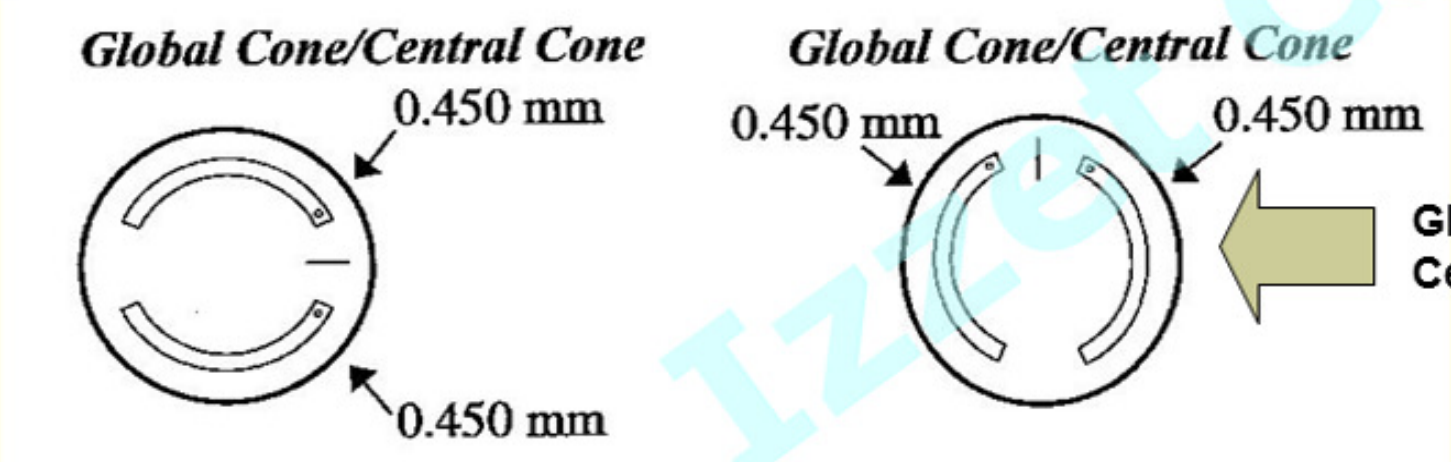
	S.E. < -3,0 D.	S.E. > -3,0 D.
Colin, 2007 Symmetric	0,40 mm	0,45 mm.
Boxer Wachler, 2003 Asymmetric	0,25 mm Sup. 0,30 mm Inf.	0,25 mm Sup. 0,35 mm Inf.

Colin, 2006 Asymmetric	Recommended Thickness (mm)	
Type of Cone	S.E. < -3,0 D.	S.E. > -3,0 D.
Asymmetrical	0.25/0.30	0.25/0.35
Moderately asymmetric	0.35/0.40	0.40/0.45
Highly asymmetric	0.25/0.40	0.25/0.45
Global	0.40/0.40	0.45/0.45
Central	0.40/0.40	0.45/0.45

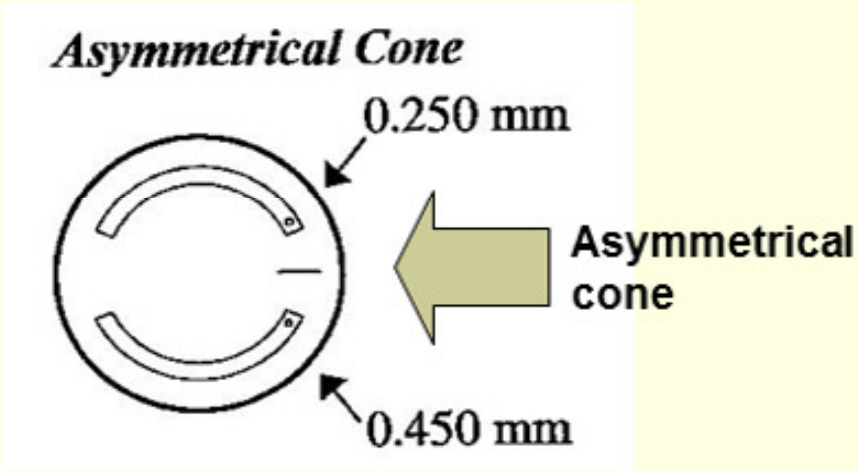
	S.E. < -2,0 D.	S.E. -2,0 - -3,0 D.	S.E. -3,0 - -5,0 D.	S.E. -5,0 - -6,0 D.	S.E. > -6,0 D.
Kanellopoulos, 2006 Asymmetric	0,25 mm Sup. 0,35 mm Inf.	0,25 mm Sup. 0,40 mm Inf.	0,25 mm Sup. 0,45 mm Inf.	0,35 mm Sup. 0,45 mm Inf	0,40 mm Sup. 0,45 mm Inf

	Topographic pattern: didn't cross the 180° meridian	Topographic pattern: cross the 180° meridian
Alio, 2005 Asymmetric, Sigle vs. Double	0,45 mm, inf. single	0,25 / 0,45 mm., sup. / inf. double

Suggested Nomograms



Keratoconus type	Thickness (mm) SE <3 D	Thickness (mm) SE >3 D
Asymmetrical cone	0.25/0.30	0.25/0.35
Moderately	0.35/0.40	0.40/0.45
Highly	0.25/0.40	0.25/0.45
Global / Central cone	0.40/0.40	0.45/0.45



Colin J. *J Cataract Refract Surg* 2006; 32:747-55.

Incision placement

- Temporal
- Superior
- At the steepest axis
- In a way to bisect the thinnest part of the cornea that will physiologically make the cornea normal by thickening the thin area. (Rabinowitz YS. Int Ophthalmol Clin 2006; 46(3):91–103)
- In a study, the incision site was temporal and at the 1 o'clock position superior to the horizontal middle meridian of the cornea. The corresponding center of the rings was also positioned to adjust to the center of the cone; therefore, the center of the virtual circle created by the 2 rings was positioned inferotemporally by 0.5 to 1.5mm toward the center of the cone and not the geometric center of the cornea. (Kanellopoulos AJ, et al. Cornea 2006; 25:29–33)

Results

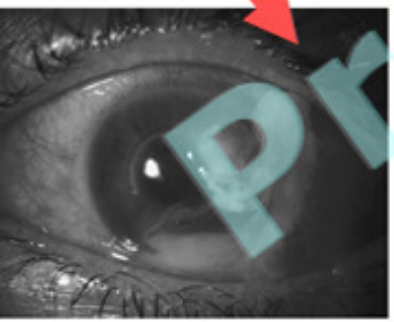
Study	Eyes (n)	Intacs/ Ferrara	Follow up	Incision site	Technique	Visual acuity change	Mean refractive change
Ibrahim TA, 2006	186	Intacs	5 y.	Steep meridian	Sym. or asym. (0,25 to 0,45mm)	UCVA 85.3 % BCVA 87.9 %	K-values improved Pre.op: 52,53 D. Post.op :48,05 D.
Colin J, 2006	57	Intacs	6 mo.	Temporal	Sym. or asym. (0,25 / 0,45mm)	UCVA 78 % BCVA 62 % (2-8 lines)	MRSE 3.1 ± 2.5 D and K-values 4.3 ± 2.8 D improved
Siganos D, 2002	33	Intacs	11,3 mo.	@ ax 90	Sym. (0,45mm)	6% and 12% eyes lost lines of UCVA and BCVA; 25 of 33 gained 1 to 6 lines of BCVA	Change in K-values: 1.94 ± 3.51 D; mean MRSE reduction: 1.82 ± 3.03D
Alio´ JL, 2006	13	Intacs	48 mo.	Temporal	Asym (0.25 / 0.45 mm)	BCVA increased from 20/50 to 20/30 and remained constant at 36 and 48 mo	MRSE improved from 5.40 D to 3.95 D; despite fluctuation in K-values, refraction remained constant at 36 and 48 mo
Alio´ JL, 2006	25	Intacs	6 mo.	@ ax 90	Single/double (0.25 / 0.45 mm)	80% gained 3 lines BCVA	When steep K<55, BCVA C3 lines; when steep K>55, BCVA 1 line; in 3 of the 5 eyes that worsened, only 1 segment was used

Results

Study	Eyes (n)	Intacs/ Ferrara	Follow up	Incision site	Technique	Visual acuity change	Mean refractive change
Colin J, 2007	100	Intacs	2 y.	Temporal	Sym. (0.45 / 0.40 mm)	UCVA: 80.5% BCVA, 68.3% gained lines	Mean MRSE improved from 6.93 D to 4.01 D
Ertan A, 2006	118	Intacs	1 y.	Temporal	Asym. (0.25 / 0.45 mm)	UCVA: 81.3% BCVA, 73.7% gained lines	MRSE improved by more than 2.00 D in 70.3% of eyes
Kwitko S, 2004	51	Ferrara	13 mo.	Steep meridian	Sym. (0.20 / 0.30 mm)	86.4% gained lines of UCVA and BCVA	MRSE decreased from 6.08 D to 4.55 D
Siganos D, 2002	26	Ferrara	6 mo.	Steep meridian	Sym. (0.15 / 0.35 mm)	BCVA improved from 0.37 to 0.60	MRSE decreased from 6.91 D to 1.11 D.
Colin, 2001	10	Intacs	1 y.	Temporal	Asym (0.25 / 0.45 mm)	BCVA improved 2 lines	Cylinder decreased from 4.00 D. to 1.30 D.
Kanellopoulos, 2006	20	Intacs	12 mo.	Temporal, superior to the horizontal meridian	Asym. (0.25 / 0.45 mm)	UCVA improved from20/154 to 20/28 BCVA improved from20/37 to 29/22	Spheric refraction decreased from 3.38 D to 1.15 D
Hellstedt, 2005	50	Intacs	6,3 mo.	Temporal	Asym. (0.25 / 0.45 mm)	BCVA improved from 20/78 to 20/43	Keratometric astigmatic change of 2.90 D.
Boxer-Wachler, 2003	74	Intacs	9 mo.	@ ax 90 (Man. Ref.)	Asym (0.25 / 0.35 mm)	UCVA improved 4 lines	MRSE decreased from 3.89 D to 1.46 D

Complications

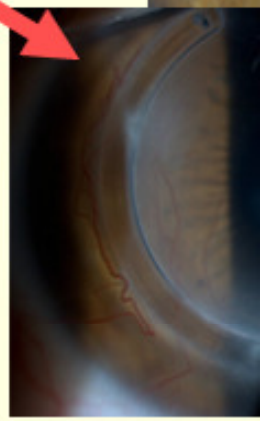
- Epithelial defects at the keratotomy site (0,2 %)
- Anterior and posterior perforations during channel creation (0,2 %),
- Extension of the incision toward the central visual axis or toward the limbus,
- Shallow placement and/or uneven placement of the Intacs segments, (0,2 %), and extrusion
- Migration of one segment toward the wound
- Infectious keratitis with the introduction of the epithelial cells into the channel during channel dissection, (0,2 %)(Ferrara rings)



- Hofling-Lima AL, et al. Corneal infections after implantation of intraestromal corneal ring segments. Cornea. 2004;23: 547–549.
- Galvis V et al. Late Bacterial Keratitis After Intracorneal Ring Segments (Ferrara Ring) Insertion for Keratoconus Cornea 2007;26:1282–1284
- Ruckhofer J, et al. Clinical characteristics of lamellar channel deposits after implantation of Intacs. J Cataract Refract Surg 2000; 26:1473–1479 69.
- Ly LT.et al.Evaluation of intrastromal lipid deposits after Intacs implantation using in vivo confocal microscopy. Eye Contact Lens 2006; 32:211–215

- Asymmetric placement,
- Persisting incisional gaping, decentration, stromal thinning, and corneal stromal edema around the incision and channel from surgical manipulation

- Sterile keratitis
- Chronic pain
- Intrastromal deposits (68%)
- Central corneal sensational decrease (5,5%)
- Induced astigmatism (3,7 %)
- Neovascularization (1,2 %)
- Iritis / uveitis (0,2%)
- Under/ over correction
- Glare/ Diplopia



- Kanellopoulos et al. report a 35% postoperative complication rate. Complications included segment movement and exposure and corneal melting after mechanical tunnel dissection. This high incidence was not reported in other studies. (Kanellopoulos AJ, et al. Cornea 2006; 25:29–33)

After ICRS

- Contact lenses
  - Soft
  - Rigid
- Photorefractive keratectomy
- Phakic IOLs
- Collagen cross linking with riboflavin
- Conductive keratoplasty
- Intacs adjustment surgery

- Ucakhan OO, Kanpolat A, Ozdemir O . Contact lens fitting for keratoconus after Intacs placement. Eye Contact Lens 2006; 32:75–77
- Budo C, Bartels MC, van Rij G. Implantation of Artisan toric phakic intraocular lenses for the correction of astigmatism and spherical errors in patients with keratoconus. J Refract Surg 2005; 21:218–222
- Colin J, Velou S. Implantation of Intacs and a refractive intraocular lens to correct keratoconus. J Cataract Refract Surg 2003; 29:832–834
- Kamburoglu G, Ertan A, Bahadır M. Implantation of Artisan toric phakic intraocular lens following Intacs in a patient with keratoconus. J Cataract Refract Surg 2007; 33:528–530.
- Alio´ JL, Shabayek MH, Artola A. Intracorneal ring segments for keratoconus correction: long-term follow-up. J Cataract Refract Surg 2006; 32:978–985
- Chan CCK, Sharma M, Wachler BS. Effect of inferior-segment Intacs with and without C3-R on keratoconus. J Cataract Refract Surg 2007; 33:75–80

Comment

- Intacs or Ferrara rings are successful devices to improve vision for over 70% keratoconus patients.
- These patients mostly regain their contact lens tolerence and able to see better than they saw before.
- This procedure seems to delay or eliminate the need for corneal graft.
- Intra corneal rings can be combined with some other procedures to make patients independent of contact lenses or glasses such as phakic IOLs and corneal surface excimer laser treatments.
- And collagen cross-linking with riboflavin is another promising procedure to combine with intra corneal rings that can also be effective on the original disease by reinforcing the corneal tissue.

- Thank you very much for your attention.