



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" – Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

INTACS vs Cross-Linking for Keratoconus

Tomaso Caporossi MD

Policlinico "A. Gemelli"-Roma

Istituto di Oculistica

Siena X-Linking: 1° Corso Nazionale Abilitante



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" – Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

Keratoconus

- Non inflammatory progressive corneal dystrophy. Collagen rigidity is reduced (3 aria structure modifications). Corneal shape is modified with progressive thinning. The infero-temporally dislocation and local curvature ray reduction produce asymmetric and hyper-refractive corneal surface. The last parameter is partially compensated by the thinning. Overmentioned shape modifications produces several optical effects.



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" - Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

Keratoconic induced optical effects

• APEX TILTING → PRISMATIC EFFECT



COMA



SECONDARY-ASTIGMATISM



• CORNEAL RAY DECREASING



INCREASED DIOPTRIC POWER
OF THE ANTERIOR SURFACE



MIOPIC SHIFT

• CORNEAL THINNING



REDUCED CURVATURE
EFFECT



HYPEROPIC SHIFT



• DECREASED POSTERIOR
CURVATURE RAY



REDUCED CORNEAL POWER



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" – Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

The ideal conservative procedure for keratoconus

- ✓ Delay or stop corneal degeneration
- ✓ Improve KC related corneal asymmetry
- ✓ Reduce secondary refractive error (pseudoastigmatism)
- ✓ Low complications rate
- ✓ Metabolic error compensation (etiopathogenetic effect)
- ✓ Increase LAC tolerance
- ✓ Possibility of alternative techniques in the future (LK, PK)



Low-Invasive Techniques

- INTACS-ICRS, Ferrara Rings
- PRK, PTK, LASIK
- Thermo-keratoplasty, Conductive KP (CK)
- Manual and automatized ARK
- Cross-Linking Riboflavin-UVA (CCL –C3R)



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" - Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

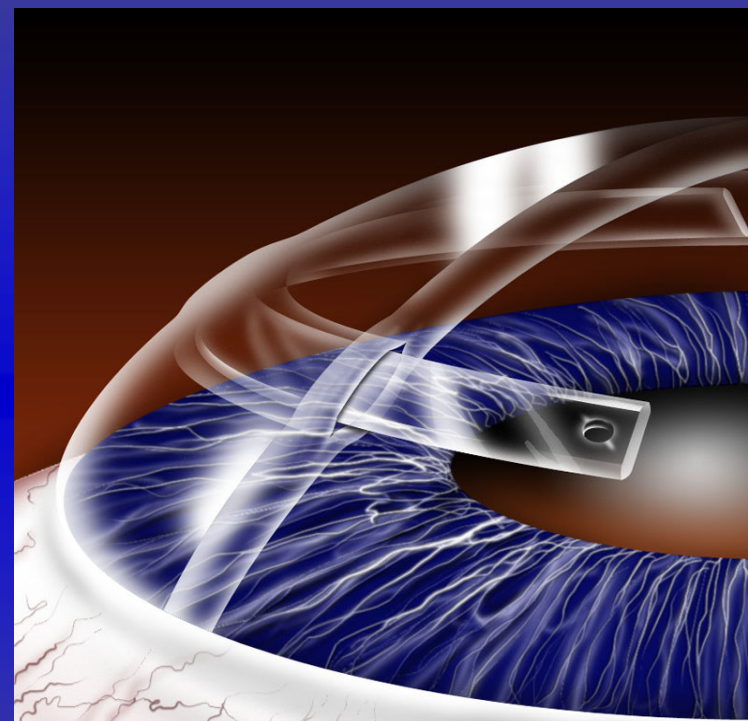
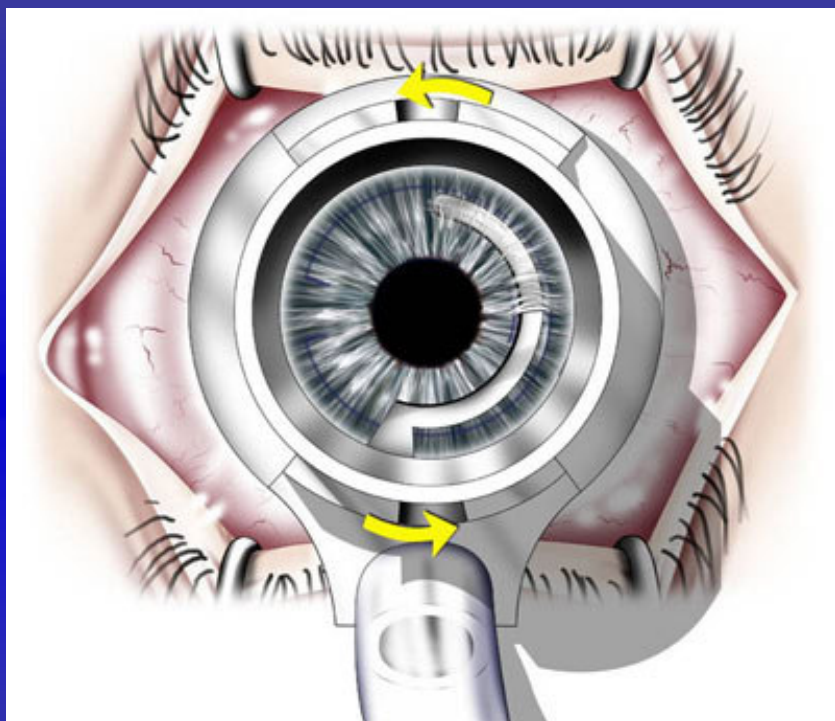
INTACS

- FDA approval for myopia: 1997
- First Keratoconus applications: 1999
- 2004 FDA approval for the reduction of myopia and irregular astigmatism associated with keratoconus
- Additive technique
- Refractive technique
- Target: astigmatism reduction
 - Improving corneal shape ?
 - Delaying keratoconus evolution ?
- Intacs (Addition technology)
- Ferrara rings: 5 thicks (150-350 μ m) implantable 5mm
- Intacs: 11 thicks (0.25-0.45 mm) implantable 7mm



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" – Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

INTACS – ICRS: procedure



- **Topic anestesia**
- **One or two (PMMA) segments insertion towards intra-stromal corneal tunnels**
- **Manual or Fotodisruptive (IntraLASE) Tunnel Dissection**
- **Insertion depth: 70 %**
- **Implant side: Steepest axis, Elevative axis, Coma axis?**



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" – Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

INTACS: indications

Keratoconus: stage I – II – III + + - -

“Analysis of results related to good and bad outcomes of
Intacs

Implantation for Keratoconus correction” J. L. Aliò JCRS
May-2006

Pellucid Marginal Degeneration: + + + +

“Management of Keratoconus With Intacs” S. Siganos AJO 2003

“Intracorneal ring segment for Keratoconus correction: long-term follow-up” J. L. Aliò JCRS 2006

“European clinical evaluation: Use of Intacs for the treatment of keratoconus” J. Colins JCRS 2006

“Intacs for the correction of Keratoconus: Two-year follow-up” J. Colins JCRS 2007



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" – Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

INTACS complications

EARLY

- Chemosys and sub-conjunctival bleeding
- Epitelial plugs at the incision site (15,2% A. Ertan)
- Inclusions cysts
- Persistent epithelial defect on the implanted ring surface
- Corneal oedema

LATE

- Tunnel haze and deposits (30.7% J. Aliò)(8,5% A. Ertan)
- Infections
- Induced myopic and astigmatic shift with axis rotation (implatation site!-Decentration)
- Reduced corneal sensitivity
- Neovascularization and corneal pannus (15.3% regressed J. Aliò)
- Corneal melting
- Migration – Extrusion (Advanced Keratoconus grade IV?) 26,9% J. Aliò

7 eyes Ferrara ICRS for Keratoconus

1 eye INTACS for low Myopia

“Corneal Infection After Implantation of Intracorneal Ring Segment” Hofling-Lima Cornea August-2004



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" – Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

Cross-linking corneale Riboflavina-UVA

Indications:

- Keratoconus stage 1, 2 with clinical-instrumental progression (f.u. 6 months)
- Corneal Thickness > 400 micron (orbscan, pentacam, visante)TM
- Thinnest point (Orbscan) > 380 micron
- Age > 14 anni

Limits:

- Dangerous for endothelium if thickness < 400 micron
- Presence of central corneal scarring
- Few treated cases
- *follow up*

Complications:

- Transient corneal oedema in over 10% patients
- *Persistent Haze* in stage III with Vogt striae or reticular *pattern of the dark micro-striae* in Confocal Microscopic Examination



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" – Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

Cross-linking advantages

- Easy procedure
- Uninvasive technique
- Pathogenetic targets
- Refractive outcomes comparable with INTACS
- Absence of long-term complications (Haze < 1%)
- INTACS-CCL combination possible
- Indication for corneal melting and post lasik ectasia
- Unexpensive procedure



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" - Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

Comparative refractive outcomes of Intacs vs CCL - UCVA / BSCVA

Authors	UCVA (pre-op.)	UCVA (post-op.)	BSCVA (pre-op.)	BSCVA (post-op.)
Colin (100 eyes) f-up: 24 m	1/10	3,8/10	4/10	5,8/10
	Mean	Mean	Mean	Mean
Siganos (33 eyes) f-up: 11 m	1,1/10	3,4/10	4,2/10	6,05/10
Boxer W. (74 eyes) f-up 12 m		Gain		Gain
		+2,3/10		+1,65/10
Aliò (13 eyes) f-up: 36 m		+ 230%		+38%
Wollensak (23 eyes) f-up: 36 m	Mean 1.7	Mean 3.9	Mean 4.05	Mean 5.95
		Gain +2,2		Gain +1.9
Caporossi (30 eyes) f-up: 18 m		+164%		+46%

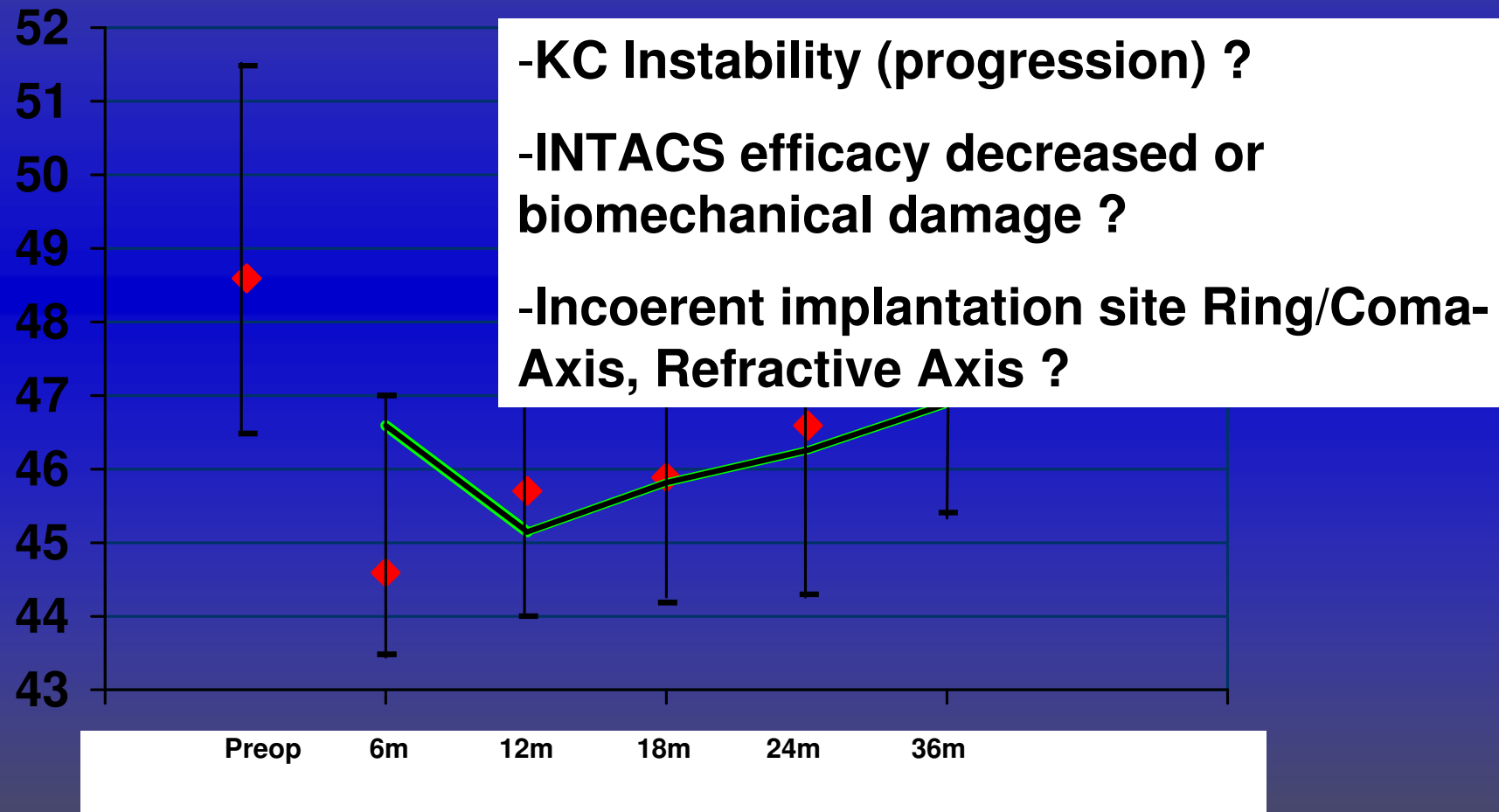


UNIVERSITA' CATTOLICA DEL SACRO CUORE

Policlinico "A.Gemelli" - Roma

Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

INTACS: Konus instability, decreased efficacy, or....?



Aliò J. Et al.: Intracorneal ring segments for Keratoconus correction: long-term follow-up. JCRS: 2006, June (13 casi)

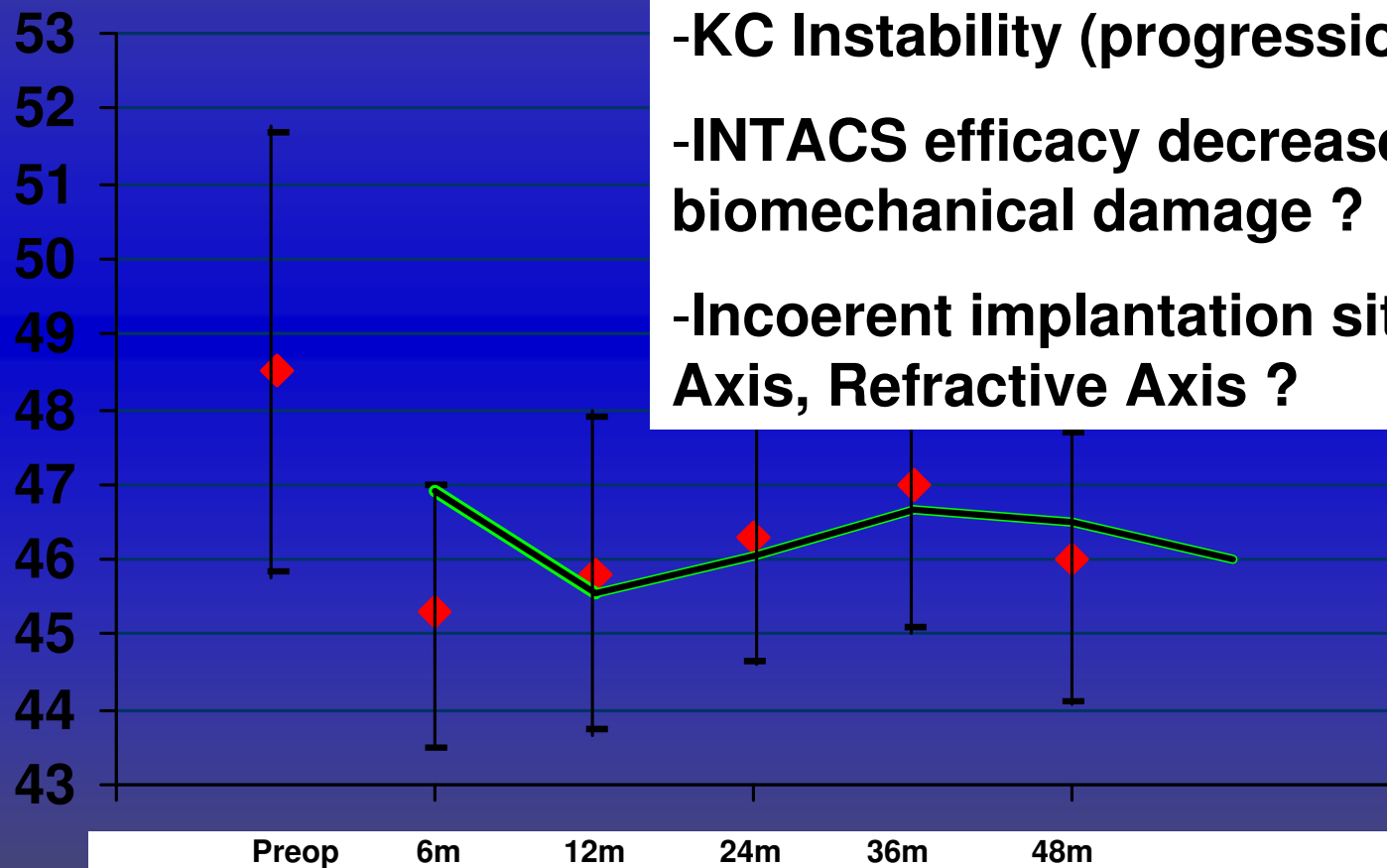


UNIVERSITA' CATTOLICA DEL SACRO CUORE

Policlinico "A.Gemelli" - Roma

Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

INTACS: Konus instability, decreased efficacy, or....?



-KC Instability (progression) ?

-INTACS efficacy decreased or biomechanical damage ?

-Incoherent implantation site Ring/Coma-Axis, Refractive Axis ?

Aliò J. Et al.: Intracorneal ring segments for Keratoconus correction: long-term follow-up. JCRS: 2006, June (6 casi)



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" - Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

Single-Segment VS Double-Segment

Segment Size	N° treated eyes	percentage
0.25	2	5.40
0.30	6	16.20
0.35	9	24.30
0.25/0.30	7	18.9
0.25/0.35	11	29.7
0.30/0.35	1	2.70
0.35/0.35	1	2.70
total	37	100

“comparison of Single-Segment and double-Segment Intacs for Keratoconus and Post-Lasik Ectasia” M. Sharma Am. J. O. May-2006



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" – Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

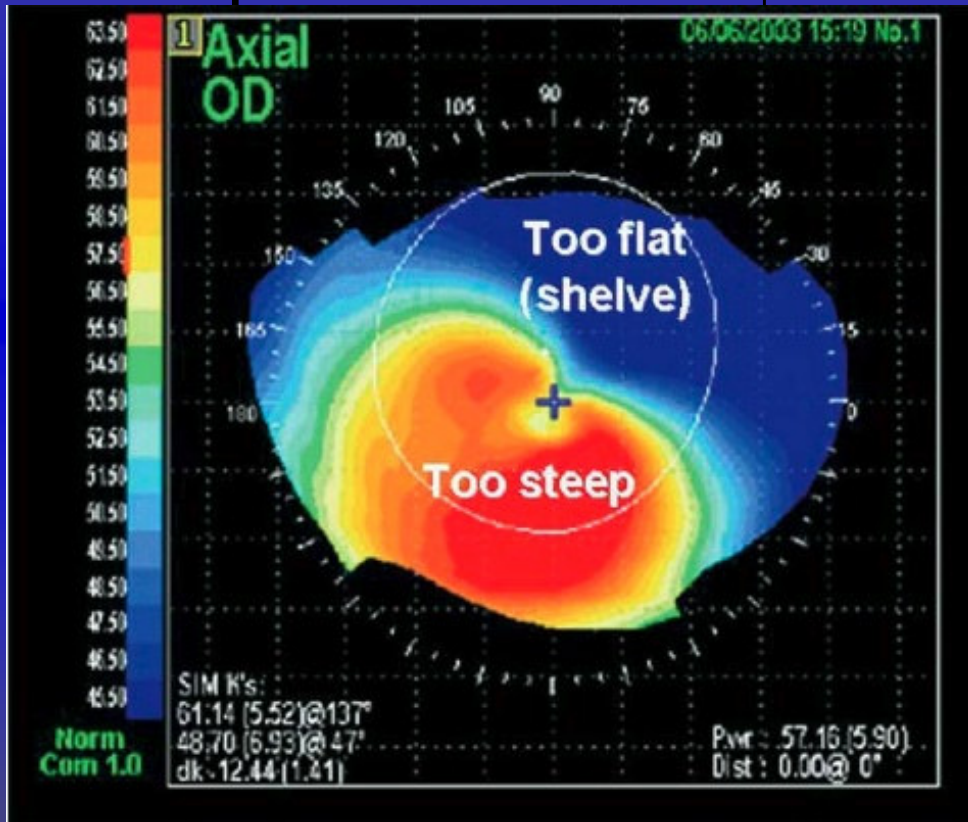
Single-Segment VS Double-Segment

	Preoperative-postoperative Change	
Variable	Single-Segment	Double-Segment
UCVA	9 lines	2.5 lines
BSCVA	2.5 lines	< 1 lines



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" - Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

Single-Segment VS Double-Segment

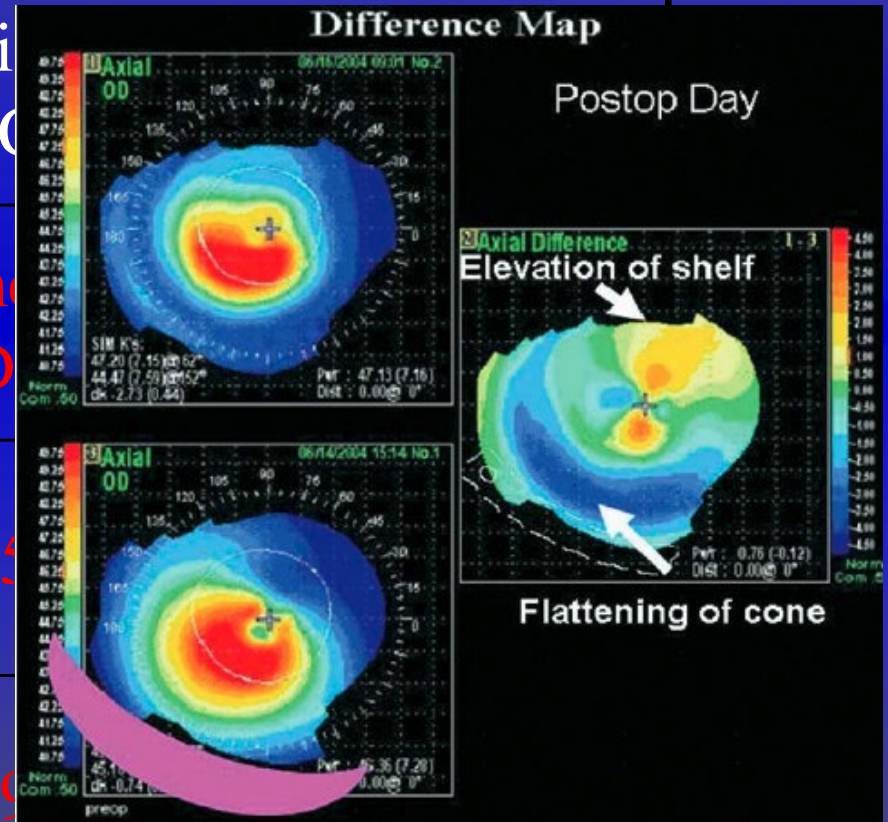


operati

e-segme
a + SD
VS

2 ± 1.5

± 7.4





UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" - Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

Cross-Linking: Konus stability or mid term efficacy?

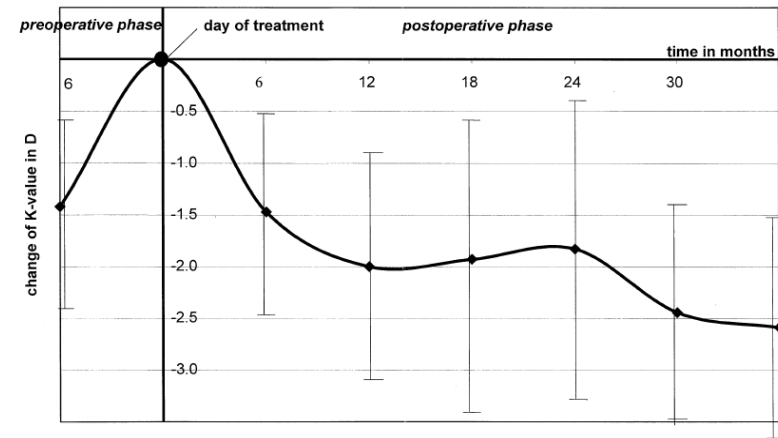
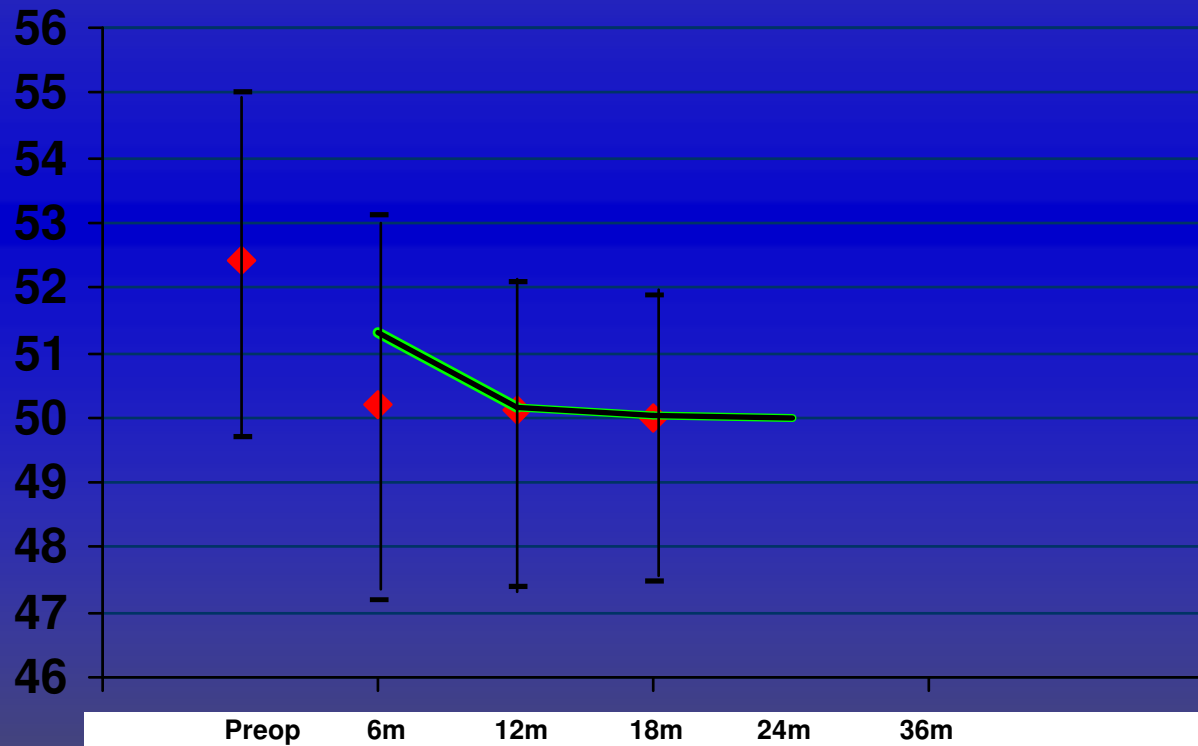


FIGURE 4. (Top) Column diagram demonstrating pretreatment progression of maximum K value in the half year before treatment and posttreatment regression as measured at the latest follow-up examination for each patient. y axis: difference in maximum K value in diopters; x axis: patient number; shaded bars = preoperative change of K value; solid bars = postoperative change of K value. (Bottom) Biphasic curve illustrating the mean change over time of the maximum K value relative to the K value on the day of treatment with mean preoperative progression by 1.4 diopters and postoperative regression by 2.0 diopters (x axis: time in months; y axis: change of maximum K value in D).

Riboflavin/Ultraviolet-A-induced Collagen Crosslinking for the Treatment of Keratoconus

GREGOR WOLLENSAK, MD, EBERHARD SPOERL, PhD, AND THEO SEILER, PhD, MD

A.Caporossi e Coll.: JCRS 2006 aggiornato



"Intacs insertion with femtosecond laser for the management of keratoconus one-year result" Aylin Ertan JCRS Dec-2006

Comparative retractive outcomes of Intacs vs Cross-linking - Astigmatism

Autors	Astigmatism (pre-op)	Astigmatism (post-op)
Colin 100 eyes F-up: 24 m	4.62 D SD: 2.80 D	3.31 D SD: 1.83 D
Siganos 33 eyes f-up: 12 m	3,3 D SD: 2,10 D	3,06 D SD: 2,14 D
Caporossi 30 eyes f-up: 18 m	4,5 D (- 1,5 - 6 D)	3,9 D (- 1 -5,50 D)
Aylin Ertan 118 eyes F-up: 12 m	3,90 D SD: 2.11 D	2.20 D SD: 1.50 D



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" - Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

Comparative refractive outcomes of Intacs vs Cross-linking - Snellen lines

Authors	Snellen lines (UCVA)	Snellen lines (BSCVA)
Colin 100 eyes F-up: 24 m	+ 2.8 lines	+ 1.8 lines
Siganos 33 eyes f-up: 12 m	+ 2,5 lines	+ 1,7 lines
Caporossi 30 eyes f-up: 18 m	+ 2,4 lines	+ 1,9 lines
Aylin Ertan 118 eyes F-up: 12 m	+ 2,0 lines	+ 1,8 lines



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" – Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

Conclusions

- CCL is a really low-invasive corneal procedure
- INTACS is a more invasive procedure for cornea
- CCL and INTACS outcomes at 12 months are very similar and comparable!
- CCL has lower complication rate!
- Biomechanically INTACS reversibility is still a open question
- CCL can be used to stabilize INTACS refractive effects
- CCL could be adjuvant therapy in several corneal diseases: melting, post-lasik ectasia, before or after refractive surgery



UNIVERSITA' CATTOLICA DEL SACRO CUORE
Policlinico "A.Gemelli" - Roma
Istituto di Oculistica: direttore Prof. Emilio Balestrazzi

The ideal conservative procedure for keratoconus

- ✓ Delay or stop corneal degeneration
- ✓ Improve KC related corneal asymmetry
- ✓ Reduce secondary refractive error (Irregular astigmatism, Sphere)
- ✓ Low complications rate
- ✓ Metabolic error compensation (etiopathogenetic effect)
- ✓ Increase LAC tolerance
- ✓ Possibility of alternative techniques in the future (LK, PK)

CCL	Intacs
+++	+/-
++	++
++	++
++	-
++	-
+	-
+++	+