

Addition Technology Inc. *Optometric Education Series*

Intacs® Corneal Implants For Keratoconus

Presented by:
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Patti Fries, OD



LaserVision Correction Omaha
Omaha, NE

- **Brief Introduction**
- **Indications**
- **Treatment Continuum**
- **Current Surgical Options**
- **Results**
- **The Procedure**
- **Post-Operative Management**
- **Conclusion**



Intacs®
CORNEAL IMPLANTS

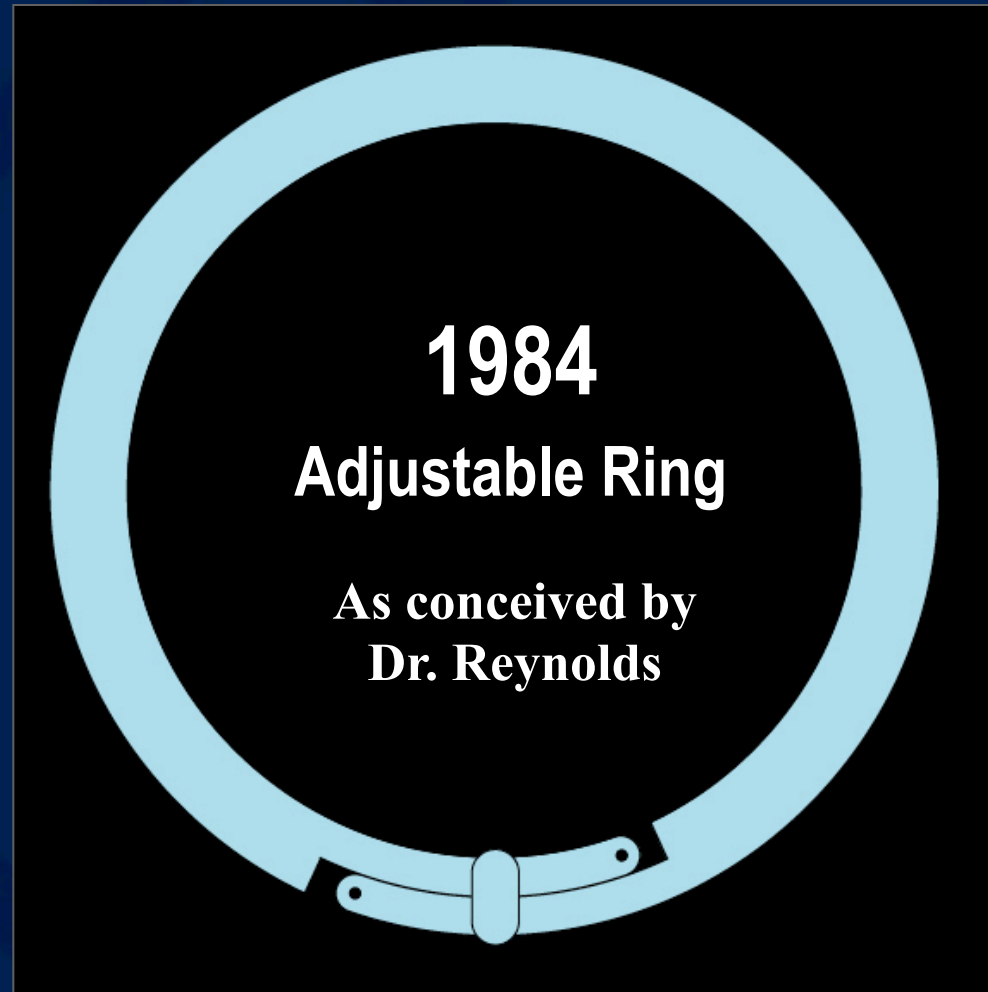
An Introduction



Gene Reynolds, O.D.

1921 - 1994

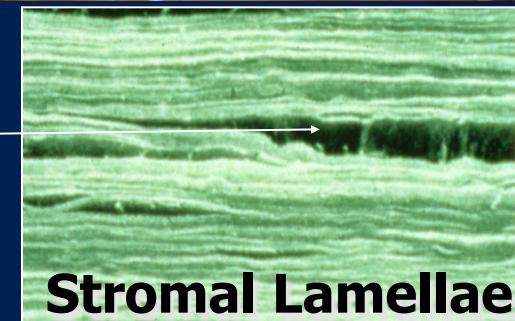
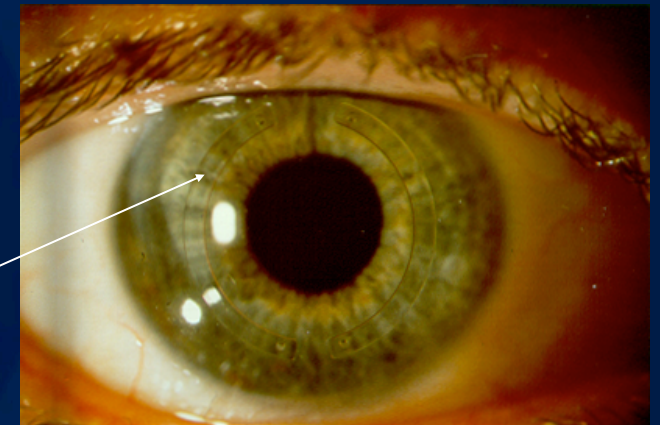
- Oklahoma optometrist first conceptualized the idea in 1978
- One of the early medical champions of contact lenses in the U.S.
- Developed CorneaScope in late 1960s - led to today's topography



Key Points In Intacs History

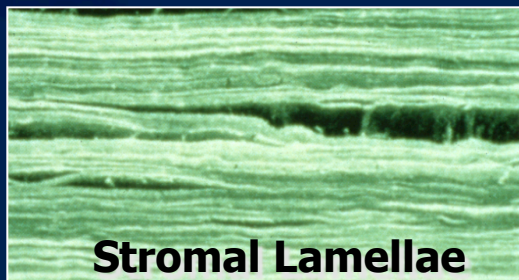
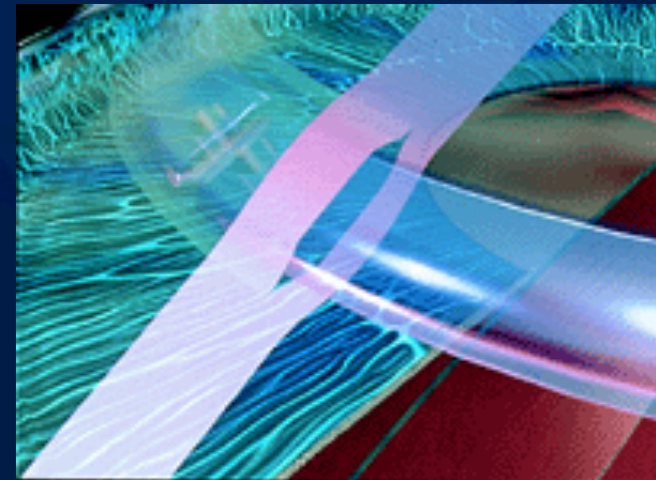
- 1978 – Intacs Conceived by A.E. Reynolds, O.D.
- 1985 – First Pre-Clinical Studies
- 1991 thru 1997 Myopia Phase I-III Clinical Trials, CE Mark Granted
- 1999 – Trade Name Intacs Adopted – FDA Approval Granted
- 2001 – Addition Technology Acquires KeraVision's Assets
- 2003 – Intacs Receives European Approval for Keratoconus
FDA Humanitarian Use Device Designation for Keratoconus
- 2004 – Intacs Receives U.S. FDA Approval to Treat Keratoconus
- 2007 – Over 100 Peer Reviewed Articles have been Written

- 150° Arcs PMMA
- Precision Lathe-Cut to $\pm 0.01\text{mm}$
- Hexagonal-Shaped Section of a Cone
- Inner Diameter = 6.8 mm
- Outer Diameter = 8.1 mm 2 Positioning Holes for Manipulation
- Intacs placement:
 - In peripheral cornea
 - Between stromal layers

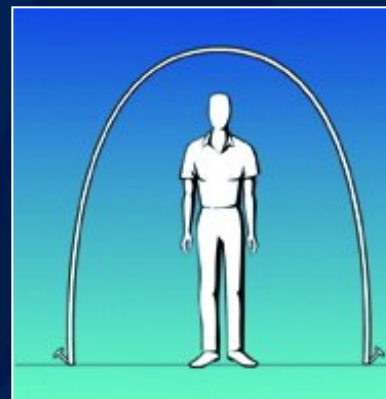


Stromal Lamellae

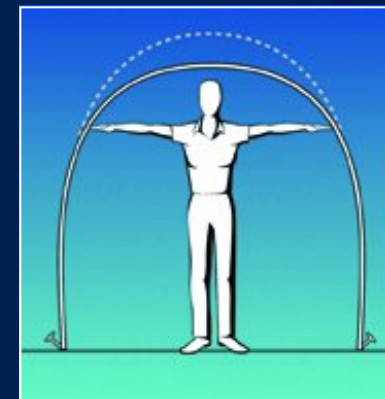
- Inserts Placed at least 70% Corneal Depth in the Peripheral Cornea
- Inserts Separate Corneal Lamellae
- Results in a Shortened Corneal Arc Length
- The Central Cornea Flattens
- Thicker Inserts Increase Flattening



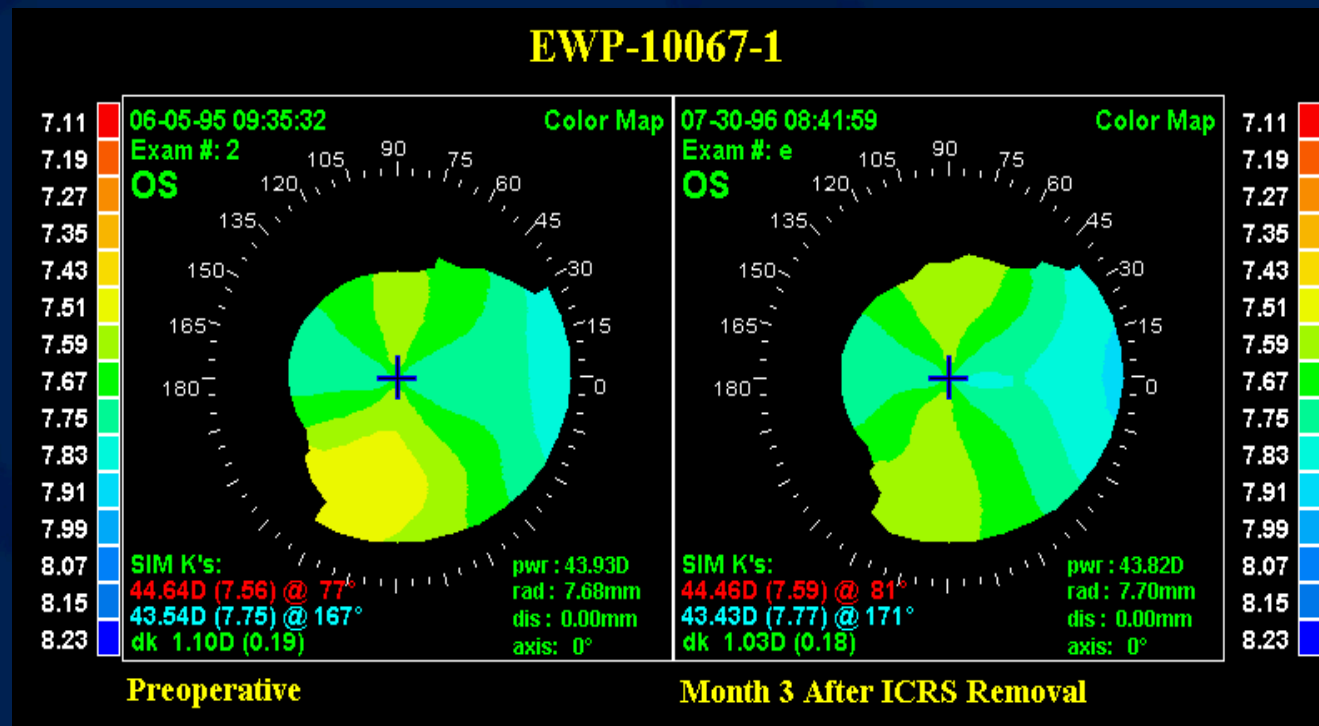
Normal Cornea



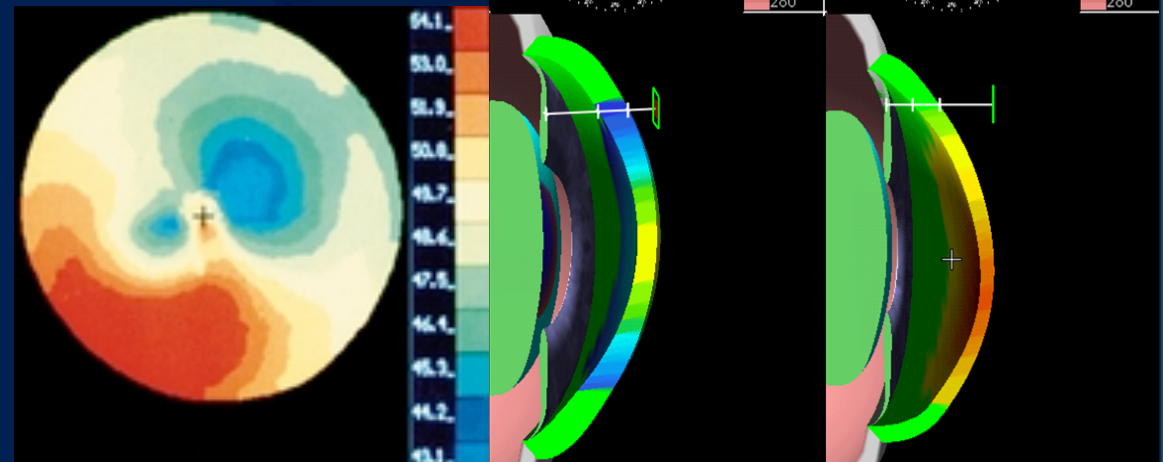
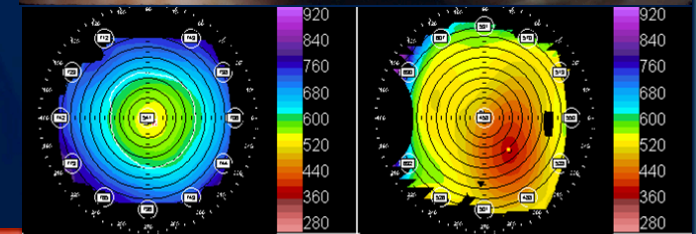
Intacs



- Maintains Original Corneal Prolate Morphology
- Additive
 - Removable/Replaceable
- Large, Clear Central Optical Zone

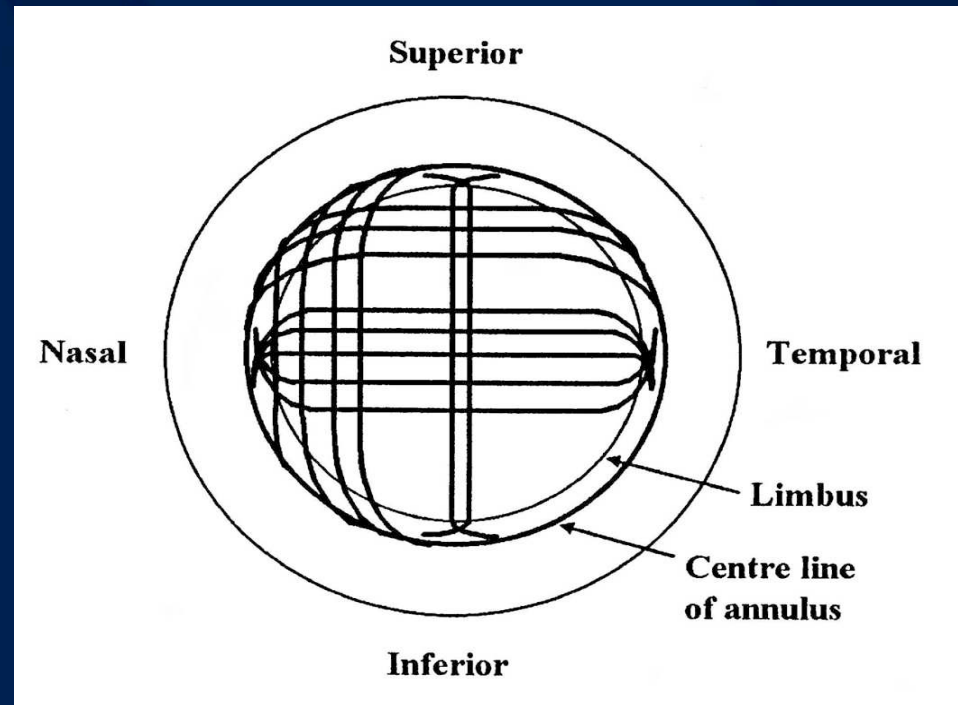


- Non-Inflammatory Ectasia
 - Stromal Thinning
 - Disruption of Bowman's Membrane
- Corneal Ectasia
 - Myopia
 - Irregular Astigmatism
- Optical Correction
 - Spectacles – early
 - Contact Lenses – early
- Demographics
 - Vary – 1 in 2000
- Obscure Etiology
 - Heredity
 - Environmental



Why Does the Cornea Bulge in KC?

- Corneal tissue is abnormal
 - Too elastic?
 - Abnormal cross-linking of collagen?
- Loss of structural integrity of Bowman's Layer?
- Keratocyte apoptosis
 - Trauma (Eye rubbing)
- Corneal tissue bulges because it's too thin?





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Indications

Keratoconus:

- Intacs are Intended for the Reduction or Elimination of Myopia and Astigmatism in Patients with Keratoconus who are No Longer able to Achieve Adequate Vision with Contact Lenses or Spectacles
- The Goal is to Restore Functional Vision Potentially Defer PKP
- Subset of Keratoconus Patients to be Treated who have Experienced a Progressive Deterioration in their Vision, such that they can No Longer Achieve Adequate Functional Vision on a Daily Basis with their Contact Lenses or Spectacles;
 - Who are 21 Years of Age or Older
 - Who have Clear Central Corneas
 - Who have a Corneal Thickness of 450 Microns or Greater at the Proposed Incision Site
 - Who have PKP as Remaining Option to Improve Functional Vision

Myopia:

- **Since FDA Approval in 1999, Intacs are Indicated for the Reduction or Elimination of Mild Myopia up to – 3.00 Diopters with Documented Stability of Refraction as Demonstrated by a Change of ≤ 0.50 Diopter for at Least 12 Months prior to the Preoperative Examination; and where the Astigmatic Component is +1.00 Diopter or Less**

- Patients with Corneal Thickness of <450 Microns at the Incision Site
- Patients with Collagen Vascular, Autoimmune or Immunodeficiency Diseases
- Patients who are Pregnant or Nursing
- In Presence of Ocular Conditions, e.g. Recurrent Corneal Erosion Syndrome, or Corneal Dystrophy
- Patients on Isotretinoin (Accutane¹) or Amiodarone HCl (Cordarone²)

¹Accutane® is a Registered Trademark of Hoffman-LaRoche, Inc.

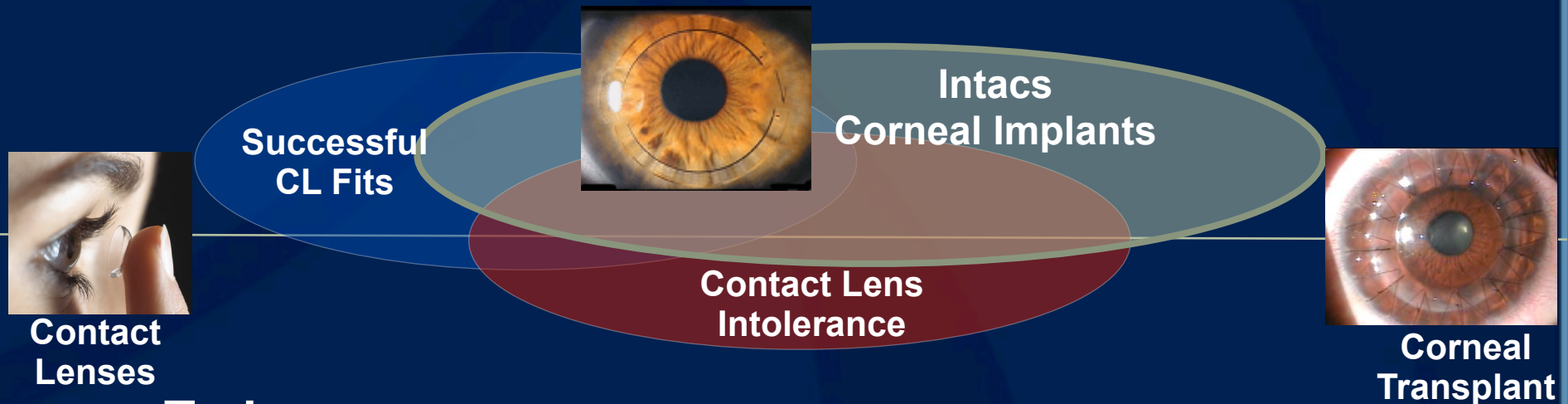
²Cordarone® is a Registered Trademark of Sanofi



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Keratoconus Treatment Continuum

New Treatment Continuum

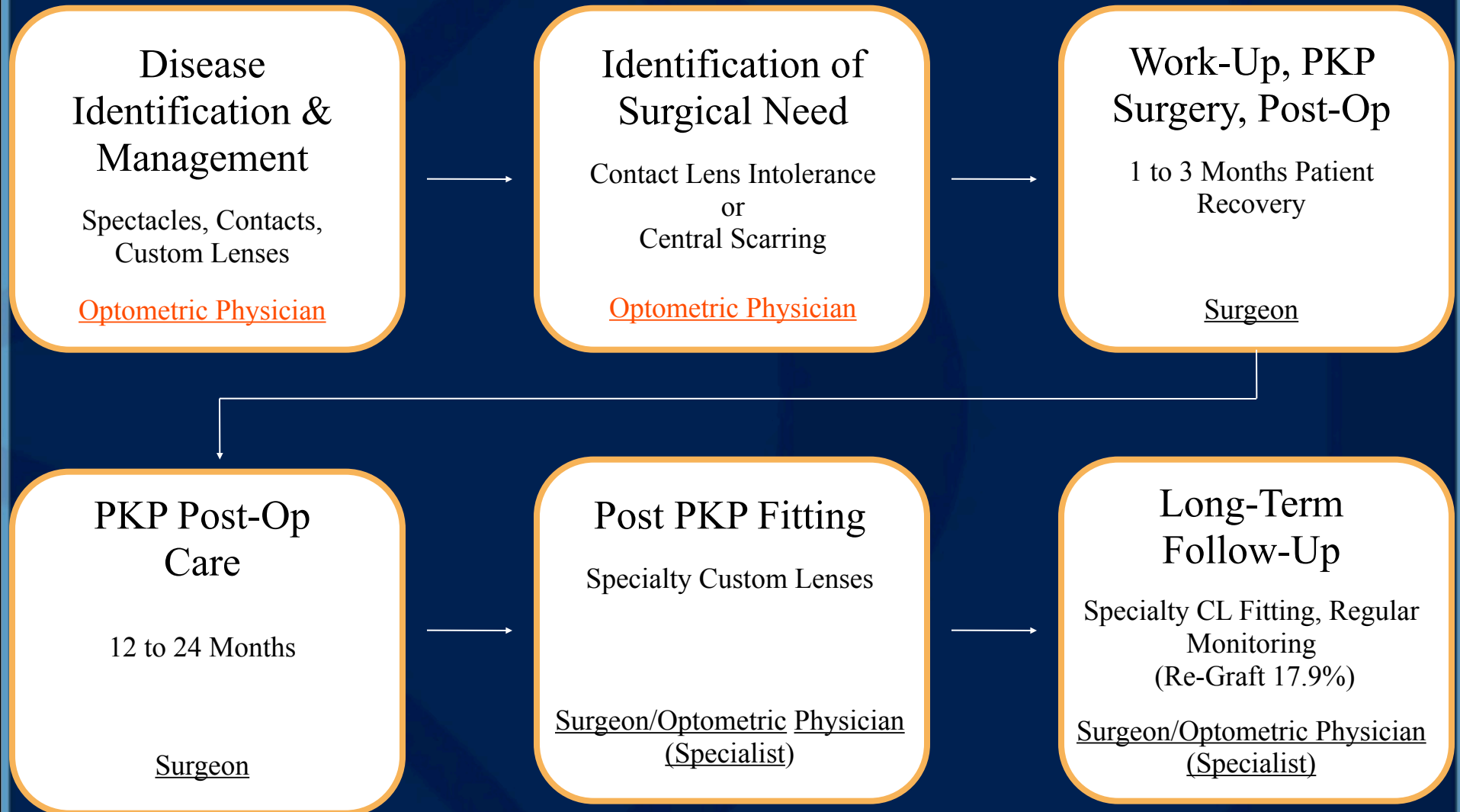


Today:

- Patient told they have Keratoconus or are Suspect
- **Patient Educated on Current and Future Options to Treat their Condition (Including Intacs)**
- Fit with Glasses or Contact Lenses
- Fit with Gas Perm or Specialty Contact Lenses **and told about Intacs**
- Re-Fit with Specialty Contact Lenses
- Becomes Contact Lens Intolerant
- Get Intacs
- **Potentially Defers** a Corneal Transplant

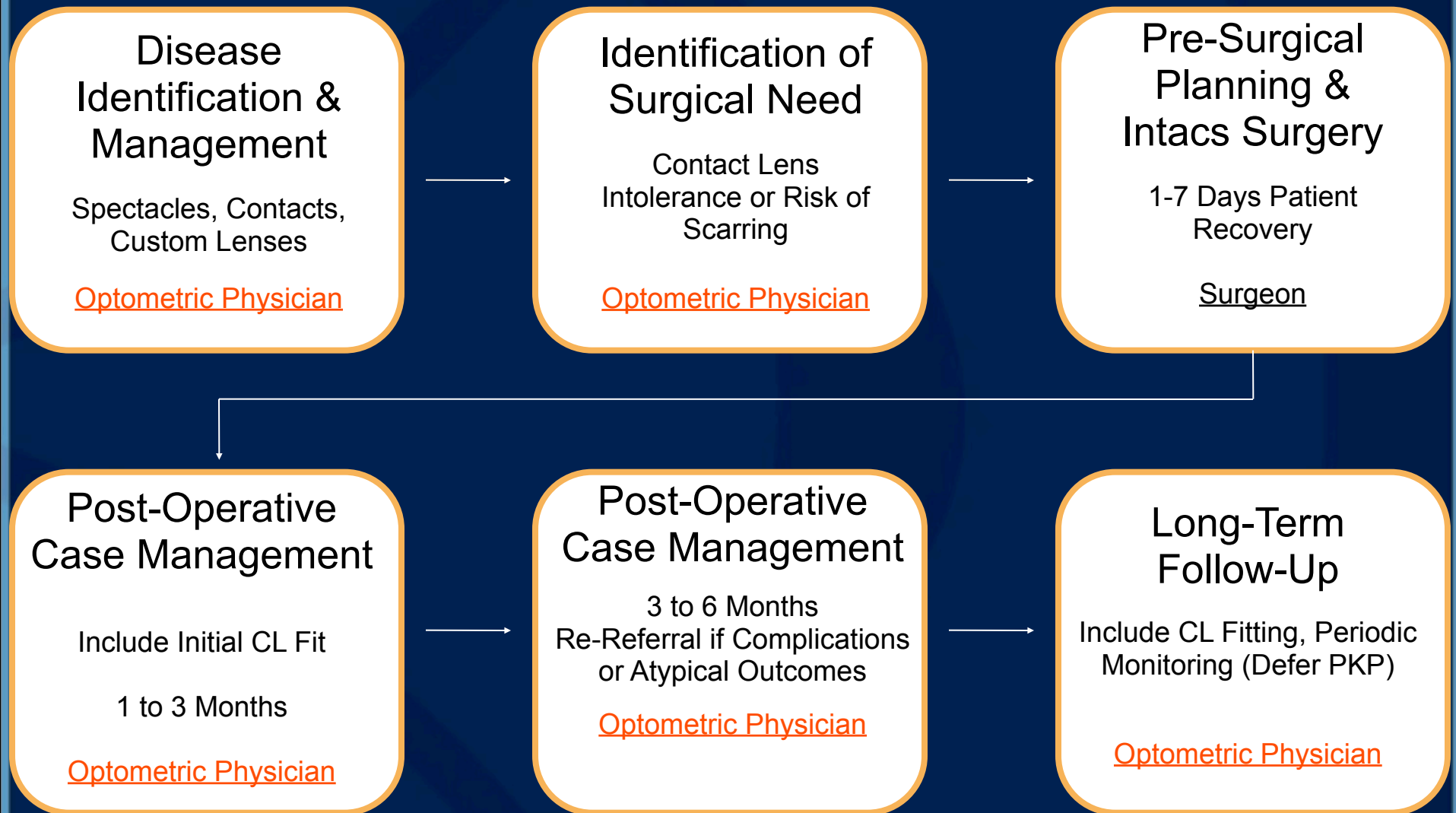
Keratoconus Treatment Flow

Old Paradigm



Keratoconus Treatment Flow

New Paradigm





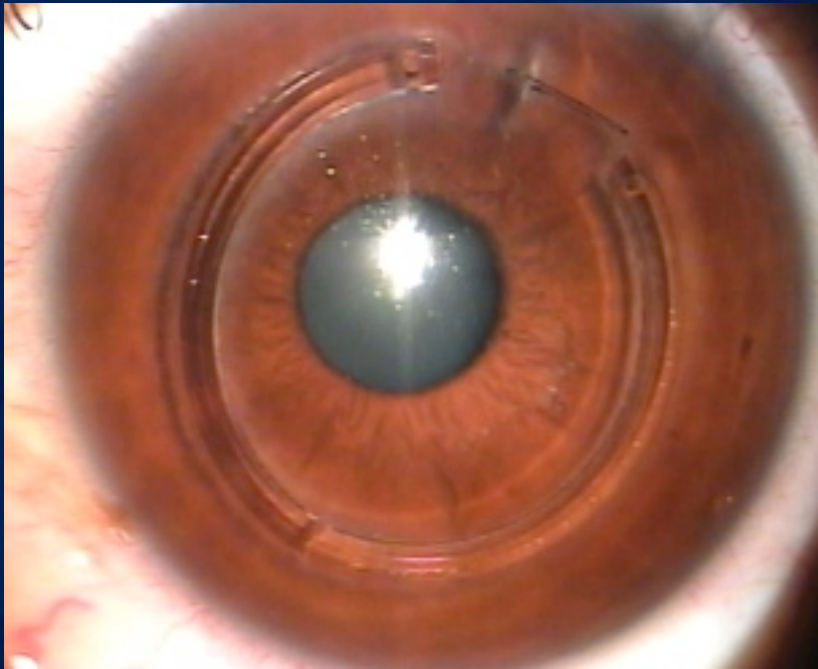
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**Current Surgical Options
For Severe Keratoconus**

Surgical Options For Keratoconus

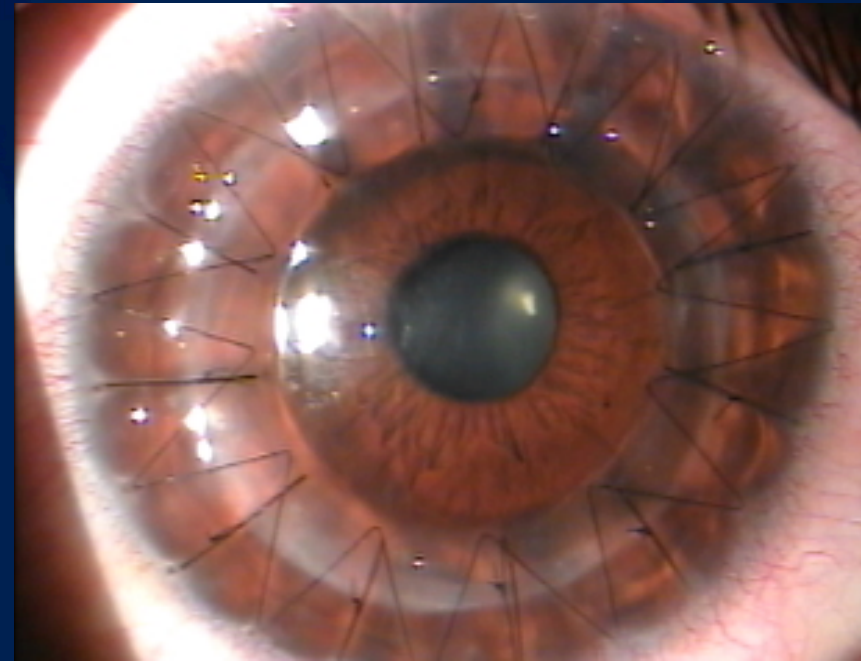
- 10% to 20% of Keratoconus Patients Ultimately Require Surgery
- Lamellar Keratoplasty
 - Interface haze limits visual result
- Penetrating Keratoplasty
 - Most frequent procedure
 - 5,092 cases in 2009 attributed to keratoconus (U.S.)
 - 80% to 90% Successful
 - Issues
 - Graft Rejection rate almost 20%
 - Continued Astigmatism
 - Endothelial Cell Loss (Limited graft longevity)
 - Recurrence of Keratoconus

Surgical Options For Keratoconus



Intacs

-0.75



Transplant

+8.00 -2.00 X 180°

INTACS

Reversible Out-Patient Procedure

Time: 20–30 Minutes

Rehab Time: 1–2 Weeks

(Visual Function Immediate)

Corneal Lamellar Procedure

Periodic Follow-up

Complications

Unsatisfactory ring placement

Segment extrusion

(All easily managed with segment removal)

PKP

Irreversible Procedure

Time: 1 Hour

Rehab Time: 12–18 Months

Intraocular Procedure

Lifetime Follow-up required

Complications

Cataract

Glaucoma

Endophthalmitis

Rejection

Expulsive hemorrhage

Corneal ulcer

Neovascularization

Induced astigmatism

Disease recurrence

Risk of viral transference

INTACS

Endothelial cell loss, not clinically significant¹

Provides structural integrity, PKP still an option without complication

Outcomes: predictable, case dependent

¹Two-Year Endothelial Cell Assessment following INTACS implantation, Azar et al, J Refract Surg. 2001 Sept-Oct

PKP

Significant loss of endothelial cells

Permanently weakened cornea with risk of additional trauma

Outcomes: unpredictable, often unstable

Financial Facts:

In addition to the overwhelming medical benefits...

According to a 2005 Milliman Research Report on the cost estimates of a corneal transplant:

- Corneal Transplants Performed : **32,840**
- Corneal Transplants for Ectasia / Corneal Thinning: **5056**
- First Year Billed Charges For a Corneal Transplant: **\$19,100.**
- Total Billed Charges for Ectasia Alone: **~\$100 Million**

Comparatively, treating these same patients with Intacs would have saved a significant amount to the healthcare system and provided a safe, “standard of care” approach to treating keratoconus.

Conclusion:

Intacs Intervention is Superior to a Corneal Transplant

Goal of Intacs is to restore functional vision

Effective functional refraction with soft, soft-toric, or rigid contact lenses is likely

Reshapes cornea resulting in contact lens tolerance

Intacs implantation reduces corneal coning

Central cone is flattened

Asymmetrical cones are repositioned centrally

Post-surgical recovery

Visual improvement can be immediate

Vision stabilizes in months rather than a year or longer

High potential to defer transplant



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Glasses & Contact Lenses

Contact Lenses

Most patients are easily treated with contact lenses or glasses in the early stages of keratoconus.

As the disease progresses, physicians must determine when a patient becomes intolerant before complications lead directly to a corneal transplant.

Intacs is a natural next step to aid in treating the myopia and astigmatism associated with keratoconus enabling the cornea to become flatter, more normal in shape. Thus allowing for a more acceptable contact lens fit and potentially avoiding a corneal transplant all together.

Develop a clear definition of contact lens intolerance.

Contact Lenses CLEK Facts

Fact:

Since inception of the study, every year about 30% of patients in the study had or developed scarred corneas*.

Prevention:

Educate patients about Intacs earlier before the cornea becomes too steep.

Does contact lens tolerance = functional vision?

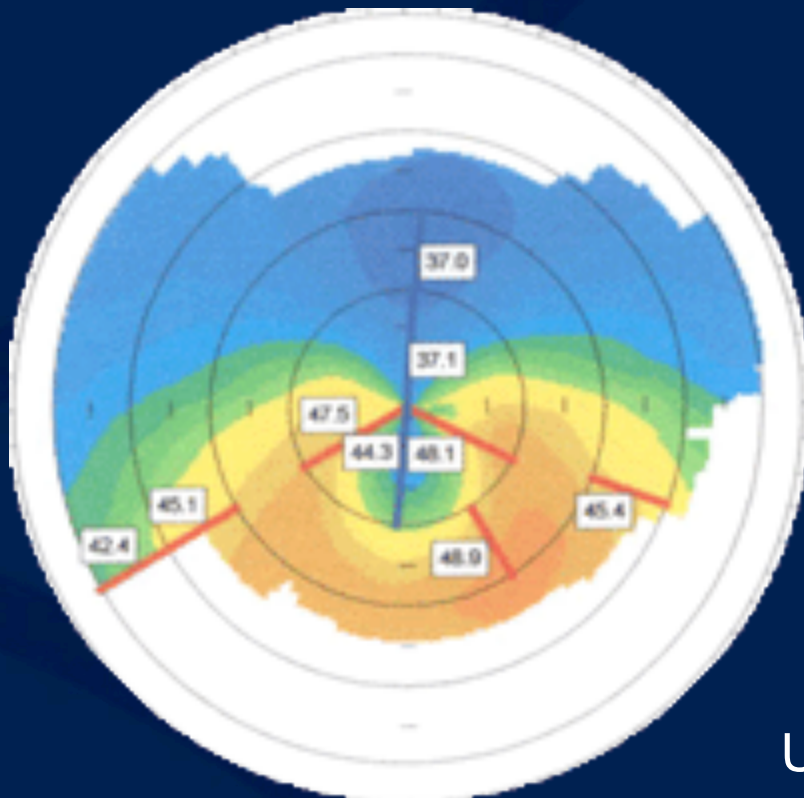
*CLEC Archive: <https://vrcc.wustl.edu/clekarchive/>



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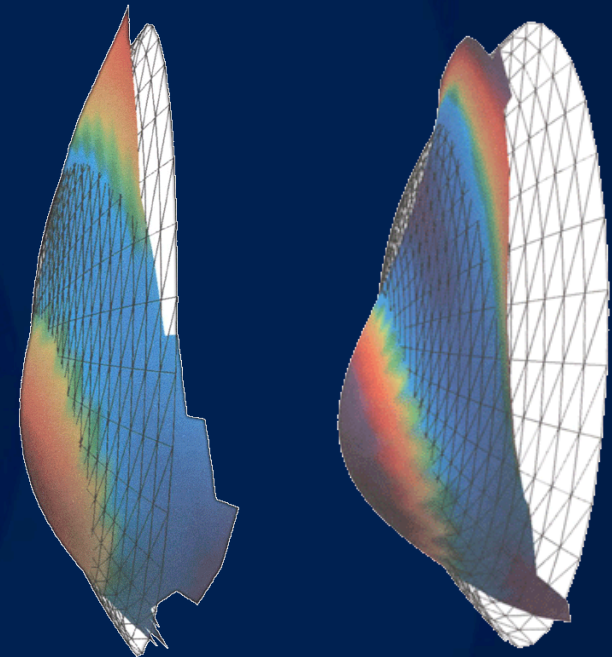
Results

Case Example 1 – Pre-Op



Anterior

Posterior



UCVA CF

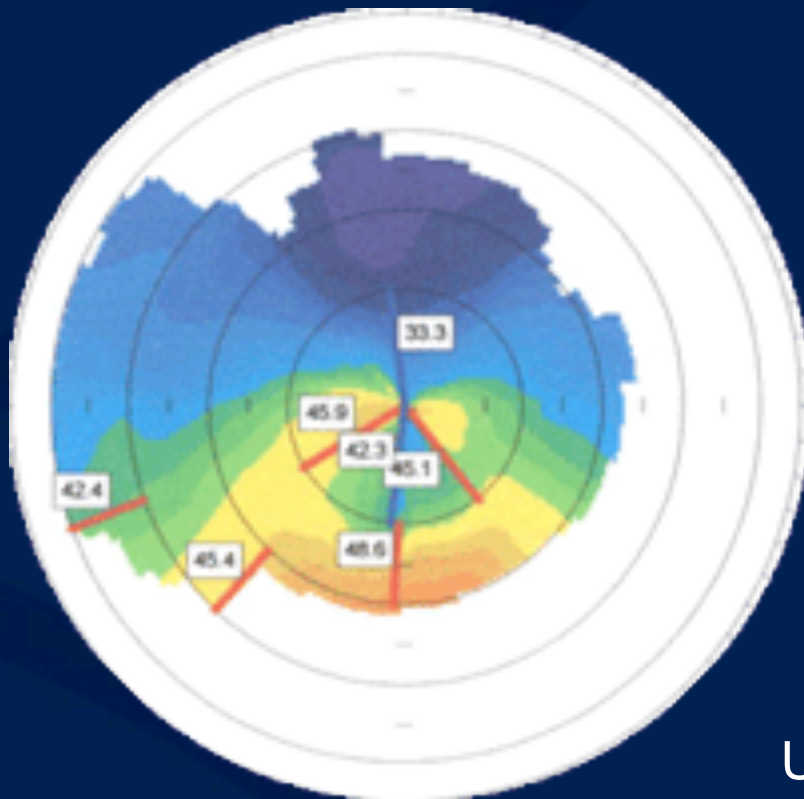
BCVA: 20/50

MR: -7.00 -6.00 @ 60

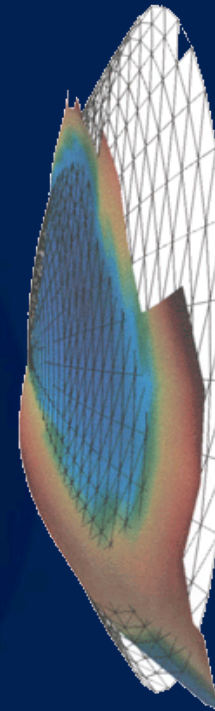
Max K: 46.60 @ 175

Custom RGP Intolerant

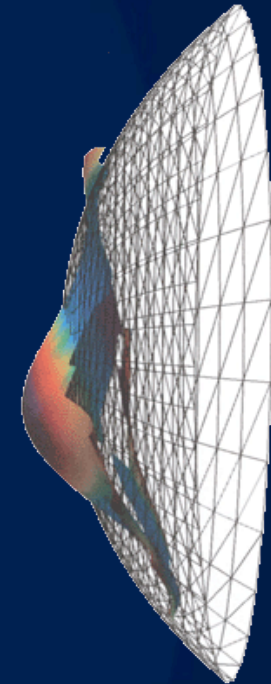
Case Example 1 – Post-Op



Anterior



Posterior



UCVA 20/80

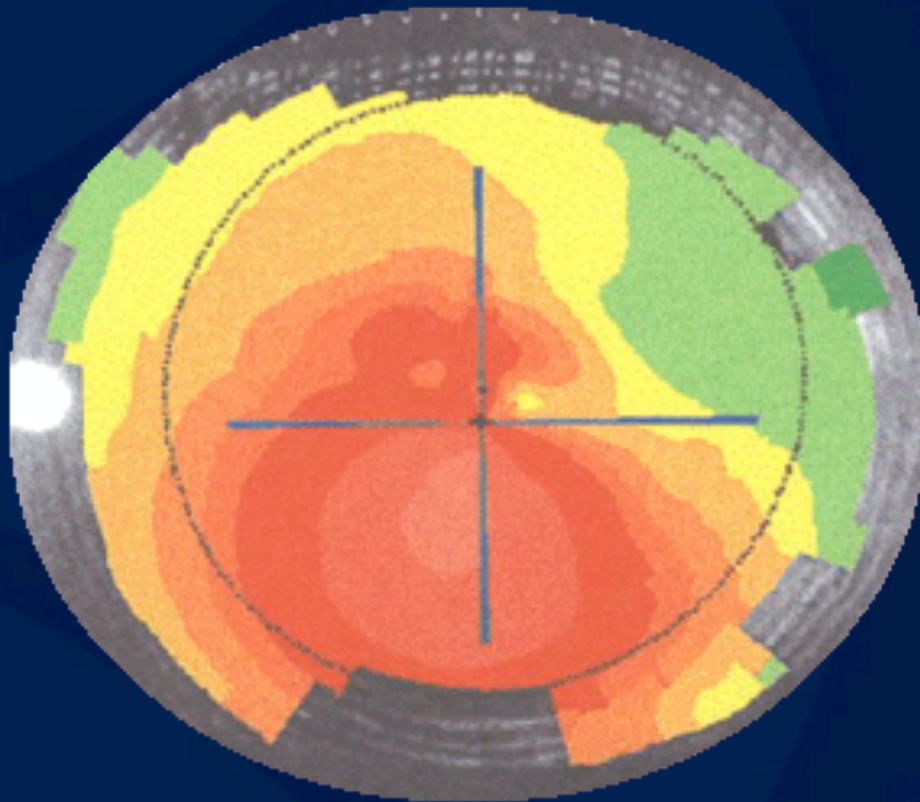
BCVA: 20/30

MR: -2.00 -2.75 @ 60

Max K: 43.40 @ 14

Soft Toric

Case Example 2 – Pre-Op



UCVA CF

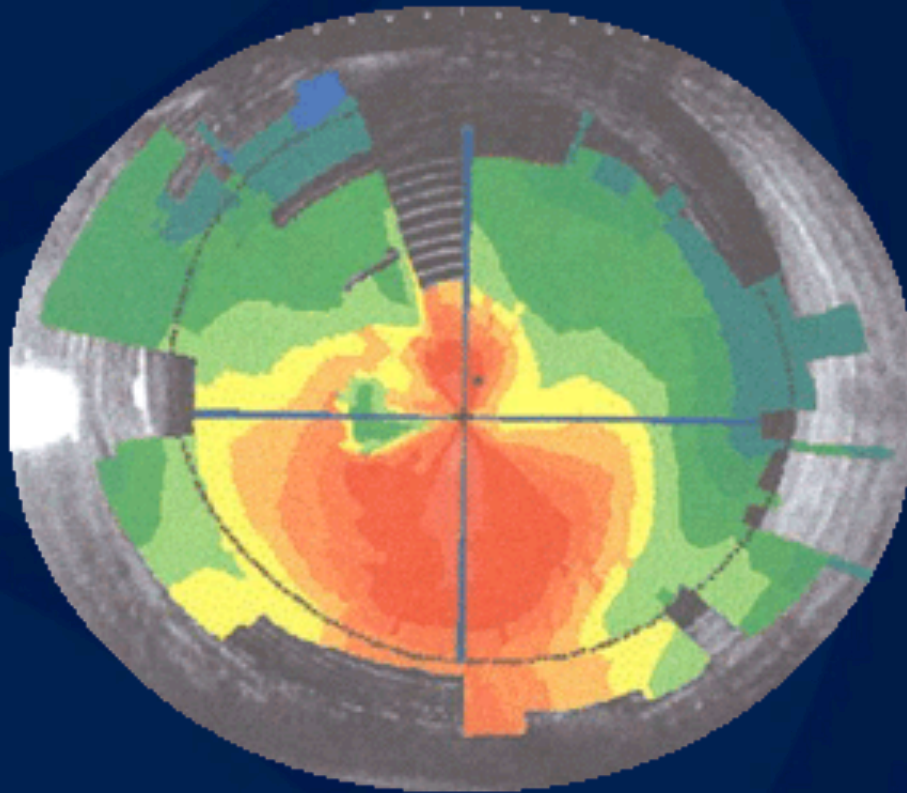
BCVA: 20/50

MR: -4.75 + 5.00 @ 20

Max K: 55.78 @ 90

Custom RGP Intolerant

Case Example 2 – Post-Op



UCVA 20/40

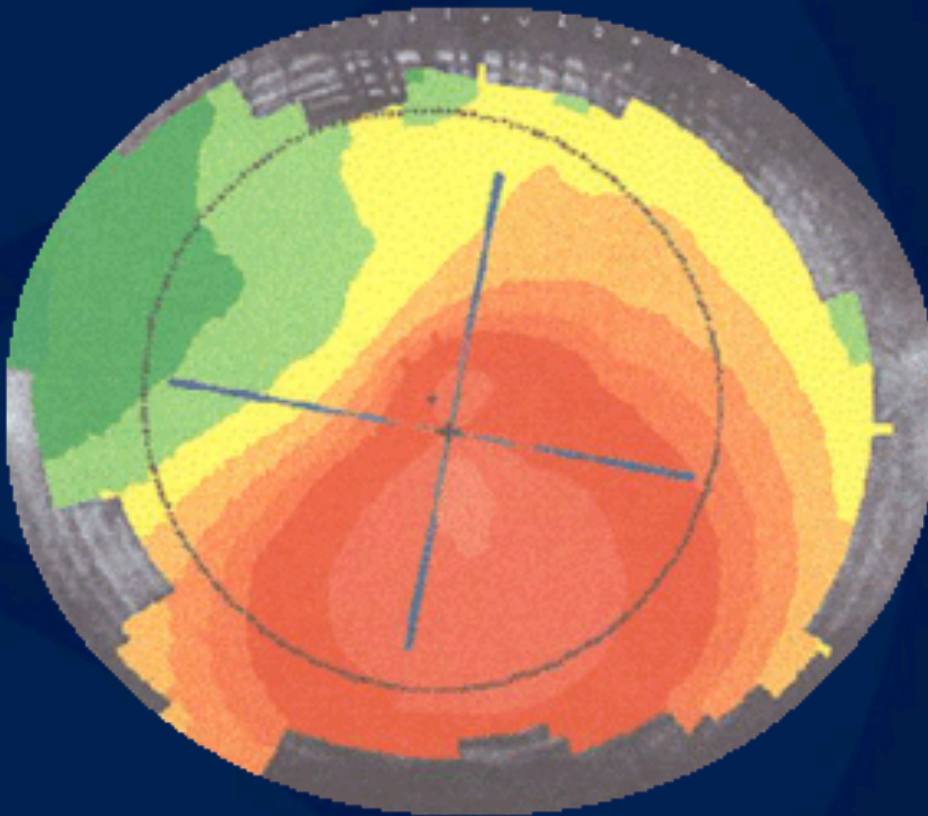
BCVA: 20/25

MR: -2.00

Max K: 51.69 @ 89

RGP Tolerant

Case Example 3 – Pre-Op



UCVA CF

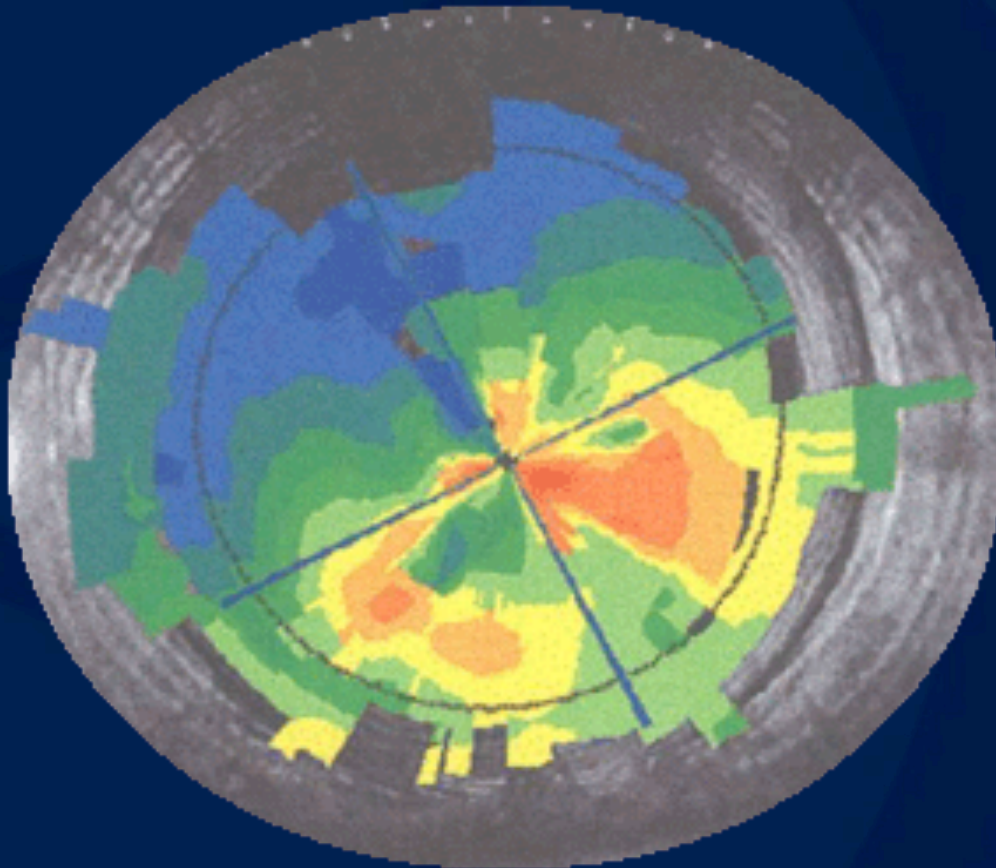
BCVA: 20/45

MR: -6.25 -4.75 @ 175

Max K: 54.43 @ 79

Custom RGP Intolerant

Case Example 3 – Post-Op



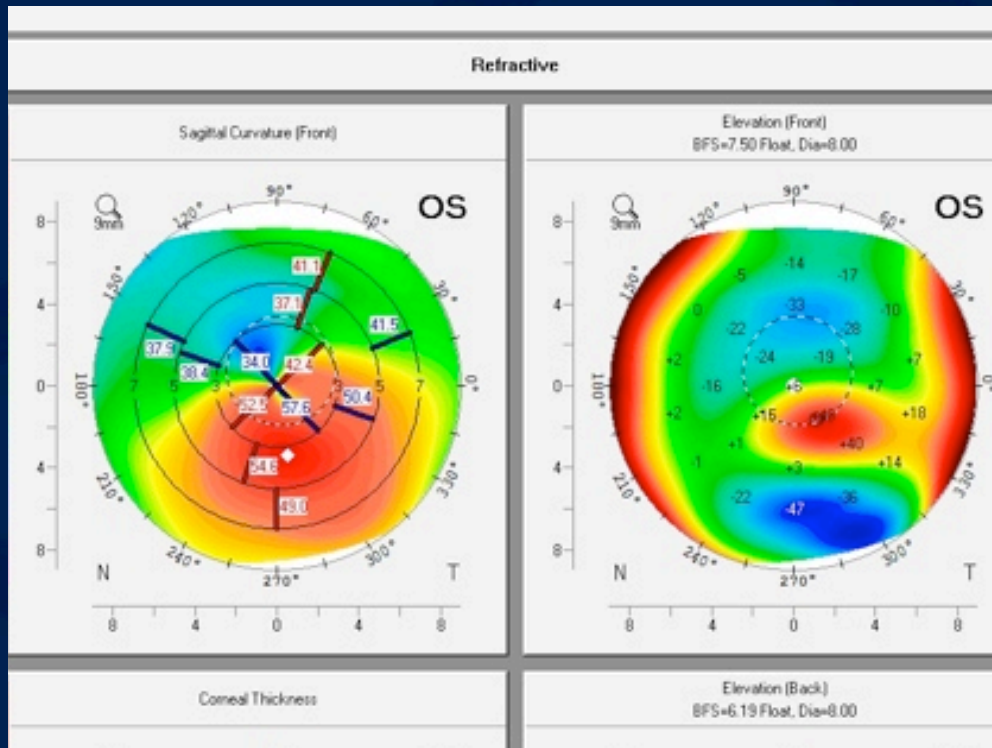
UCVA 20/80

BCVA: 20/30

MR: -.50 -3.00 @ 135

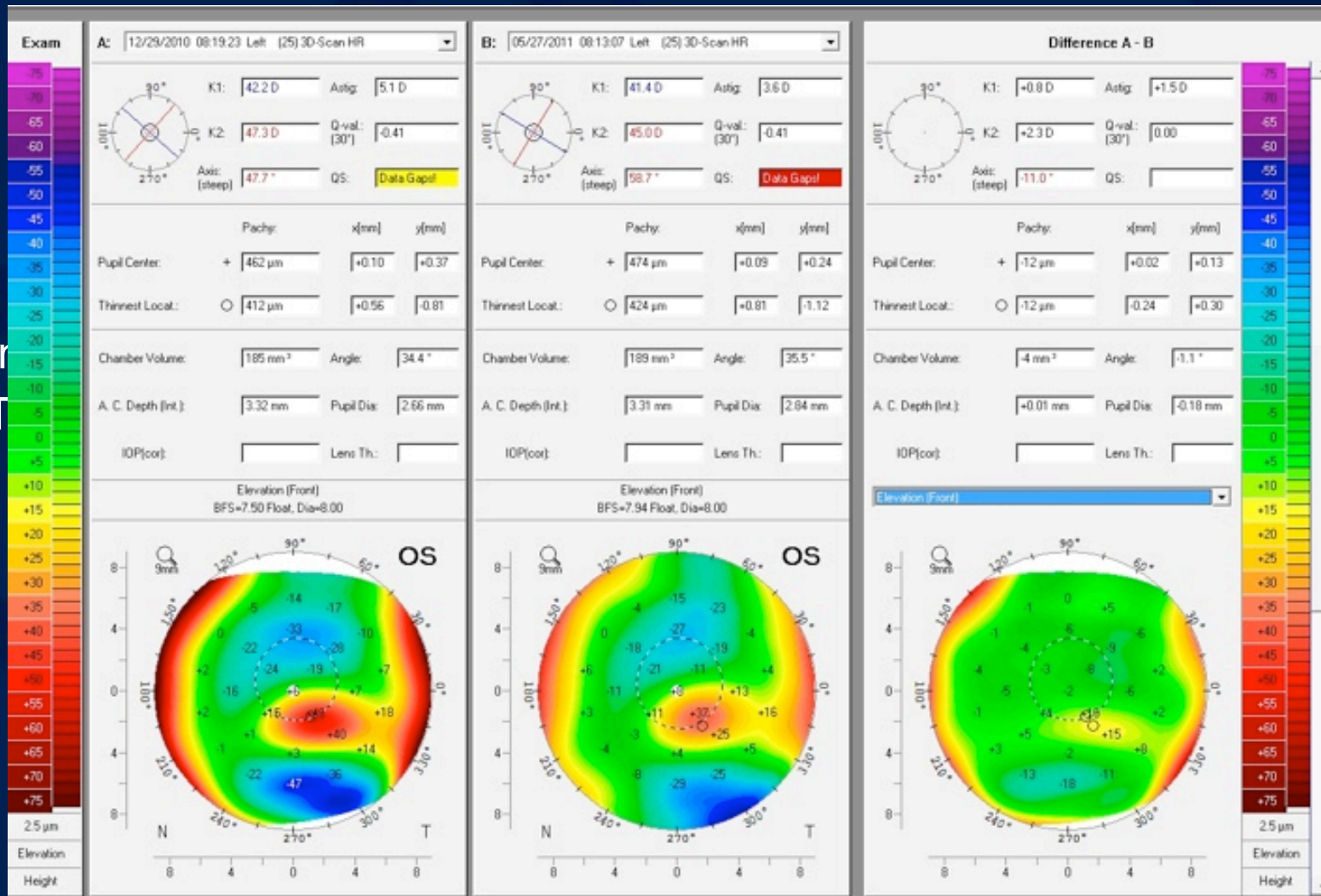
Max K: 51.69 @ 89

RGP Tolerant

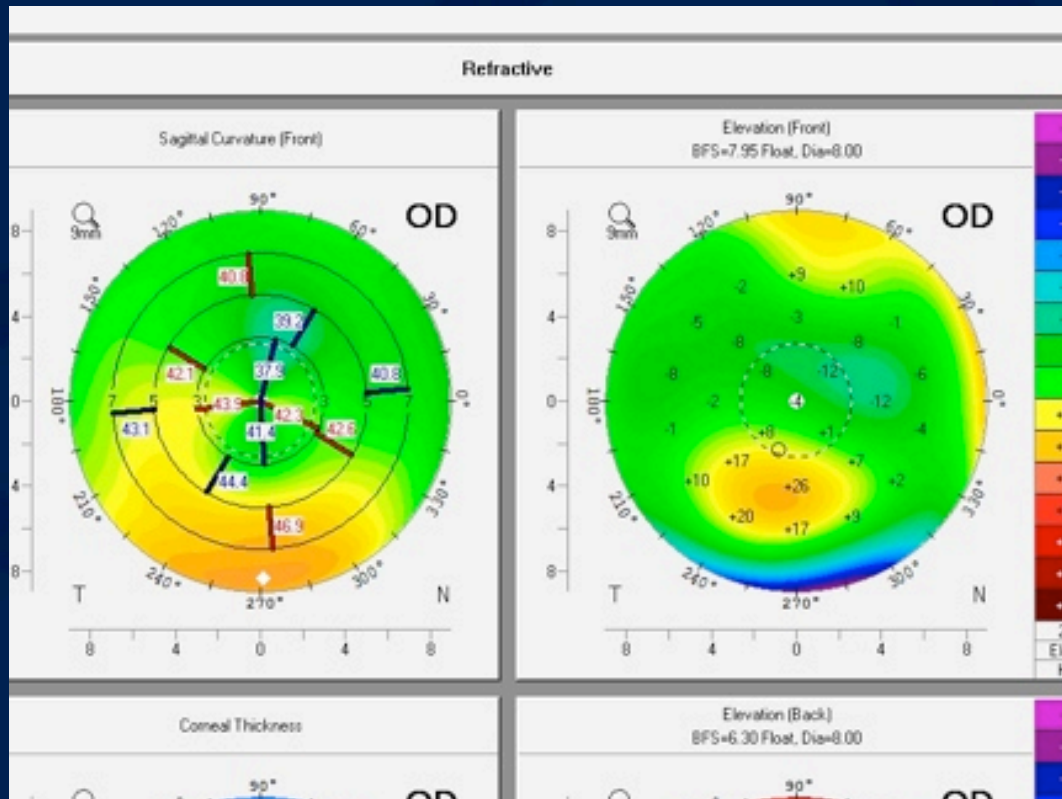


UCVA 20/CF
 BCVA: 20/50
 MR: -1.00 +4.75 x 025
RGP Intolerant

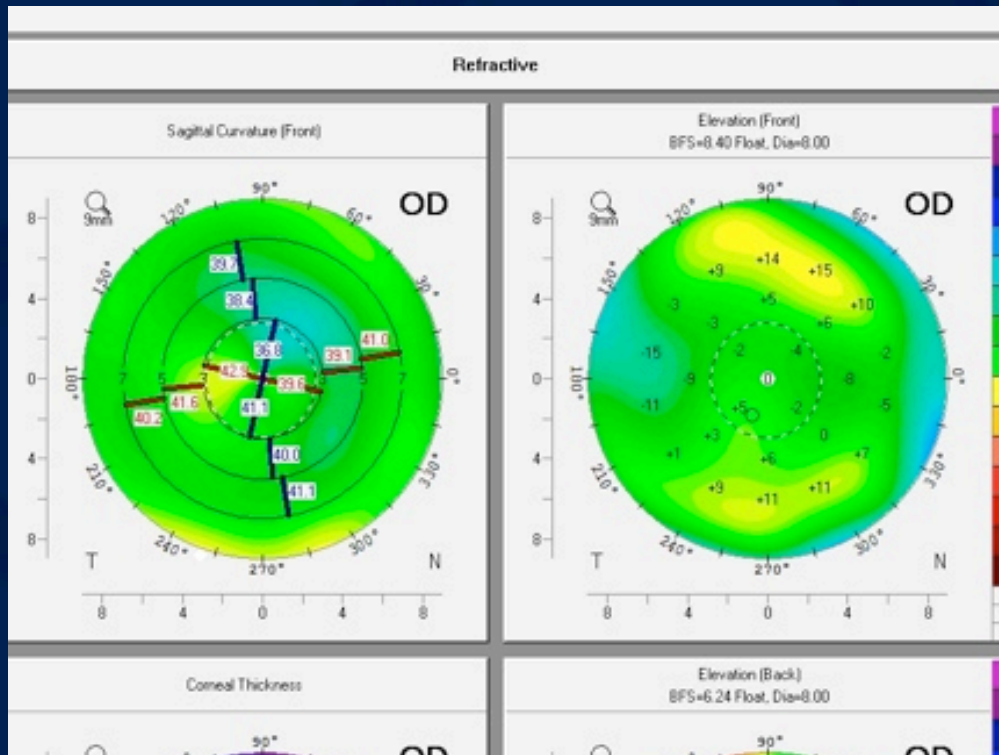
Case T.J. – Compare



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T

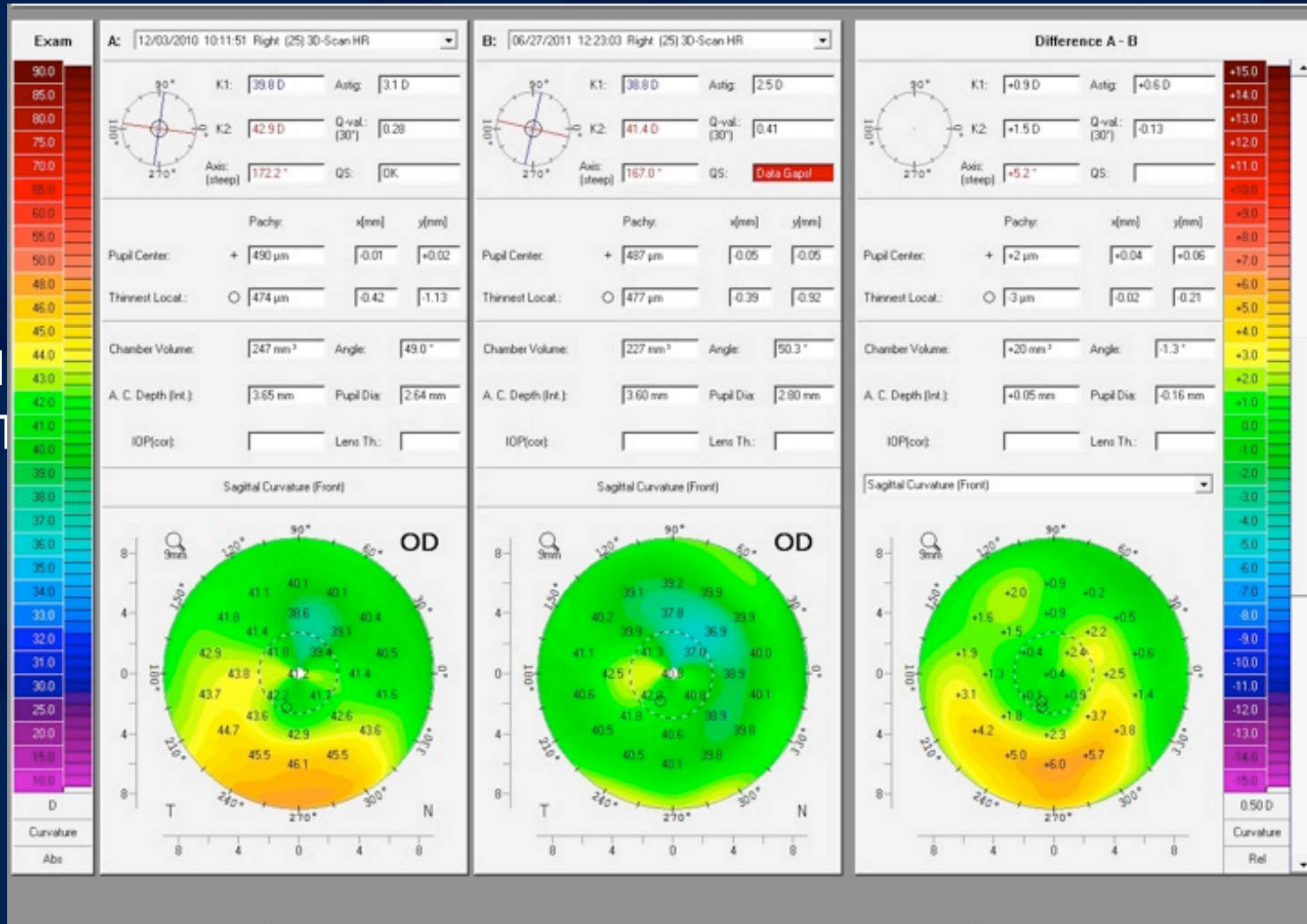


UCVA 20/200
 BCVA: 20/20
 MR: -1.75 +3.50 x 150
 CL Intolerant



UCVA 20/30
BCVA: 20/20

Case M.M. – Compare

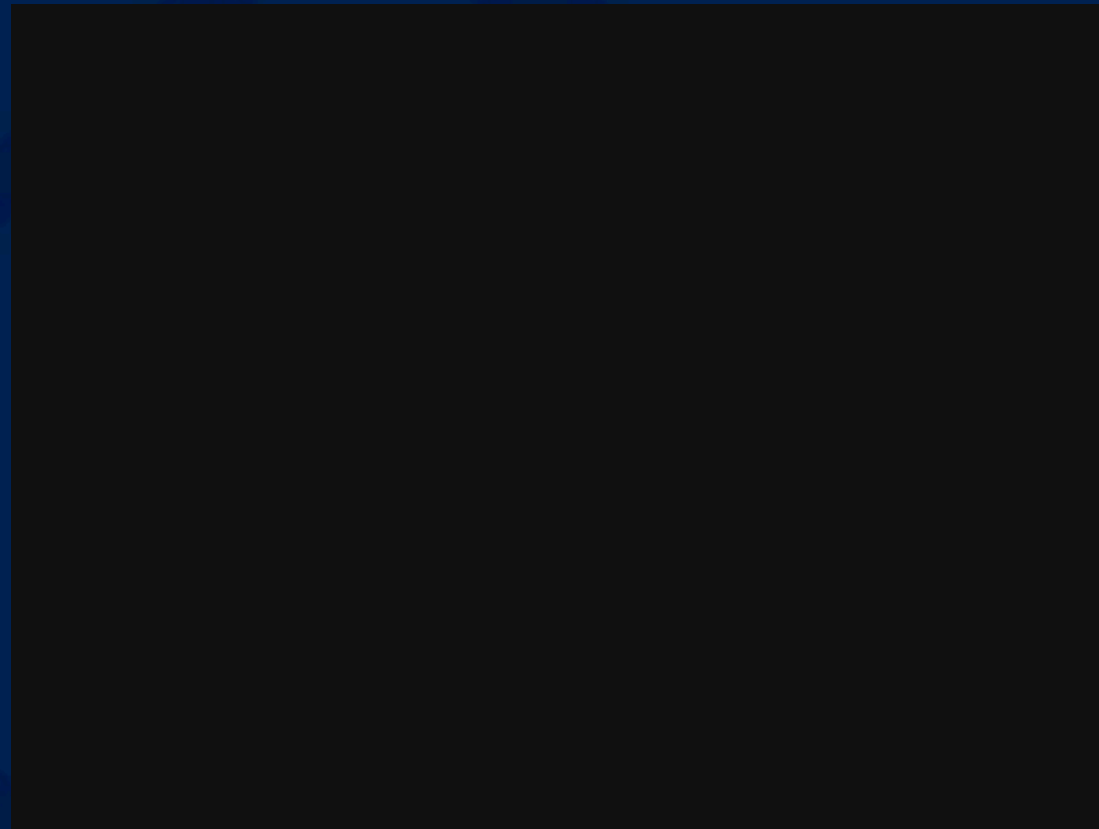




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The Intacs Procedure

Using FS Laser



Watch the Pre-op and Post-op mire

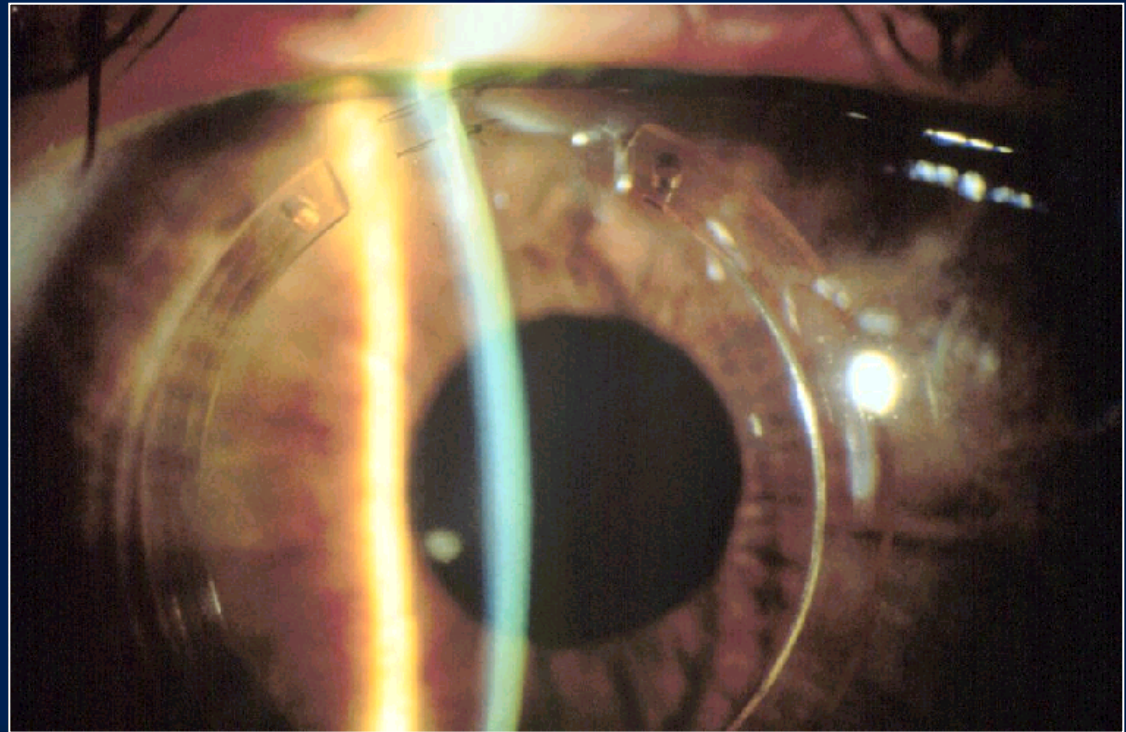
Intacs Normalize Corneal Shape



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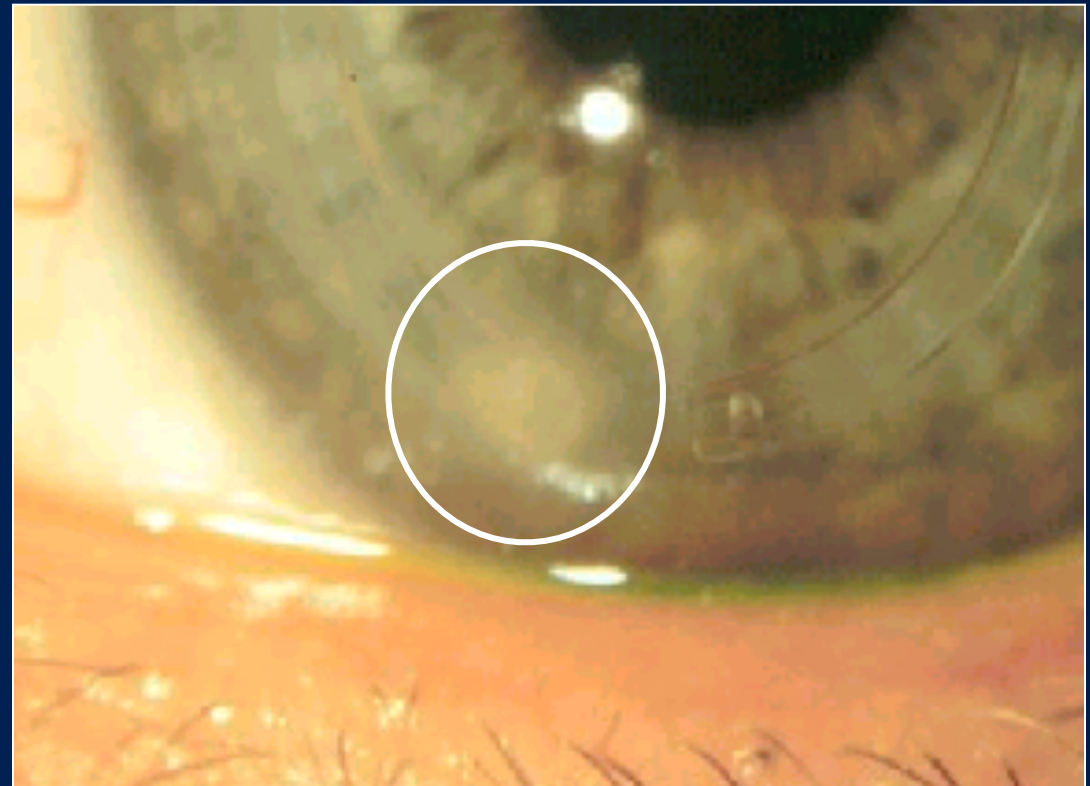
Post-Operative Management

- **Filamentary Keratitis**
 - **Symptoms**
 - Foreign Body Sensation
 - Photophobia
 - **Action**
 - Debridement
 - Bandage Contact Lens



- **Drug Toxicity/Allergy**
 - **Symptoms**
 - **Foreign Body Sensation**
 - **Irritation**
 - **Findings**
 - **Superficial Punctate Keratitis**
 - **Chemosis**
 - **Lid Edema and Erythema**
 - **Action: Stop the Offending Medication**

- **Infection**
- **Symptoms**
 - Pain - Hallmark
 - Photophobia
 - Decreased Vision
- **Findings**
 - Infiltrate at Incision or in Tunnel
- **Medication**



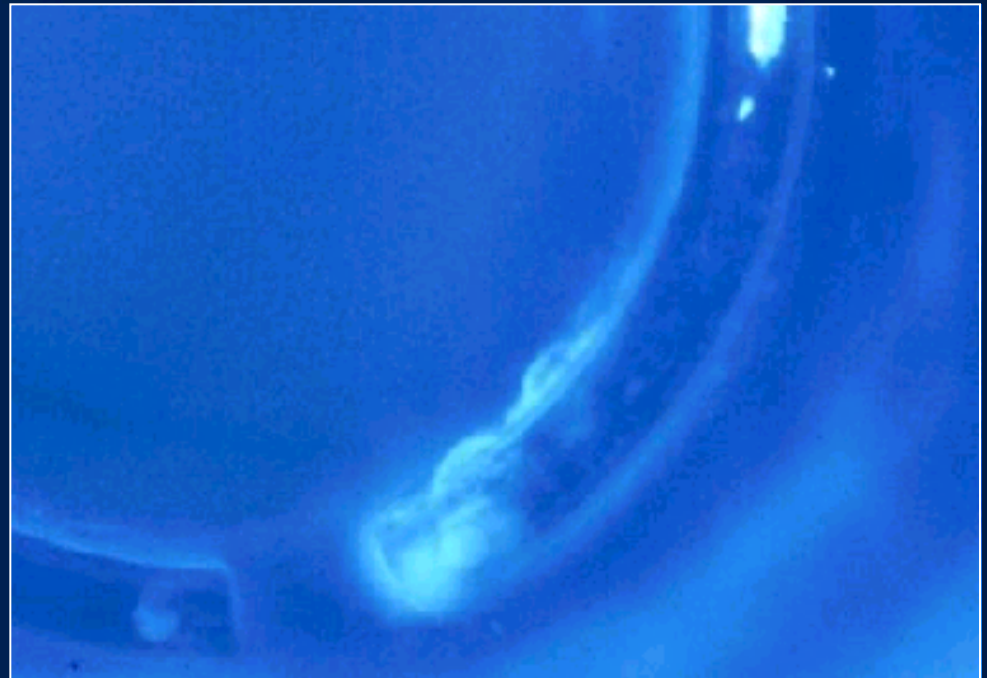
- **Management of Infection**
 - **Initiate Fortified Antibiotic Therapy**
 - **Follow Closely**
 - **If Continued Progression**
 - **Remove the Intacs**
 - **Refer to Manual for Suggested Treatment**

- **Epithelial Cyst or Plug In Incision**
- **Epithelial Plugs Associated with**
 - **Against the rule Astigmatism**
 - **Loss of Refractive Effect**
 - **Foreign Body Sensation**



Corneal Thinning (Melting)

- **Symptoms**
 - Foreign Body Sensation
- **Findings**
 - Epithelial Breakdown Over the Intacs
 - Shallow Placement
- **Cause**
 - Shallow < 50% Depth
- **Treatment**
 - Removal as Soon as You Notice Shallow Placement
 - Re-Tunnel and Reposition at > 50% Depth
 - This should be Noted at the Day 1 or Day 7 Examination
 - Early Intervention is Recommended



- **Corneal Infiltrates – Differential Diagnosis**

- **Sterile**

- Onset 7 - 21 Days
- Symptoms of Iritis
- Usually No Pain

- **Infectious**

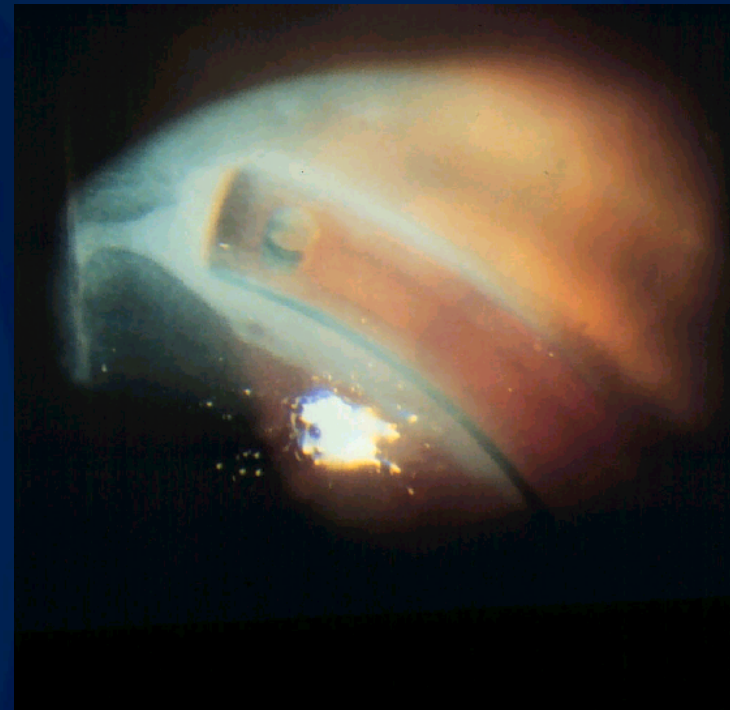
- Onset 1-14 Days
- Severe Pain

- **Symptoms**

- Redness
- Photophobia

- **Findings**

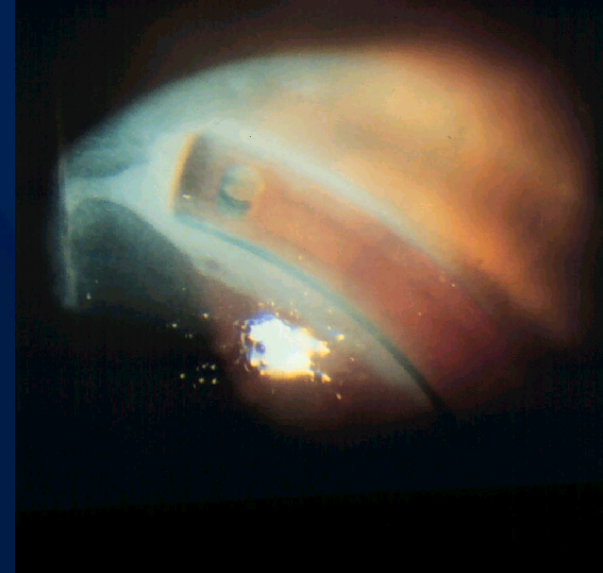
- Focal Whitish Infiltrate in the Tunnel Between the Incision and the Superior Intacs
- Iritis
- May Represent Epithelial Streaming and the Stromal Reaction to the Epithelial Cells



- **Corneal Infiltrates – Differential Diagnosis**

- **Possible Causes**

- **Poor Wound Healing**
- **Incomplete Wound Closure**
- **Inadequate Steroid Dosing**
- **Mechanical Trauma**
- **Epithelial Cells in Tunnel**

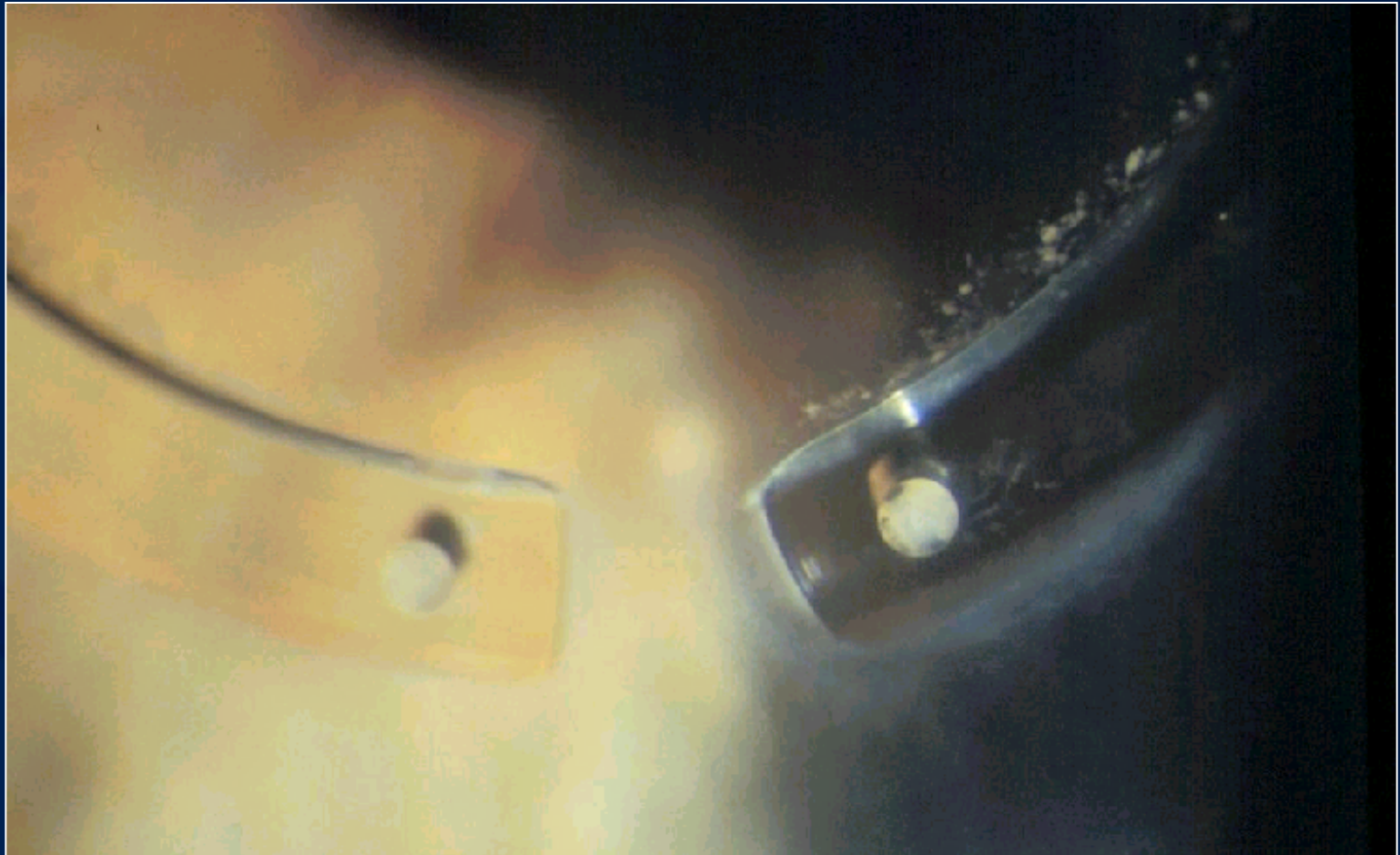


- **Solutions**

- **1% Pred-Forte qid, Fluroquinolone qid**
- **Symptoms Improve Quickly and Resolve within a Few Days**
- **Infiltrate Resolved in 1 - 3 Weeks**
- **Infiltrate Resolution Occurs With or Without Topical Medications**

- **Glare – Pupil Size**
 - **Possible Causes**
 - **Mesopic Pupil Greater than 7mm**
 - **Findings**
 - **Glare**
 - **Solutions**
 - **More Careful Patient Selection**
 - **Remove Intacs**

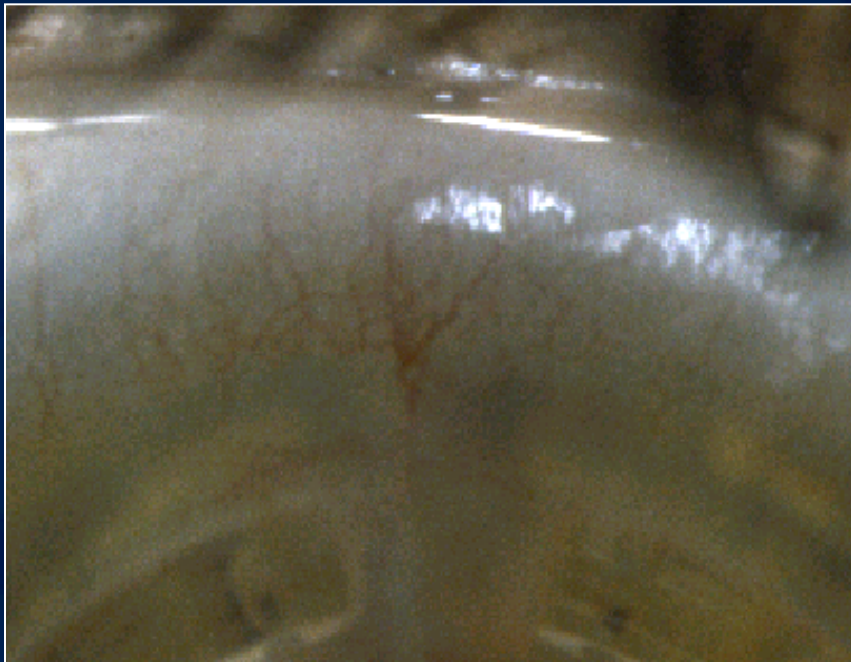
Ring-Hole Debris



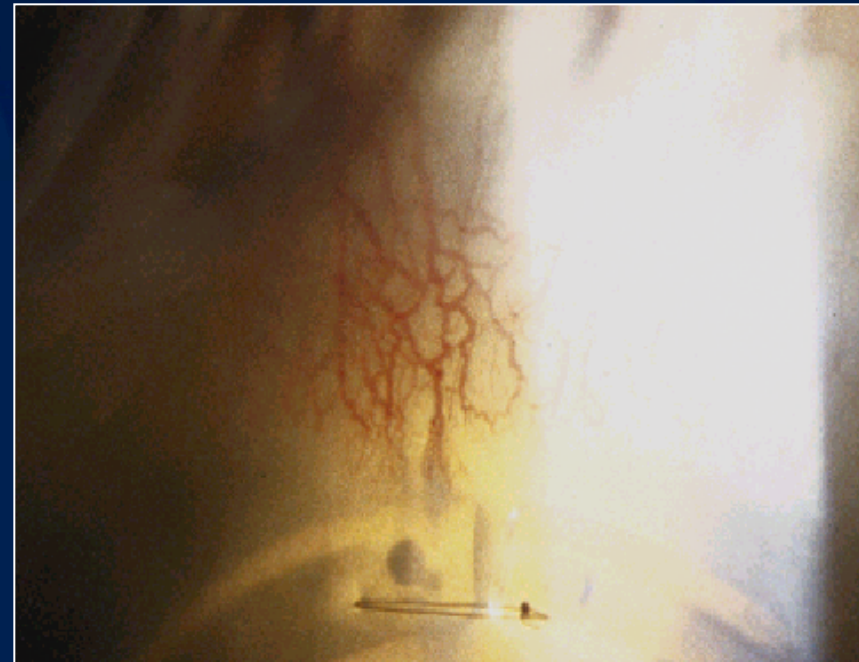
Pannus & Tunnel Neovascularization

- Pannus Risk Factors
 - Prior Contact Lens Wear
 - Preoperative Pannus
 - Incision to Limbal Vessels
 - Intacs Too Close to Limbus
 - Loose Sutures
- Wound and Tunnel Vascularization
 - Use Corticosteroids to Stop Surface Vessels from Reaching or Entering the Wound

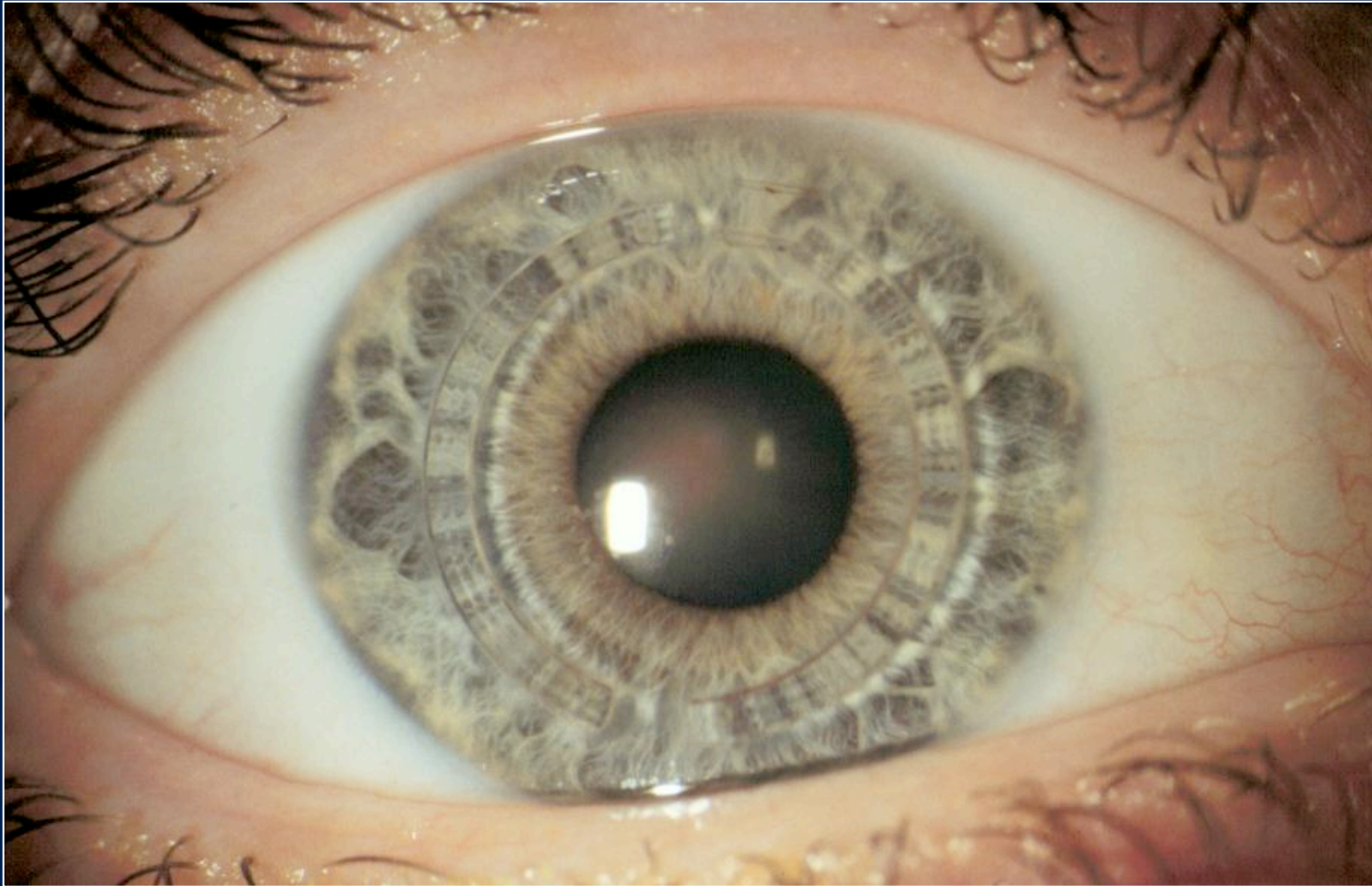
Pannus & Tunnel Neovascularization



corticoid steroids was not done



Loose suture with open / close
Wound causing irritation inciting
an Angry vessel response.





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Peer Reviewed Data

Keratoconus Peer Reviewed Data

Title	Authors	Publication
Comparison of outcomes of 2 channel sizes for intrastromal ring segment implantation with a femtosecond laser in eyes with keratoconus.	Ertan A., Kamburoglu G.,	J J Cataract Refract Surg. 2007 Apr; 33 (4): 648-53
Penetrating keratoplasty versus intrastromal corneal ring segments to correct bilateral corneal ectasia; preliminary study.	Rodriguez LA, Guilen PB, Benavides MA, Garcia L., Porras D., Daqui-Garay RM	J Cataract Refract Surg 2007 Mar; (33) (3) 488-96
Implantation of Artisan toric phakic intraocular lens following Intacs in a patient with keratoconus.	Kamburoglu G., Ertan A., Bahadir M.	J J Cataract Refract Surg. 2007 Mar; 33 (3): 528-30
Histopathological findings after intracorneal ring segment implantation in keratoconic human corneas.	Samimi S., Leger F., Touboul D., Colin J.	J Cataract Refract Surg 2007 Feb; (33) (2) 247-53
Management of superior pellucid marginal degeneration with a single intracorneal ring segment using femtosecond laser.	Ertan A., Bahadir M.	J Cataract Refract Surg 2007 Feb; (23) (2) 205-8
Long-term follow-up of Intacs in keratoconus.	Kymionis GD, Siganos CS, Anastasakis a., Yoo SH, Pallikaris AI, Astyrakakis N., Pallikaris IG	Am J Ophthalmol. 2007 Feb; 143 (2) 236-44
Topography-guided vertical implantation of Intacs using a femtosecond laser for the treatment of kertoconus	Bahadir, Memet, Ertan, Aylin	J Cataract Refract Surg 2007 Jan; (33) (1) 148-151
Reduced best spectacle-corrected visual acuity from inserting a thicker Intacs above and thinner Intacs below in keratoconus.	Chan CC, Boxer Wachler B.	J Cataract Refract Surg 2007 Jan; (23) (1) 93-5
Effect of inferior-segment Intacs with and without C3-R on keratoconus	Boxer Wachler, Chan, Franzco	J Cataract Refract Surg 2007 Jan; (33) 75-80
Intacs for the correction of keratoconus: Two-year follow-up	Colin, Joseph, Malet, J.	J Cataract Refract Surg 2007Jan; (33) 69-74
New Surgical approaches to the Management of Keratoconus and Post-Lasik Ectasia	Tan, Purcell, Torres, Schanzlin	Trans Am Ophthalmol Soc / Vol 104 / 2006

Keratoconus Peer Reviewed Data

Title	Authors	Publication
Intacs insertion with femtosecond laser for the management of keratoconus: one-year results	Ertan A., Kamburoglu G., Bahadir M.	J Cataract Refract Surg 2006 Dec; 32 (12) 2039-42
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Title	Authors	Publication
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Thank You.