

Amniotic membrane contact lens



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Coworkers



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Dr. Amy Waymire

Dr. Michael George

Dr. Annie Yeh

Mr. Chris Adams

Financial interest: owner of U.S. patent on AMCL

Irreversible corneal blindness






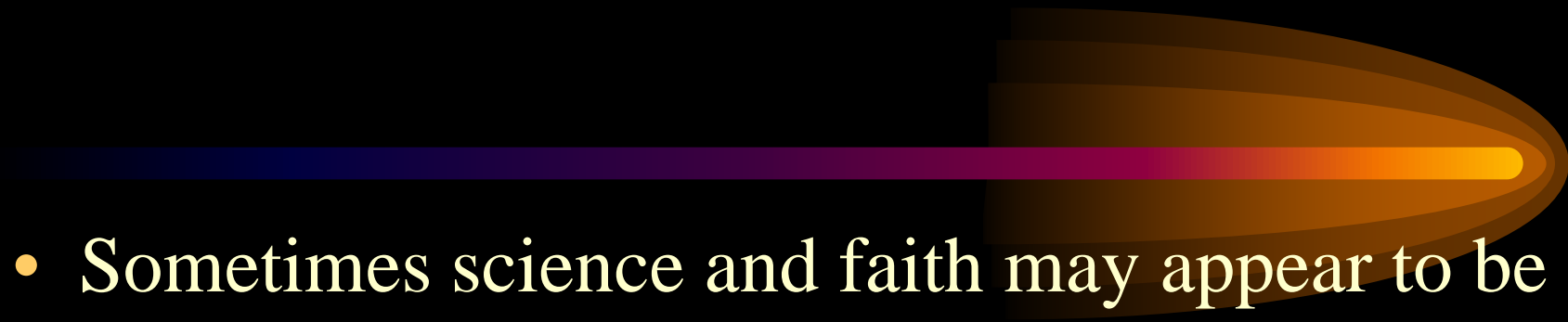
Young person heals faster and better



*Hint: a fetal wound heals
WITHOUT scar*



*How can we **understand** and **utilize**
findings in fetal wound healing
without hurting a baby?*

- 
- Sometimes science and faith may appear to be at odds with each other;
 - Do we do research without moral guidance? Or do we not do research at all? Is the world full of contradiction as such?
 - God has created this world and it is without contradiction

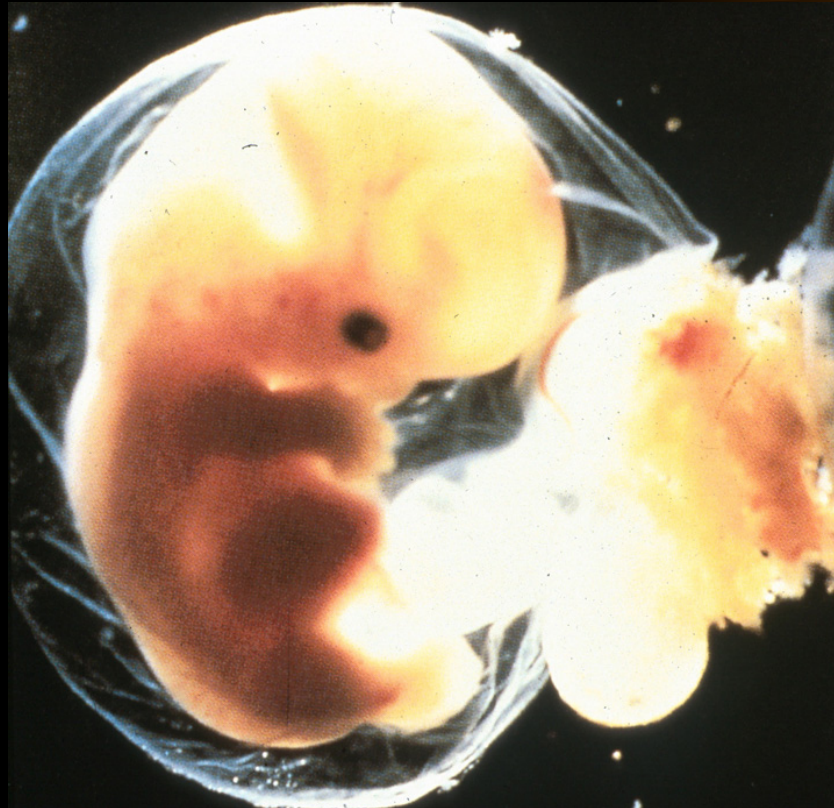


What should we do?

God wants us to persevere

- James 1:4. Perseverance must finish its work so that you may be mature and complete

A God given opportunity:
amniotic membrane!



Amniotic membrane transplantation

- Amniotic membrane donated by mothers who gave birth to children;
- Transplanting the membrane onto adult injured eye surface, to “*re-create*” a fetus-like environment, to re-activate **regenerative** ability in an adult eye, tapping the “fountain of youth”.

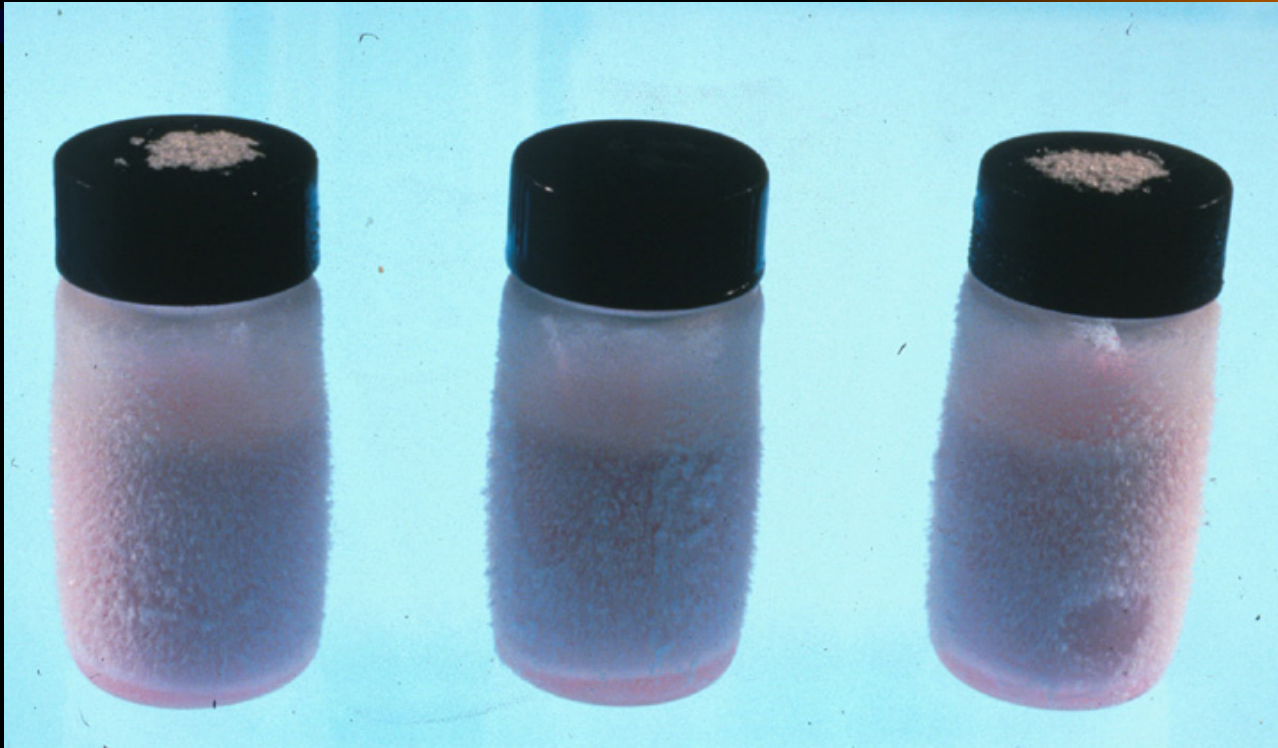


*Harvesting amniotic membrane
(always discarded after a child is
born)*







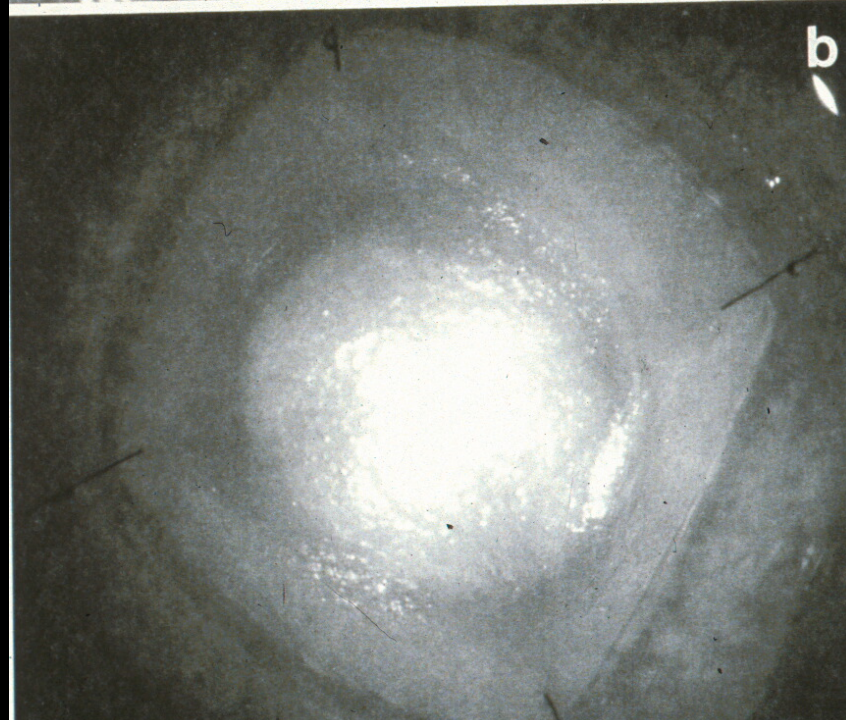
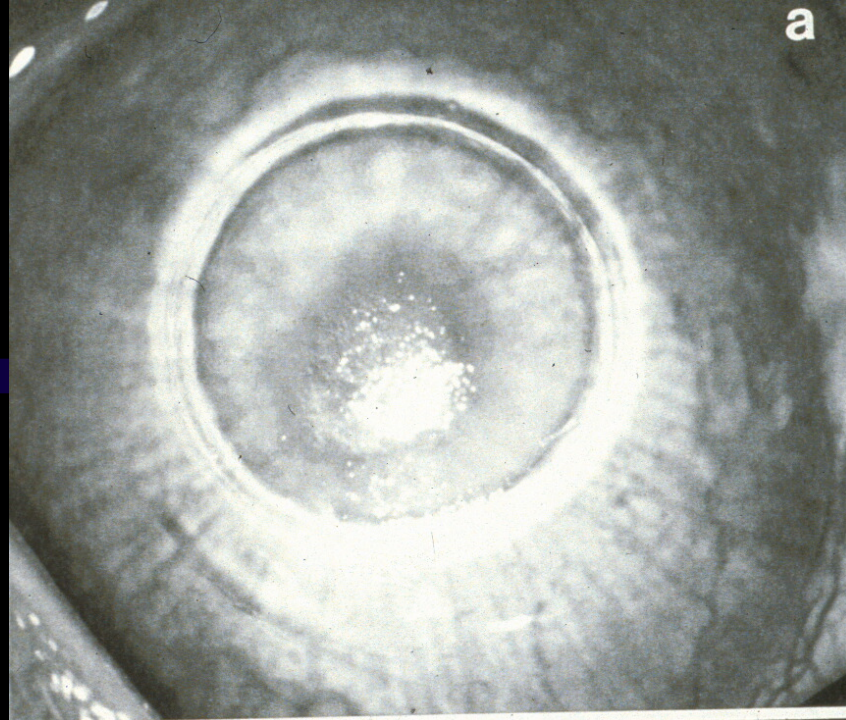


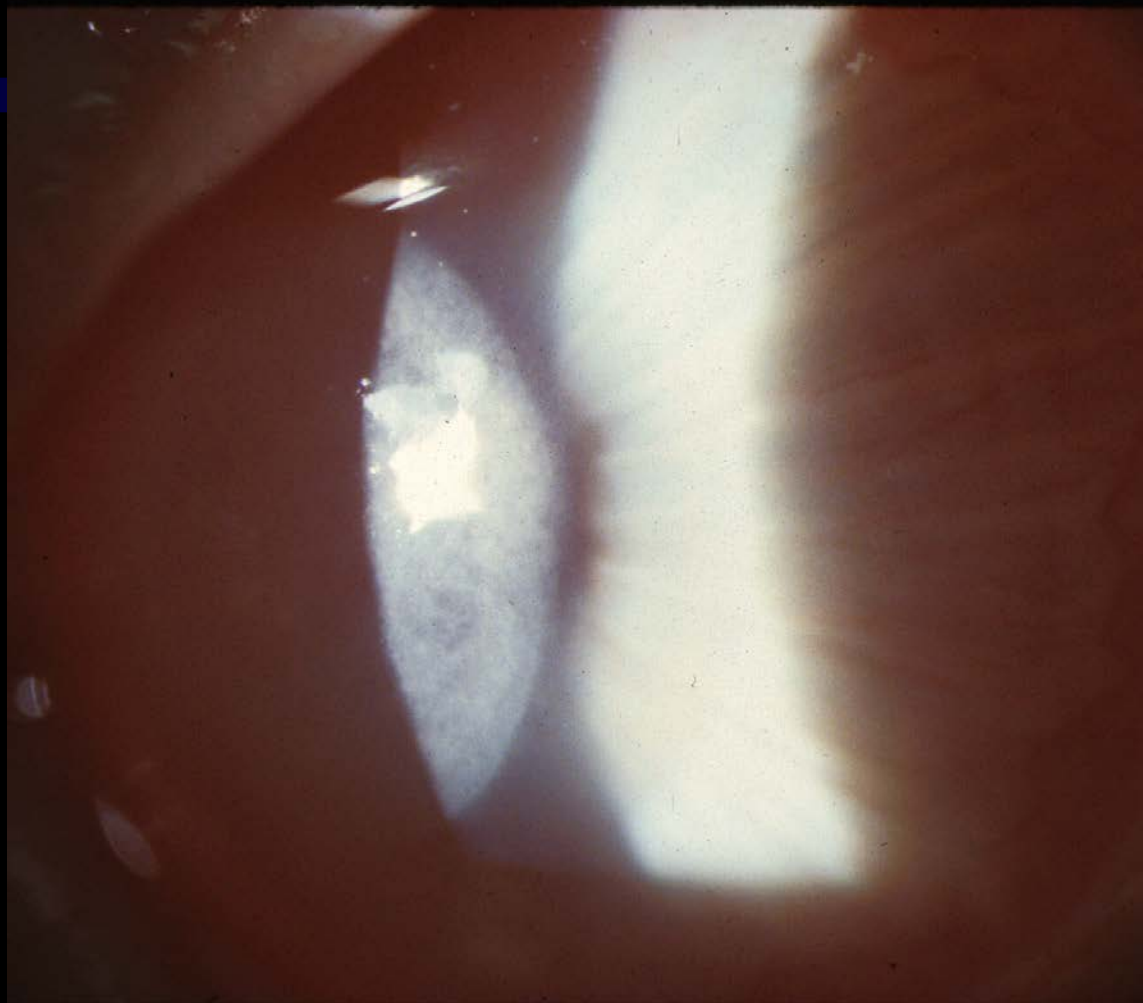


Laboratory research

Does amniotic membrane transplantation
reduces corneal scar?

What is the **molecular mechanism** by which
it reduces corneal scarring?

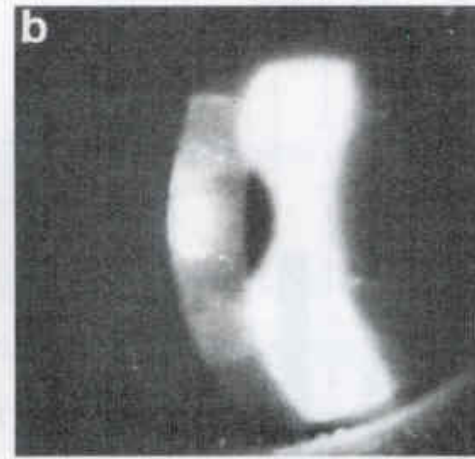
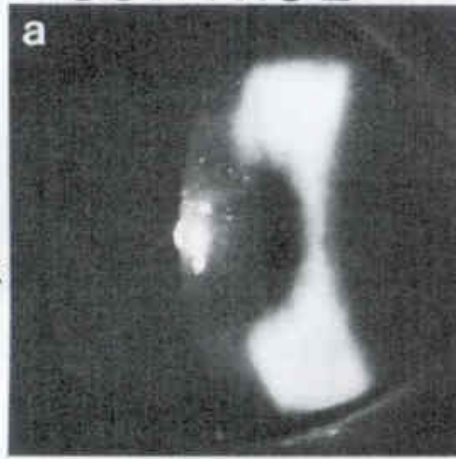




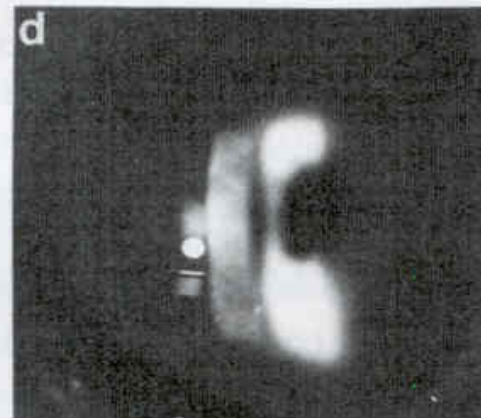
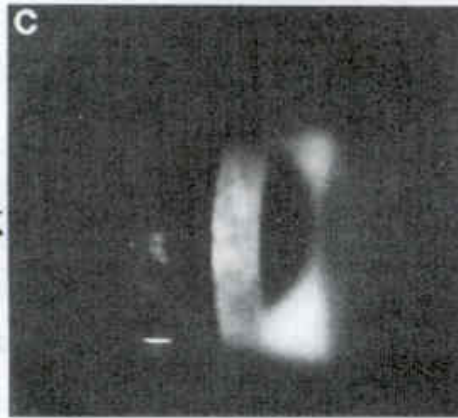
CONTROL

AM

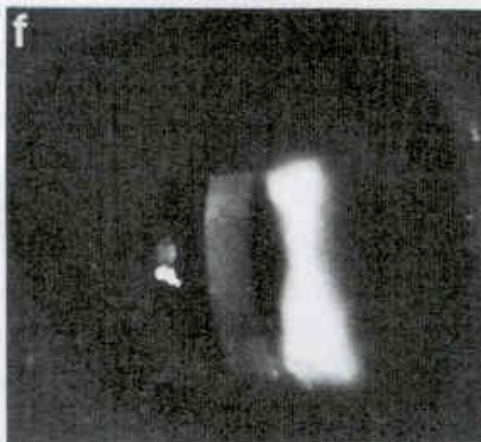
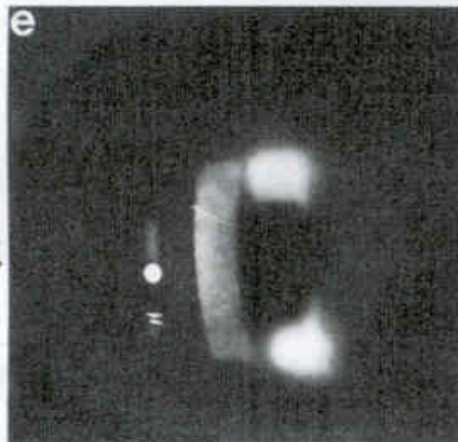
1Wk



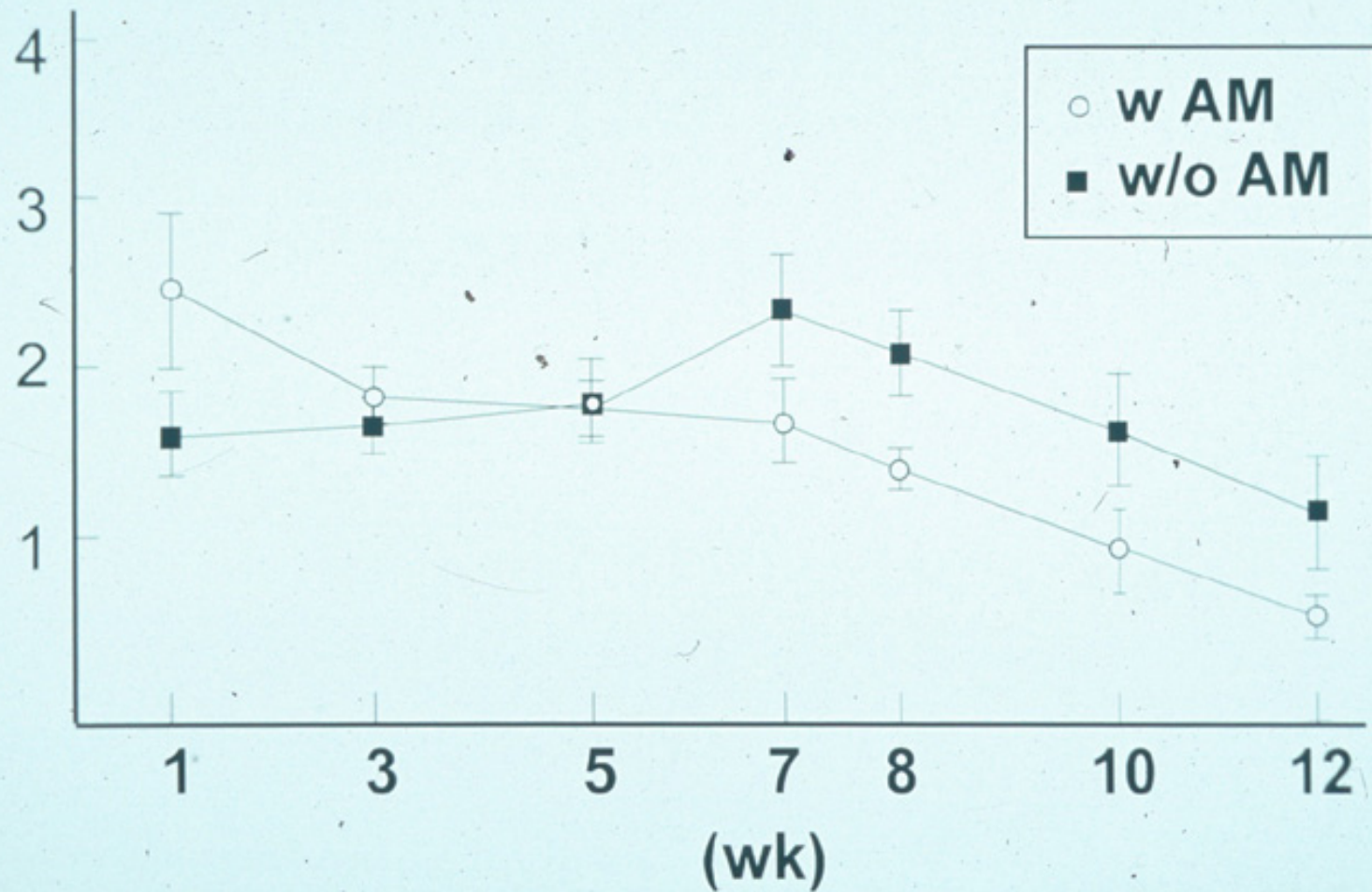
7Wk



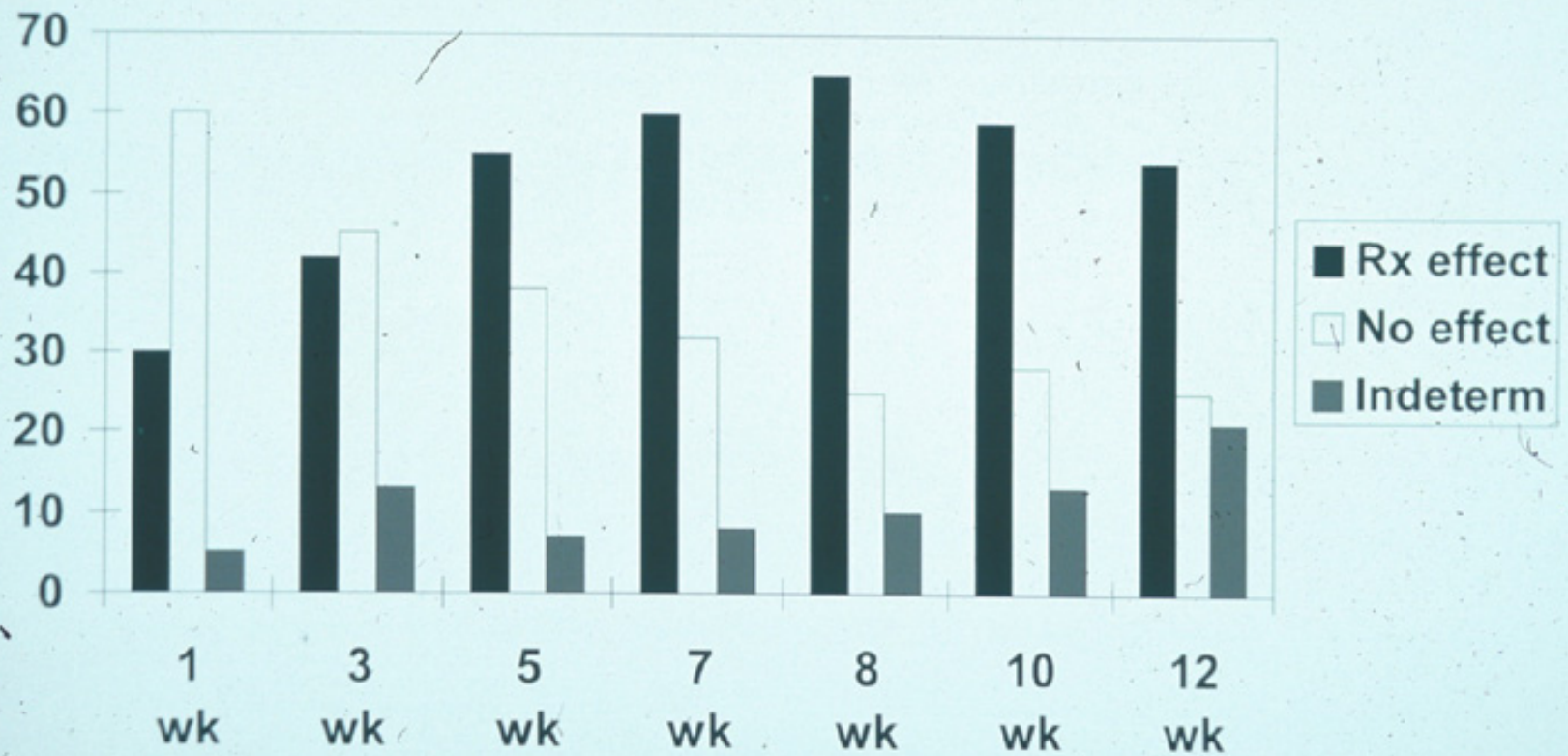
12Wk

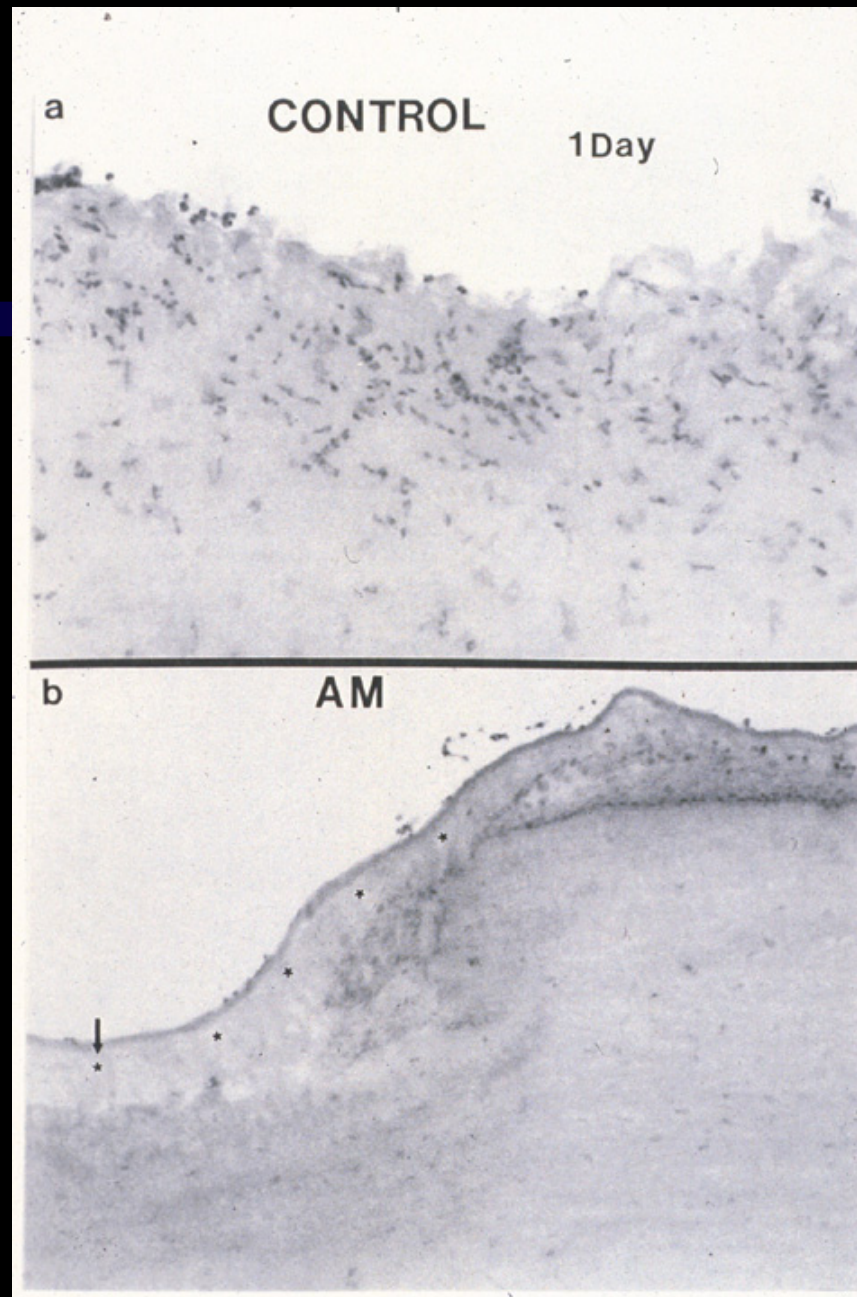


Temporal Profile of Haze

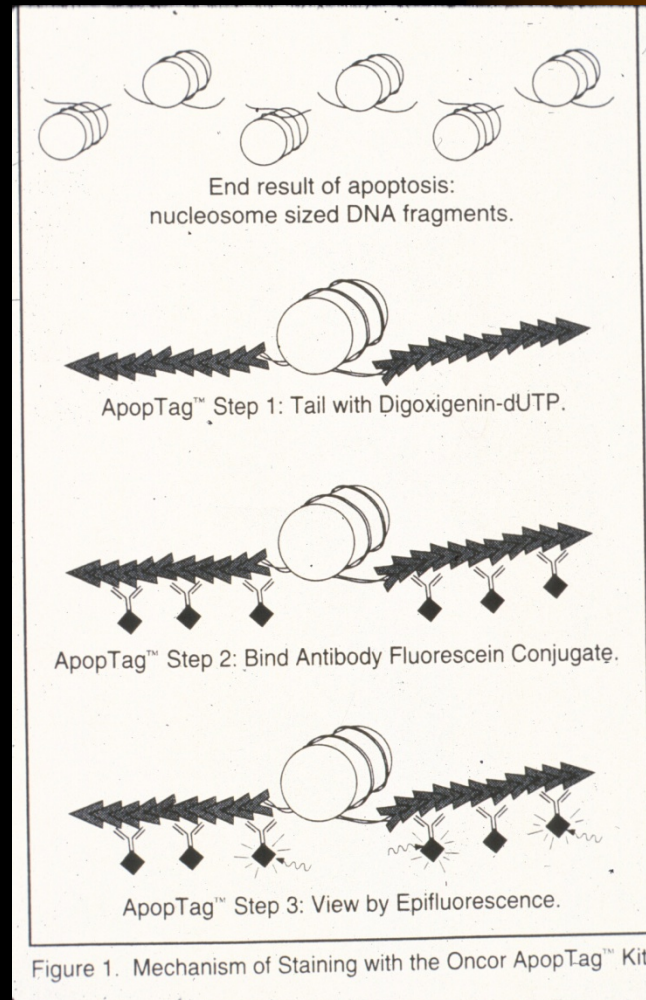


Percentage of Rx effect





Keratocyte apoptosis – marker of the excessiveness of wound-healing response



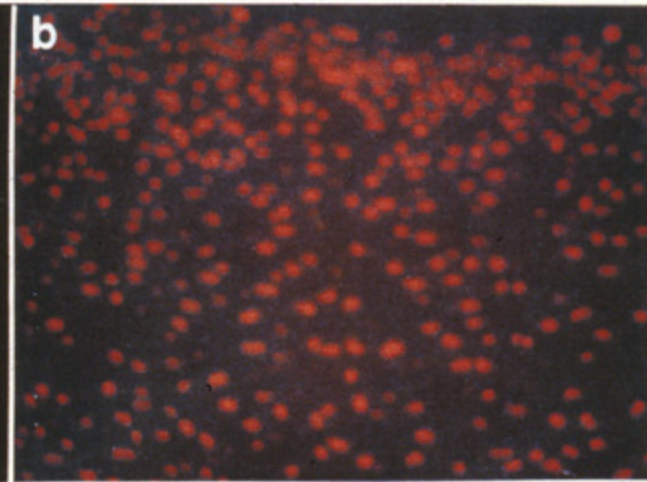
1 Day

Control

a



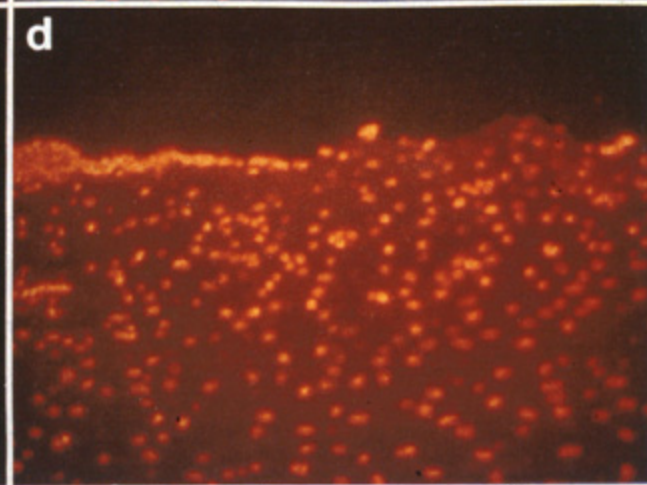
b



c



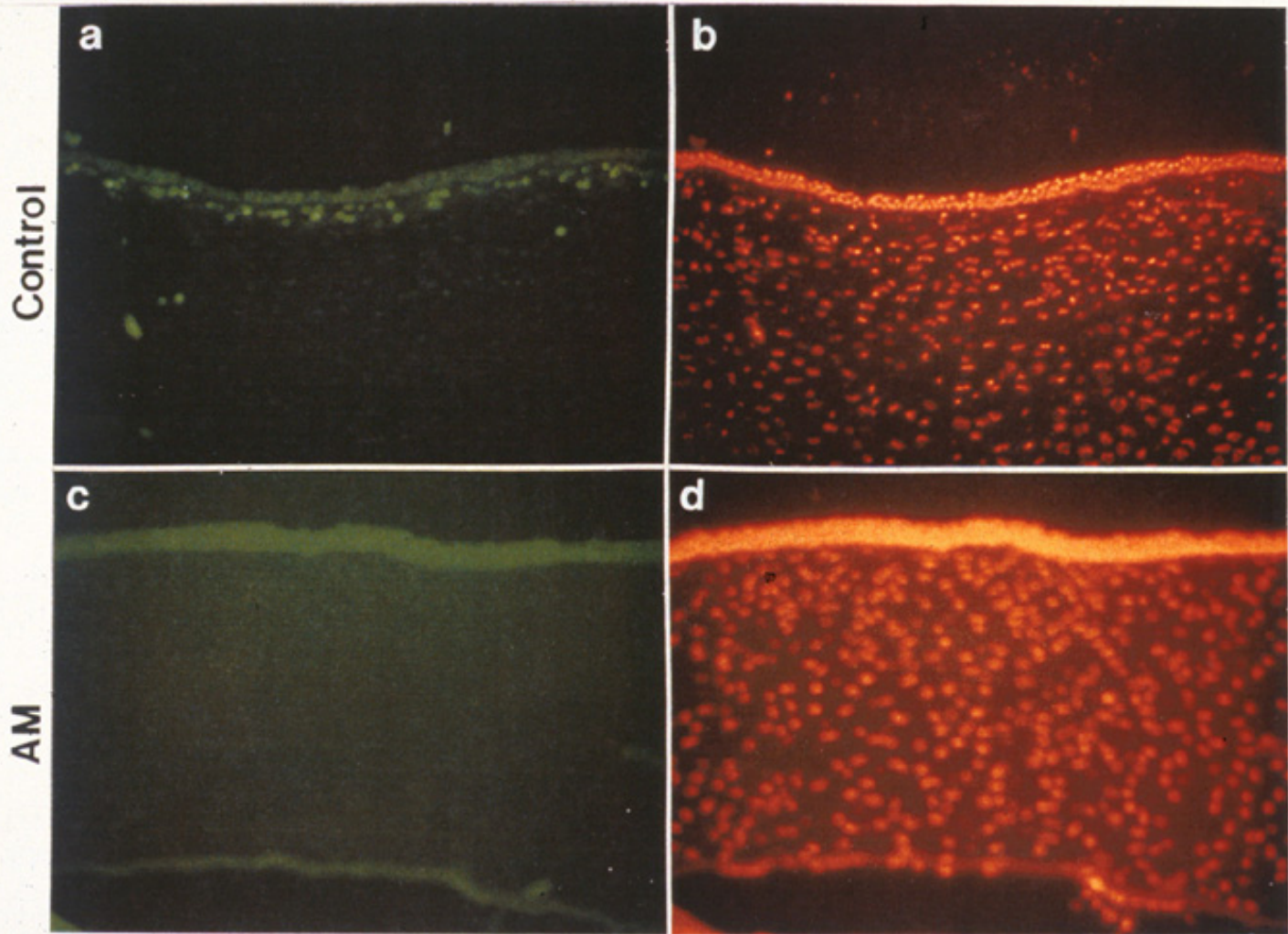
d



Apop-FITC

PI

1 Week



Anon-EITC

PI



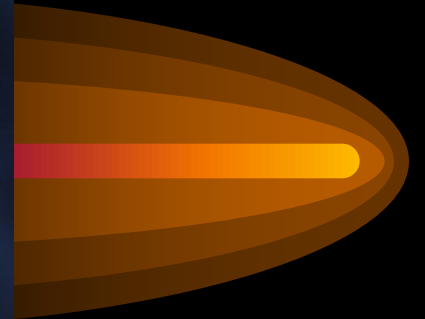
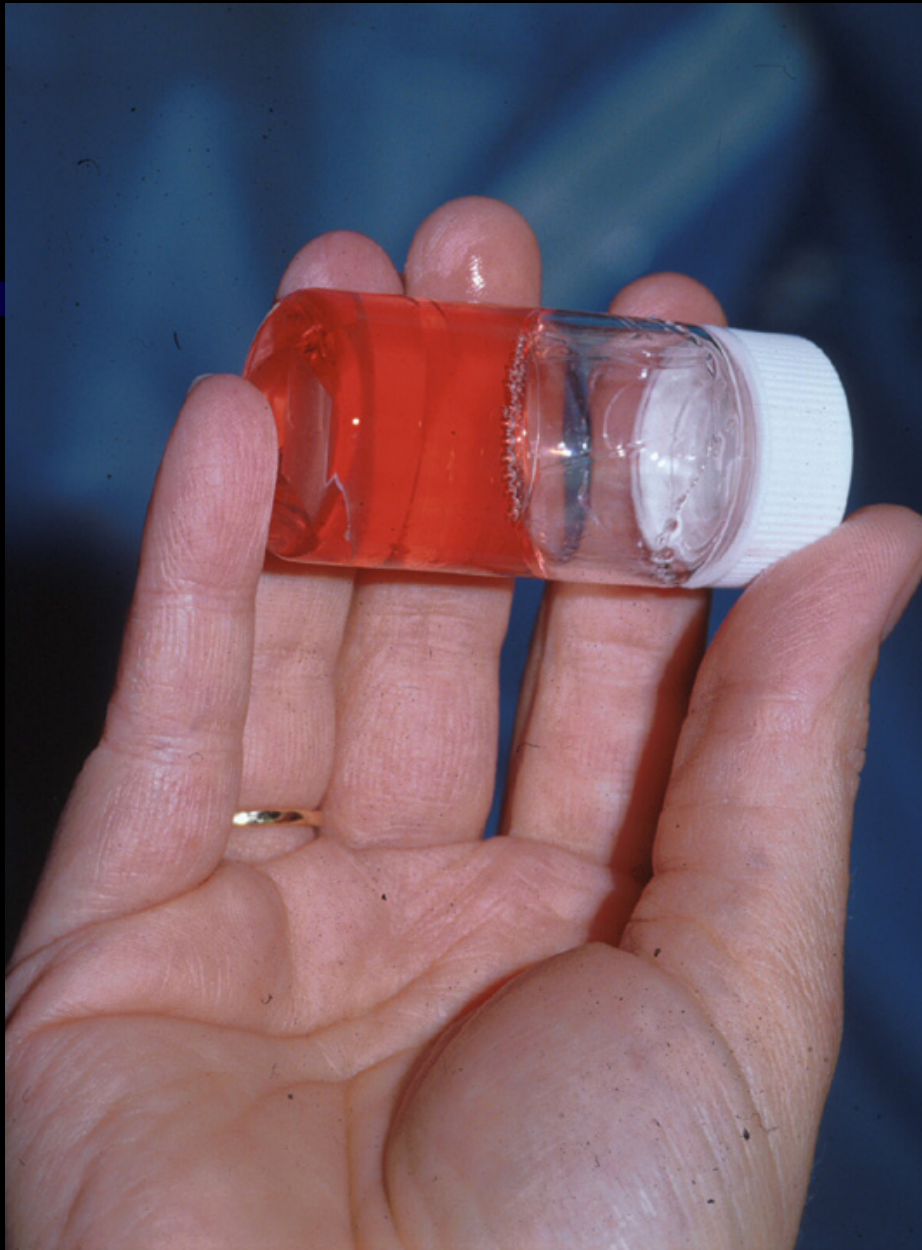
Result of laboratory research

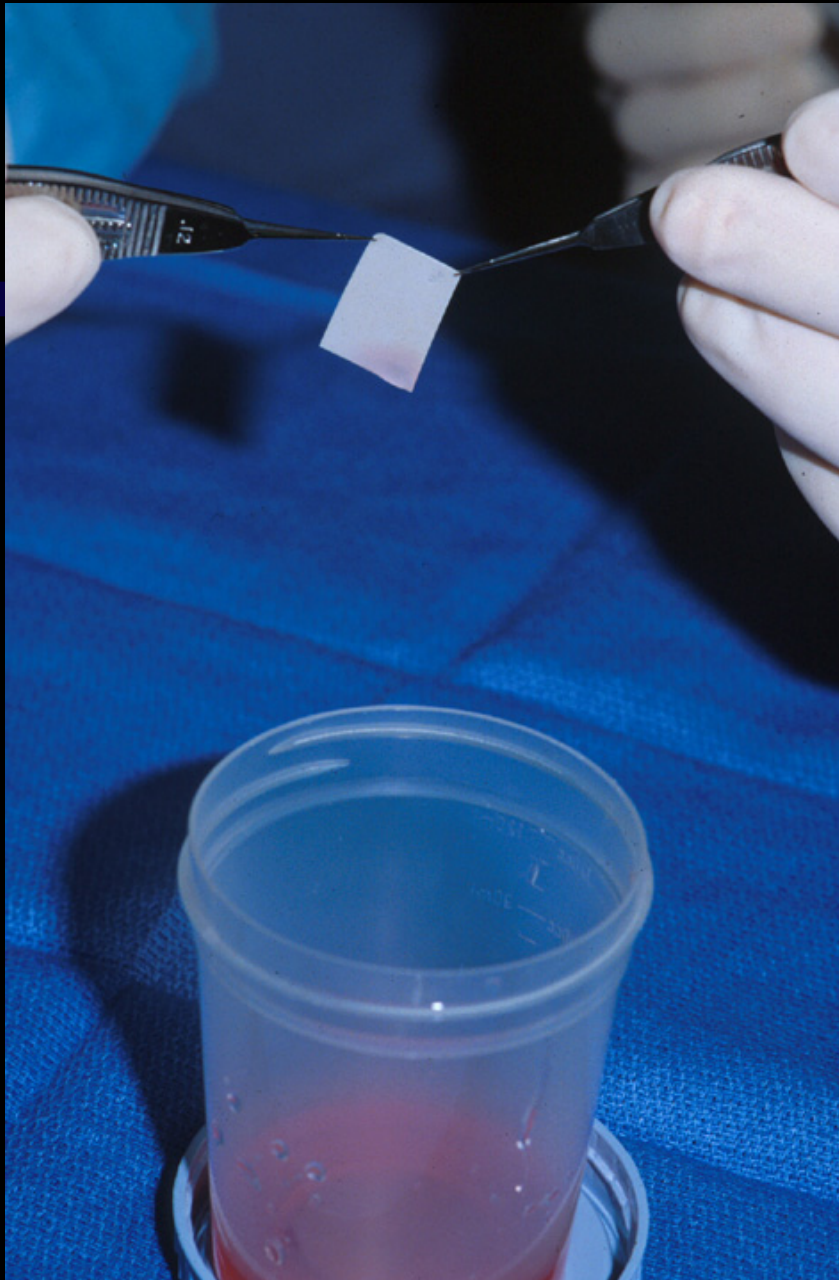
Publication ((Journal of Cataract & Refractive Surgery, Volume 27, Issue 2, Pages 310-319, 2001).

- The first laboratory demonstration of reduction of corneal scarring with AMT.
- The first elucidation of molecular mechanism of AMT corneal scar reduction (keratocyte apoptosis)

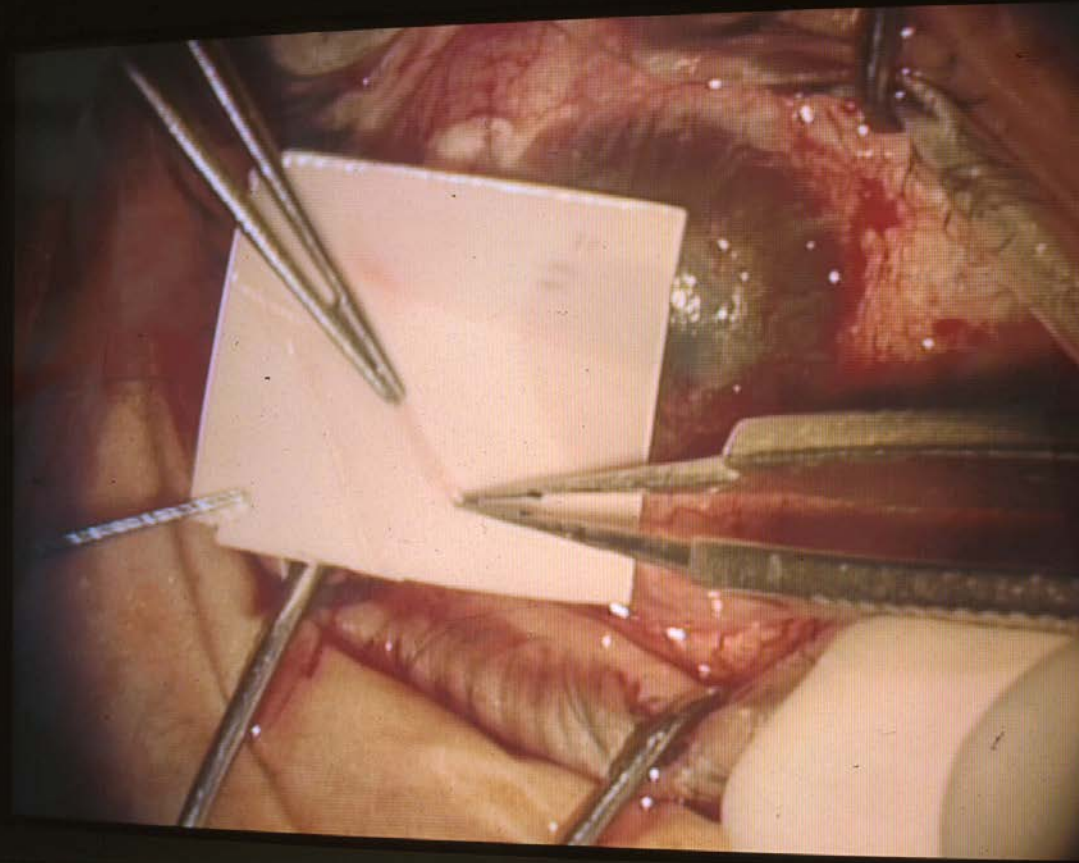


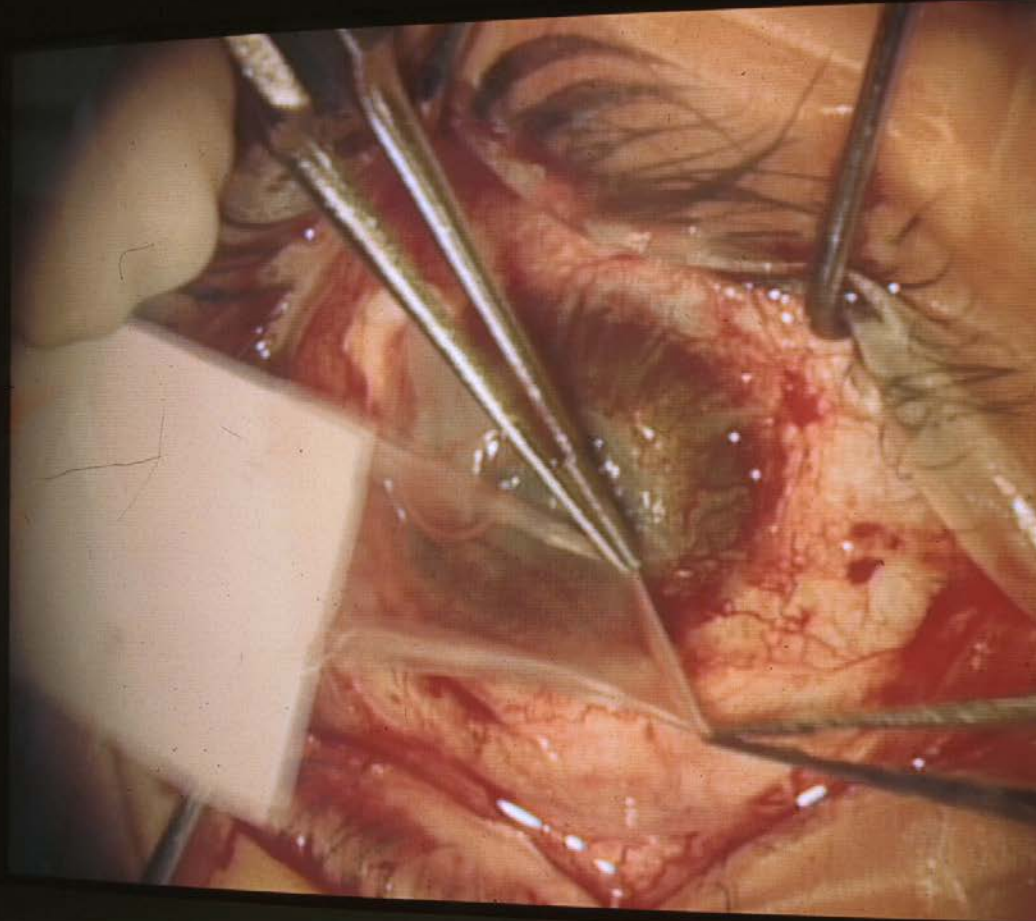
Amniotic membrane transplantation (AMT)

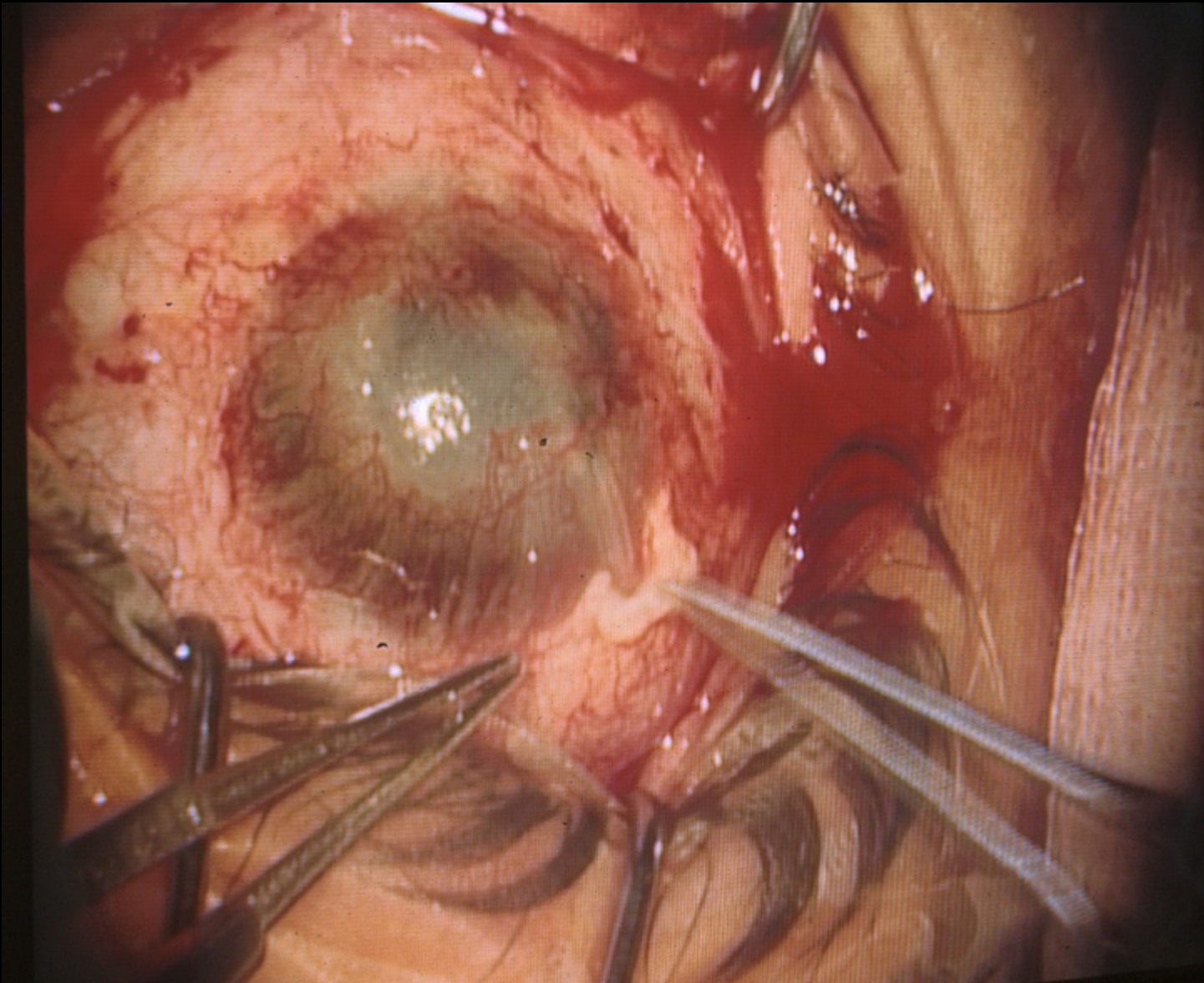


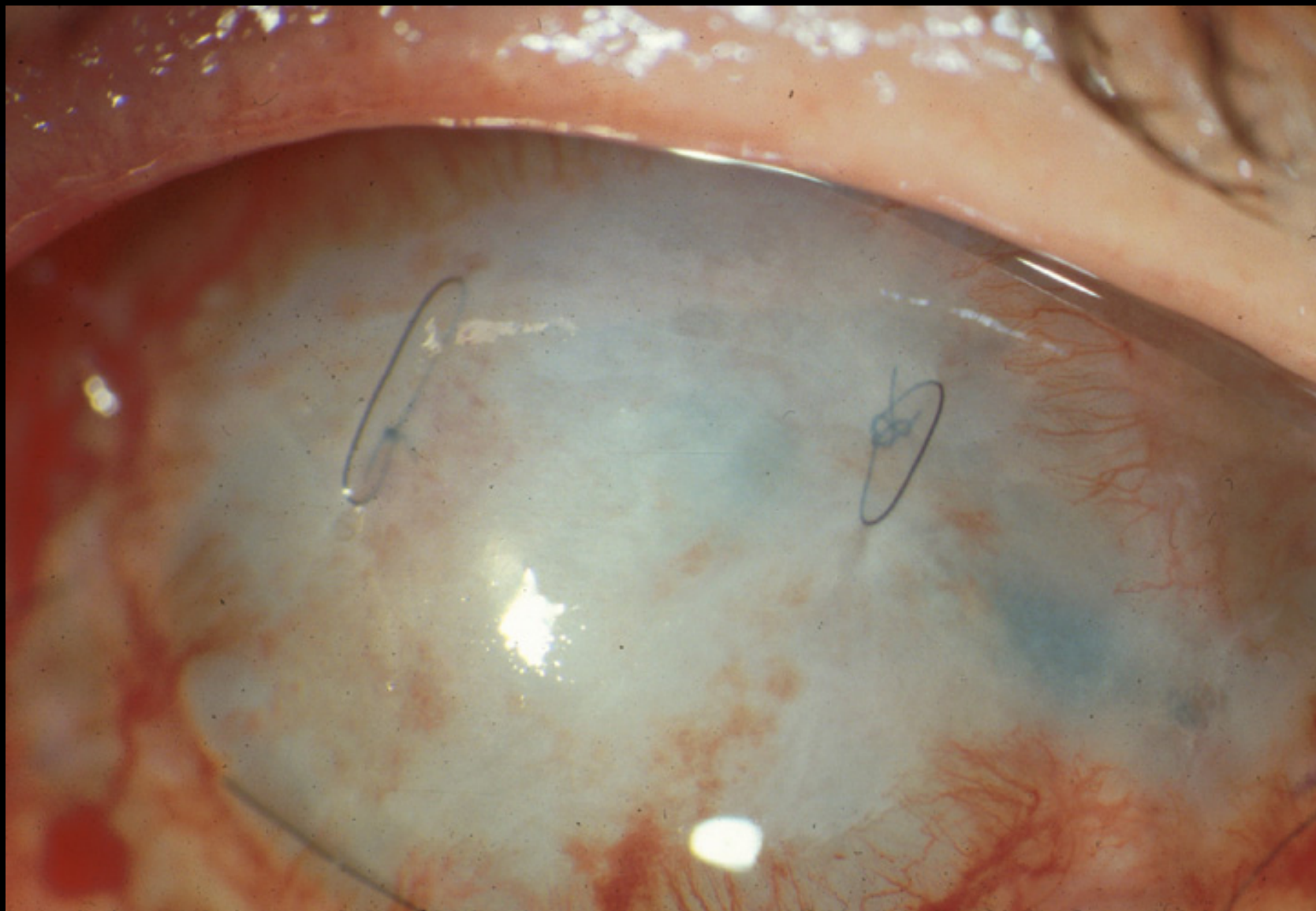




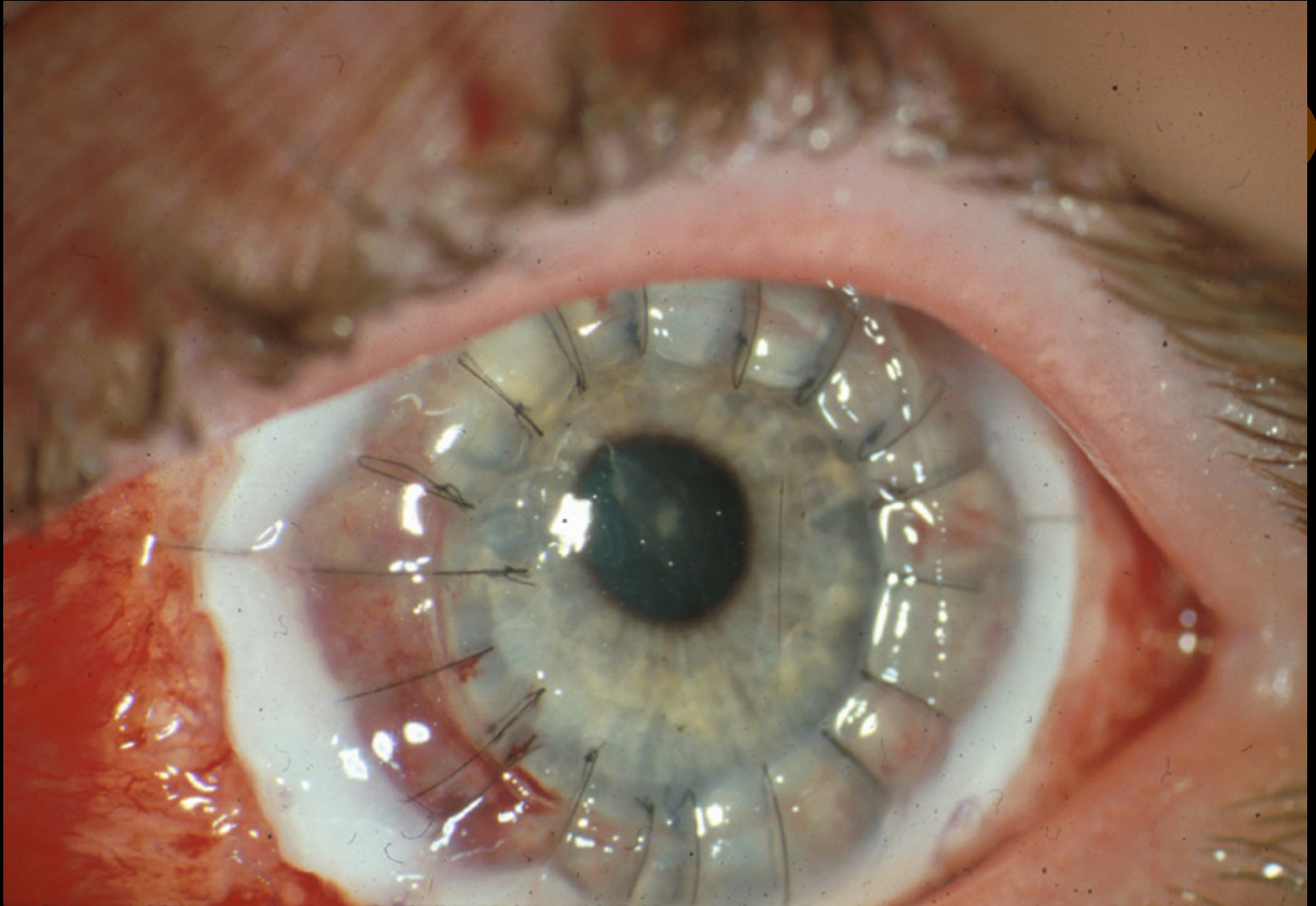




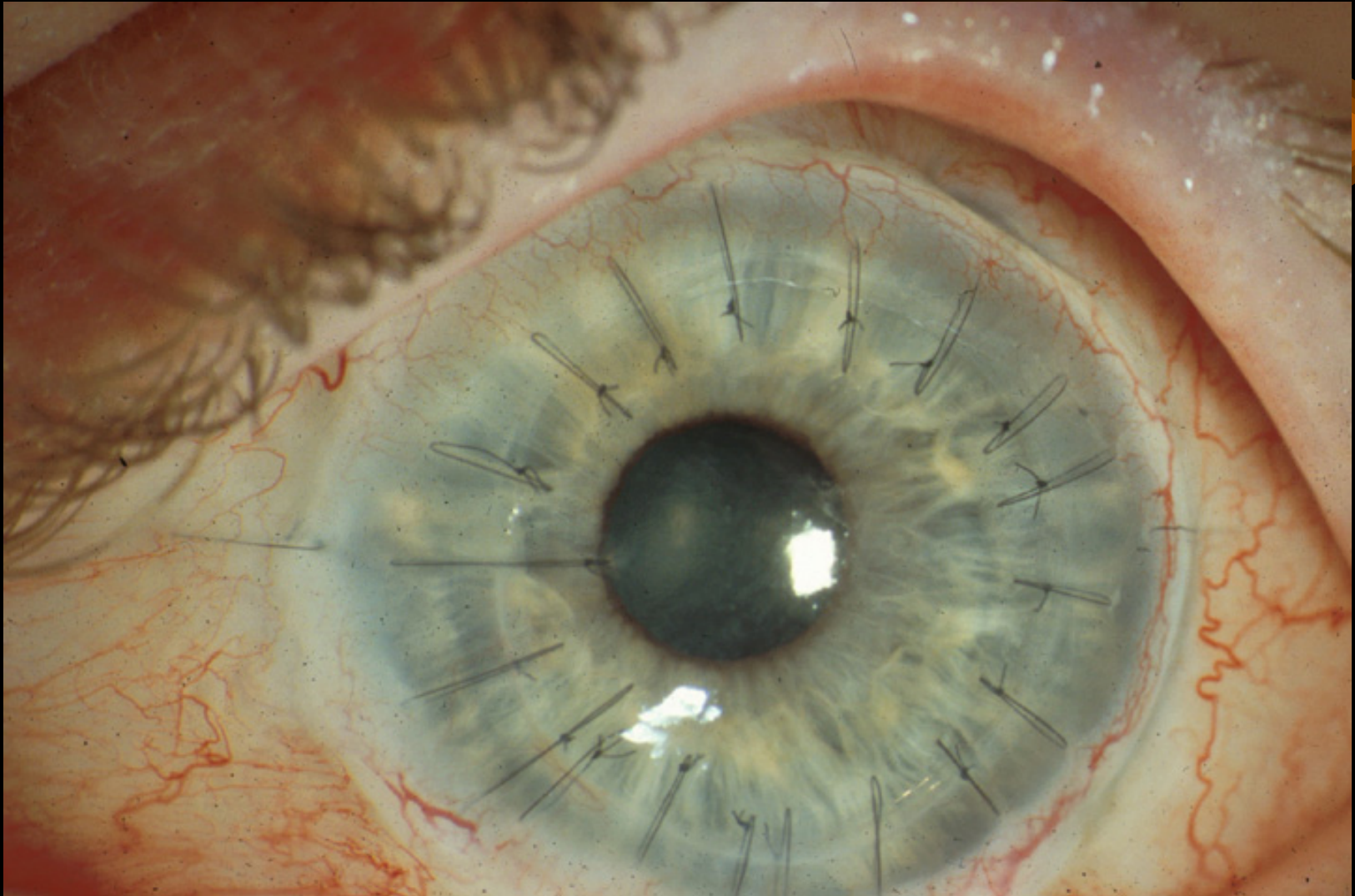




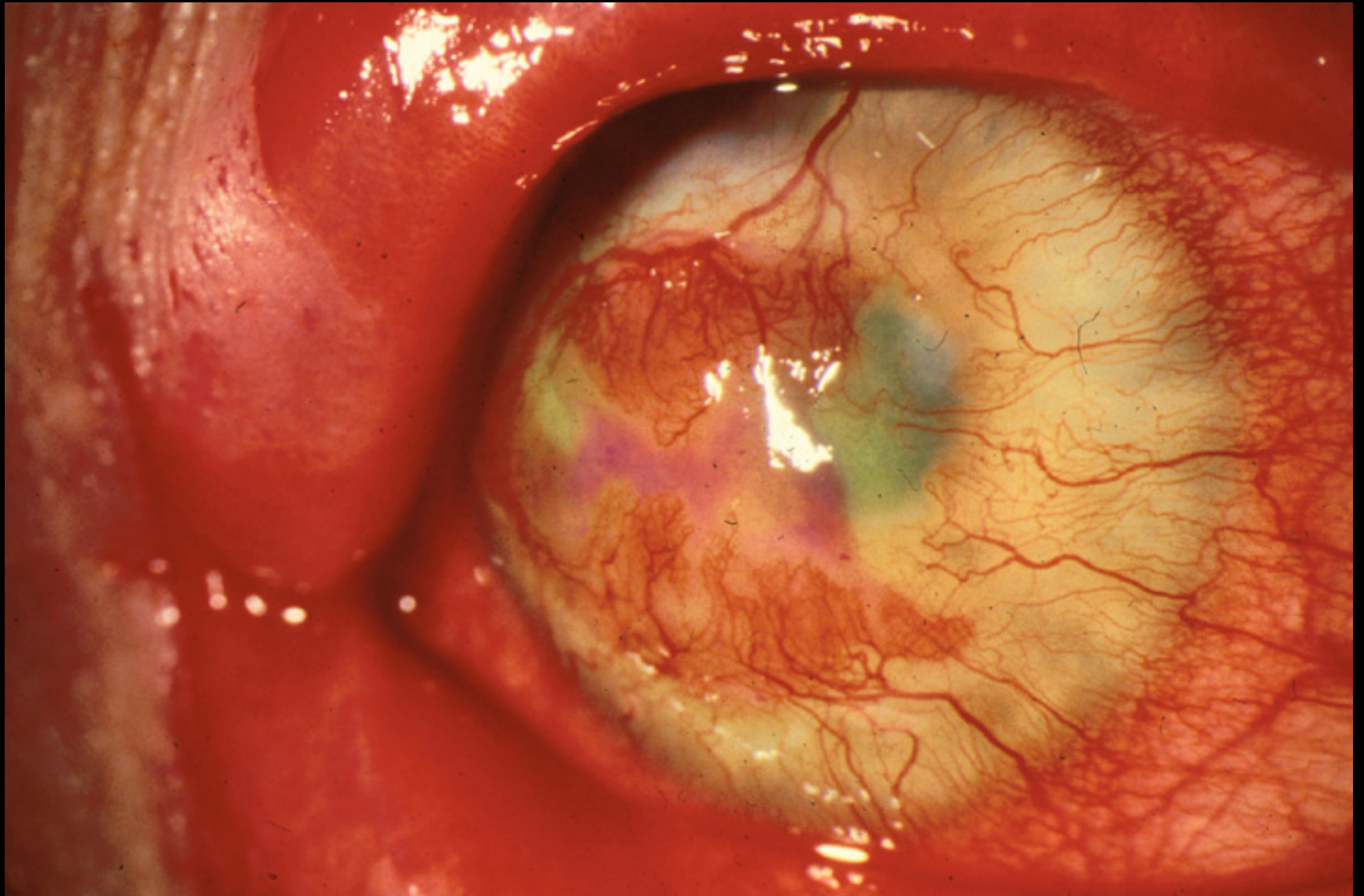
Patient 3 con't



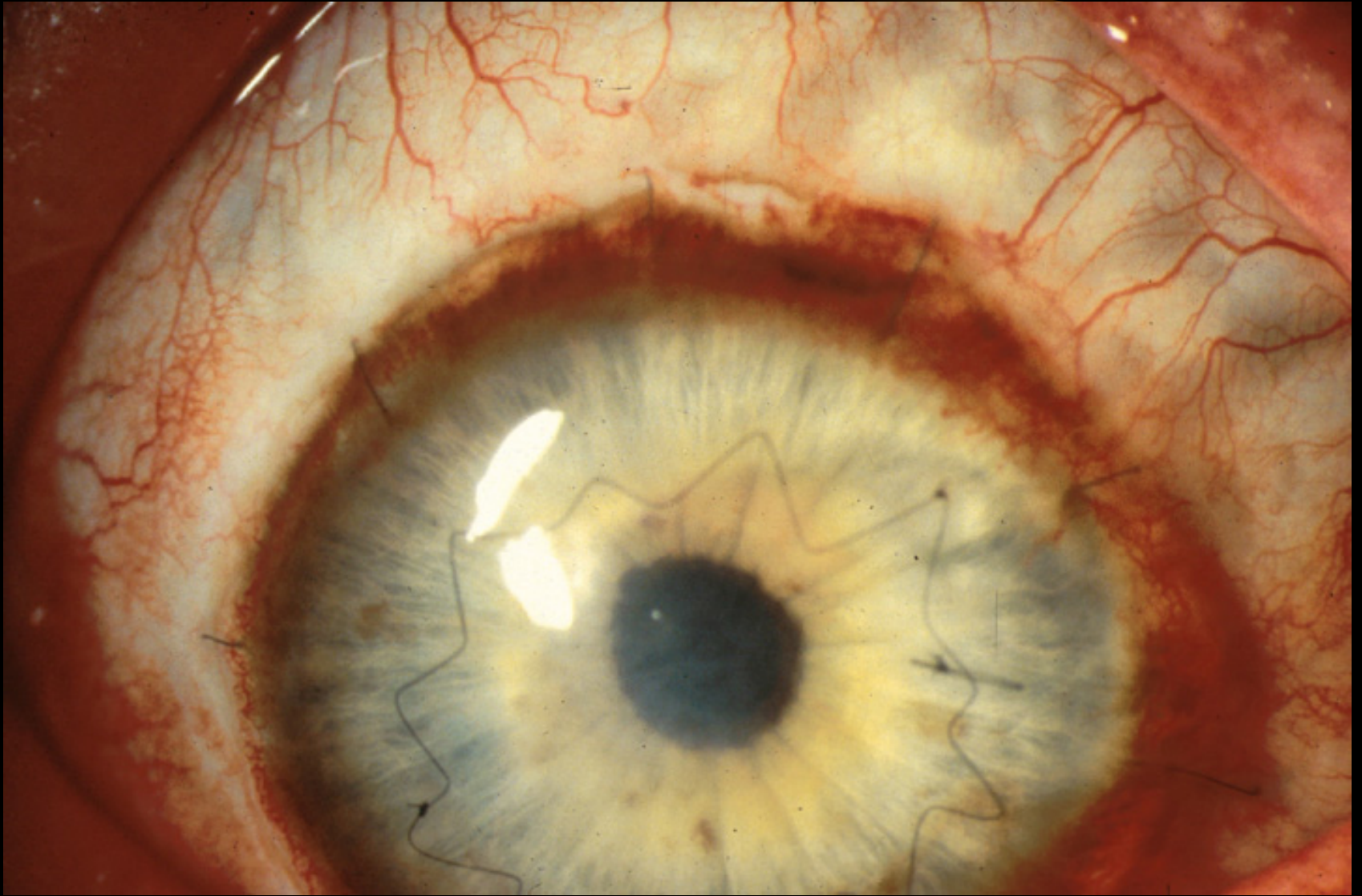
Patient 3 con't



Patient 4



Patient 4 con't



Problems with AMT:



Risk & complications associated with a surgery with suture.

Time is of essence. Within 24 hrs after injury, AM needs to cover injured ocular surface

Specialized AMT surgeons are few.

Injuries are occurring anywhere at any time.

The solution



- Amniotic membrane contact lens.



US006143315A

United States Patent [19]**Wang et al.**[11] **Patent Number:** **6,143,315**[45] **Date of Patent:** ***Nov. 7, 2000****[54] BIOCHEMICAL CONTACT LENS FOR TREATING INJURED CORNEAL TISSUE**

[76] Inventors: **Ming X. Wang**, 200 Grand Ave., Apt. 406, Nashville, Tenn. 37212;
Christopher P. Adams, 255 Broadway, Winter Hill, Mass. 02145

[*] Notice: This patent is subject to a terminal disclaimer.

[21] Appl. No.: **09/365,136**

[22] Filed: **Jul. 30, 1999**

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/899,783, Jul. 24, 1997, Pat. No. 5,932,205.

[51] Int. Cl.⁷ **A61K 9/00**; A61K 31/74;
A61K 47/30

[52] U.S. Cl. **424/427**; 424/78.04; 514/772.3

[58] Field of Search 424/429, 78.04;
514/772.3

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Primary Examiner—Carlos A. Azpuru

Attorney, Agent, or Firm—Giulio A. DeConti, Jr.; Lahive & Cockfield, LLP

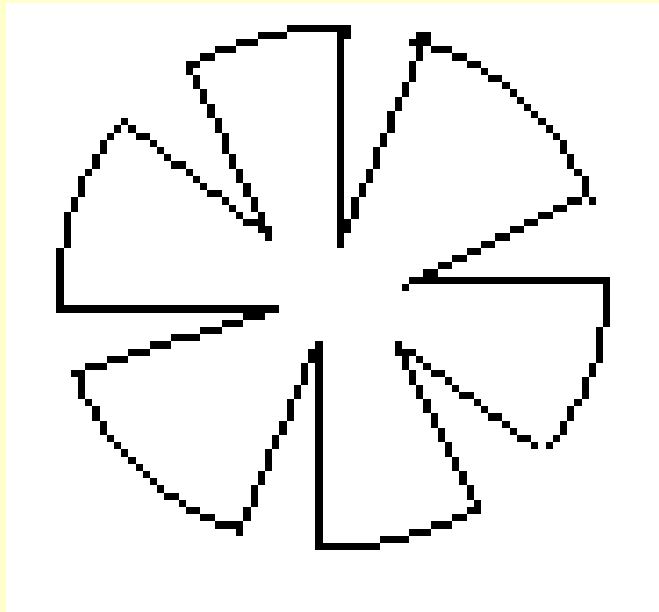
[57]

ABSTRACT

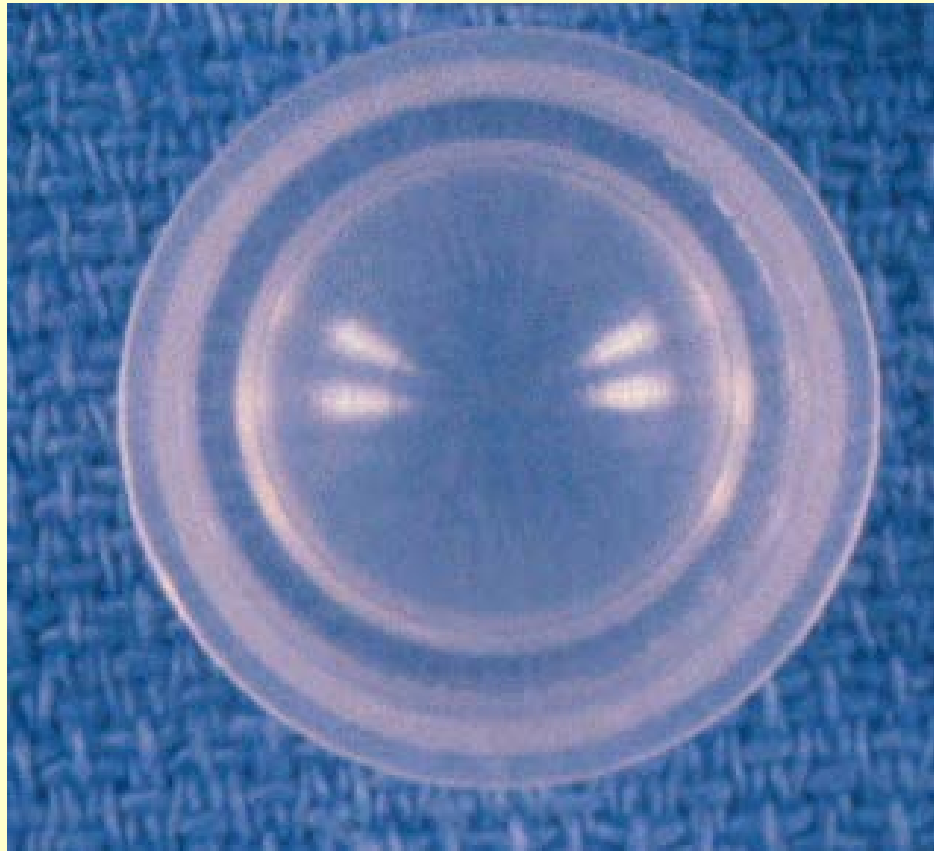
Methods for treating injured corneal tissue are described. The methods include contacting injured corneal tissue with a contact lens which includes an amniotic composition such that scarring of the injured corneal tissue is reduced. Methods for conditioning a contact lens for treatment of injured corneal tissue are also described. The methods include contacting the contact lens with an amniotic composition whereby the amniotic composition is deposited in or on the surface of said contact lens. Additionally, contact lens packages for treatment of injured corneal tissue are described. The contact lens package includes a container holding a contact lens which includes an amniotic composition and instructions for using the contact lens for treatment of injured corneal tissue.

22 Claims, No Drawings

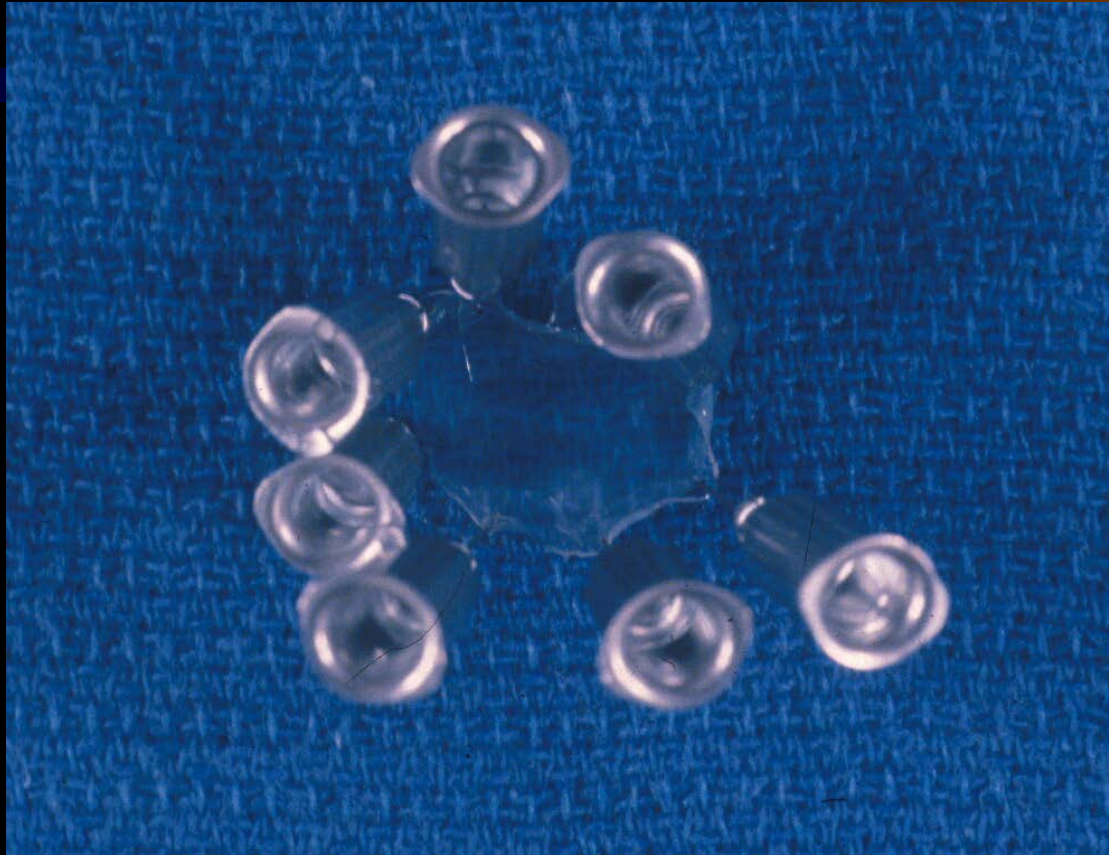
The issue of tissue folding/excess



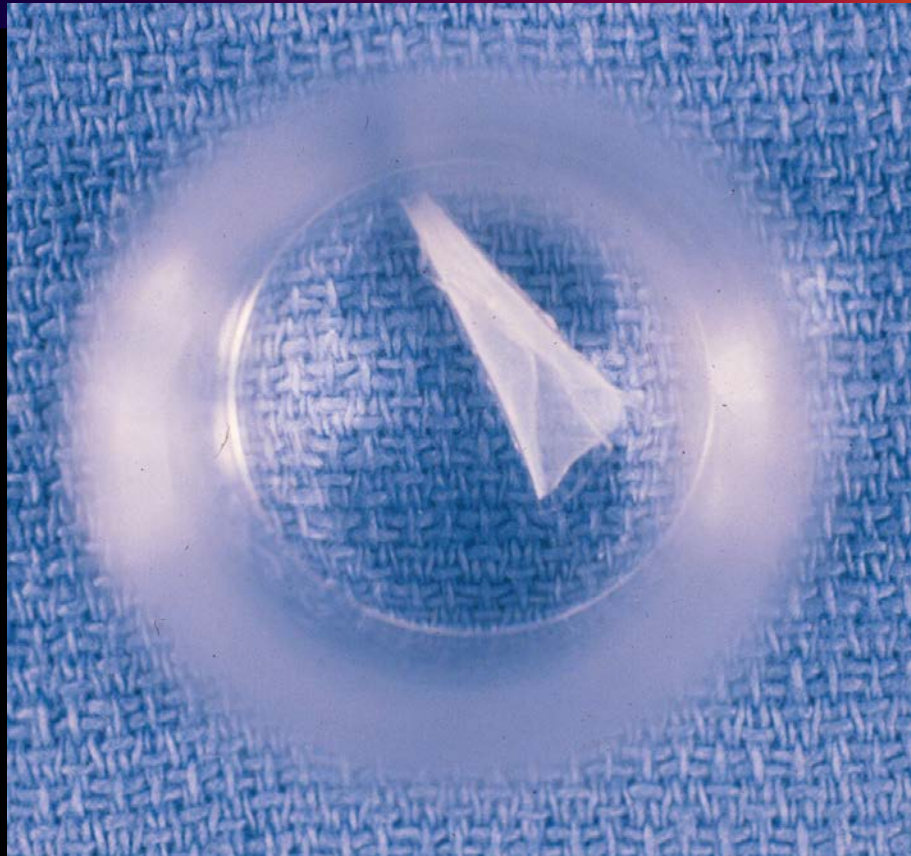
The issue of fixation of AM onto CL



Membrane rigidity, stability, bioactivity



Biocomponent retention of AMCL



AMCL stability and transport



Packaging and distribution



Science and business ventures



- Lab research, 1996.
- US patents 6,143,315, 5,932,205, 2000.
- Publication: JCRS 27:310-319, 2001.
- EyeVU, founded in 2001.
- The world's first AMCL prototype, 2001.
- Patents licensed to IOP, Inc.
- Product launch: Nov 2011.

The world's first amniotic contact lens



AmbioDisk™

Office Procedure: Sutureless, overlay use of AmbioDry2™ Amniotic Membrane on the ocular surface

Conventional Uses

- Non-Healing Epithelial Defects
- Neurotrophic Ulcerations
- Corneal Erosions
- Acute Chemical/Thermal Burns
- Post-Infectious Keratitis (herpetic, vernal, bacterial)

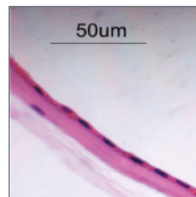
Surgical Pearls

For optimal adherence, maintain a dry ocular surface during placement of the Ambio graft. In order to prevent bunching of the graft, avoid sliding the lens from side-to-side during positioning.

Naturally, small air bubbles and folds in the Ambio graft may be noted immediately following placement. The bubbles and creases – along with the opacity of the Ambio graft – will resolve over a 1-2 day time period leaving a normal translucent appearance.

Typically, the Ambio graft will absorb 5-7 days following placement.

Tarsorrhaphy is not required.



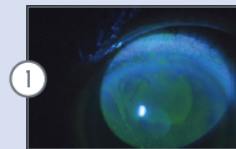
More Biostructurally Intact

- Contains an intact epithelial, columnar cell matrix on the surface of the basement membrane
- Maintains an intact dense basement membrane
- Provides a loose collagen layer bordered by retained fibroblasts



15mm AmbioDry2 Disk

Case Technique: Persistent Epithelial Defect



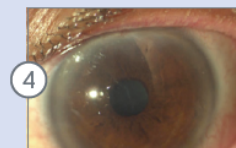
Patient presented with a large, superior persistent epithelial defect, secondary to previous melanoma excision with topical mitomycin C. Previous treatment with bandage contact lens yielded insignificant healing.



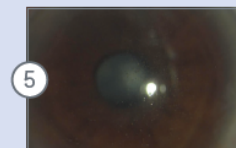
Topical anesthesia was applied. The area of the defect was denuded. A 15mm AmbioDry2 amniotic membrane graft was placed on the ocular surface – to cover the entire cornea and limbal regions. No tarsorrhaphy required.



Slit lamp image immediately after the procedure notes small bubbles and creases in the AM graft. Light haze indicates intact presence of the graft. The patient is comfortable and functioning.



At 9-day post-op, fragmented globules of the AM graft are noted – at the interface of the contact lens and the cornea. The defect appears to have healed. The eye remains comfortable and functional.



At 30-day post-op, slit lamp image shows spherical particles of retained amnion between lens and corneal surface. Slit lamp image with fluorescein stain and cobalt blue filter shows pooling but not staining with fluorescein, demonstrating that epithelium has healed. Pooling of stain is also evident elsewhere in the cornea in small, circular indentations in the epithelium where remnants of the amniotic membrane remained until the contact lens was removed.

AmbioDisk AMCL

The CPT code is 65778 (non-surgical fixation of AM, an in-office procedure).

Indication: poor ocular surface, non-healing.

Order AmbioDisk from IOP, Inc: AD-5150: ambioDry2 (11mm disk, 35 um thick), comes with a 18mm scleral lens: \$600.

Reimbursement:

Medicare reimburses \$1,352.31.

Commercial insurance reimburses \$1,300+.

Global period is 10 days, repeat AMCL application is allowed if it is clinically indicated.

AmbioDisk amniotic membrane contact lens (AMCL):

(copy and paste, into browser window, to see)

<http://www.iopinc.com/store/ambiodisk/>, 1-800-535-3545

U.S. Patent Nos. 5,932,205 and 6,143,315), Wang and Adams.

(copy and paste, into browser window, to see)

<http://www.google.com/patents/US5932205>, <http://www.google.com/patents/US6143315>

**SPECIAL HANDLING
INSTRUCTIONS:**

Please take great care when removing the graft from the internal pouch and while handling in the sterile field. In its dry state, the graft is translucent and extremely lightweight.

PEEL TO OPEN

Ambio●**dry**²

Processed Human Amniotic Membrane Allograft
For Human Transplantation

- One (1) dehydrated substrate-free amniotic membrane tissue graft.
- Single patient use only. Discard unused material.
- Internal pouch and contents considered sterile.
- **DO NOT RESTERILIZE.**
- Refer to package insert for detailed instructions for use.

Innovative Ophthalmic Products, Inc., Costa Mesa, CA 92626 USA ● Phone (800) 535-3545 (714) 549-1185
ADLP0102.003

Amniotic Membrane Allograft 15.0mm



AD15-2012166-010
Expires: 02/2017

Amniotic Membrane Allograft 15.0mm



AD15-2012166-010
Expires: 02/2017

Amniotic Membrane Allograft 15.0mm



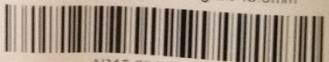
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Amniotic Membrane Allograft 15.0mm



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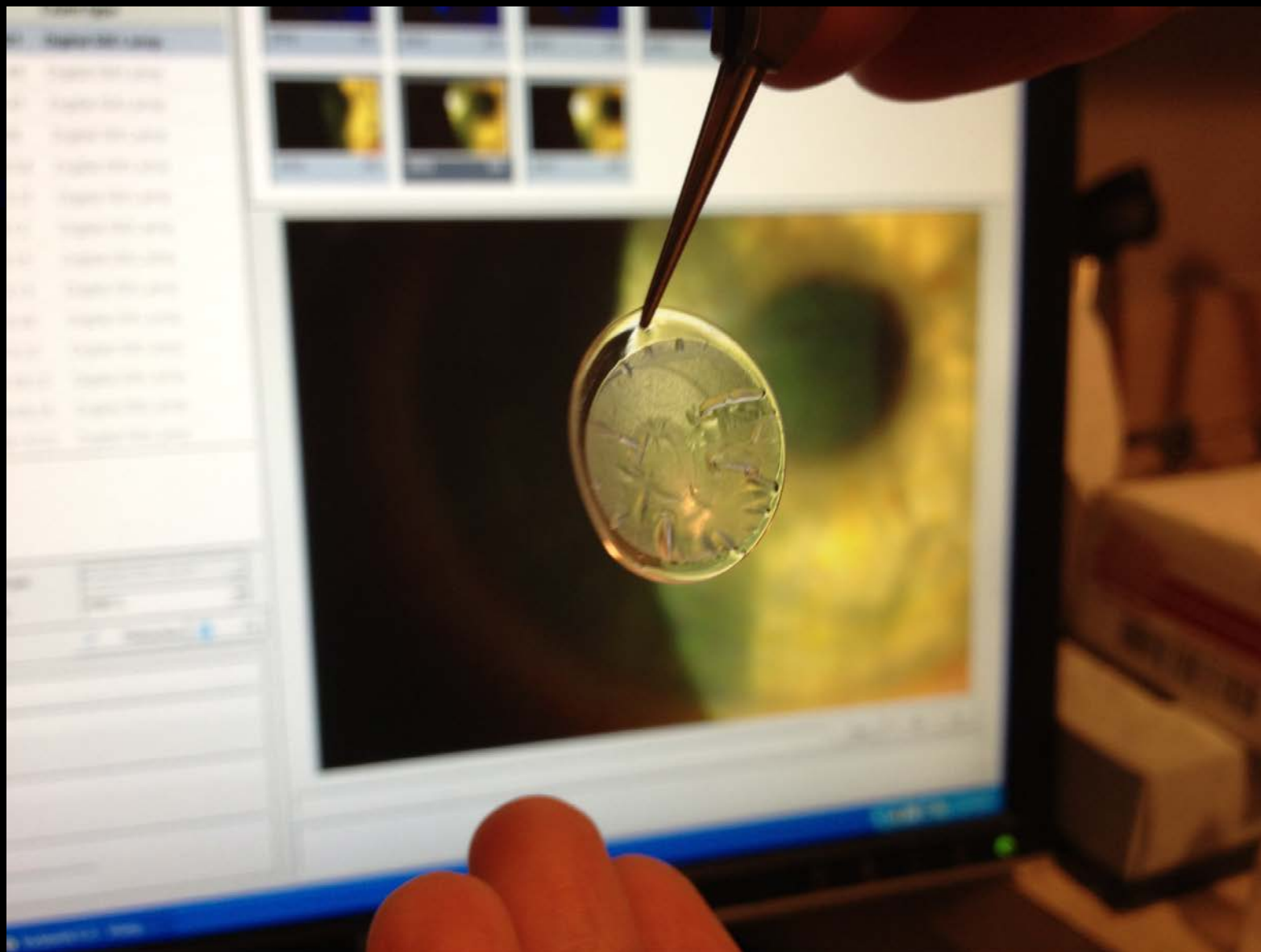


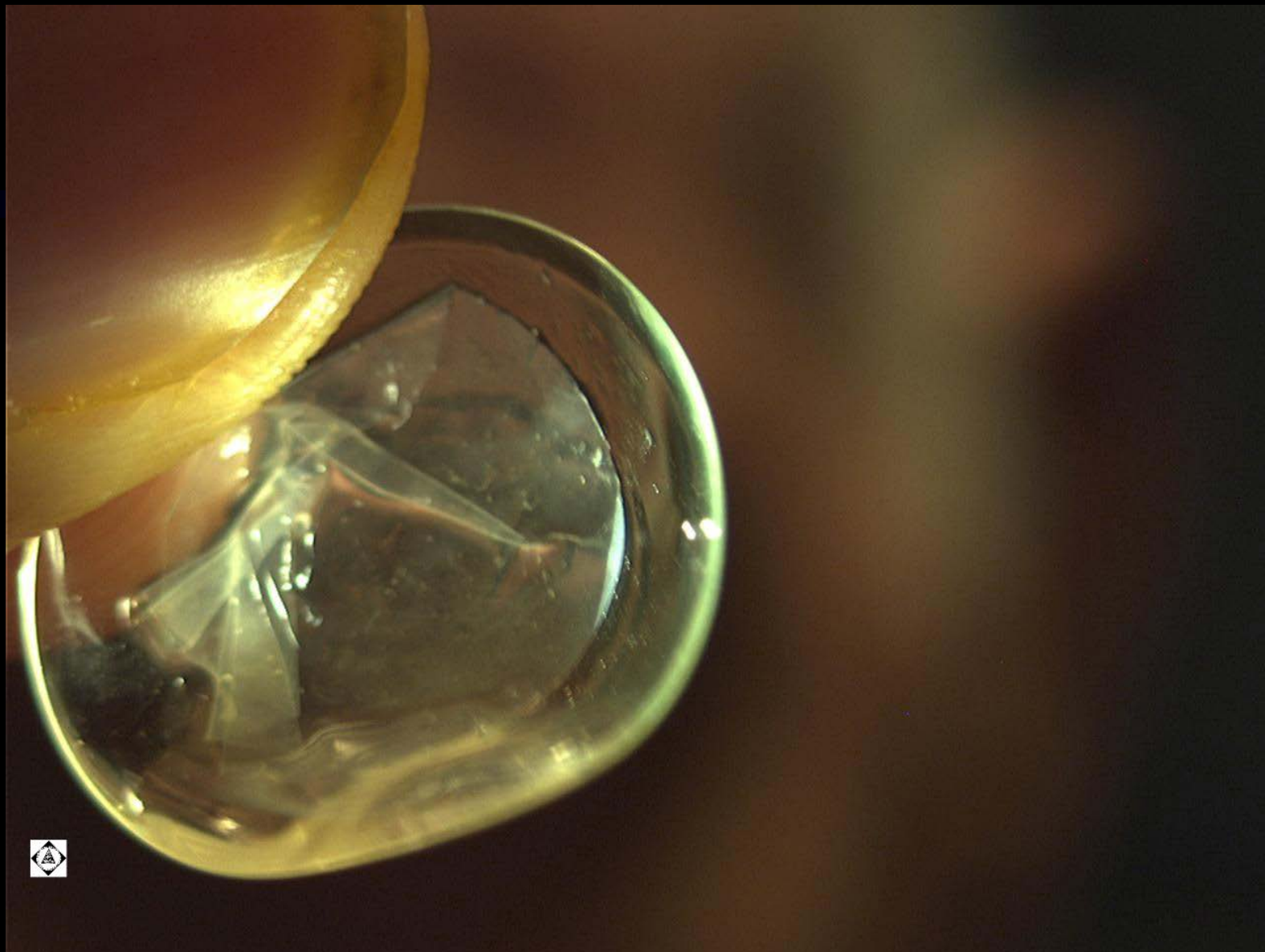


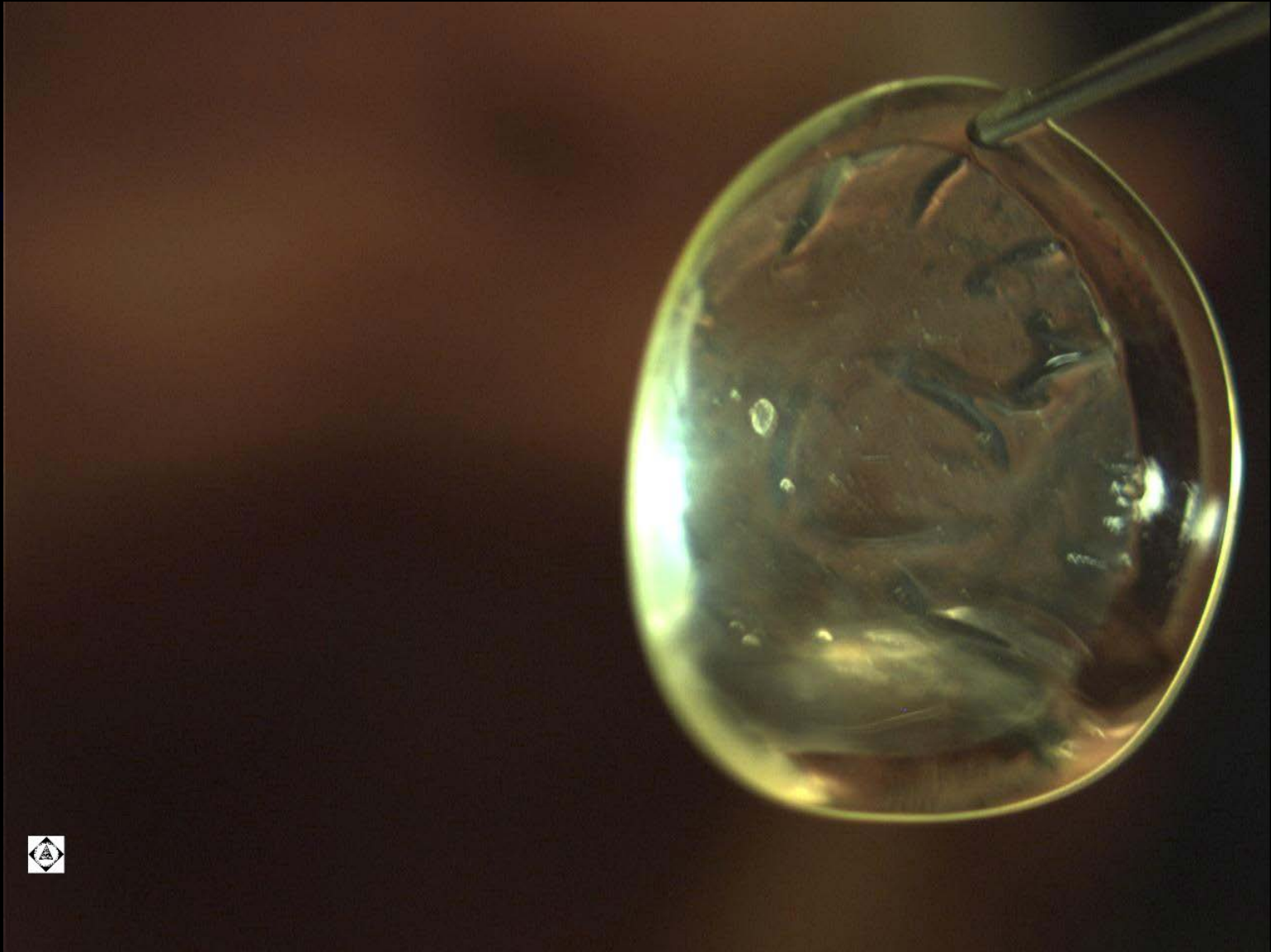














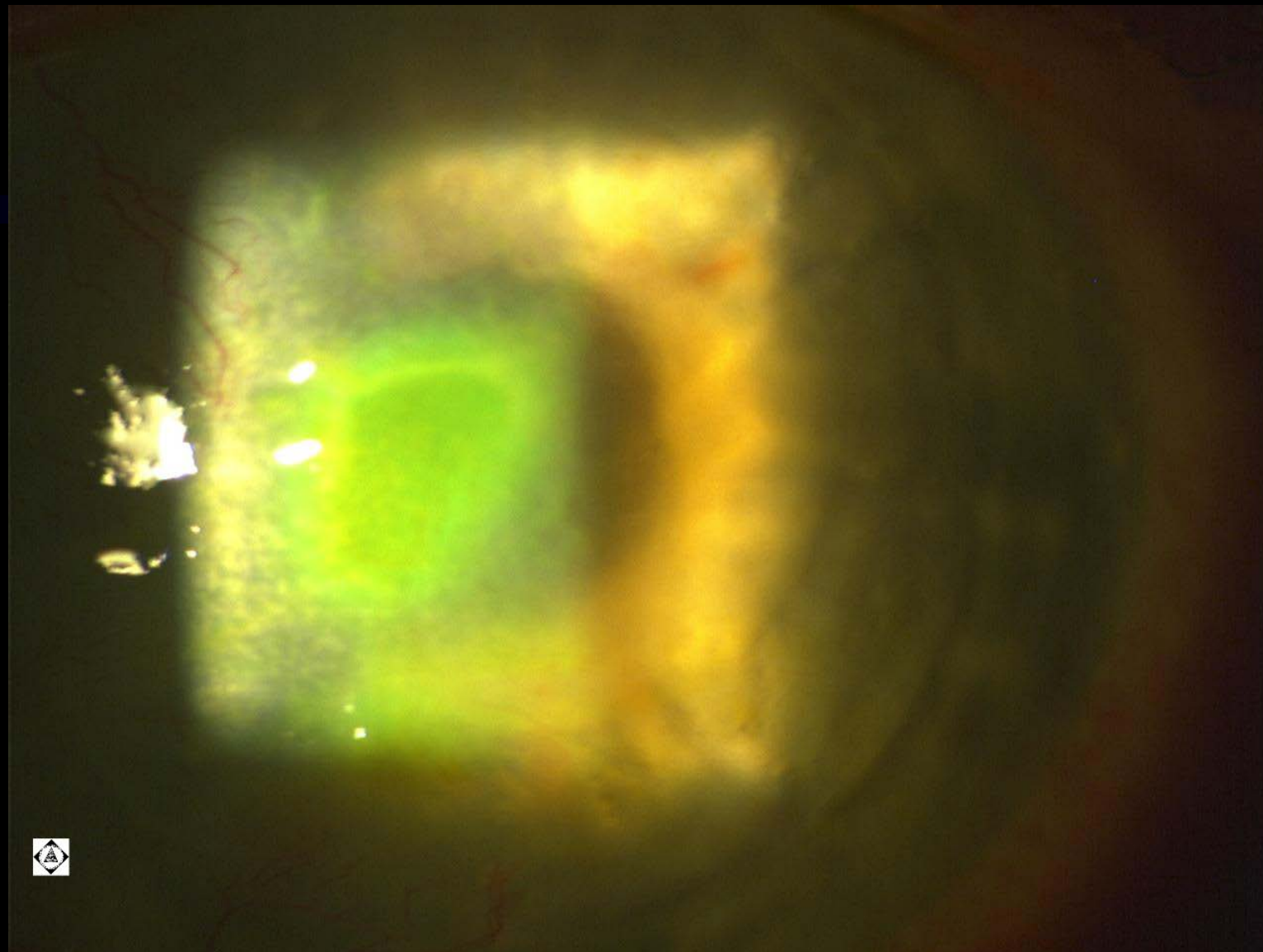




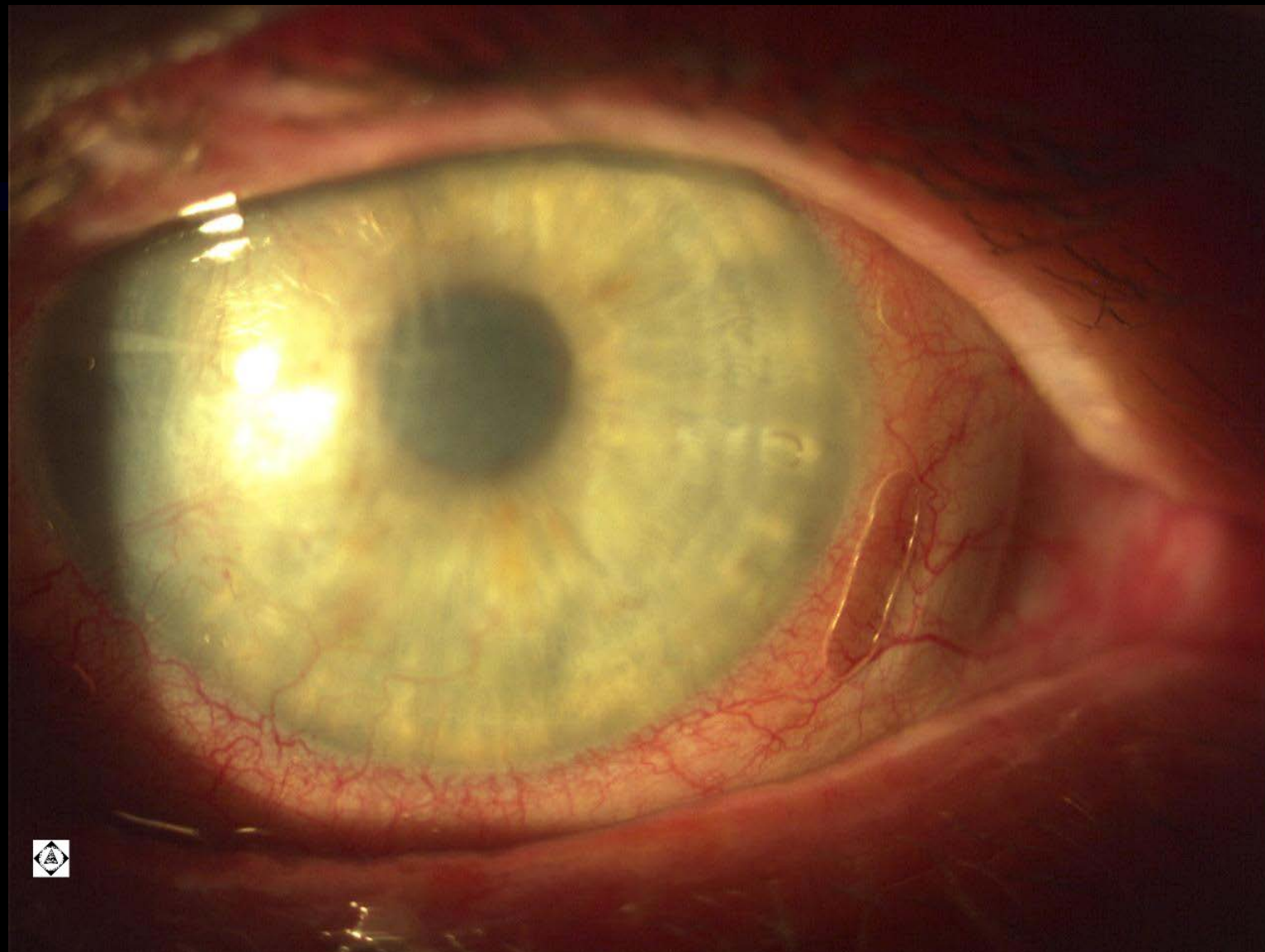


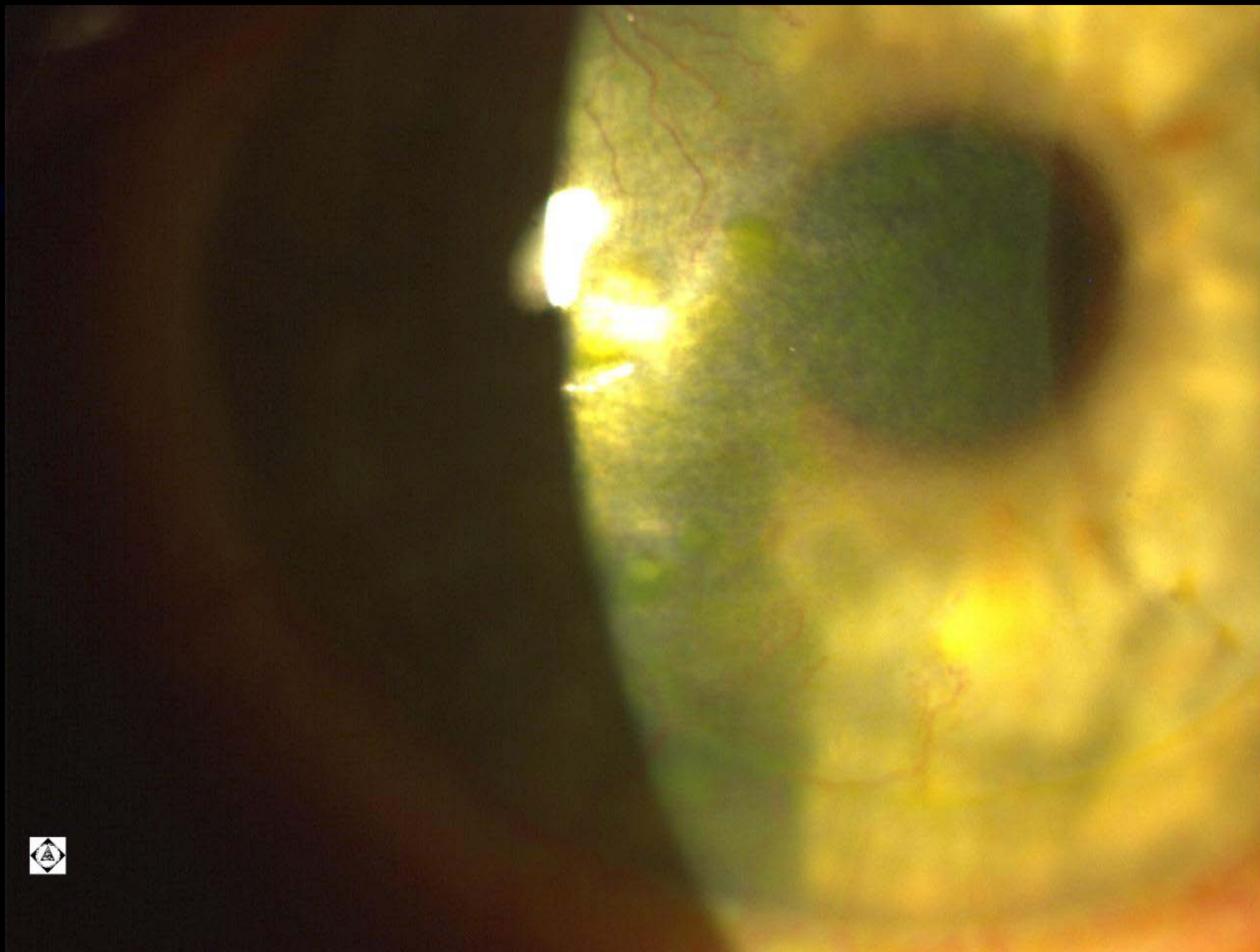


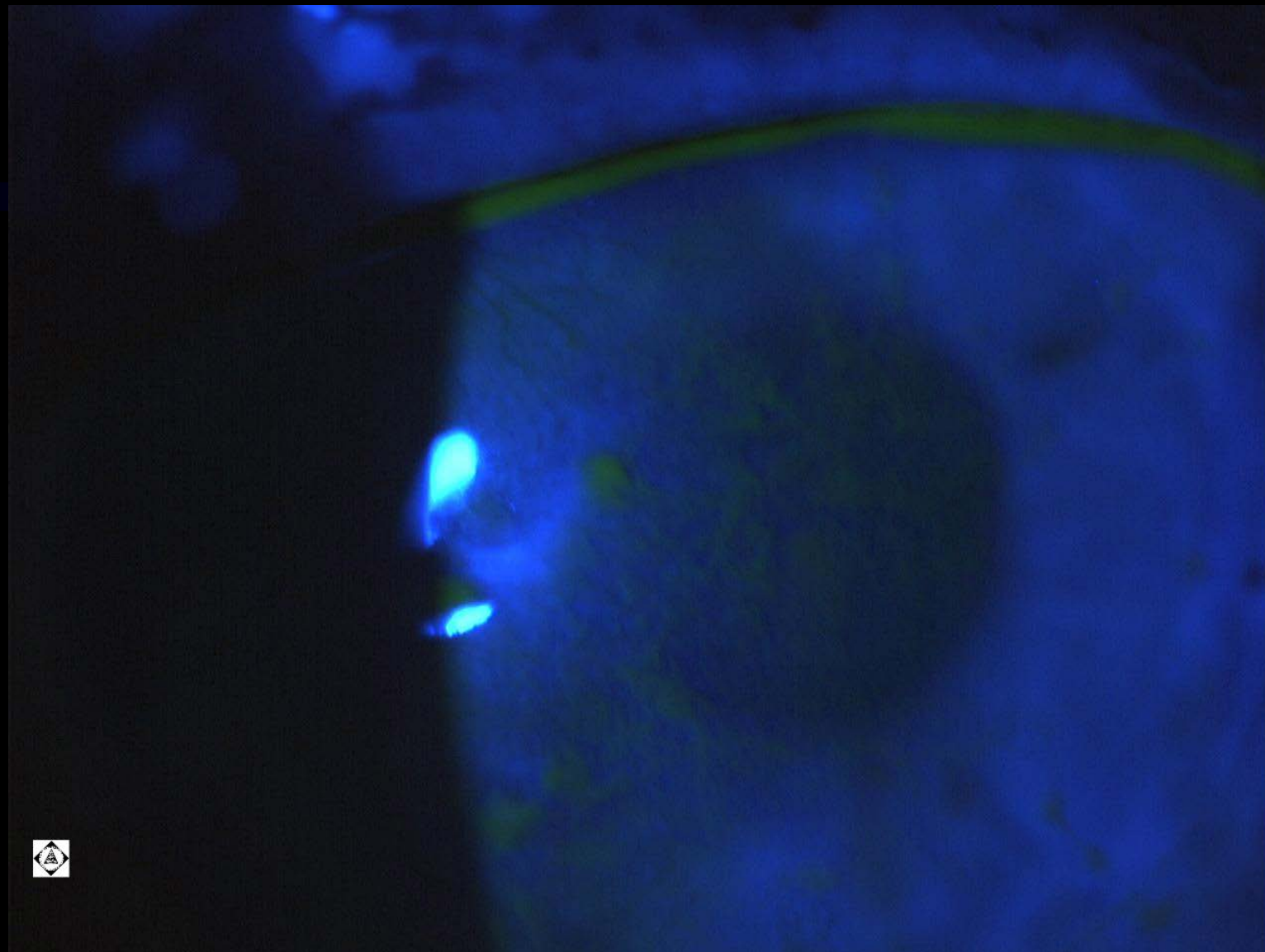


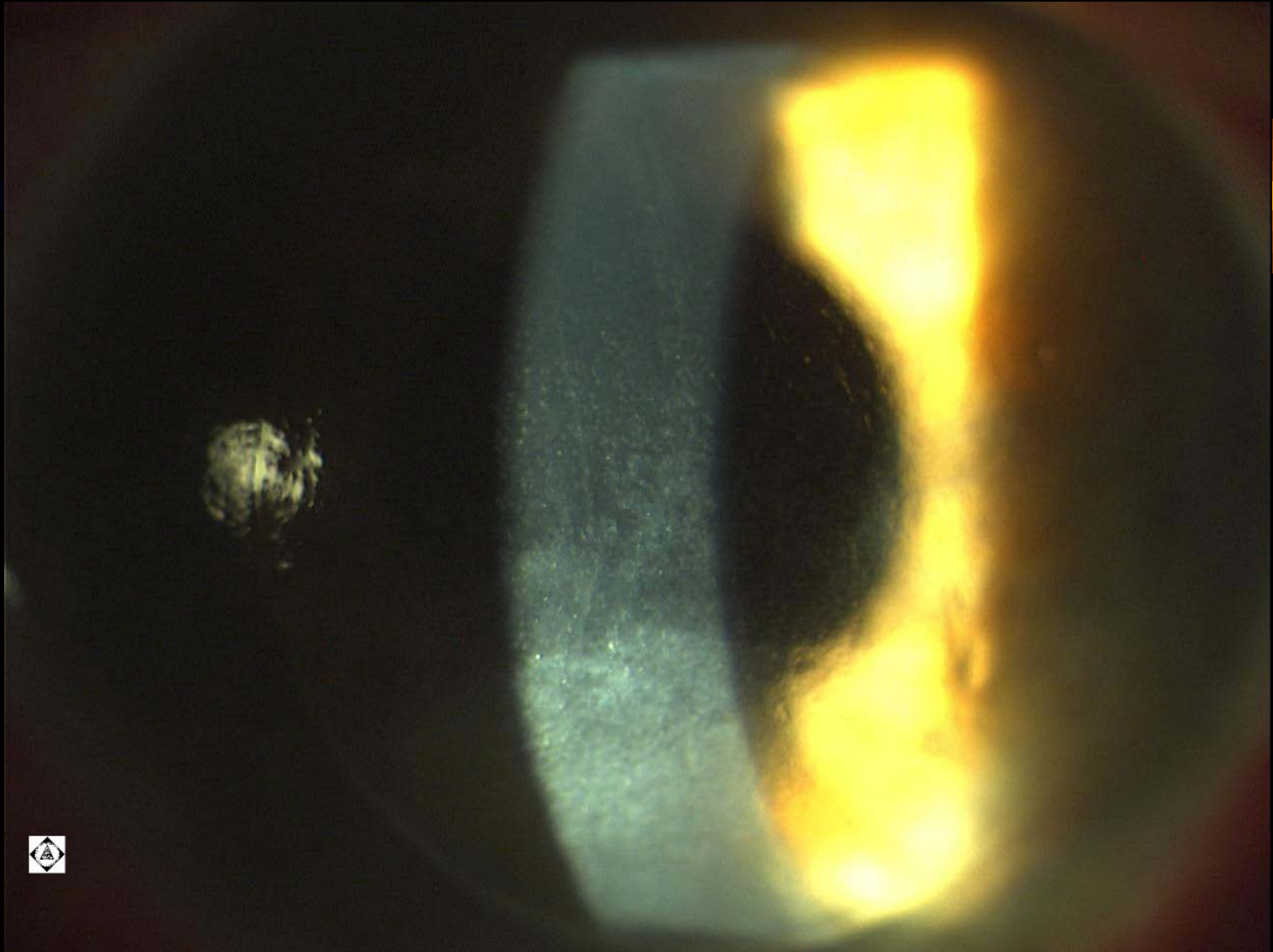


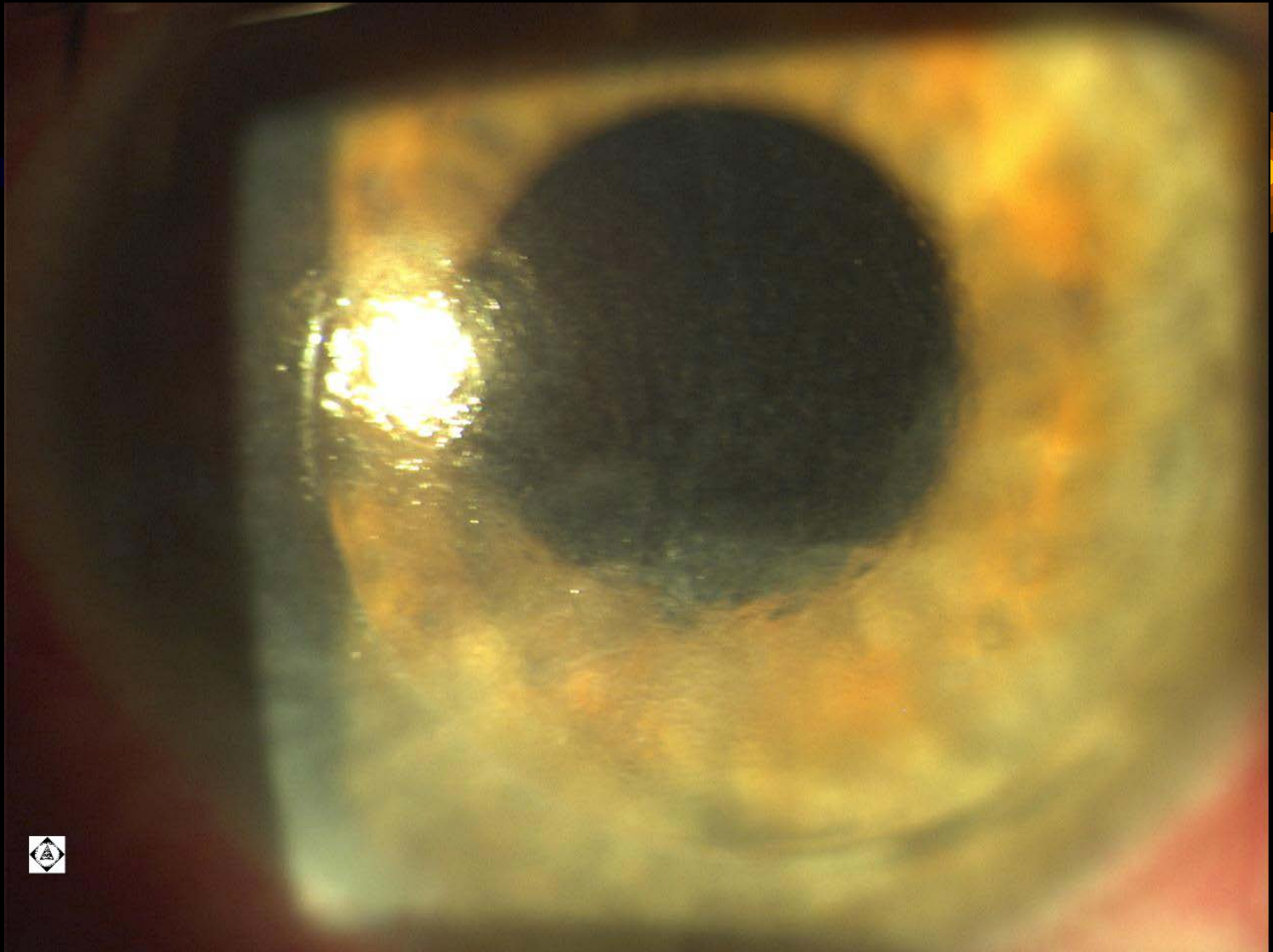


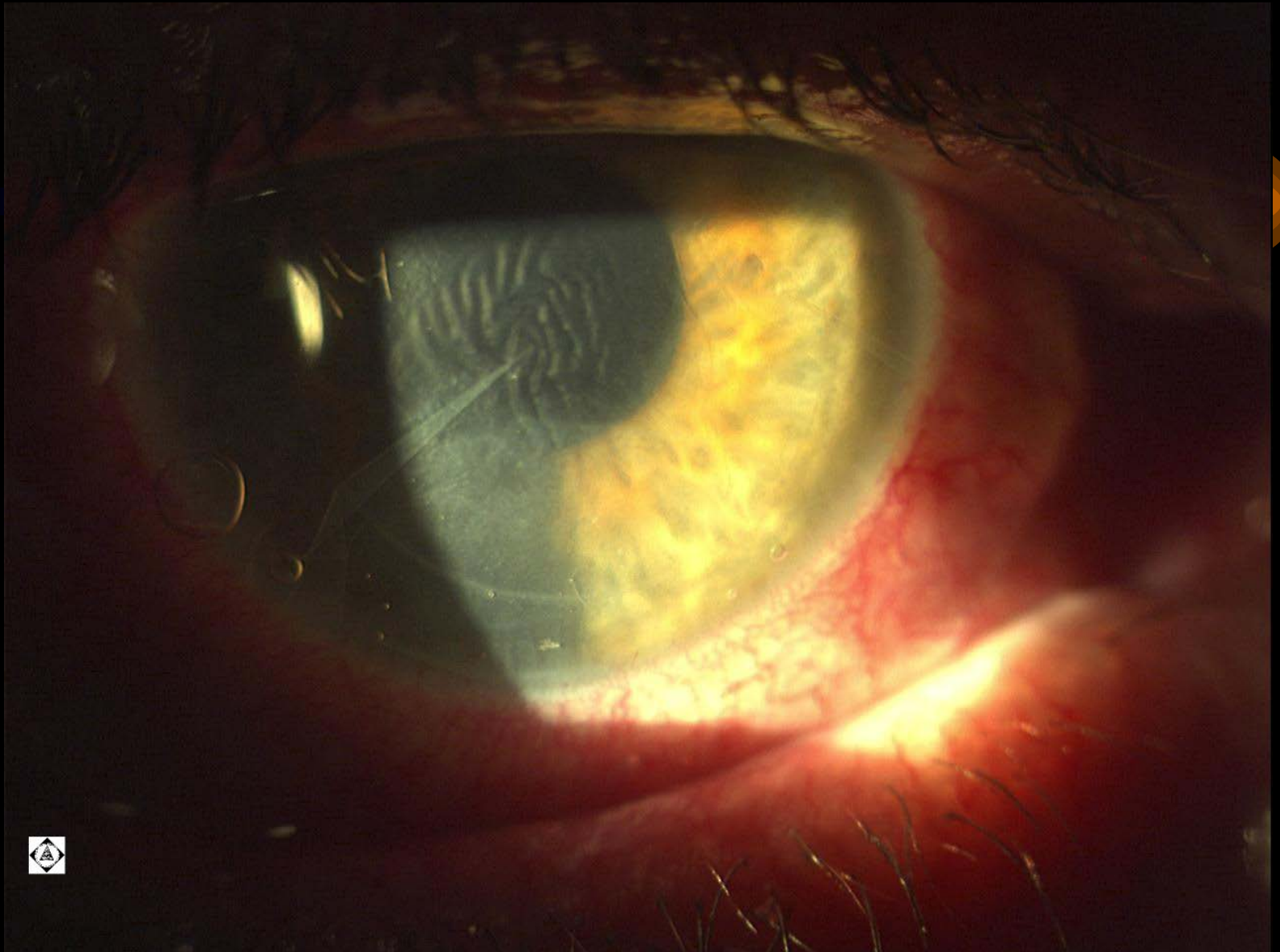


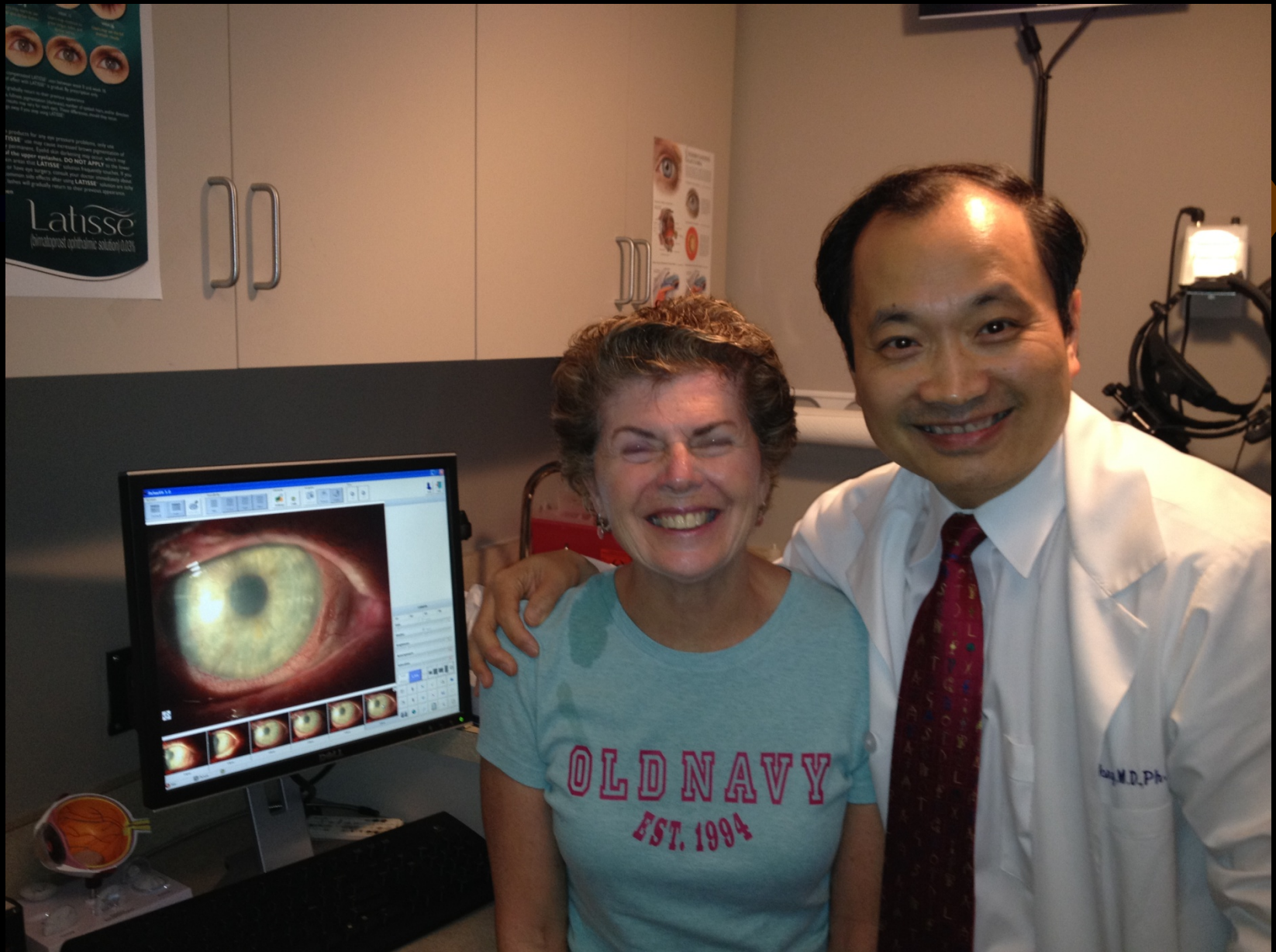












AMCL: tapping the fountain of youth - a new technology that combines the advances in molecular/cellular biology and bioengineering, may bring a new ray of hope patients with poor ocular surface.

