Advances in Medical & Surgical Anterior Segment Therapy

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Medical Director & Founding Partner
Ophthalmic Consultants of CT

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Disclosures

- Speaker
  - Alcon
  - Allergan
  - PRN
  - Tear Lab
  - Shire
  - Zeiss
  - B&L
  - Diopsys
  - Reichart
  - Glaukos
  - InFocus
  - Aerie

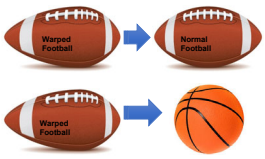
2

The Future of Keratoconus

- Topography Guided PRK

3

Topography-Guided PRK + CXL



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Topography Based Ablations

Less light sensitivity, ND, reading difficulty, and glare
30% saw better without glasses after surgery than ever before
98.4% would do it again
92.6% saw 20/20 UCVA
64.8% saw 20/16 UCVA
34.4% saw 20/12.5 UCVA

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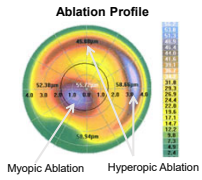
Topography-Guided PRK

- Curvature data linked to the excimer laser
- Custom ablation to regularize the cornea



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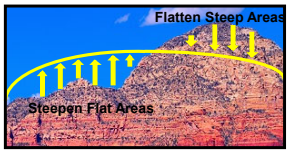
Regularize Cornea



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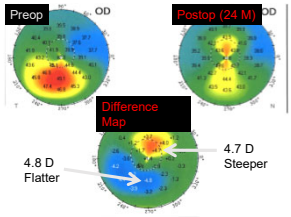

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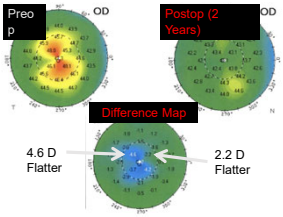

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Lessons Learned in TG-PRK + CXL

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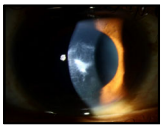
Best Candidates

- Clear corneas
- Reduced BCSVA
- Minimum corneal thickness > 450 um
- Topographic changes in pupillary zone



Corneal Scarring is Relative Contraindication

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Lessons Learned in TG-PRK + CXL

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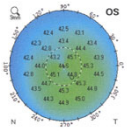
Bilateral CXL in Patients Under 25 with Unilateral Disease

- Theoretically the "normal" eye followed for progression
- In some cases the disease can progress with a rapid loss of BCSVA
- Keratoconus occurs bilaterally in 90% of patients



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Lessons Learned in TG-PRK + CXL

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Patients With Stable Keratoconus May Benefit

- Patients at any age can benefit to reduce irregular astigmatism
- May allow patients to switch from RGP lenses to glasses or SCLs

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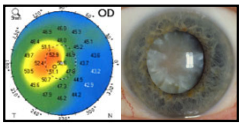
Lessons Learned in TG-PRK + CXL

Keratoconus Patients with Cataracts may Benefit

- Reduce irregular astigmatism prior to cataract surgery
- Potential to discontinue RGP lenses post-cataract surgery



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Lessons Learned in TG-PRK + CXL

Complications of TG-PRK & CXL are Uncommon

N = 345 Eyes

- Corneal ulcer 0%
- Delayed epith healing (>5 days) 2.9%
- Corneal haze (> mild) 4.9%
- Loss of BCSVA (6 M) > 2 lines 1.2%
- Loss of BCVA (12 M) > 2 lines 0.5%

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Point of Care Diagnostic Systems: The Next Step in Anterior Segment Care

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Laboratory Testing Primary Care: A Paradigm Shift

- Every specialty other than Eye Care Practitioners (ECP) couldn't practice without Lab Tests
  - Cholesterol
  - Strep throat
- FACT: Impacts 70% of all medical decisions / represents less than 3% of healthcare costs
- Only ECP do not have luxury of using reference laboratories
  - Must become a CLIA tear testing laboratory
- Primary Outcome - Clinical
  - Better patient care / satisfaction
  - Can "manage" the Disease (i.e. Disease Management)
  - Accredited Dry Eye Center (ADEC)

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Moderate to Severe

- Autologous Serum:
  - Blood draw 30 cc (~$15)
  - Spin @ 4000 RPM for 20 min.
  - Serum placed in container
  - Makes 6-7 containers 5 ml (mix with sterile water) 3mo supply
  - Some put antibiotic in e.g.
  - Freeze all containers except one being use
  - Dose q2h beginning then adjust
  - Cost of compounding pharmacist ~$120

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Managing MGD in the Primary Care Setting

- OM3's
- Cycline's
- Hot compresses
- Lid Hygiene
- Meibomian Gland Expression
- Lipiflow

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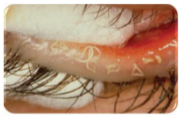
Because Not All MGD Is Obvious,
Active Disease Identification Is Crucial

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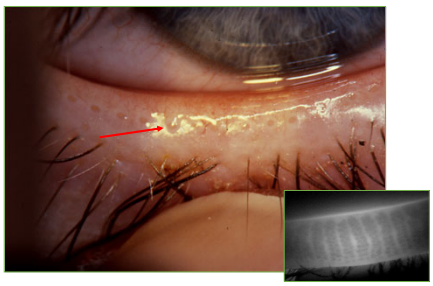
Meibomian Glands



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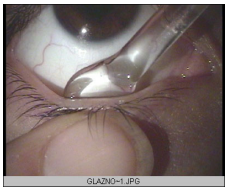
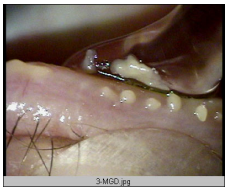
Meibomian Gland Expression

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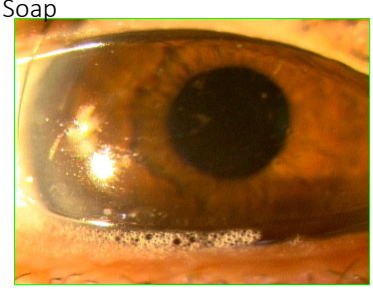
Bacterial Lipases Breakdown
Lipids to Soap



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Meibomian Gland Expression

- Arita Meibomian Gland Expression System
- With or without anesthesia
- Grade I-IV
- Non- billable
- More difficult at the punctal region.

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A Novel, Targeted, Open Eye, Thermal Therapy and Meibomian Gland Clearance in the Treatment of Dye Eye: A Randomized Controlled Investigator Masked Trial (OLYMPIA)

Jennifer M. Loh, MD, ABO; William B. Trattler, MD, ABO; Kavita P. Dhamdhere, MD, PhD; Marc R. Bloomenstein, OD; John A. Hovanesian, MD; Mitchell A. Jackson, MD, ABO; Bobby Saenz, OD
Presented by Jennifer M. Loh, MD, ABO; ASCRS May 16, 2020

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Study Overview:

- ✓ **Masked**
  - Investigator performing the endpoint assessment was masked to the subject's treatment to avoid potential bias
- ✓ Randomized, Controlled
- ✓ Multi-center (10 sites)
- ✓ The protocol was amended to introduce an improved version of SmartLids® after first 100 subjects were treated and additional 135 subjects were enrolled for effectiveness assessment

Objective:

- ✓ Non-inferiority study to demonstrate effectiveness and safety of a single TearCare® System treatment compared to a single LipiFlow® treatment to treat the **signs and symptoms of dry eye disease**

Study visits: Baseline, Treatment, Day 1,Week 2, Month 1

Sample size: 235 total subjects

- ✓ 100 in pre-amendment cohort 1
- ✓ 135 in post-amendment cohort 2

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Key Inclusion & Exclusion Criteria

•Key Inclusion Criteria:

- Dry eye symptoms within the past 3 months
- Artificial tears used regularly over the past month
- OSDI Score of 23-79 (Moderate-Severe)
- TBUT of ≤7 seconds in both eyes
- Meibomian Gland Secretion Score ≤12 OU
  - At least 15 expressible glands in lower lid

Key Exclusion Criteria:

- Use of Restasis® or Xiidra® within 60 days
- Antihistamines within 10 days
- Systemic meds known to cause DE within 30 days
- IPL or LipiFlow® within 12 months
- MG expression within 6 months
- BlephEx®/debridement within 3 months
- Punctal occlusion within 30 days
- Contact lens wear within 2 wks
- Active or recurring eye infection, eyelid & ocular surface ailments, systemic diseases causing dry eye, Ocular trauma within 3 months, history of oculoplastic, and RK

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Effectiveness Analysis

•Data from cohort 2 subjects (N=135) only, was used for effectiveness assessment

•Effectiveness was assessed at 1 month as mean change from baseline and non-inferiority compared to LipiFlow® was evaluated for primary effectiveness endpoints

- **Primary Effectiveness Endpoints**
  - Tear Break-Up Time (TBUT)
  - Total Meibomian Gland Secretion Score (MGSS)
- **Secondary Effectiveness Endpoints**
  - Ocular Surface Disease Index (OSDI) score
  - Corneal staining scores
  - Conjunctival staining scores
  - Symptom Assessment in Dry Eye (SANDE) scores
  - Eye Dryness Score
  - Number of Meibomian Glands Yielding any liquid
  - Number of Meibomian Glands Yielding clear liquid

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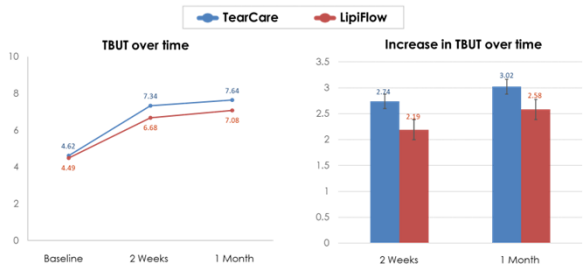
Primary Endpoint: Tear Film Break-Up Time (TBUT)



- Statistically significant increase ($p<0.0001$) in mean TBUT in both groups at all f/u time points
- **TearCare® System is non-inferior to LipiFlow®**

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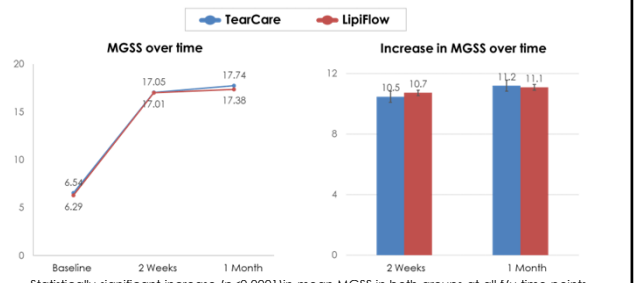
Primary Endpoint: Meibomian Gland Secretion Score (MGSS)



- Statistically significant increase (p<0.0001)in mean MGSS in both groups at all f/u time points
- **TearCare® System is non-inferior to LipiFlow***

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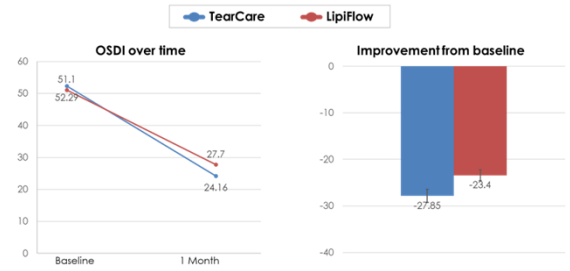
Secondary Endpoint: Ocular Surface Disease Index (OSDI)



Statistically significant improvement (p<0.0001) in mean OSDI score compared to baseline

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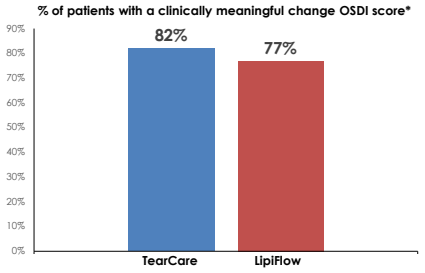
82% of TearCare® System Subjects Showed *Clinically Meaningful Improvements* in OSDI*



*per Miller definition

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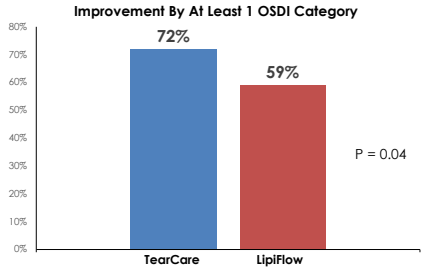
Greater Proportion of TearCare® System Subjects Showed Clinically Significant Symptom Relief compared with LipiFlow*



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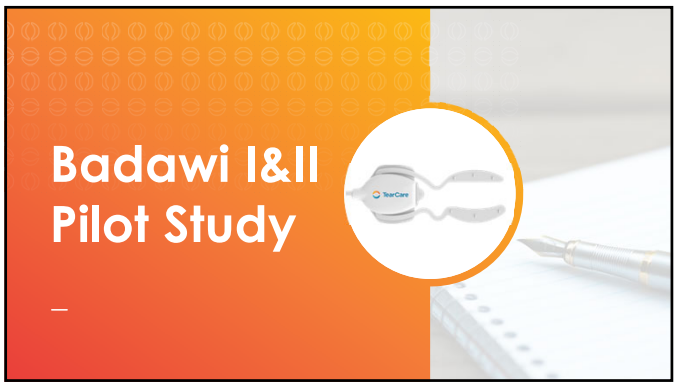

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TearCare® Pilot Study[1,2]

Initial 6-month data published in *Clinical Ophthalmology*, April 2018
Re-Treat data published in *Clinical Ophthalmology*, January 2019

•Purpose:

- Preliminary assessment of the long-term safety & effectiveness of the TearCare® system in the treatment of the signs & symptoms of dry eye disease
- Assess re-treatment at 6 months
- Gather data to help design pivotal study

•Study details:

- Single center: David Badawi, MD
- Prospective, randomized, controlled trial
- 24 subjects followed for 6 months
  - 12 TearCare subjects
  - 12 warm compress subjects (5 minutes daily for 1 month)
- All 12 original TearCare subjects were re-treated at 7 months and followed for another 6 months (13 months total)

1. Badawi D. A novel system, TearCare®, for the treatment of the signs and symptoms of dry eye disease. Clinical Ophthalmology 2018:12: 683-694. 2. Badawi D. TearCare® system extension study: evaluation of the safety, effectiveness, and durability through 12 months of a second TearCare® treatment on subjects with dry eye disease. Clin Ophthalmol. 2019:13:189-198.

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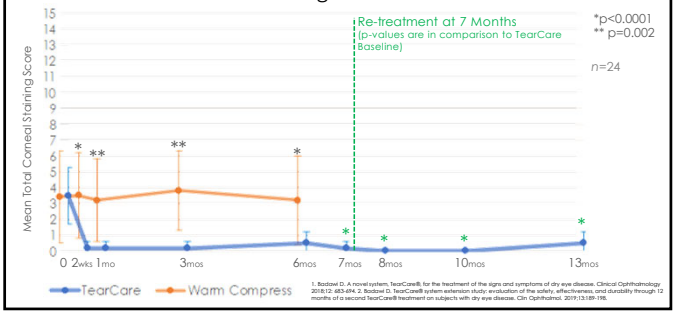
Pilot Data: Corneal Staining Score



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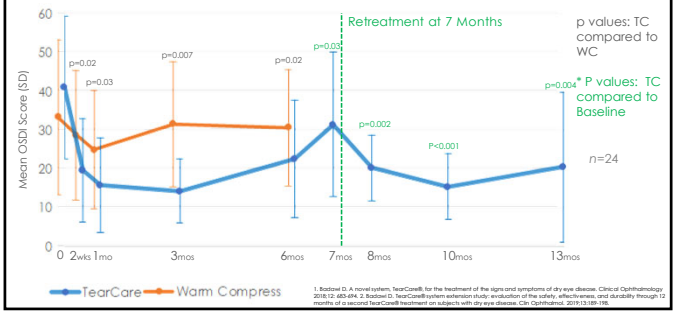
Pilot Data: OSDI



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Pilot Study Conclusions[1,2]

The findings of this pilot study suggest that the TearCare® System is a safe and effective treatment option for patients with DED, with the treatment effects persisting for at least 6 months.

•The findings of the extension study through 12 months suggest that a second TearCare® treatment after 6 months provides additional improvement in the signs and symptoms of DED.

1. Badawi D. A novel system, TearCare®, for the treatment of the signs and symptoms of dry eye disease. Clinical Ophthalmology 2018;12: 683-694. 2. Badawi D. TearCare® system extension study: evaluation of the safety, effectiveness, and durability through 12 months of a second TearCare® treatment on subjects with dry eye disease. Clin Ophthalmol. 2019;13:189-198.

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Advances in Office Technology in Glaucoma

- Falck Multisystem
- Melbourne Rapid Fields

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Falck Multisystem

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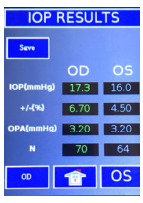
Intraocular Pressure

- ✓ Optical Applanation Measurement
- ✓ Compensates for Corneal Biomechanics
- ✓ Multiple Serial IOP Measurements – N Value
- ✓ Systolic and Diastolic IOP
- ✓ Average IOP Displayed
- ✓ IOP Variation with Cardiac Cycle - OPA
- ✓ Precision Displayed
- ✓ CPT: 92100



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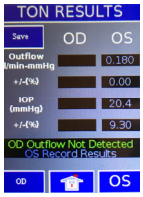
TONOGRAPHY

- ✓ Optical Aqueous Humor Outflow Measurement.
- ✓ Aqueous Outflow Decreased in Glaucoma.
- ✓ Decreased Outflow = Increased TM Resistance.
- ✓ Decreased Outflow = Increased IOP Fluctuation.
- ✓ Document Therapeutic Efficacy of Outflow Interventions.
- ✓ Document Need for Additional Intervention.
- ✓ Glaucoma risk assessment.
- ✓ CPT: 92499



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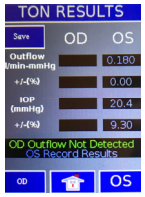

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The Case of the Asymmetric ONH

- 63 y/o white male presented for consultation for glaucoma evaluation
- VA: 20/20 OU
- Peak IOP: 26/23
- Ta: 21/19 mmHg
- Tonography: 0.18 OD / 0.24 OS
- Pach: 560/558
- CH: 8.9/9.1

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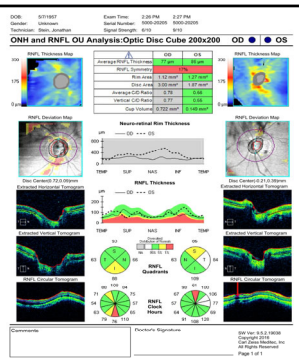

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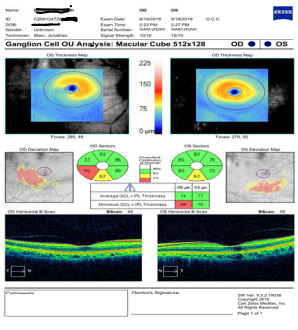

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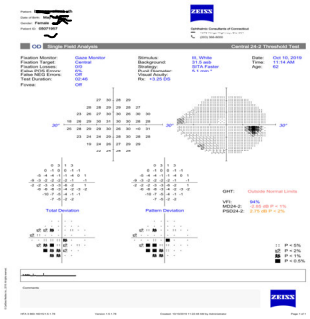

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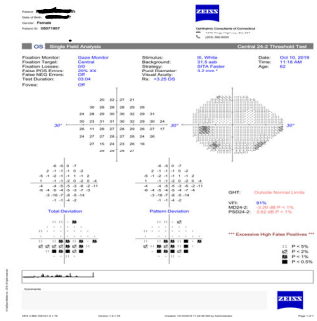

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The Case of the Asymmetric ONH

- Tx: Vyzulta 1 gtt qhs OU
- Follow up: 3 weeks
- IOP post Tx:
  - OD 17
  - OS 15
  - Tonography: OD 0.25 / OS 0.29
- Next step?

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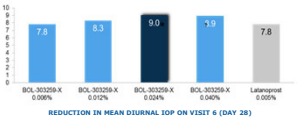
Efficacy Results: Primary Endpoint Voyager Study

At highest doses, lowered IOP 1-1.5 mmHg more than latanoprost

Most common AE: pain upon instillation



REDUCTION IN MEAN DIURNAL IOP ON VISIT 6 (DAY 28)

1. Weinreb RN et al. Br J Ophthalmol. 2015;99(6):738-45

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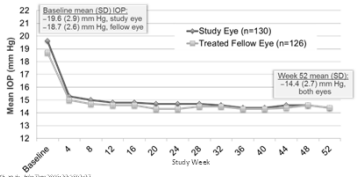
JUPITER: Sustained IOP-lowering Efficacy through One Year

- IOP was reduced by ≥22% with LBN at each post-treatment visit vs. baseline (*P*<0.001 for all).



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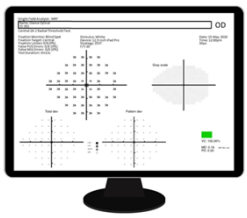
P hoerxugh#Udslg#Ilhogv

Dxwrp dwhg#wkurvkrg#shulp hwhu



- MRF registered as Medical Device with TGA (Australia) and MedSafe (NZ)
- Complies with MBS 10940, 10941 11221, 11224 definition

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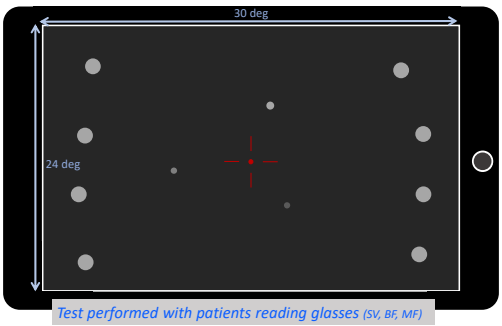

Test performed with patients reading glasses (SV, BF, MF)

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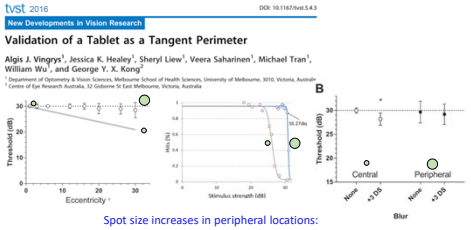
Increasing spot size improves threshold estimate.



Spot size increases in peripheral locations:

- large spots are easier to see & robust to blur
- return a fixed threshold with eccentricity
- reduce variability
- make early losses easier to find

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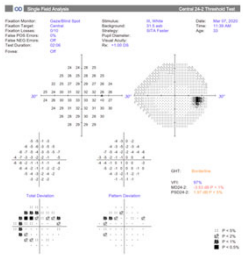
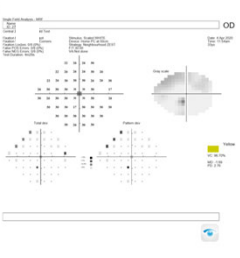
Results: outputs in familiar formats

HFaA



MRF



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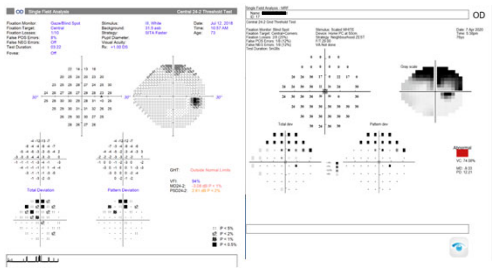
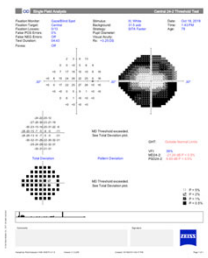


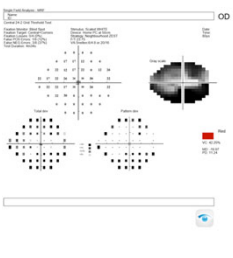
57

Results: outputs in familiar formats. Advanced defect

HFA



MRF



58

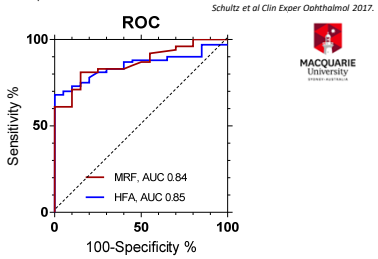
Equivalent diagnostic ability between MRF and HFA

Independent study from Macquarie University, NSW

N=60 OAG: 43 manifest HFA defects, 17 GS: 20 controls

Diagnoses based on Optic Disc

Schultz et al Clin Exper Ophthalmol 2017.



59

Ongoing Trial
IPL for Rosscea and Ocular Surface Disease

- Prospective clinical trial of patients with significant ocular surface disease and rosacea who were treated with intense pulses light therapy (IPL).

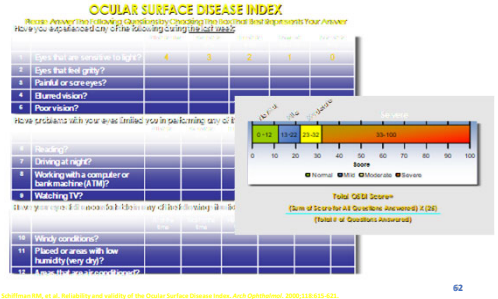
60

Methods

- Twenty patients with moderate to severe ocular surface disease and rosacea were enrolled in the prospective clinical trial
- Inclusion criteria included: corneal staining, reduced tear break-up time, meibomian gland changes and OSDI scores in the moderate to severe range.
- Patients underwent monthly IPL treatment for six months.
- OSDI scores and slit lamp exams were performed at baseline, after each treatment and at the conclusion of the study,

61

OSDI Questionnaire



62

62

Results

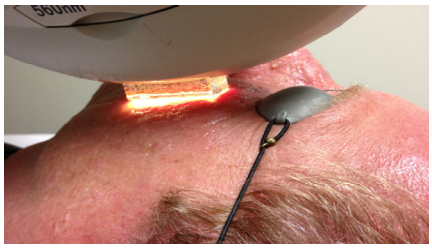
- All patients in the study improved in both their signs and symptoms of ocular surface disease compared to baseline
- The degree of improvement ranged from minimal to becoming symptom and sign free
- The median time to improvement of signs and symptoms was 4 months, with some changes coming as early as 2 months and others as late as 6 months
- All patients noted improvement in their facial appearance at a median of 2 months with improvements continuing through the entire treatment period.

63

M22 Pre-treamtment

64

M22 Treatment



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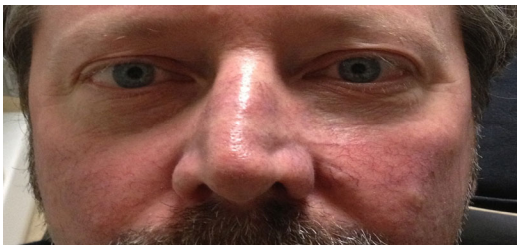
Baseline

66

4 Months



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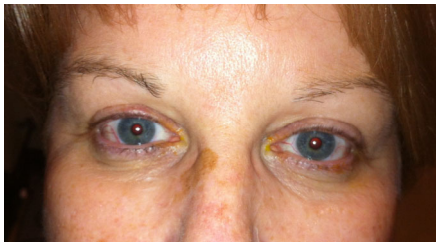
Pt DD

68

Pigmented Lesion



69

How does IPL with M22 work?

- Visible wavelengths of light used
- Chrompohores (such as melanin, hemoglobin) absorb light and convert energy into heat
- Variable filters can be used to adjust for skin type and target tissue as well as penetration depth into skin

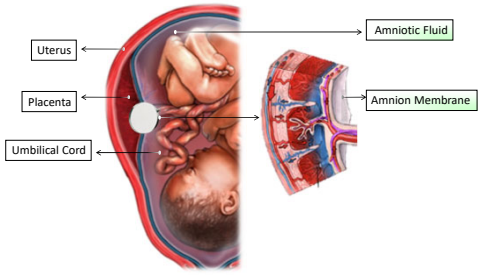
70

Amniotic Membrane

- ProKera (Biotissue)
- Bio D

71

Maternal Birth Tissues Anatomy



72

The Structure of the Fetal Amniotic Membrane

Epithelium
- Metabolically active cuboidal cells with microvilli present on its apical surfacce

Basement Membrane
- Made up type IV, V and VII collagen (also found on conjunctival and corneal basement membranes)
- Fibronectin and Laminin

Stroma
- Compact Layer provides tensile strength
- Fibroblast Layer
- Spongy Layer

73

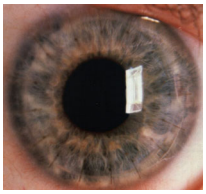
Mechanisms of Action

- Mechanical
- Promote Epithelialization
- Anti-fibrotic and anti-inflammatory Properties
- Anti-Angiogenic
- Anti-microbial

74

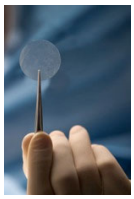
Potential Clinical Applications

- Persistent Corneal Epithelial Defects
- Corneal Ulcers
- Pterygium Surgeries
- Conjunctival Surface Reconstruction
- Bullous Keratopathy
- Chemical/Thermal Burns
- Ocular Surface Reconstruction
- SJS http://www.aao.org/publications/eyenet/200807/cornea.cfm
- Leaking Filtering Blebs after Glaucoma Surgery
- Cicatricial Entropion



75

- Product Sizes
  - 9mm disc
  - 12mm disc
  - 15mm disc



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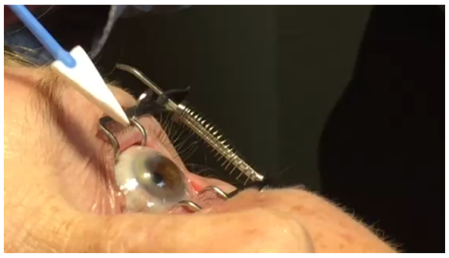
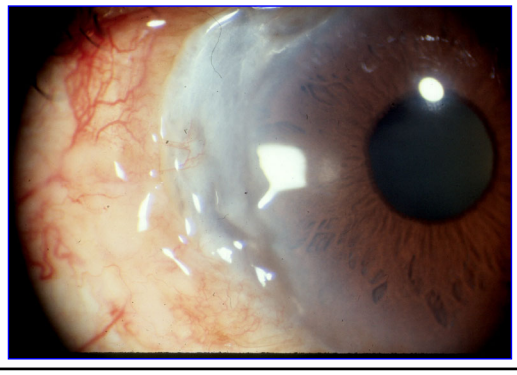


77

Product Specifications

Outer Diameter:	21.6	21.6	21.6
Inner Diameter:	17.9	15.5	15.5
Device Height	0.7	1.1	1.1
Tissue Thickness	100 microns	100 Microns	200 microns
Ring Description	Ring & elastomeric band system (polycarbonate)	Dual ring system (polycarbonate)	Dual ring system (polycarbonate)

78



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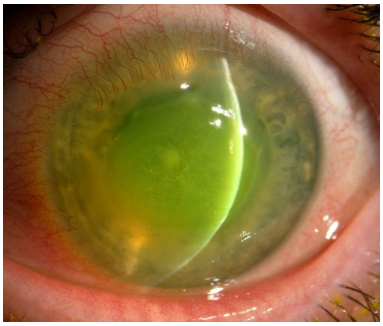

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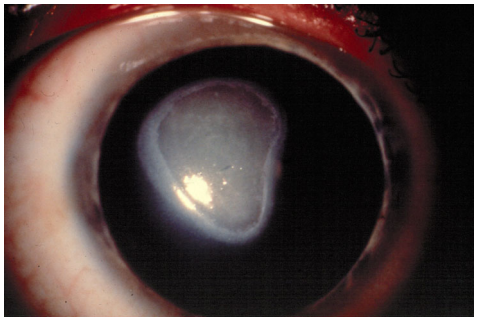

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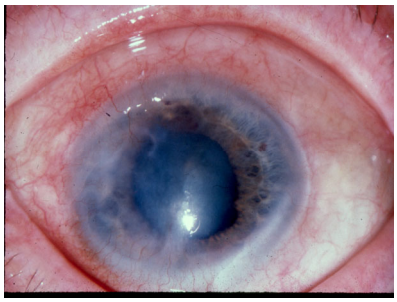

82

83

84

ProKera

- Reimbursement
  - $1,628.38
- Code: 65778

85

Persistent Epithelial Defects

- Treatment
  - cyanoacrylate tarsorrhaphy
    - Indications
      - lagophthalmos
      - exposure keratitis
      - neurotrophic keratitis
      - dry eyes
      - persistent epithelial defects

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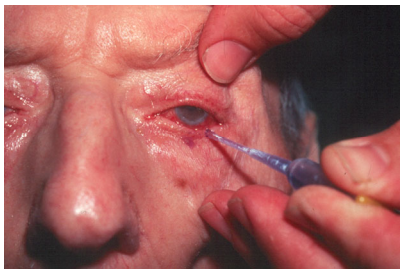
Temporary Cyanoacrylate Tarsorrhaphies

- Age (27-85) 62
- Dx:
  - Persistent epithelial defects
  - Neurotrophic keratitis
  - Exposure keratitis
  - Lagophthalmos

87



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Oculoplastic Procedures for the Primary Care Clinician

J. James Thimons, O.D., FAAO

90

Comprehensive Lacrimology Therapy

- Includes Therapeutics
  - Topical
  - Oral
- Includes Punctal Occlusion
- Dilation & Irrigation
- Nasolacrimal Probed
- Multiple Medical Visits

91

Predisposing factors

- Age
- Gender
- Environment
- Anterior Segment Disease
- Medications
- CL Wear
- Refractive surgery
- Systemic Disease

92

Pathophysiology of Epiphora

- Increased Reflex Tear Production
  - Rapid tear break up time
  - OSDI
  - Ocular surface irritation
  - Corneal changes:
    - Punctate epithelial erosions
    - Infiltrates related to staph hypersensitivity
- Decreased Outflow
  - Punctal Stenosis
  - Naso-Lacrimal obstruction
  - Anatomic Abnormality
    - Floppy Lid
    - Ectropian/Entropian
    - Trichiasis
  - Dacryocystitis

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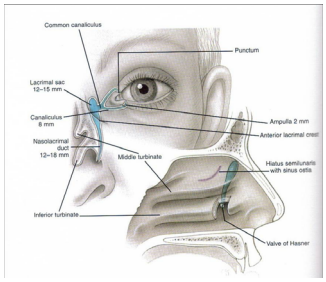
Anatomy



From Kersten RC Basic and Clinical Science Course (BCSC) Section 7: Orbit, Eyelids, and Lacrimal System

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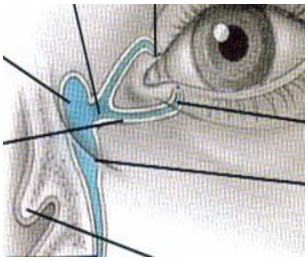
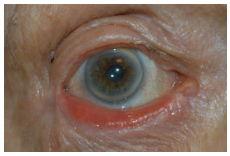


95

Cicatricial Ectropion



- Chronic irritation from blepharitis and tearing can lead to cicatricial changes of eyelid skin
- Chronic wiping can exacerbate age-related laxity of lid
- Exposure and hypertrophy of conjunctiva increases tendency of lid to evert

96

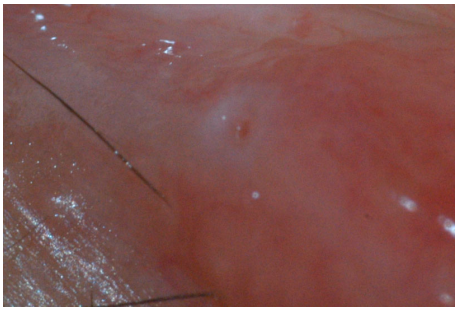
Floppy Lid Sydrome

- C:\Do G

97

Punctal Stenosis

98



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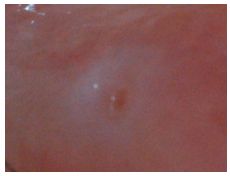
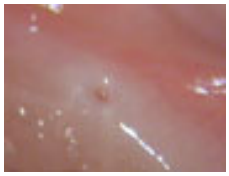


PUNCTAL STENOSIS



NORMAL PUNCTUM

100

Dilation & Irrigation

- Equipment
  - Sterile saline
  - Pediatric/Adult dilator
  - 1 or 3 ml syringe
  - 135 degree canulla
- Clinical pearl: Use antibiotic or steroid in syringe to enhance taste by patient

101

Naso-lacrimal Probe

- Equipment
  - Pediatric / Adult dilator
  - Bowman's probe(multiple diameters)
  - Sterile saline
  - Anesthetic
  - Syringe
  - Cannula

102

- ..\Des

103

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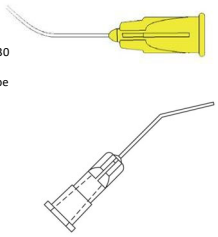
Irrigating Cannula

Lacrimal Cannula 10 per box. Lacrimal Cannula [Shahinian] .30 mm aspiration port. Smooth bullet shape end for punctal dilation and irrigation of the nasolacrimal system. May also be used as punctal dilator. 5 per box.



105

Naso-Lacrimal Procedures

- Re-imbursement
  - D&I: $143.15
  - NLP: $278.61
- Codes
  - D&I 68801
  - NLP 68810

106

Punctal Stents

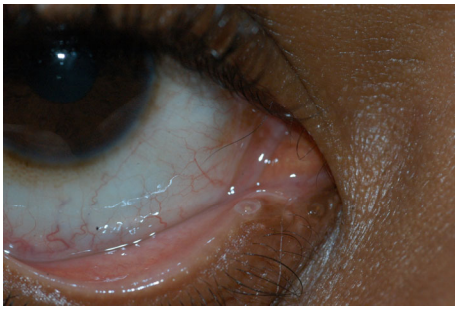
- Oasis Flow Control
- Small & Medium

107

Billing for Punctal Occlusion

- 68761
- Punctal Occlusion Permanent or Temporary
  - E Codes
    - E1 Superior Left
    - E2 Inferior Left
    - E3 Superior Right
    - E4 Inferior Right
  - NGS reimbursement: $168.64
  - Silicon Plug cost: $40-50
  - Extended Collagen: $7-8

108



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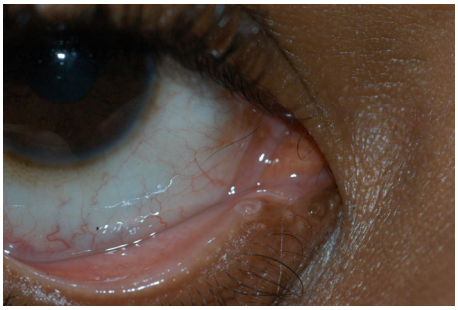


110

Punctal/Canalicular Intubation for Punctal Stenosis

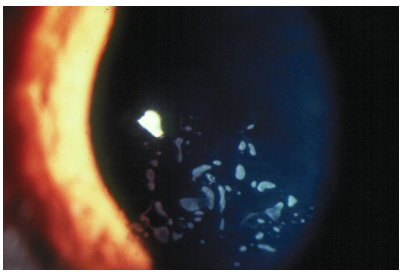
- Advantages
  - Quick, in office procedure under topical anesthesia
  - In experienced hands, essentially no risk
  - Easy to remove
- Disadvantages
  - Epiphora may increase over short term due to footplate occlusion of punctum
  - Problem may recur if underlying inflammation inadequately treated
  - No good billing code for procedure

111

Anterior Segment Surgical Procedures

- Debridement
- Anterior Basement Membrane Micropuncture
- Complex Foreign Body Management

112



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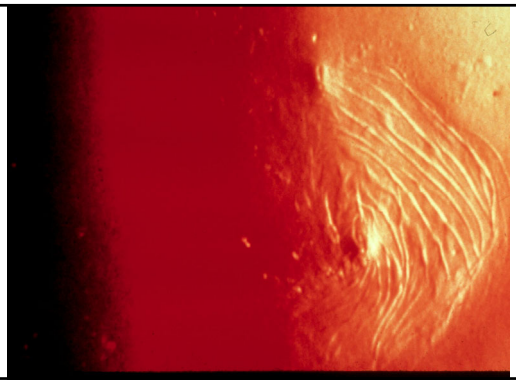

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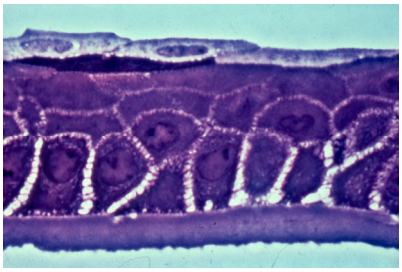


115

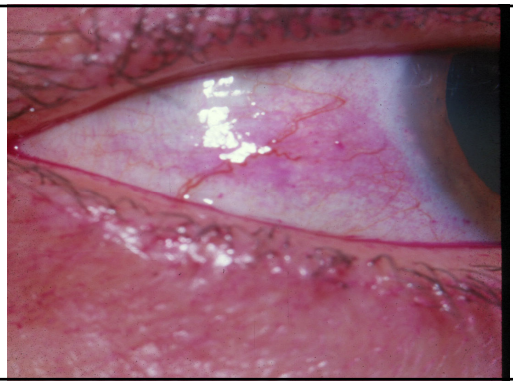
Rodriguez MM, Fine BS, Laibson PR, Zimmerman LE. Disorders of the corneal epithelium. A clinicopathologic study of dot, geographic, and fingerprint patterns. Arch Ophthalmology 1974;92:475-82

116

Recurrent Erosions

- Contributing Factors
  - Dry eyes
  - Blepharitis
  - External disease / tear film abnormalities

117

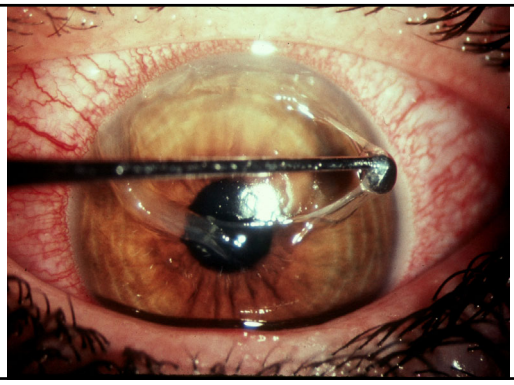


118

Recurrent Erosions

- Surgical Management
  - Epithelial debridement
    - chalazion curette
    - 57 Beaver Blade

119



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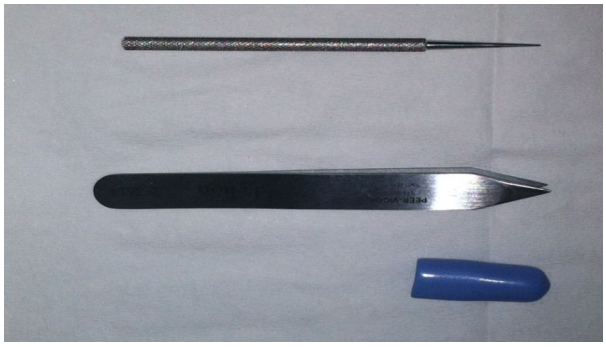
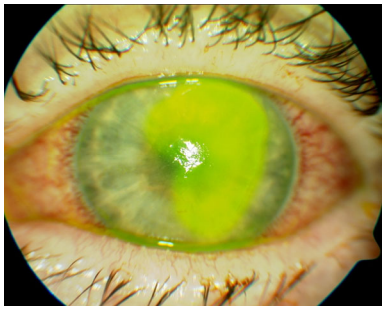


122

Debridement Tools

123



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Anterior Segment Procedures

- Codes:
  - Corneal Debridement: 65435 / $91.25
  - Penetrating FB: 65222/ $79.07
  - Corneal FB: 65222/

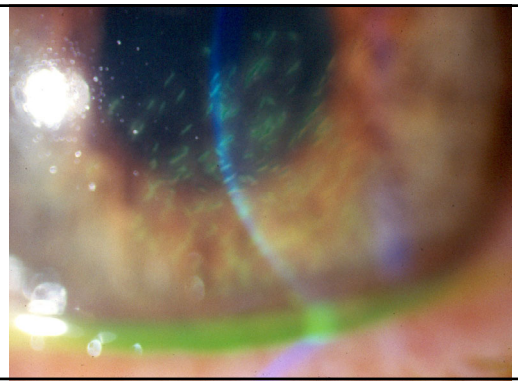
125

Recurrent Erosions

- Anterior Basement Membrane Puncture
  - 20-gauge needle

126

127



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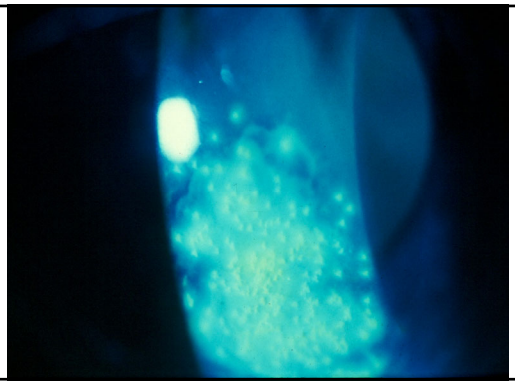

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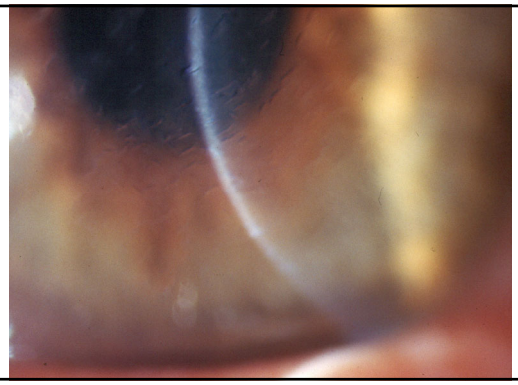

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