How to Make Sure All our Keratoconus Patients Preserve Their Useful Vision Through Early Diagnosis and Early Treatment

Co-Management Update August 2022

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Woo University and Wellish Vision Institute

Top 100 Doctor Las Vegas

Preserve KC Patients' Useful Vision Through Early Diagnosis and Early Treatment

Co-Management Update August 2022

Course Description:

Preparing the ocular surface for surgical success is imperative when it comes to keratoconus patients.

Early Diagnosis and Managing Dry Eye Syndrome prior to corneal crosslinking, corneal inlays, and other corneal procedures is incredibly important to produce the best outcomes.

Wellish Vision Institute

Preserve KC Patients' Useful Vision Through Early Diagnosis and Early Treatment

Co-Management Update August 2022

Course Description:

We will:

Learn about tips and tricks on diagnosing dry eye in keratoconus patients and effective treatment options.

We will be discussing pharmaceutical options, nutraceuticals, punctal plugs, amniotic membranes, and much more.

Preserve KC Patients' Useful Vision Through Early Diagnosis and Early Treatment

Co-Management Update August 2022

Course Description:

Emphasis on Early Detection
and Overcoming Barriers

Wellish Vision Institute

Preserve KC Patients' Useful Vision Through Early Diagnosis and Early Treatment

Co-Management Update August 2022

We have just heard a terrific presentation from Dr. Mitch Ibach on

Earlier Keratoconus Diagnosis to Save Vision

In my Experience, Today's Optometrists have no Problem Identifying Topographies suspicious for KC

Main Barrier: Screening Routine Patients for Earlier Diagnosis & Treatment

Preserve KC Patients' Useful Vision Through Early Diagnosis and Early Treatment

Co-Management Update August 2022

Up until last year, we were all taught that the prevalence of KC was 1:1500 to 1:5000

That all changed in April 2021
when the **The Raine Study** found that it is **1 in 84**

We now know that 1 in 84 people have Keratoconus

Current Population of Clark County, Nevada is 2,839,000
That means there are about 34,068 people with KC
in the Las Vegas area

The Raine Study April 2021 – 1 in 84 have KC

Ophthalmology

Pentacam

ORIGINAL ARTICLE | VOLUME 128, ISSUE 4, P515-521, APRIL 01, 2021

Prevalence of Keratoconus Based on Scheimpflug Imaging

The Raine Study

Elsie Chan, MBBS * • Elaine W. Chong, PhD * • Gareth Lingham, MOrth • ... Alex W. Hewitt, PhD • David A. Mackey, MD • Seyhan Yazar, PhD • Show all authors • Show footnotes

Published: August 26, 2020 • DOI: https://doi.org/10.1016/j.ophtha.2020.08.020 •

Wellish Vision Institute

Ophthalmology

Purpose

To describe the prevalence and systemic associations of keratoconus in young adults in Perth, Western Australia.

Design

Cross-sectional study.

1,259 Participants
20 years of age

Participants

One thousand two hundred fifty-nine participants 20 years of age.

Methods

The Raine Study is a multigenerational, longitudinal cohort study based in Perth, Western Australia. This study represents a cross-sectional analysis of the birth cohort on returning for a 20-year follow-up. Participants underwent a detailed ophthalmic examination, including visual acuity assessment and Scheimpflug imaging using the Pentacam (Oculus, Wetzlar, Germany), and completed a health questionnaire. Keratoconus was defined as a Belin/Ambrósio enhanced ectasia display score of 2.6 or more in either eye based on Pentacam imaging.

Main Outcome Measures

Prevalence of keratoconus in this cohort.

Ophthalmology

Results

Of the 1259 participants, 50.8% were women and 85.7% were White. Fifteen participants had keratoconus in at least 1 eye, giving a prevalence of 1.2% (95% confidence interval, 0.7%–1.9%), or 1 in 84. A significant difference was found in best-corrected visual acuity (0.01 logarithm of the minimum angle of resolution vs. –0.05 logarithm of the minimum angle of resolution; $P = 0.007$), cylinder (1.25 diopters [D] vs. 0.25 D cylinder; $P < 0.001$) and spherical equivalent (–1.42 D vs. –0.50 D sphere; $P = 0.02$) on objective refraction, mean keratometry of the steep meridian (45.19 D vs. 43.76 D; $P < 0.001$), and mean corneal thickness at the thinnest point (475 μm vs. 536 μm; $P < 0.001$) between those with and without keratoconus. Keratoconus was associated with regular cigarette smoking (38.5% vs. 14.6%; $P = 0.04$), but showed no association with gender, race, body mass index, use of spectacles or contact lenses, history of allergic eye disease, or pregnancy.

Conclusions

The prevalence of keratoconus in this Australian population-based study of 20-year-old adults was 1.2% (95% confidence interval, 0.7%–1.9%), or 1 in 84, which is one of the highest reported in the world. This has important implications for screening individuals at a younger age so that treatment can be initiated before disease progression.

15 / 1259 had KC in at least one eye → **Prevalence of KC 1.2% or 1 in 84**

Mean Corneal Thickness in those w/ KC 475 um vs. 536 um in NLs w/o KC

Wellish Vision Institute

Ophthalmology

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50.8% were women

Mean Refractive Cylinder 1.25 D vs. 0.25 D in NLs w/o KC

Mean keratometry of steepest axis 45.19 vs. 43.76 in NLs

Wellish Vision Institute

Ophthalmology

Results

The Raine Study – April 2021 – Perth Australia

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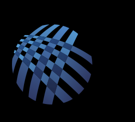
KC WAS Associated with Regular Cigarette Smoking 38.5% vs. 14.6%

No Association with – Gender, Race, Body Mass Index, or Pregnancy

No Association with – Use of Spectacles or Contact Lenses

No Association with – History of Allergic Eye Disease



Preserve KC Patients' Useful Vision Through Early Diagnosis and Early Treatment

Co-Management Update August 2022

Current Population of Clark County, Nevada is 2,839,000

That means there are about **34,068** people with KC in the Las Vegas area

As the leading Provider of CXL Treatments for Keratoconus

We have performed about 300 CXL procedures on about 175 patients.

That is about 0.51% of the population who has KC

We have been told we perform more than half of all CXL procedures in the Las Vegas area.

That means **< 1% of the KC population has been treated**.

Preserve KC Patients' Useful Vision Through Early Diagnosis and Early Treatment

Co-Management Update August 2022

In our Experience, About ½ of all KC Patients Become Unstable and Worsen, while another ½ Remain Stable

Therefore, using Las Vegas as an example, < 1% of the KC population has been treated, and < 2% of those who have unstable KC have been detected and treated. The other 98% are the ones at risk!

When we see patients referred for evaluation of KC, the average BSCVA is worse than 20/60 and often often worse than 20/100

That means we are not diagnosing and Treating KC early enough

We really should be detecting and treating at the 20/20 – 20/30 stage, so patients can drive with glasses and not be as dependent on advanced Contact Lenses in order to function

The Raines Study – April 2021 – Perth Australia
Practical Implications for Primary Eye Care in 2022

OPEN ACCESS

ARVO Annual Meeting Abstract | July 2018

Economic impact of Keratoconus -a patient's perspective

Srujana Sahebjada; Elsie Chan; Sara Vogrin; Vijaya Sundararajan; Mark Daniell; Paul N. Baird

Purpose: cross-sectional study to evaluate the economic cost associated with KC and estimate the lifetime cost associated with the disease

Methods: KC patients were recruited from ophthalmology clinics in Melbourne, Australia. A KC health expenditure questionnaire was completed by KC patients to assess direct and indirect expenditures by these subjects, referring to their bills or receipts, where possible

The Raines Study – April 2021 – Perth Australia
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Results: 100 participants completed the questionnaire, median age of 31, 57% were males

Mean cost per KC subject per year was approximately AUD $4398 = $3,562 US Dollars per year

At the time of the study (2018) KC Prevalence was thought to be 1 in 2,000 and the total cost AUD$ 40.5 million per year in Australia ($32.8 million US Dollars).

Now that we know the Prevalence is 1 in 84, the total cost is $780 million US Dollars per year for Australians with KC

July 2018
Vol: 59, Issue 9

The Raines Study – April 2021 – Perth Australia
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Applying Lessons of Australia to U.S.

Population of Australia 26,180,149

Population of U.S. 334,805,269

Estimation of Cost for KC patients in U.S. (Direct & Indirect)
Mean cost per KC subject per year was approximately $3,562 US Dollars per year

334,805,269 x 1/84 = 3,985,777 (3.985 Million) People with KC in US
Annual Cost: $9.75 - $14.197 Billion / year US Dollars

The Raines Study – April 2021 – Perth Australia
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42,000 **Optometrists** currently employed in the United States (Zippia.com)

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The Raines Study – April 2021 – Perth Australia
Practical Implications for Primary Eye Care in 2022

Cost Benefit Analysis - Optometry as a Public Health Profession

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334,805,269 x 1/84 = 3,985,777 (3.985 Million) People with KC in US
Annual Cost: $9.75 - $14.197 Billion / year US Dollars (average estimate $11.973 Billion / year)

That works out to **$285,087 per Year in Direct & Indirect Costs that KC patients are burdened with per OD**

The Raine Study – April 2021 – Perth Australia

Practical Implications for Primary Eye Care in 2022

Cost Benefit Analysis – Optometry as a Public Health Profession

What would it cost to greatly reduce that burden for KC Patients?
Who should pay for it?

There are two approaches:

Lobbying for Insurance Coverage and Keep Waiting for that to happen…

The Raine Study – April 2021 – Perth Australia

Practical Implications for Primary Eye Care in 2022

Cost Benefit Analysis – Optometry as a Public Health Profession

What would it cost to greatly reduce that?
Who should pay for it?

There are two approaches:

Lobbying for Insurance Coverage
and Keep Waiting for that to happen…

The Raines Study – April 2021 – Perth Australia
Practical Implications for Primary Eye Care in 2022

Cost Benefit Analysis – Optometry as a Public Health Profession

What would it cost to greatly reduce that?
Who should pay for it?

There are two approaches:

Or take Immediate Proactive Action…

The Raine Study – April 2021 – 1 / 84 Have KC

Practical Implications for Primary Eye Care in 2022

How to Take Action Without Waiting

- Buy a Corneal Topography Machine – Cost $10 – 15,000
  - Monthly payments about $300 / month or $3,600/year for 5 years, then next to nothing after that

(Customize top of form with name, address &phone) *(Provide 1 copy to patient; keep original in your files.)*

Patient's Name:

NOTICE OF EXCLUSION FROM HEALTH PLAN BENEFITS

You need to make a choice about having ***(LIST SERVICE/PROCEDURE).*** This service is not a covered benefit and consequently your health plan will not pay for it. When you receive a service that is not a covered benefit, you are responsible to pay for it.

The purpose of this notice is to help you make an informed choice about whether or not you want to receive these items or services, knowing that you will have to pay for them yourself. Before you make a decision about your options, you should read this entire notice carefully. ***Ask us to explain, if you don't understand why your health care service plan won't pay.***

Your doctor has recommended ***(describe service in detail providing options for patient consideration)***.

You are responsible for all of the fees associated with a non-covered service. The charge for the surgeon's professional fee is $______ and the charge for hospital or ASC facility fee is $_______.

Beneficiary Agreement
Accordingly, the undersigned accepts full financial responsibility for the non-covered services described above. ________________________________ ____________________ Signature of patient or person acting on patient's behalf Date

This Form Makes it Ethical and Legal to Charge for a Non-Covered Service Such as Screening Corneal Topography

Available as a download through Woo University

The Raine Study – April 2021 – 1 / 84 Have KC
Practical Implications for Primary Eye Care in 2022

Take Action Without Waiting - Buy Corneal Topography Machine – Cost $3,600/year

- Cost Benefit Analysis for the OD (Screen <= age 35 = 1/3 of pts)
  - Average OD in U.S. sees 62 Patients / week = 3,000 / yr
  - Many ODs in Las Vegas see 100+ Pts / week = >4,800 / yr
  - Estimated number of KC pts detected via Screening Topo is 1 in 84 or 12 – 19 in 1st year alone
  - Savings of $42,000 - $67,000 per year the rest of their lives for patients with KC through early detection & treatment
  - If you are not seeing and diagnosing 12 – 19 KC per year you are missing them & not diagnosing early enough to fully benefit your patients and save them from lifelong costs of over $3,562 per year

The Raine Study – April 2021 – 1 / 84 Have KC
Practical Implications for Primary Eye Care in 2022

Take Action Without Waiting - Buy Corneal Topography Machine – Cost $3,600/year

- Cost Benefit Analysis for the OD – Who should be Screening?
  - Every patient aged 35 and under initially, and then
    - Every 2 years until age 35 if topography is NL
    - Every 6 months if suspicious for KC but clinically stable
    - Refer ASAP for CXL eval if KC becomes unstable based on Corneal Topography or other changes
  - Estimate: 1/3 of OD patients are <= 35 yrs of age
  - Therefore most ODs should be screening about 1/3 of your patients

Pentacam for Definitive Dx

The Raine Study – April 2021 – 1 / 84 Have KC

Practical Implications for Primary Eye Care in 2022

Take Action Without Waiting - Buy Corneal Topography Machine – Cost $3,600/year (5 year financing)

After 5 yrs years cost is close to zero

- Cost Benefit Analysis for the OD – Who should be Screening?
  - So if you are seeing the U.S. average amount of 62 patients per week or 3,000 patients per year, that means screening about 1,000 patients per year and detecting 12 KC patients per year

The Raine Study – April 2021 – 1 / 84 Have KC

Practical Implications for Primary Eye Care in 2022

Take Action Without Waiting - Buy Corneal Topography Machine – Cost $3,600/year Yrs 1-5, then zero thereafter

- Cost Benefit Analysis for the OD - Business Plan:
  - Capture rate est. 80% = 800 per year x $29 / exam = $23,000 Year 1
  - The other 20% recommend you do “Pro Bono”
  - Estimated number of KC pts detected 1 in 84 or 12 – 19 in first year alone
  - Year 1 Revenue: $23,000 on $15,000 purchase
  - Year 1-5 Cost: $3,600/yr

Net to OD: $19,000 / yr or $1583 / mo

The Raine Study – April 2021 – 1 / 84 Have KC
Practical Implications for Primary Eye Care in 2022

Take Action Without Waiting - Buy Corneal Topography Machine – Cost $3,600/year

- Cost Benefit Analysis for the OD and KC Patient
  - Net to OD: $19,000 / yr or $1583 / mo Year 1, then est $12,000 / yr thereafter
  - Benefit to KC Patients through early detection & Treatment – aggregate of $42,000 per year the rest of their lives!

That's What "Win – Win" Looks Like!

The Raine Study – April 2021 – 1 / 84 Have KC

Practical Implications for Primary Eye Care in 2022

Take Action Without Waiting - Buy Corneal Topography Machine – Cost $3,600/year

- Most Difficult Challenges are Mental
  - Overcoming Your Current Habits and Inertia
  - Staff & Doctor Recommendations to all Patients <= age 35
    re: Screening Corneal Topography – self pay
  - Patient Education is Critical

The Raine Study – April 2021 – 1 / 84 Have KC
Practical Implications for Primary Eye Care in 2022

Take Action Without Waiting - Buy Corneal Topography Machine – Cost $3,600/year

- Most Difficult Challenges are Mental
  - Patient Education is Critical
  - Use Your Mental Picture of those Advanced KC patients we wished we had diagnosed earlier as your motivation to overcome the above self – limiting barriers

The Raine Study – April 2021 – 1 / 84 Have KC

Practical Implications for Primary Eye Care in 2022

Take Action Without Waiting - Buy Corneal Topography Machine – Cost $3,600/year

- If you need any support or suggestions, feel free to contact me personally at drwellish@mac.com
- Saving and Preserving Eyesight of People with KC is a Passion of Mine.
  - I am committed to doing whatever I can to support Optometry and the KC Community to overcome all barriers to save KC patients' eyesight at earlier and earlier stages
  - If done properly, this should be a "Win – Win" for Optometry and for Patient Care

The Raine Study – April 2021 – 1 / 84 Have KC
Practical Implications for Primary Eye Care in 2022

Take Action Without Waiting - Buy Corneal Topography Machine – Cost $3,600/year

- If you need any support or suggestions, feel free to contact the Cross Linking Surgeon you work with and ask them to put you in touch with your local Glaukos Cross Linking Rep
- They should be able to provide you and your staff with all the training and resources you need.

Co-management Guidelines for Corneal Collagen Crosslinking (CXL)

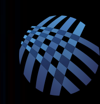
Shaping the Future

This Course reviews for the Primary Eye Care Practitioner

Advanced Concepts in the Co-management of Corneal Collagen Crosslinking (CXL)

Course Learning Objectives

- To review pre-op care for patients being treated with Corneal Collagen Crosslinking (CXL)
- To share clinical pearls for targeted diagnosis and treatment, including Indications
- To review Evaluation by the Primary Eye Care Physician



Keratoconus vs. Pseudo KC

- KC
  - Elevated posterior cornea
  - Epithelial Thinning Over Apex of Cone
- Pseudo KC
  - No elevation of Posterior Cornea
  - Epithelial Thickening of Apex of Cornea

“Keratoconus Referrals that Turn Out to be Not KC”

True KC: Increased Posterior Elevation

Anterior Float

Diff: 0.088 mm
Meridian: 228 °
Radius: 0.8 mm

Diff: 0.213 mm
Meridian: 228 °
Radius: 0.8 mm

Float

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Sim K's Astig: -6.6 D @ 70 deg
Max: 57.6 D @ 160 deg
Min: 51.0 D @ 70 deg
3.0 MM Zone: Irreg: ± 11.4 D
Mean Pwr 52.3 ± 9.1 D
Astig Pwr 5.3 ± 6.9 D
Steep Axis 139 ± 45 deg
Flat Axis 29 ± 45 deg
5.0 MM Zone: Irreg: ± 11.3 D
Mean Pwr 47.3 ± 9.0 D
Astig Pwr 0.8 ± 6.7 D
Steep Axis 93 ± 49 deg
Flat Axis 51 ± 48 deg
White-to-White [mm] : 11.4
Pupil Diameter [mm] : 3.5
Thinnest : 299 um @ (-0.6, -0.6)
ACD (Endo): 3.58 mm
Kappa : 4.69° @ 189.36°
Kappa Intercept : -0.34, 0.74

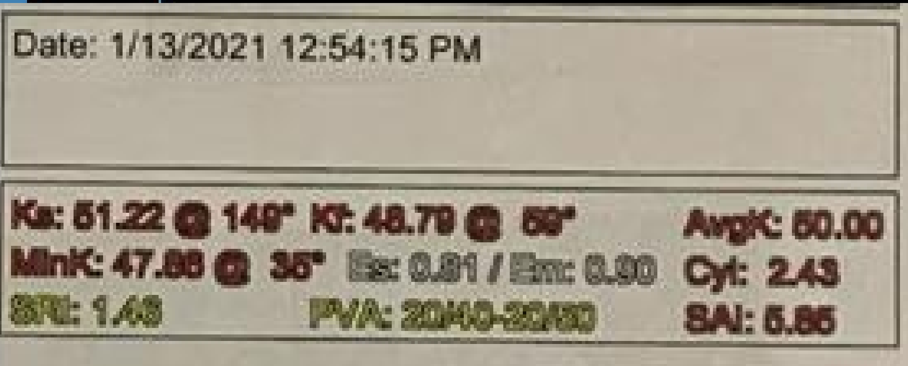
T

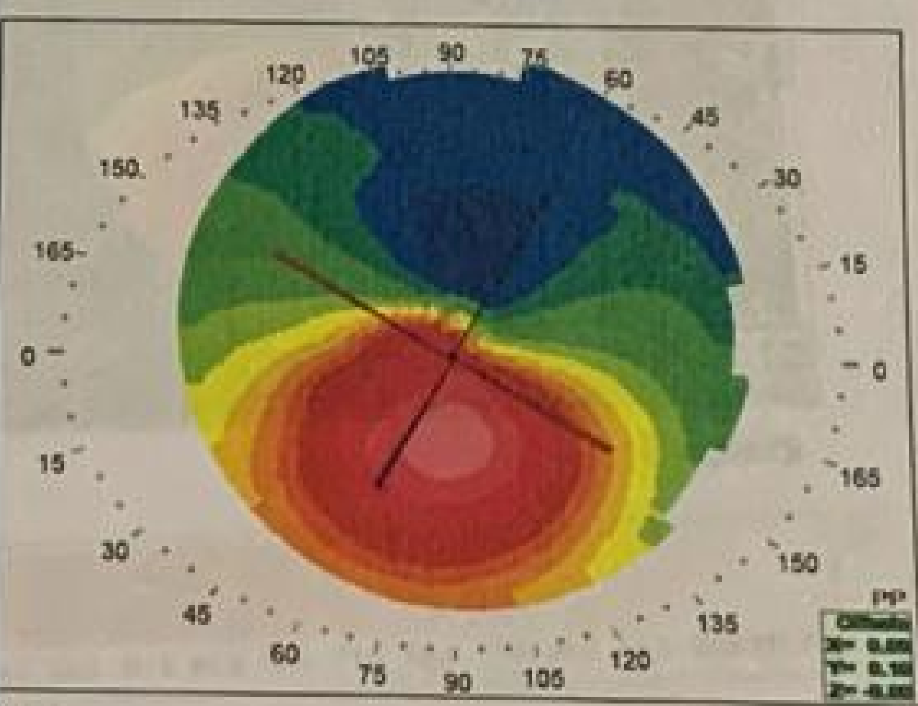
N

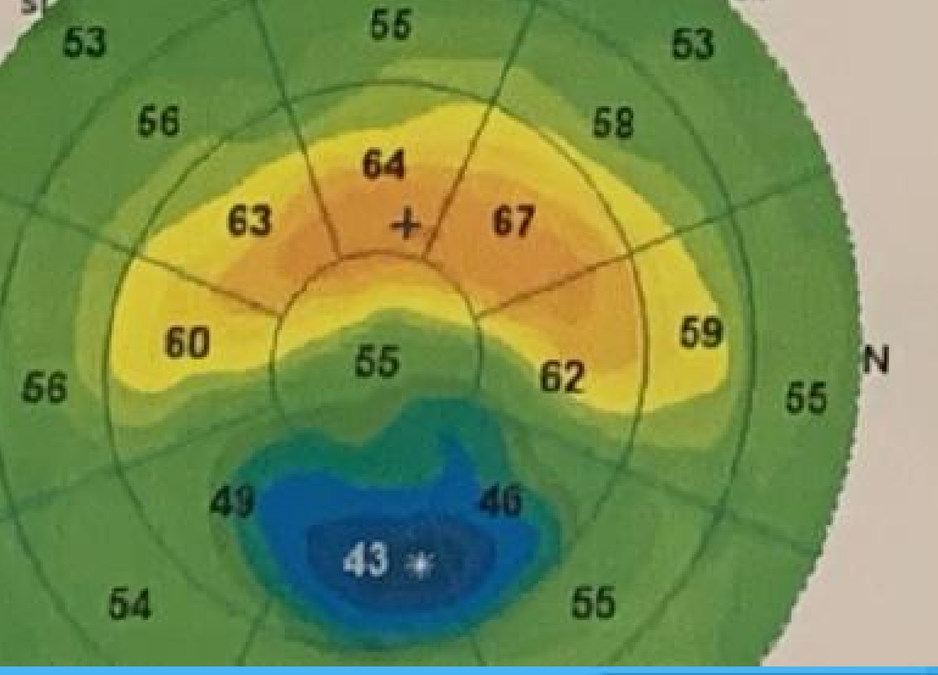
OD

v3.14

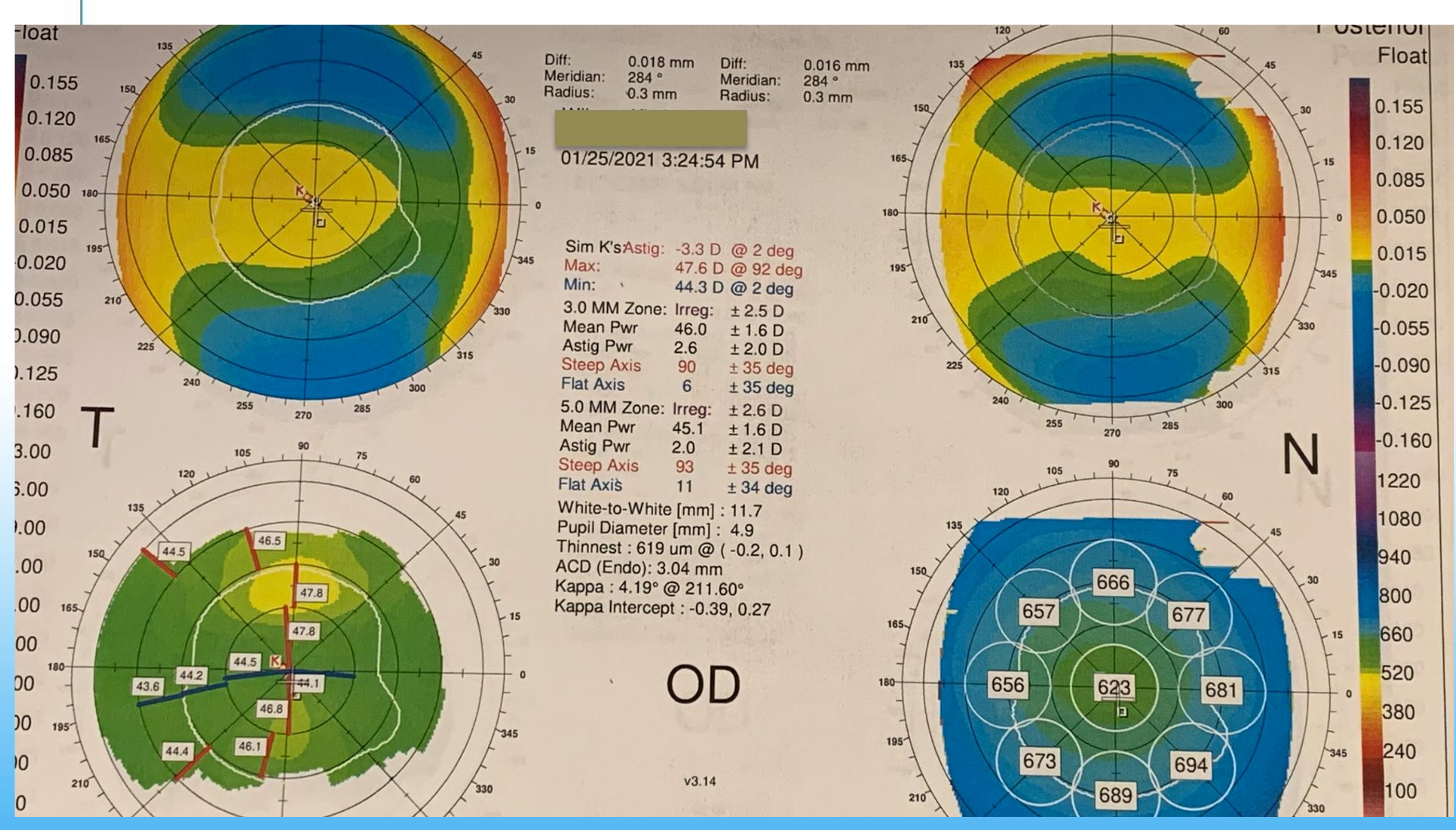
True KC: Epithelial Thinning over Apex



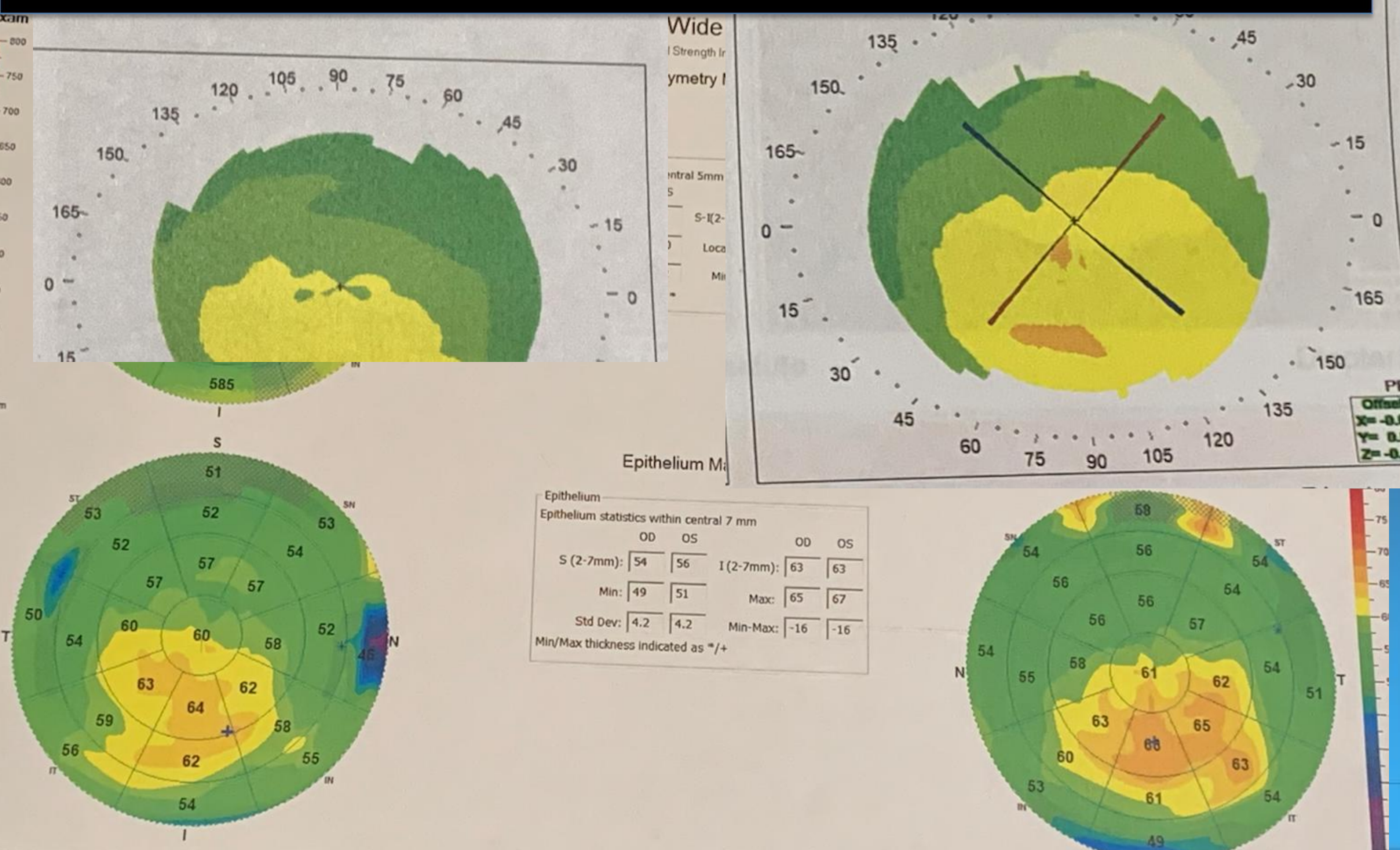




Pseudo KC: NL Posterior Elevation < 40 um



Pseudo Keratoconus:
Epithelial THICKENING Over Area of Steepening



Then CXL Was Developed in 1998 Dresden Protocol –> LV Use in 2012

- In 2012 Wellish Vision Institute was one of 90 sites around the country invited to serve as an FDA Study site for the Avedro KXL treatment for KC & Corneal Ectasia

CXL Performed since 1998: WVI a Leader in FDA Trials

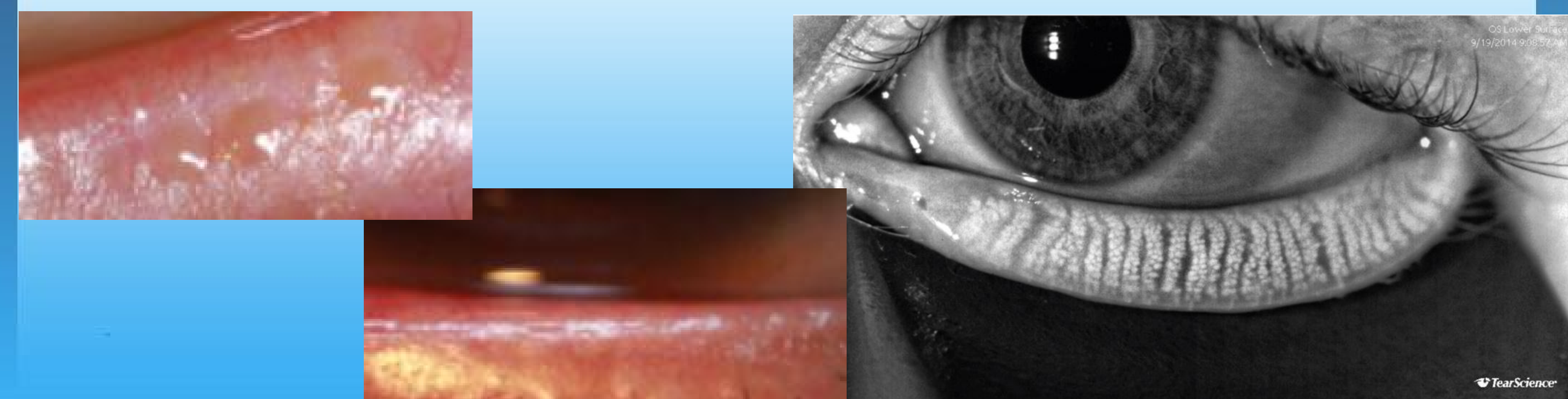
- Wellish Vision Institute was one of the few sites to have a very high rate of f/u
- our **data** and **successful outcomes** were instrumental in the FDA's decision to approve CXL here in the U.S. in July 2016

Lessons Learned from Intacs & CXL

- No excuse just watching KC & Ectasia worsen when we now have great treatments

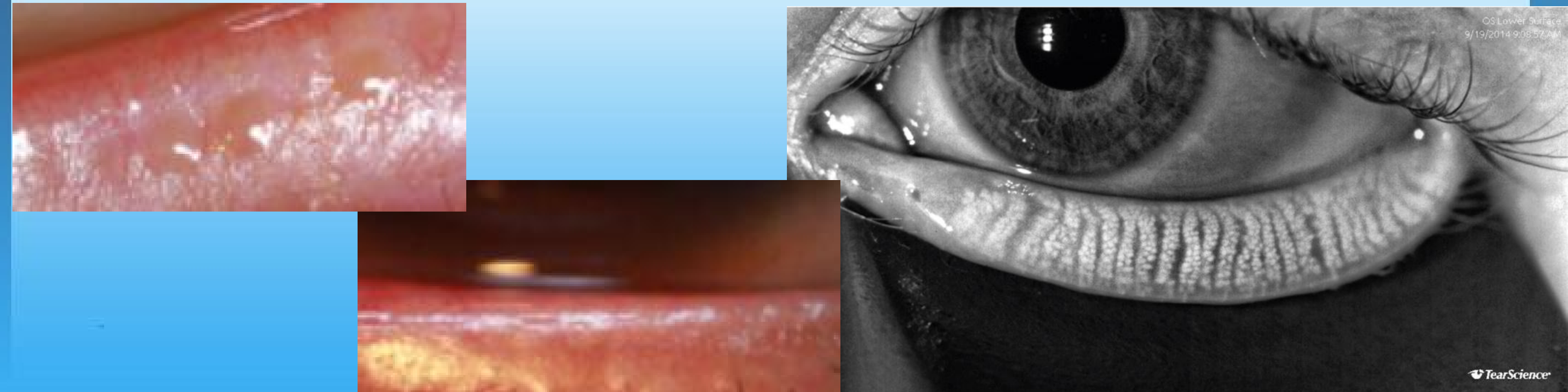
Lessons Learned from Intacs & CXL After 10 Years of Experience & > 300 treated

- Keys to Success: Follow the Science -> DEWS2
- **Aggressive Dx & Tx of Dry Eye / MGD BEFORE CXL is critical to attaining good outcomes – LipiView, Lipiflow & IPL are important parts of this approach, along with the overall assessment and treatment plan outlined in the WVI Dry Eye Passport**

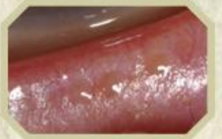


Lessons Learned from Intacs & CXL After 10 Years of Experience & > 300 treated

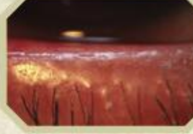
- The Vast Majority of CXL Patients will Never Need IPL, Lipiflow, or Anything More than Stage 1 or 2 DEWS 2 Treatments
  - **AFTs, Lid Hygiene, Omega-3's, maybe Lacrimal Plugs**
  - **Possibly Topical Cyclosporin, Lifitegraft, Loteprednol 0.25%, or Varenicline**
- 5-10% May Need IPL, Lipiflow, Serum Tears, and/or Amniotic Membrane Tx to Treat the Pre-Existing or Resulting Dry Eye
- **Well Known: All Corneal Procedures Can Cause or Worsen Dry Eye**



Meibomian Gland

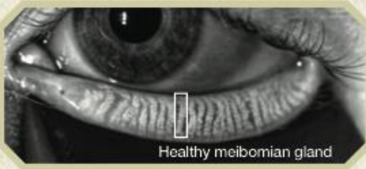


Normal Glands
(Liquid Oil)



Blocked Glands
(No Secretions)

Meibomian Gland Dysfunction (MGD)

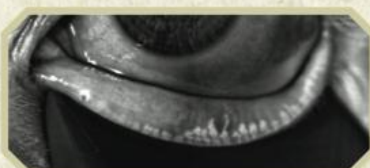


Normal

Meibomian glands are glands that are arranged vertically within the eyelid near the lashes. The eyelid blink causes oil to be excreted onto the posterior lid margin. The oil is the "staying power" of the tears that helps lubricate tears & prevent rapid tear evaporation.

Gland Atrophy

Progression of MGD / clogged oil glands decreases oils in our tears. Early detection & treatment to prevent further loss of glands & oils are key.



Severe Gland Dropout

Blockage and chronic inflammation result in gland atrophy. Irreversible damage to the meibomian glands. Once these glands are gone, we cannot bring them back.

DIAGNOSTIC TESTING

- Review of patient's symptoms
- SPEED test questionnaire
- Exam by dry-eye specialist
- Slit lamp exam, including
  - Schirmer's tear production test
  - Tear break-up time
  - Lissamine™ Green staining of cornea & conjunctiva
  - Fluorescein staining/ grading of cornea
- LipiView 2 evaluation of meibomian glands
- iTrace and/or AcuTarget™ assessment of effect of dry eye on patient's vision
- Sjögren's screening test (SJÖ) in certain cases for early detection and treatment of Sjögren's syndrome

DEPARTMENT OF EYEBALL SECURITY • U.S. OCULA
10

Let the dry-eye
experts at Wellish
Vision Institute
help you find dr
eye relief.

Call today.
702-733-202

WellishVision.
dry-eyes.or

East Location
2110 East Flamingo Road, Suites 2
Las Vegas, NV 89119

West Location
2555 Box Canyon Drive, Las Vegas

Henderson Location COMING SOON!
10424 S. Eastern Ave., Henderson

Dry Eye Passport Part 2

- **Artificial Tears:** Systane® Balance, Ultra, Liquigel; Theratears: regular for CTL wearers, Liquigel for bedtime; Refresh Optive; Simulsan; FreshKote *(by Rx)*. For more severe cases- Oasis tears for CTL wearers or Oasis TEARS PLUS or Celluvisc for severe cases without CTL, every two hours
- **Restasis®** 2x/day *(use PAR Rx)*
- **Zaditor®** 2x/day for itching *(over the counter)* Stronger allergy drops by prescription if needed
- **Optivar®** for Nonallergic vasomotor ocular irritation, irritation, burning and/or itching
- **Retaine MGD** for severe cases
- **Lotemax Gel** 2x/day for 7 days, then as directed

Eye Drop Land

- **Lacrimal plugs, Punctal Occlusion**
- **Prokera®** Slim Cell slim living contact lens for about 4 days per eye
- **Repair of lower lid** and/or punctal ectropion, if present
- **Repair of CCH** *(conjunctivochalasis)* if present

TREATMENT OPTIONS

Moistland

- **Z-Pack** for 5 days (improves MGD in about 30% of cases. Better choice now than Doxycycline)

- **Omega-3s:** 1st choice: PRN vitamins 2x/day; 2nd choice: Bio Tears; 3rd choice: generic omega-3s (ProOmega 1000-3000 to 4000 mg every day (Nordic Naturals); 4th choice: vegetarian omega-3s
- **Evoxac** for severe cases

"Gateway" Treatments Visit Future Treatment Land Today

- **Self Pay: LipiFlow®, Intense Pulsed Light (IPL), LipiFlow Plus** *(LipiFlow® plus IPL)*
- **Get paid: FDA Studies.** Find out if you are eligible for new FDA study
- **Benefit from tomorrow's treatments today**

Home Treatmentina

- **Hot Moist Packs** 2x/day
- **Erythromycin** ophthalmic ointment at bedtime
- **Lid wipes: Ocusoft®, Systane®, TheraTears®** 2x/day *(can substitute dilute baby shampoo)*
- **Cliradex** tea tree oil lid wipes each morning for 2 straight months to wipe out Demodex if present
- **Avenox** for lid hygiene in more severe cases
- **Blinking exercises** if indicated on LipiView 2
- **64 oz of water every day.** Stay well hydrated. Avoid too much caffeine or alcohol as these can be dehydrating.
- **Try to avoid** ceiling fans or other fans blowing directly on you, day or night.
- **Manuka honey** *(medical grade)*

Contact Lens Land

- **Mini-scleral lens**
- **PROSE contact lens**

Treatment of Nocturnal Lagophthalmos

When the eyes dry out overnight ... the ounce of prevention that's worth a pound of cure

- **Retaine® PM™**, or **Lacri-Lube®**, or **Systane® Lubricant Eye Gel or Altalube ointment** at night
- **OCuSOFT®** Tranquileyes moisture goggles
- **Venta humidifier** *(works great for most-but requires maintenance)*
- **CPAP machine.** If using, consider air leak around mask drying out eyes. Consider referral to sleep specialist or respiratory therapist.

DRY EYE TREATMENT IN 4 STEPS

STEP **1** - Patient Education & First Line of Treatment

- Education regarding the Dry Eye condition, its management, treatment and prognosis, including iTrace & LipiView.
- Education regarding potential Dietary Modifications (including Importance of high quality Omega-3 vitamins such as HydroEye with DHA & GLA 2 pills 2x/day) & 8 Cups of water per day
- Environmental Modifying Factors (ceiling fans, smoky environments, etc.)
- Medication Modifying Factors
- High Quality Artificial tears
- Lid hygiene & warm compresses of various types. Importance of high quality Beaded Mask **& Blink every 10 seconds**
- Lid scrubs & Topical antibiotic or antibiotic/steroid combination applied to lid margins for anterior blepharitis if present. Consider Blephex eyelid cleaning
- Start treatment with Tea Tree Oil (Cliradex) if Demodex is present
- At Step 1 visit, a decision is made as to whether:
  - *Lacrimal Plugs* will likely be needed at next visit. Doctor & staff to discuss with patient as well as need for *LipiView* if Meibomian Gland Dysfunction is present

Adapted from DEWS II Recommendations

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- Tear conservation:
  - Extended duration "tear duct" lacrimal plugs for most patients, silicone plugs for keratoconus, PRK & other patients
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Prepping for CXL: Dry Eye Treatment

- 80% of Patients will be ready and cleared for CXL if they follow the above protocol of

1. Quality NP-AFTS such as Oasis Tears Plus or Retaine MGD
2. HMP with Beaded Mask BID (microwave heat)
3. High Quality Omega-3’s unless contraindicated
4. Silicone Lacrimal Plugs if Needed

These are all things that can be done by ODs

DRY EYE TREATMENT IN 4 STEPS

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- Education regarding the Dry Eye condition, its management, treatment and prognosis, including iTrace & LipiView.
- Education regarding potential Dietary Modifications (including Importance of high quality Omega-3 vitamins such as HydroEye with DHA & GLA 2 pills 2x/day) & 8 Cups of water per day
- Environmental Modifying Factors (ceiling fans, smoky environments, etc.)
- Medication Modifying Factors
- High Quality Artificial tears
- Lid hygiene & warm compresses of various types. Importance of high quality Beaded Mask **& Blink every 10 seconds**
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Adapted from DEWS II Recommendations

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Loteprednol etabonate 0.25%

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What's New & Novel? **Loteprednol Etabonate 0.25%** Great for "Flares"

Loteprednol Etabonate 0.25% - "Eysuvis"

The loteprednol etabonate 0.25% suspension formulation is a proprietary **mucus-penetrating particle technology** that **increases surface exposure to the drug** (Figure 1).[13]

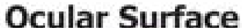
Preclinical studies of a 0.4% formulation showed that **peak drug concentrations in the cornea and conjunctiva were 3.6- and 2.6-fold higher**, respectively, than those achieved with a commercial loteprednol etabonate 0.05% suspension.[25]

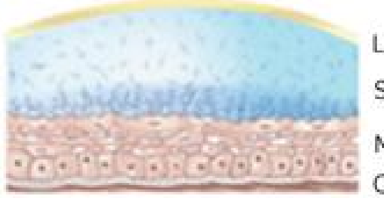
In addition to having **nanometer-scale particle size** and a **coating that prevents adherence to mucins after administration**, the **drug can be stored at room temperature.**[13,16]

Authorization from STAAR required.

What's New & Novel? **Loteprednol Etabonate 0.25%** Great for "Flares"

Ocular Surface Drug Delivery Using Mucus-Penetrating Particles (MPP)





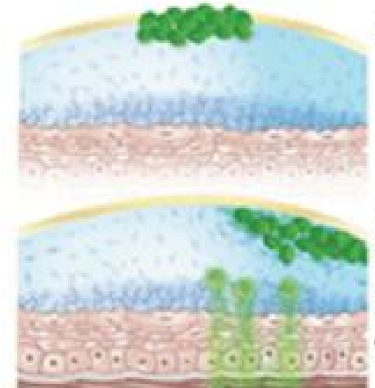
Lipid layer

Secreted mucins

Membrane-associated mucins

Corneal epithelium

Traditional Drug Treatment

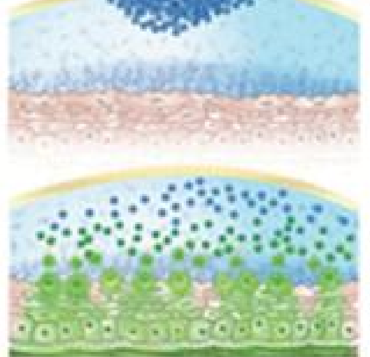


Drug (green) is administered

Most drug particles are bound to secreted mucins and are cleared from the tear film

Remaining drug reaches the corneal epithelium

Drug-Core MPP Treatment



MPPs (blue) are administered

MPPs penetrate through secreted mucins

Drug (green) is released and reaches the corneal epithelium

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Tyrvaya (Varenicline) nasal spray

- o Topical secretagogues (TheraTears over the counter; prescription meds not

Dry Eye Updates – Wht's New & Novel? Tyrvaya

Tyrvaya Varenicline solution 0.03 mg Nasal Spray: Pearls

- highly selective **cholinergic agonist** that **stimulates natural tear production**, and it is useful in the treatment of mild, moderate and severe disease
- Mechanism of action is similar to the now discontinued, TrueTear (Allergan): **activate the fibers of the trigeminal nerve in the nose** in order to **stimulate tear production**

Authorization from STAAR required.

Tyrvaya Varenicline solution 0.03 mg Nasal Spray: Pearls

Varenicline solution is a nicotinic activator of muscarinic receptors.

When it is properly applied in the nose, it activates the trigeminal nerve, which in turn sends signals to all three elements of the lacrimal functional unit (lacrimal gland, goblet cells, meibomian glands).

This leads to a nearly instantaneous increase in basal tear production…and then you sneeze.

Authorization from STAAR required.

Tyrvaya Varenicline solution 0.03 mg Nasal Spray:

Dosage, Directions , Pearls for Success:

- One spray into the lateral wall of each nostril (toward to ear) BID

- Before you use the spray for the first time, the bottle needs to be primed. “Seven pumps and you are good to go.”

- **Varenicline**, and likely all nasal sprays, is actually designed to be delivered just below the inferior meatus, about 0.5 inch in, with the tip angled toward the ear on the same side as the nostril you spray.

Authorization from STAAR required.

Tyrvaya Varenicline solution 0.03 mg Nasal Spray:

Dosage, Directions , Pearls for Success:

- Advise patients: Push your tongue against the roof of your mouth to slow down flow in the back of your throat (helps prevent & minimize burning in the back of the throat)

- When writing the Rx be sure to prescribe “dispense 2 bottles”

  That is enough to last about 45 days

- If there is a pause in usage for > 2 days, the bottle needs to be primed again (sometimes only 2 pumps)

Authorization from STAAR required.

Tyrvaya Varenicline solution 0.03 mg Nasal Spray:

Dosage, Directions , Pearls for Success:

- There are no special storage requirements for either samples in the office or at home, but use your judgment (i.e try to stay close to room temperature)

Cost

- The company has a generous program to help patients with commercial insurance get the first year of treatment at a low cost (ask your Rep for details)
- Unfortunately, no coverage for Medicare patients, so not worth even prescribing for these patients

Authorization from STAAR required.

Tyrvaya Varenicline solution 0.03 mg Nasal Spray:

Expected "Normal" Side Effects:

- In the pivotal phase 3 trial, *82% of subjects **sneezed***.

This is a side effect you should inform every patient about. It is to be expected.

- When our doctors & office staff tried it out, we experienced of **burning in the nose** and **back of the throat**, but that was pretty much it for side effects in our group.

Authorization from STAAR required.

Tyrvaya Varenicline solution 0.03 mg Nasal Spray:

Who is a Good Candidate for Varenicline nasal spray for Dry Eye Disease?

- First use DEWS 2 Step one treatments: AFTs, Lid Hygiene, High Quality Omega-3 vitamins, Environmental Controls, etc.
  - Then treat ocular surface inflammation if needed,
  - Then if needed extended duration lacrimal plugs,
  - Then be sure Meibomian Gland Dysfunction is being adequately addressed.
  - Then if more is needed, consider Varenicline nasal spray.

Authorization from STAAR required.

Tyrvaya Varenicline solution 0.03 mg Nasal Spray:

This spray **acts** by stimulating the trigeminal nerve, which in turn sends signals to all three elements of the lacrimal functional unit -

- Lacrimal gland,
- Goblet cells, and
- Meibomian glands (MGs),

But if MGs are clogged with solid oils from MGD, that critical part of the triad will be the missing link that holds back effectiveness. So treat MGD first.

Authorization from STAAR required.

DRY EYE TREATMENT IN 4 STEPS

STEP **1** - Patient Education

& First Line of Treatment

- Education regarding the Dry Eye condition, its management, treatment and prognosis including iTrace & LipiView

STEP **2** - If STEP 1 treatments are found to be inadequate consider:

- Tear conservation:
  - Extended duration "tear duct" lacrimal plugs for most patients, silicone plugs for keratoconus, PRK & other patients

STEP **2** (continued)

- Consider starting prescription drugs to manage Dry Eye Disease:
  - **Topical** non-glucocorticoid **anti-inflammatory eye drop** meds such as
    - > Cyclosporine (esp. for neurotrophic keratitis). (Caution if pregnant or nursing, OK to use in HSV stromal keratitis, stop if active dendritic keratitis is present).
      - * **Restasis**, **Cequa** 2x / day (TruCare pharmacy), if reasonably priced with insurance coverage or

2x / day –90 day supply self pay

o Topical Xiidra (Lifitegrast) 2x /day

Electric Dry Eye Mask

Introducing: The electric Dry Eye Mask – Step 2: Like a DIY Lipiflow

Authorization from STAAR required.

Introducing: The electric Dry Eye Mask

– Step 2: Like a DIY Lipiflow

Nice “do it yourself at home” option that is one step beyond hot compresses with microwavable gel mask, but before going to the step of Intense Pulsed Light and/or Lipiflow.

Authorization from STAAR required.

Introducing: The electric Dry Eye Mask

– Step 2: Like a DIY Lipiflow

- Melts the hardened oils stuck in the Meibomian Glands
- Allows the Meibomian Glands to secrete the oils that are necessary for a healthy tear film

Authorization from STAAR required.

Dry Eye Workshop DEWS 2 - STEPS 3 & 4

- Make sure patient is drinking 8 cups of water per day
- Make sure patient is complying with environmental controls as noted in Step 1.

Vitaltears.org

Step 3 - If above options are inadequate consider (step 2 treatments not already done), then:

- **Autologous serum eye drops** (our managers can help arrange) – 90 day supply - every 2 hours while awake
- Therapeutic contact lens such as **scleral lens**
- Oral secretagogues such as oral pilocarpine, cevimeline (trade name: Evoxac). Must clear with PCP due to systemic side effects

Autologous serum eye drops. Advanced Dry Eye Treatment

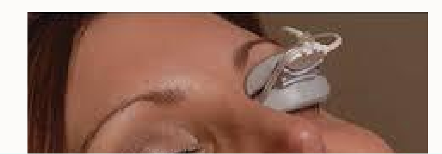
Scleral contact lens. Advanced Dry Eye Treatment

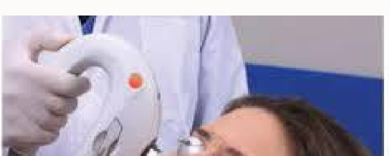
Step 4 - If above options are inadequate consider:

- Topical corticosteroid eye drops for longer duration (be careful, watch for IOP spikes, risk of cataract, etc)
- **Amniotic membrane graft contact lens treatment for about 1 week**
- Surgical thermal punctal occlusion
- Other surgical approaches (such as tarsorrhaphy, salivary gland transplantation)

Amniotic membrane helps rejuvenate ocular surface

Contact lens is usually placed on top for comfort





THE DRY EYE EXPERTS AT

Dry Eye Workshop DEWS 2 - STEPS 3 & 4

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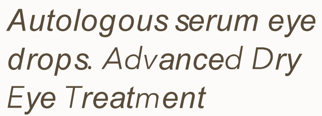

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THE DRY EYE EXPERTS AT WELLISH VISION

Dry Eye Workshop DEWS 2 - STEPS 3 & 4

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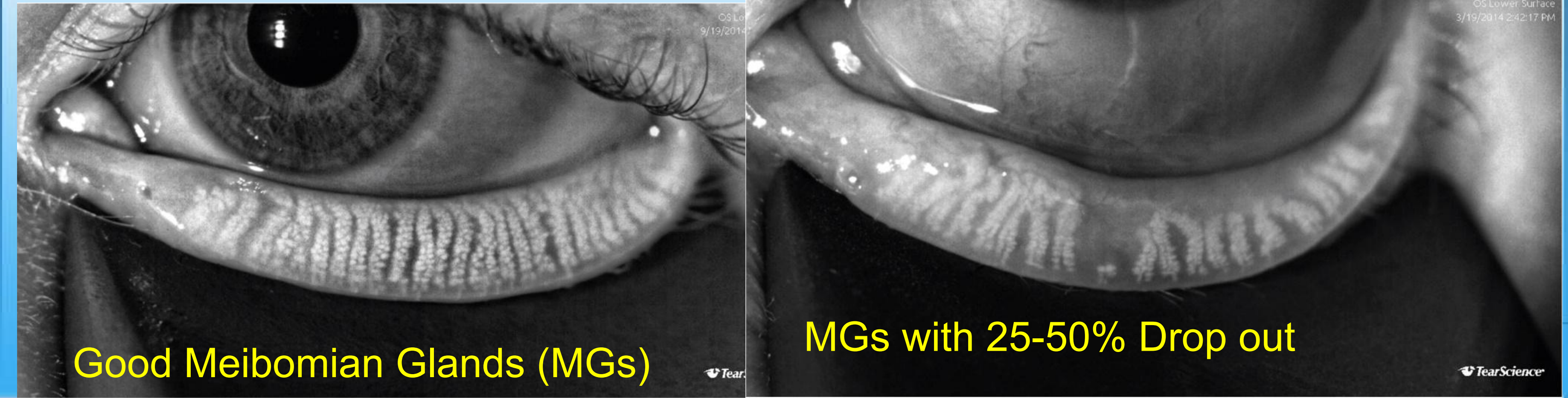
THE DRY EYE EXPERTS AT WELLISH VISION

Lessons Learned from Intacs & CXL

- No excuse just watching KC & Ectasia worsen when we now have great treatments
- **BUT, Aggressive Dx & Tx of Dry Eye / MGD BEFORE Tx is critical to attaining good outcomes – LipiView, Lipiflow & IPL are important parts of this approach, along with the overall assessment and treatment plan outlined in the WVI Dry Eye Passport**



Good Meibomian Glands (MGs)

MGs with 25-50% Drop out

Lessons Learned from Intacs & CXL

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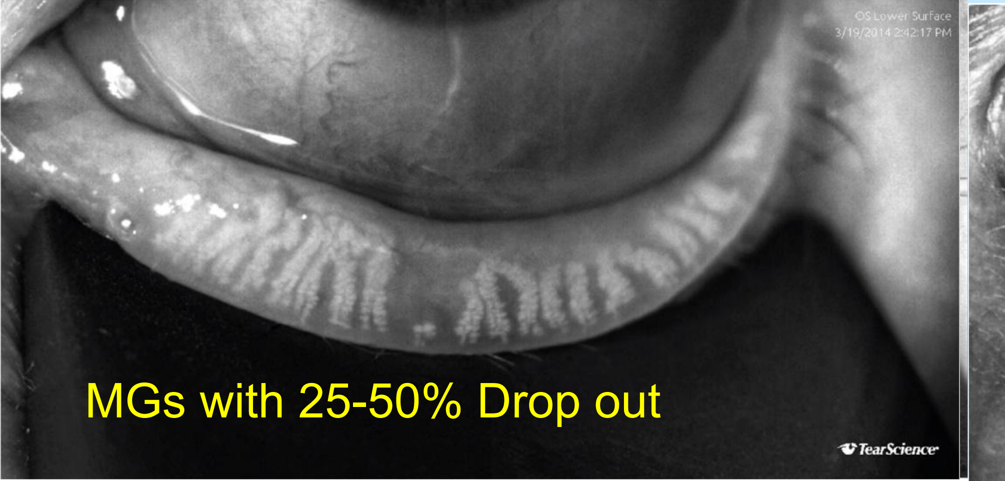
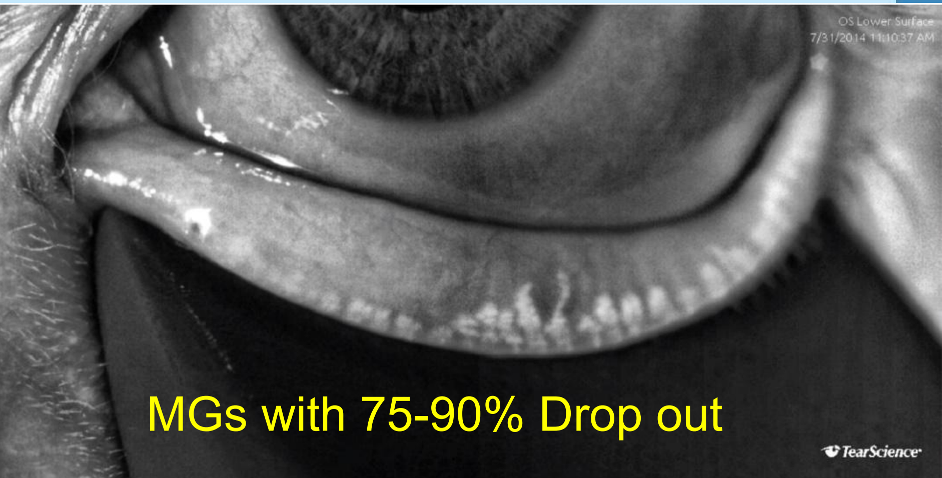




Lesson: 5 Minute Fluorescein Test

Many cases of Dry Eye are missed because of Delayed Corneal Staining:

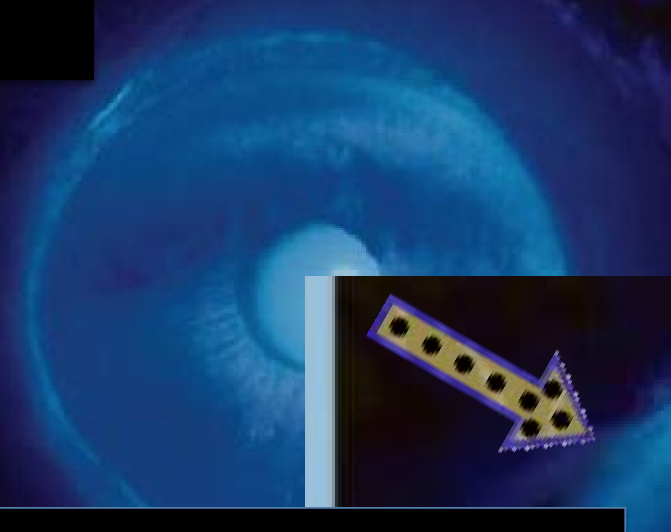
No Visible Staining Immediately After Fluorescein Instilled

Lesson: 5 Minute Fluorescein Test

Many Cases of Clinically Significant Dry Eye are Missed Unless this Test is Rigorously Performed Pre-op

Corneal Staining noted
5 Minutes After Fluorescein Instilled

Lesson: 5 Minute Fluorescein Test



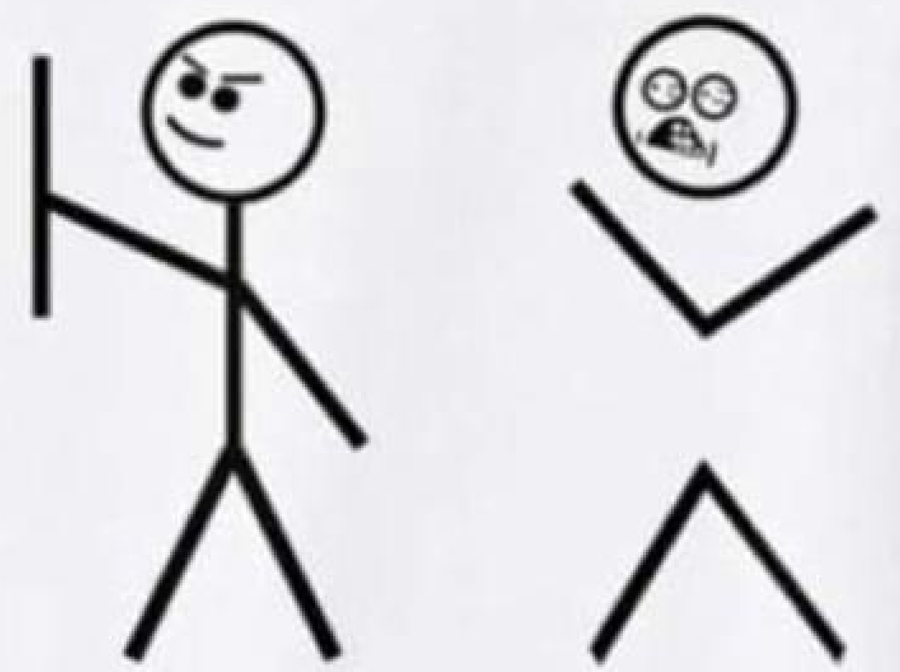
Many Cases of Clinically Significant Dry Eye are Missed Unless this Test is Rigorously Performed Pre-op

This Test is Above & Beyond the “Standard of Care”, but.. Failure to Perform this Test Results in Delayed Epith Healing → Corneal Haze & Decreased BSCVA

Why Is All This Dry Eye Testing, Education & Treatment so Important?

Because it lets our patients know something even more important than just doing their CXL for KC…

… It lets our patients know that…literally...


I've got your back!

FDA Avedro Study - Lessons Learned:
8-10% of Patients Lost >= 1 Line of BSCVA

- **In the FDA Avedro study, although the results were good enough to gain approval, we felt that loss of BSCVA was an unexpected disappointment**
- **In looking at our data, we saw that this occurred in those with delayed epithelial healing**

FDA Avedro Study - Lessons Learned:
8-10% of Patients Lost >= 1 Line of BSCVA

- **These patients were not cleared for surgery if they had pre-existing moderate to severe dry eye**
  - **> unless adequately treated pre-op with no fluorescein staining on pre-op exam,**
  - **> clearly the FDA protocol missed something, and therefore so did we…**

FDA Avedro Study - Lessons Learned: 8-10% of Patients Lost >= 1 Line of BSCVA

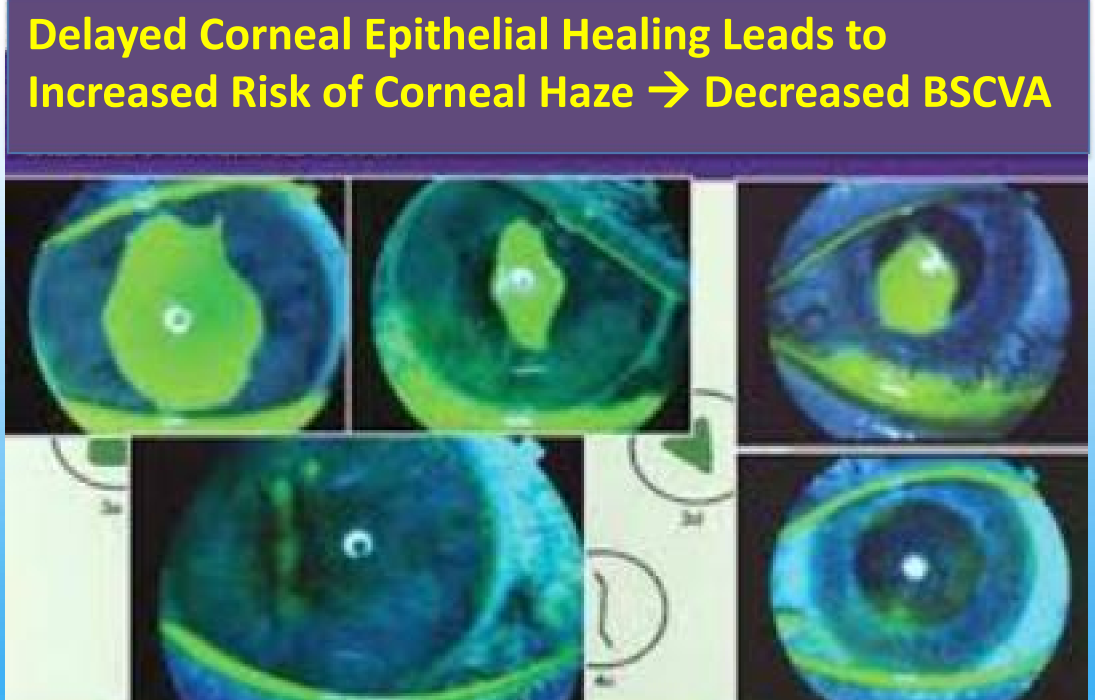
- **Shortly after starting this FDA study in 2012, we were invited to be an FDA study site for a Dry Eye treatment that was later called Xiidra**
- **In the Xiidra study, the protocol required judging corneal staining immediately after instilling fluorescein and than again 5 minutes after instilling fluorescein**

FDA Avedro Study - Lessons Learned:
8-10% of Patients Lost >= 1 Line of BSCVA

- **We were surprised at how often patients with little to no staining immediately after instilling fluorescein developed *very significant staining after 5 minutes*, even though we had them keep their eyes closed for the 5 minutes**

FDA Avedro Study - Lessons Learned:
8-10% of Patients Lost >= 1 Line of BSCVA

- **It's easy to see how this undetected staining could lead to delayed epithelial healing and hence corneal haze & decreased BSCVA**



FDA Avedro Study - Lessons Learned: 8-10% of Patients Lost >= 1 Line of BSCVA

- **We theorized that if we added a "5 minute fluorescein test" to our pre-op clearance, and followed the DEW2 Study recommendations in order to achieve complete lack of corneal staining in the area to be debrided and treated, this could prevent the loss of BSCVA**

FDA Avedro Study - Lessons Learned:
8-10% of Patients Lost >= 1 Line of BSCVA

- **Today, after treating over 300 Eyes with our protocol (and a few other surgical pearls we developed & adopted based on our observations), we are aware of only 3 patients (1%) with a slight loss of BSCVA, with no need for re-treatment at present (2/3 due to eye rubbing)**
- **If there are 1 or 2 we don't know about, we are still at about 1% vs. 8-10% in the FDA Trial, following the "on label" FDA Protocol**

FDA Avedro Study - Lessons Learned:
8-10% of Patients Lost >= 1 Line of BSCVA

- **We have many who actually gained one or more lines of BSCVA!**
- **This is especially gratifying when we consider that all treated patients were actually worsening & unstable prior to their CXL**

CONCLUSION

- We all waited many years of waiting for FDA approval
- Now that CXL has been approved and available for the past 6 Years
- There is no excuse to delay diagnosis and treatment!
- Write down your action plan today!

CONCLUSION – ACTION PLAN

- Download Support Materials I have Provided to Woo University
- Customize the NEHB to your practice and the use of Topography as a Screening Test for Early Detection of Keratoconus
- Develop your own protocol on how to explain to patients & parents the need for screening

CONCLUSION – ACTION PLAN

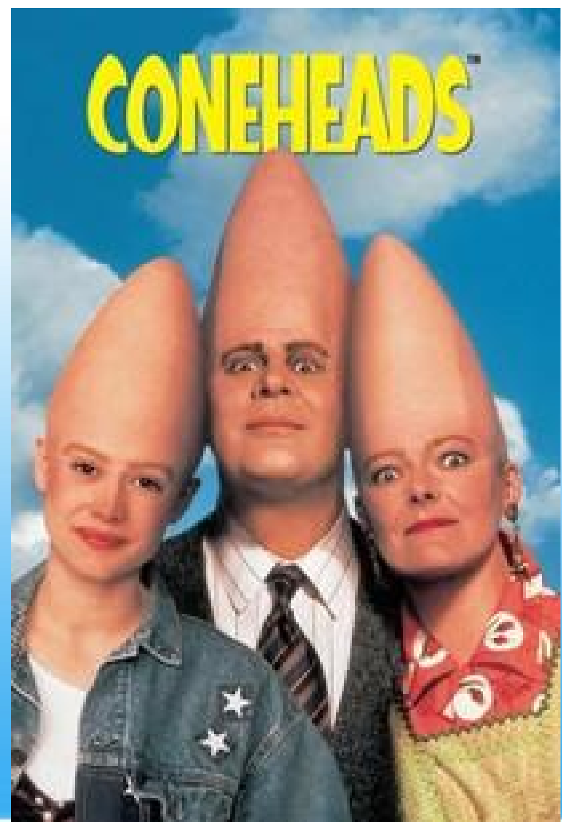
- Get comfortable with the idea that you will be screening patients and charging for the screening using the NEHB form
- ? $29 per test
- You decide who is suspicious for KC, who is stable, who is unstable
- Advise any KC suspects or KC patients of the importance of no eye rubbing

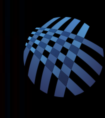
CONCLUSION – ACTION PLAN

- With the Diagnostic and Treatment Tools we now have available, There is no excuse to delay diagnosis and treatment!
- We thank Avedro for bring this technology to the U.S. and making it available to our patients!

CONCLUSION

- Thank you for attending our educational program today!

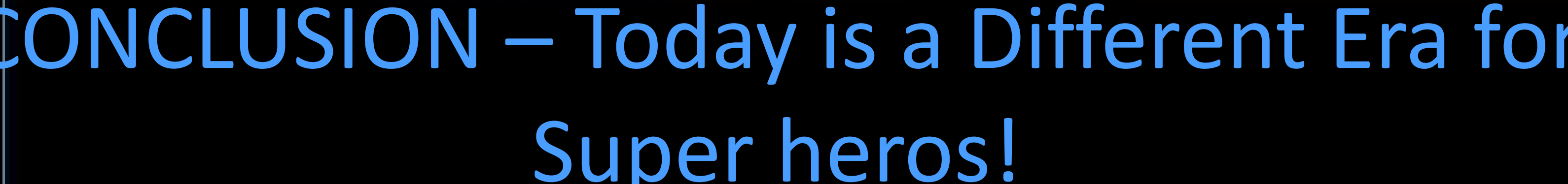




CONCLUSION

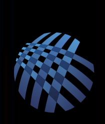
By the Way,

If You’re Going to Be a Superhero and Start Screening Patients with Topography More Proactively, Beware…



CONCLUSION – Today is a Different Era for Super heros!

Spider-man is always here to save the day



CXL to Prevent Worsening of KC is One of the Most Rewarding Parts of our Practice

- Please take the next step toward Early Detection of our Patients By Actively Screening with Corneal Topography Everyone Aged 35 and under!
- Thank you for attending our educational program today!
- Questions?

702-339-2020 (cell)

drwellish@mac.com