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Just Say No: Drug-Free Treatments for Dry Eye

The Dry Eye Explosion

- Prevalence
- Evolving research
- New generation RF's
- Need for earlier intervention
- Custom cataract/refractive surgery
- Increasing interest in non-drug therapies



ARE WE OVERMEDICATING? A look at the numbers.

Studies have shown that:

- 67%** of Medicare recipients have two or more chronic conditions
- 39%** of adults 45 and older take five or more medicines
- 60%** of adults 45 and older have taken medicines that they may not need
- 67%** of adults 42 to 85 years old taking prescription medicines also take supplements

OVERVIEW OF DRY EYE TREATMENT OPTIONS

| THERMAL/HEAT | HYGIENE | TOPICAL/SUPPLEMENTAL | ORAL |
|---|---|---|--|
| Compresses/Washcloth | Diluted 3% Shampoo | Targeted Artificial Tears | Omega-3 Supplements (Concentrated) |
| Heat Mask (Bruder) | Detergent-based Products (Ocusoft, Steri-lid) | Topical Antibiotics (ointments/gels) | Oral Tetracycline Derivatives (short-term) |
| MiBo Thermaflow Intense Pulse Light (IPL) | Hypochlorous Acid (Avenova, Hypochlor) | Steroid/Combo | Oral Tetracycline Derivatives (chronic) |
| Thermal Pulsation (LipiFlow, iLux) | 4-Terpineol, Tea Tree Oil (Citradox) | Cyclosporine/Lifitegrast | |
| | Microblepharoexfoliation (BlephEx) | Punctal Plugs Autologous Serum Amniotic Membrane TruTear | |

Drug-Free Treatments for Dry Eye

- Non-Drug Therapies
- Device-Based Treatments



Non-Drug Therapies

- Artificial tears
- Heat masks
- **Omega-3 supplements**
- **Tea-tree oil based therapy**
- Punctal plugs
- Hypochlorous Acid
- Amniotic Membranes



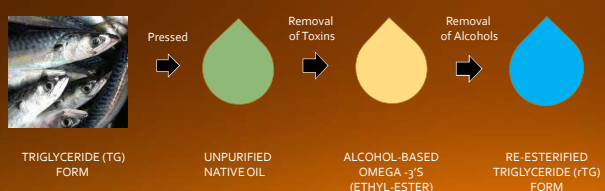
Omega-3 Supplements

Re-Esterified Trygliceride Form (rTG)

- Mechanism of action
- Definition
- Results
 - Tear osmolarity
 - Omega-3 index levels
 - TBUT
 - MMP-9
 - OSDI scores
- **DREAM study**



Not All Omega-3's Created Equal



TRIGLYCERIDE (TG) FORM → UNPURIFIED NATIVE OIL → ALCOHOL-BASED OMEGA-3'S (ETHYL-ESTER) → RE-ESTERIFIED TRIGLYCERIDE (TG) FORM


Tea-Tree Oil Based Therapy

- γ -Terpineol, active component of TTO
- All natural, Preservative-free
 - Anti-inflammatory
 - Anti-microbial
 - Anti-bacterial
 - Anti-fungal
 - Anti-mitocidal
- Lid, lash and facial cleanser
- Variety of treatment options




Device-Based Treatments

- Intranasal neurostimulation (TruTear)
- MicroBlepharoExfoliation
 - BlephEx/AB Max/NuLids
- Thermal pulsation/compression
 - Lipiflow
 - ILux system
- Intense Pulse Light Therapy (IPL)



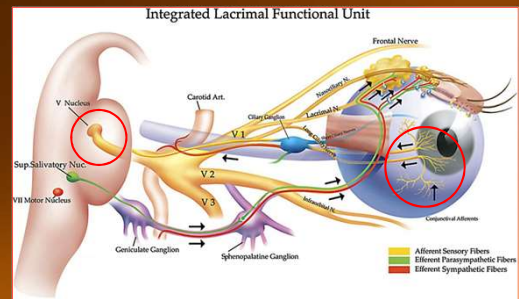
Intranasal Neurostimulation TruTear (Allergan)

- Targets nasolacrimal reflex
- Increases tear production thru lacrimal gland stimulation
- Clinical trials shown to reduce corneal and conj staining
- New data suggests pathway increases MG secretion and mucin production



Afferent Neural Signals

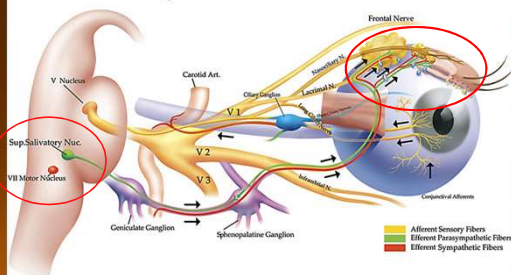
Travel from LFU to CNS



Efferent Nerve Signals

Travel from CNS to LFU

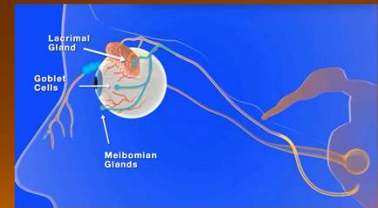
Integrated Lacrimal Functional Unit



Intranasal Neurostimulation

TruTear (Allergan)

- Pivotal trials (FDA)
OCUN-009
OCUN-010
- Indications?
- Contraindications?
- How supplied?
- Patient acceptance?



Micro Blepharo Exfoliation

BlephEx / AB Max

- Gentle exfoliation of lid margins
- Removes scurf, biofilm, and bacterial exotoxins
- Effective for removing hyperkeratinization
- Provides relief for MGD and LWE
- Source of income
- Repeat q6-12m most patients



Microblepharoexfoliation (BlephEx)





| | BlephEx Healthy Lids for Life! | AB Max |
|--------------------------|-----------------------------------|--------|
| PRICE | \$4200-\$5000 | \$1400 |
| TIPS (PER PATIENT) | \$37 | \$17 |
| ACCESSORIES | | |
| PULSE MODE OPTION | NO | YES |
| ALGERBRUSH CONVERSION | NO | YES |

NuLids

NuSight Medical

- Cordless, at-home device
- Removal of biofilm and scurf
- Daily cleaning, 15/sec per lid
- Soft disposable silicone tip
- Company-based studies report efficacy and safety

- Costs?
~\$319 patient
Tips \$1/use

Recommended daily use

Thermal Pulsation

LipiFlow (TearScience/Johnson&Johnson)

- Vaulted applicator design to protect the cornea
- Temperature regulation feedback technology
- Heats MG's from inside to liquefy meibum
- Pulsed pressure sequences to expel stagnate and blocked material from glands

LIPVIEW II

LIPISCAN



Thermal Compression

ILux Device (Tearfilm Innovations/Alcon)

- Handheld portable device
- Light-based (LED) heat and compression
- Direct visualization of MGs
- Temperature sensors maintain safe therapeutic heat levels
- Pivotal study 142 pts, 8 locations



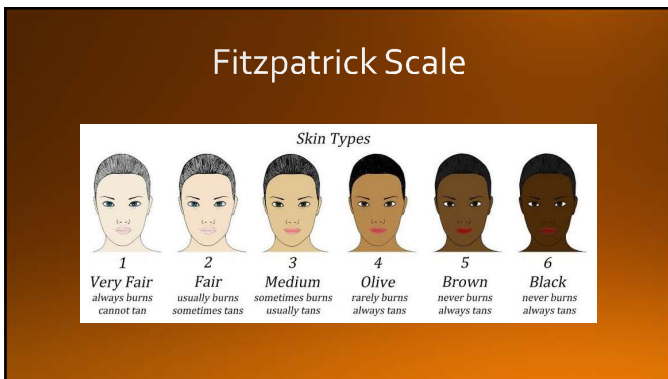
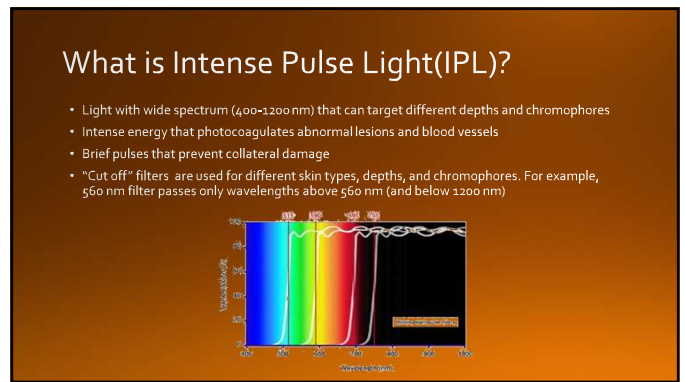
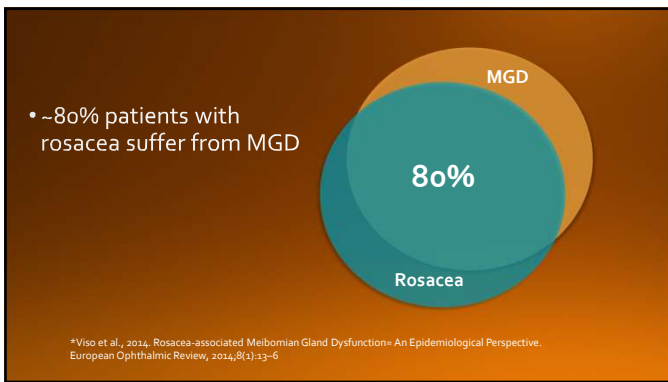
ILux Device

| Device Cost | Consumables (Tips) 1 per/pt | Cost to Patient Per procedure | Support Program |
|-------------|-----------------------------|-------------------------------|---------------------------------|
| \$12,000 | ~\$260-\$295 | \$550-\$650 | DEEP Dry Eye Excellence Program |

*Based on 2019 SECO pricing

Intense Pulse Light Therapy

- Originally designed for dermatologic use
- Targets abnormal vasculature surrounding the eyes
- Non-Laser (Optometry?)





IPL Possible Mechanisms of Action

- Destroys abnormal vessels
- Liquefaction of the meibum
- Eradication of demodex mites
- Decrease bacterial load
- Reducing turnover of dead skin cells
- Increases expression of anti-inflammatory agents

Intense Pulse Light Therapy

| Investment | Cost to Patients | Maintenance Treatment | Consumables | Additional Benefits |
|-------------|-------------------------|------------------------|-------------|---------------------|
| \$50-55,000 | ~\$1200 initial (4 txs) | ~\$300-\$400 q6-12 mos | None | Cosmetic |

Summary

- Interest in Non-Drug therapies for DE is growing
 - Younger population
 - Chronic nature of disease
- Overmedicated population / Side effects
- Challenge of treating DE concomitantly with other conditions
- Increasing difficulty with insurance coverages
- Better business model for practitioners?