

SCIENCE SUMMARY

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AMD & DIETARY MACULAR PIGMENTS (ZEAXANTHIN AND LUTEIN)

AREDS 2 Clinical Research Study

(Emily Chew, et. al. – JAMA Ophthalmology, 2013)

- 4,203 subject multi-center study
- Intermediate to advanced AMD
- 50-85 years of age
- AREDS 1 formula along with lutein + zeaxanthin vs. no lutein and zeaxanthin
 - 10% incremental slowing of progression to advanced AMD
 - 26% incremental slowing of progression to advanced AMD in the lowest quintile of lutein and zeaxanthin intake, which is more representative of the general population

AREDS Report 22: The Relationship of Dietary Carotenoids and Vitamin A, E and C Intake with AMD

(Emily Chew, et. al. - Archives of Ophthalmology, 2007)

- 4,757 subjects
- Participants reporting highest intake of zeaxanthin & lutein less likely to have advanced AMD (NV & GA) and large or extensive intermediate drusen.

Case Report of Dietary Supplements Improving Macular Pigment and Visual Function

(Herman, Kleiner-Goudey, Davis - Advances in Ophthalmology and Visual System: January, 2017)

- 521 subjects supplemented with EyePromise Restore
- 24-month study with follow-ups at 6, 12, 18 and 24 months

-
- Objective: to investigate the visual, retinal and macular pigment optical density (MPOD) changes of a diverse group of subjects in a clinical setting with a supplement formulated to increase MPOD.

- Testing:

- QuantifEye MPOD measurement (accurate and repeatable)
- Retinal Photography
- SD OCT
- Slit lamp of the posterior pole
- Amsler grid
- Visual acuity
- Contrast
- Glare

- 82.6% mean MPOD increase across the group at 24 months.
- 88.3% of participants achieved an MPOD increase of at least 30%.
- 67.9% reported improved glare recovery.
- 62% reported contrast improvement.

- **Results & Conclusion:**

- Improvements were recorded in macular pigment density and visual functions, with improvement in macular appearance and changes in metamorphopsia.
- 24-month EyePromise Restore supplementation, along with sun protection, dietary changes, and smoking cessation, improved visual function and exhibited positive retinal changes documented by SD-OCT and fundus photography.
- The series demonstrates the value of MPOD measurement, supplementation, and comprehensive retinal health assessments.
- Author quote: "MPOD testing is a very valuable, if not critical, clinical tool for not only detecting low levels of macular pigment density, but identifying the population at risk for AMD and giving the clinician the ability to follow the progress of treatment plans."



AMD & DIETARY MACULAR PIGMENTS (ZEAXANTHIN AND LUTEIN)

Improvement of Retinal Function in Early Age-Related Macular Degeneration after Lutein and Zeaxanthin Supplementation: A Randomized, Double-Masked, Placebo-Controlled Trial

(Le Ma, et. al. - *American Journal of Ophthalmology* October, 2012)

- Randomized, double masked, placebo controlled clinical research study
- 144 subjects (Early AMD)
- 4 study arms:
 - 10 mgs lutein
 - 10 mgs lutein & 10 mgs zeaxanthin
 - 20 mgs lutein
 - Placebo and age matched controls
- Pre and post supplementation multi-focal ERG was measured in 6 concentric annular zones around the macula.
- MPOD increase related positively to increases in N1P1 response in ring 1 and ring 2 with little effect in ring 3 through 6.
- Improvement of N1P1 response densities was positively associated with MPOD increase, suggesting a causative effect of MPOD on retinal function and health.
- Early functional abnormalities of the central retina in the early AMD patients may be improved by lutein and zeaxanthin supplementation.
- The 10 mgs lutein/10 mgs dietary zeaxanthin arm had the greatest ERG documented retinal function improvement in ring 1. (fovea)

POLA Study: Plasma Lutein and Zeaxanthin and Other Carotenoids

(Delcourt, et. al. - *Investigative Ophthalmology and Visual Science*, 2006)

- 263 Chinese subjects
- Serum levels of carotenoids and retinol were significantly lower in subjects with exudative AMD than in controls.
 - Zeaxanthin (96% Relative Risk Reduction)
 - Lycopene (78% Relative Risk Reduction)
- The data suggests that higher levels of serum carotenoids, in particular zeaxanthin and lycopene, are associated with a lower likelihood of exudative AMD.

The Rotterdam Study: Reducing the Genetic Risk of AMD

(Lintje Ho, et. al - *Archives of Ophthalmology*, 2011)

- 2,167 subjects
- Subjects with genetic AMD risk factors in the highest tertile of dietary zinc, β -carotene, lutein/zeaxanthin, and EPA/DHA intake achieved a significant early AMD hazard ratio risk reduction of approximately 40%.
- High dietary intake of nutrients with anti-oxidant properties reduces the risk of early AMD in those at high genetic risk.

Serum Carotenoids and Risk of AMD

(Zhou, et. al. - *Investigative Ophthalmology and Visual Science*, 2011)

- 263 Chinese subjects
- Serum levels of carotenoids and retinol were significantly lower in subjects with exudative AMD than in controls.
- Zeaxanthin (96% Relative Risk Reduction)
- Lycopene (78% Relative Risk Reduction)
- The data suggests that higher levels of serum carotenoids, in particular zeaxanthin and lycopene, are associated with a lower likelihood of exudative AMD.

Blue Mountains Eye Study: Dietary Antioxidants and the Long-term Incidence of AMD

(Tan, et. al. - *American Academy of Ophthalmology*, 2008)

- 2,454 subjects
- Higher dietary intake of zeaxanthin and lutein reduced risk of AMD by 65%.
- Confirmed protective influence of zinc
- Higher beta-carotene was associated with increased risk of AMD.



AMD & DIETARY MACULAR PIGMENTS (ZEAXANTHIN AND LUTEIN)

Lutein and Zeaxanthin Status and Risk of AMD

(Gale, et. al. - *Ophthalmology and Visual Science*, 2003)

- 380 subjects
 - Risk (early or late) was significantly higher in people with lower plasma concentrations of zeaxanthin.
 - These findings provide support for the view that zeaxanthin may protect against AMD.
-

Bone & Landrum: Macular Pigment in Donor Eyes

(Bone, et. al. - *Investigative Ophthalmology and Visual Science*, 2001)

- 112 cadaver donors (56 with AMD and 56 controls), a total of 224 eyes.
 - Lutein and zeaxanthin levels in all three concentric regions of the retina were less, on average, for AMD donors than controls.
 - Donor eyes in the highest quartile of lutein and zeaxanthin per unit area had an 82% lower prevalence of AMD compared with those in the lowest quartile.
-

Sunlight Exposure, Antioxidants and Age-Related Macular Degeneration (EurEye)

(Astrid E. Fletcher, et. al. - *Archives of Ophthalmology*, 2008)

- 4,753 subjects
- 65 years or older
- Subjects were questioned for adult lifetime sunlight exposure throughout their working life and retirement up to current age.
- Fundus photography conducted and evaluated
- Blood analysis of antioxidant levels
- Blue light exposure was estimated by combining meteorological and questionnaire data.
- The combination of blue light exposure in the presence of low levels of zeaxanthin, alpha-tocopherol and vitamin C was associated with a nearly four fold risk of neovascular AMD.
- EurEye is the first clinical study to report an adverse association of blue light exposure with neovascular AMD in humans with low levels of antioxidants including zeaxanthin.

CATARACT & LENS (ZEAXANTHIN AND LUTEIN)

AREDS 2 Clinical Research Study

(Emily Chew, et. al. - *JAMA Ophthalmology*, 2013)

- Results showed subjects in the lowest quintile of dietary lutein and zeaxanthin intake had a 30% reduction in cataract development post supplementation.
-

Women's Health Initiative Study

(Moeller, et. al. - *Archives of Ophthalmology*, 2008)

- 1,802 female subjects
 - Women with highest quantity of lutein and zeaxanthin intake had 32% lower incidence of nuclear cataract.
-

POLA Study: Plasma Lutein, Zeaxanthin, and Other Carotenoids

(Delcourt, et. al. - *Investigative Ophthalmology and Visual Science*, 2006)

- 899 subjects
 - Subjects with high plasma levels of zeaxanthin had a 77% reduction of nuclear cataract occurrence.
-

Blue Mountains Eye Study: Dietary Antioxidants and the Long-term Incidence of AMD

(Tan, et. al. - *American Journal of Clinical Nutrition*, 2008)

- 2,454 elderly subjects
- Vitamin C and combined dietary antioxidants intake reduced nuclear cataract occurrence by 50%.



MACULAR PIGMENT OPTICAL DENSITY MEASUREMENT

Macular Pigment Optical Density: Repeatability, Inter-eye Correlation and Effect of Optical Dominance

(Davey, et.al., College of Optometry, Western University of Health Sciences, Clinical Ophthalmology, August, 2016)

- 72 test subjects
- The MPOD measurements obtained using the QuantifEye show good short-term repeatability.
- There is excellent inter-eye correlation, indicating that the MPOD values of one eye data can predict the fellow eye value with 89% accuracy.
- The ocular dominance had no bearing on the outcome of this psychophysical test in ocular healthy eyes.

A New Desktop Instrument for Measuring Macular Pigment Optical Density

(Van Der Veen, et. al. - Ophthalmology and Physiological Optics, 2009)

- MPOD was measured with the QuantifEye instrument and the method demonstrated good repeatability of 97%.

Desktop Macular Pigment Optical Density Measurement: A New Approach Based On Heterochromatic Flicker Photometry

(Berendschot, et. al. - E, volume 25,)

- We found high agreement between test and retest measurements of QuantifEye (0.02 ± 0.18 density units) and the fundus reflectance method.

The Value of Measurement of Macular Carotenoid Pigment Optical Densities and Distributions in Age-Related Macular Degeneration

(Bernstein, et. al. - Vision Research, 2010)

- The antioxidant and blue light filtering functions of lutein and zeaxanthin have an impact upon eye health beyond just decreasing the risk of age-related eye disease. Macular pigment has also been shown to influence visual function and comfort.
- The panel concluded it might be possible to identify individuals at reduced, medium, and elevated risk for age-related eye disease based on high, medium, and low central MPOD levels.
- The panel members agreed a central MPOD below 0.2 density units (du) should be considered low, between 0.2 du and 0.5 du mid-range, and levels above 0.5 du high MPOD.
- Approximately 78% of the US population has a central MPOD below 0.5 du.

Macular Pigment Optical Density Associated With and Without Zeaxanthin and Lutein Supplementation

(Davis - Advances in Ophthalmology & Visual System 2015)

- 198 healthy subjects
- Twelve-month study
- Objective: To determine the change in macular pigment optical density (MPOD) after subjects with low macular pigment (<0.30 density units) elect to supplement with EyePromise Restore or forgo supplementation.
- 2 study arms:
 - Group 1 supplemented 1 EyePromise Restore softgel per day
 - Group 2 did not consume supplements
- Subjects supplementing with Restore achieved an increase of density units. Subjects not supplementing experienced an MPOD decrease.
- Nutritional counseling alone did not increase MPOD scores.



MACULAR PIGMENT OPTICAL DENSITY MEASUREMENT

Women's Health Initiative: Diet Intervention Did Not Increase Macular Pigment Optical Density in an Ancillary Study of a Subsample of the Women's Health Initiative

(Moeller, et. al. - *The Journal of Nutrition*, 2009)

- Macular pigment density was compared in women 60-87
- 394 subjects
- The study examined the impact of long-term (>8 y), low-fat, high-fruit and vegetable diets on levels of lutein and zeaxanthin in the macula.
- 2 study arms
 - 158 received dietary and behavioral modification counseling and intervention
 - 236 did not receive dietary and behavioral modification counseling
- The intervention group participated in 18 dietary and behavioral counseling sessions in year 1 and quarterly sessions thereafter.
- Macular pigment density did not differ between the intervention (0.36 ± 0.02 density units) and comparison (0.35 ± 0.01 density units) groups.
- Macular pigment tended to be higher in women consuming lutein and zeaxanthin in the highest amount compared with the lowest however the difference was not statistically significant.
- The increase in fruit and vegetable intake among dietary modification participants of this WHI subsample was not of sufficient magnitude to alter the mean density of retinal carotenoids.
- Intensive dietary and behavioral counseling did not result in a significant macular pigment density increase in the intervention group, suggesting that supplementation may be necessary to achieve a significant macular pigment increase.

BENEFITS OF ZEAXANTHIN & LUTEIN IN VISUAL PERFORMANCE

Zeaxanthin and Visual Function (ZVF) Clinical Research Study

(Richer, et. al. - *Journal of Optometry*, 2011)

- 60 elderly subjects with early to moderate AMD were supplemented
- 12 month study period
- 3 study arms: (1) Patients were supplemented with 8 mg of dietary zeaxanthin per day or (2) 9 mg of lutein, or (3) a combination of the 2 carotenoids. (17 mg total)
- Results: Subjects supplementing high dose (8mg) dietary zeaxanthin daily achieved
 - Improved high contrast near visual acuity of 8.5 letters or 1.5 lines
 - Clearing of central scotomas
 - Improved foveal shape discrimination
 - Improved night driving skills
- Only EyePromise brands contain 8 mg or more dietary zeaxanthin

Macular Re-pigmentation Enhances Driving Vision in Elderly Adult Males with Macular Degeneration

(Richer, et. al. - *Clinical & Experimental Ophthalmology*, 2012)

- 60 elderly subjects with early to moderate AMD
- Supplemented 8 mgs of dietary zeaxanthin per day for 12 months.
- Self-described improvement of driving skills was strongly associated with macular re-pigmentation via high dose dietary zeaxanthin supplementation.



BENEFITS OF ZEAXANTHIN & LUTEIN IN VISUAL PERFORMANCE

The Influence of Dietary Lutein and Zeaxanthin on Visual Performance

(Stringham, Hammond, et. al. - Journal of Food Science, 2009)

- Retinal increase of zeaxanthin and lutein (MPOD) reduced glare disability and improved photo-stress recovery time.
- Contrast sensitivity improvement was achieved in supplemented subjects.
- Glare induced photostress recovery times can be reduced by 5 seconds by increasing macular pigment via supplementation. This equates to 440 ft. of improved reaction time at 60 MPH while driving at night.

A Double-Blind, Placebo-Controlled Study on the Effects of Lutein and Zeaxanthin on Neural Processing Speed and Efficiency

(Bovier, Renzi, Hammond, et al. - Public Library of Science (PLOS), 2014)

- 64 subjects (young healthy adults)
- 18-32 years of age
- 4 month study
- 3 study arms
 - EyePromise Zeaxanthin (20 mgs of dietary zeaxanthin)
 - EyePromise visual EDGE PRO™ supplement (26 mgs dietary zeaxanthin, 8 mgs lutein)
 - Placebo
- Subjects in the EyePromise Zeaxanthin and EyePromise visual EDGE PRO arms experienced significant improvements in visual processing speed and reaction time, each $P = <0.005$:
- A 14% improvement in Temporal Contrast Sensitivity Function
- A 12% improvement in Critical Flicker Fusion Threshold
- A 10% improvement in Visual Motor Reaction Time
- A 20% increase in Macular Pigment Optimal Density (MPOD)
- High dose zeaxanthin and lutein supplementation improved visual processing speed, even among young healthy adults.
- Supplemented subjects achieved improved ability to process information and react faster.



BENEFITS OF ZEAXANTHIN & LUTEIN IN VISUAL PERFORMANCE

A Double-Blind, Placebo-Controlled Study on the Effects of Lutein and Zeaxanthin on Photostress Recovery, Glare Disability, and Chromatic Contrast

(Hammond, Fletcher, Roos, et. al. – *Investigative Ophthalmology and Visual Science*, 2014)

- 115 subjects (young healthy adults)
- Average age of 22 years
- Macular pigment optical density increased significantly in the zeaxanthin and lutein arm versus placebo at all eccentricities (10, 30, 60, and 105 minutes from the center of the macula).
- Serum zeaxanthin and lutein increased significantly at first follow-up visit (3 months), and remained elevated throughout the 1 year intervention period.
- Chromatic contrast and photostress recovery time improved significantly versus placebo.
- Glare disability was correlated with increased macular pigment density during the study period.
- Daily supplementation with zeaxanthin and lutein resulted in significant serum increase, MPOD score, improved chromatic contrast, and photostress recovery.

A Randomized Placebo-Controlled Study on the Effects of Lutein and Zeaxanthin on Visual Processing Speed in Young Healthy Subjects

(Bovier, Hammond, et. al. – *Archives of Biochemistry and Biophysics*, 2014)

- 69 subjects (young healthy adults)
- 18-32 years of age
- 4 month study
- 3 study arms
 - EyePromise visual EDGE PRO supplement (26 mgs dietary zeaxanthin, 8 mgs lutein)
 - EyePromise Zeaxanthin (20 mgs of dietary zeaxanthin)
 - Placebo
- Neither MPOD nor temporal contrast sensitivity function changed in the placebo arm.
- Both improved significantly with high dose dietary zeaxanthin supplementation.

Macular Pigment and Visual Performance in Glare: Benefits for Photostress Recovery, Disability Glare, and Visual Discomfort

(Stringham, Garcia, Smith, et. al. – *IOVS*, 2011)

- 26 healthy subjects
- Average age of 31 years
- Higher macular pigment levels correlated with all outcome measures
 - Improved photostress recovery time
 - Reduced glare
 - Diminished visual discomfort
- Higher macular pigment levels resulted in faster photostress recovery, lower disability glare contrast thresholds, and lower visual discomfort.

The Influence of Dietary Lutein and Zeaxanthin on Visual Performance

(Stringham, Bovier, Wong, Hammond, et. al. – *Concise Reviews in Food Science*, 2009)

- High-intensity lamps (such as stadium lights) often cause visual discomfort.
- Macular Pigment Optical Density (MPOD) filters high energy visible blue light.
- Visual discomfort was strongly attenuated for much of the blue region of the visible light spectrum, suggesting the filtering properties of macular pigment serve to reduce visual discomfort associated with central viewing of any light containing short wavelengths.
- Findings suggest small increases in MPOD could contribute to visual comfort benefits.
- There was a significant inverse relationship between photostress recovery and MPOD.
- Higher MPOD values resulted in shorter photostress recovery time.



BENEFITS OF ZEAXANTHIN & LUTEIN IN VISUAL PERFORMANCE

The Effects of Macular Carotenoid Zeaxanthin on Visual Performance and Neural Efficiency in Young, Healthy Subjects and College Athletes

(Renzi, Bovier, Shon, et. al. – Macular carotenoids & AMD conference poster 2011)

- 7 college baseball players (male)
- Average age of 20.3 years
- Subjects supplemented with 20 mgs of dietary zeaxanthin per day experienced:
 - MPOD increase
 - Reduced glare and improved photostress recovery time
 - Improved contrast enhancement
 - Improved fixed and variable reaction times
 - Improved coincidence anticipation timing accuracy at the highest frequency
 - Improved temporal processing speed

Contrast Sensitivity and Lateral Inhibition Are Enhanced With Macular Carotenoid Supplementation

(James M. Stringham, Kevin J. O'Brien, and Nicole T. Stringham - Invest Ophthalmol Vis Sci, 2017)

- 59 healthy subjects (18-25 years of age)
- 12-month, double-masked, placebo-controlled study
- Objective: investigate whether increasing macular pigment optical density (MPOD) could enhance lateral inhibitory processes, thereby improving contrast sensitivity.
- Results:
 - MPOD, lateral inhibition sensitivity (LIS), and contrast sensitivity (CS) increased significantly between baseline and 6 months and between 6 and 12 months.
 - The relationships between changes in MPOD and both LIS and CS were significant at 6 and 12 months.
 - Changes in CS and LIS over the 12-month study period were found to be significantly related
- Conclusion:
 - Increases in MPOD led to enhanced lateral inhibitory processes, which correspond to improved contrast sensitivity.
 - Improvement in CS with increases in MPOD appear to involve enhancement of the fundamental physiological systems that give rise to edge detection.



BENEFITS OF ZEAXANTHIN & LUTEIN FOR SCREEN TIME

Supplementation with macular carotenoids reduces psychological stress, serum cortisol, and sub-optimal symptoms of physical and emotional health in young adults

(Nicole Tressa Stringham, Philip V. Holmes, James M. Stringham - *Nutritional Neuroscience*, 2018)

- 59 healthy subjects
- 12-month, double-blind, placebo-controlled trial
- Objective: evaluate the effects of macular carotenoid (MC) supplementation on blood cortisol, psychological stress ratings, behavioral measures of mood, and symptoms of sub-optimal health
- Results:
 - Significant correlations were found between MPOD and Beck anxiety scores as well as Brief Symptom Inventory scores.
 - 6-month supplementation improved psychological stress, serum cortisol, and measures of emotional and physical health compared to placebo.
- Conclusion:
 - Supplementation with the MCs significantly reduces stress, cortisol, and symptoms of sub-optimal emotional and physical health.

Macular Carotenoid Supplementation Improves Visual Performance, Sleep Quality, and Adverse Physical Symptoms in Those with High Screen Time Exposure

(James M. Stringham, Nicole T. Stringham, and Kevin J. O'Brien - *Foods*, 2017)

- 10,329 US adults
 - VisionWatch survey
- Objective: examine increasing usage of digital devices and their impact on vision and provide actionable insight
- Results:
 - 90% of adults use devices for 2+ hours a day
 - 60% use devices for 5+ hours a day
 - 65% of Americans report experiencing screen time symptoms
 - Eye strain
 - Tired eyes
 - Blurred vision
 - Dry eyes
 - Headaches
 - Neck, back, and shoulder pain
 - Adults 30 and younger experience the highest rates of screen time symptoms
 - 90% of adults don't talk to their eye care provider about their screen use

Photochemical damage of the retina

(Wu J1, Seregard S, Algvere PV. - *Surv Ophthalmol*. 2006)

- Meta-analysis
- Objective: review studies to determine if blue light causes photochemical damage to the retina and if it's linked to age-related macular degeneration (AMD).
- Results: blue light may play a role in the pathogenesis of AMD. Laboratory studies have suggested that photochemical damage includes oxidative events. Retinal cells die by apoptosis in response to photic injury. Modern molecular biology techniques help to study in-depth the basic mechanism of photochemical damage of the retina and to develop strategies of neuroprotection.



BENEFITS OF ZEAXANTHIN & LUTEIN FOR SCREEN TIME

Effects of dietary supplementation with a combination of fish oil, bilberry extract, and lutein on subjective symptoms of asthenopia in humans

(Fuminori Kawabata and Tomoko Tsuji – *Biomedical Research*, 2011)

- 22 healthy participants
- 4-week, double, -blind, randomized, placebo-controlled trial
- Objective: determine the effects of dietary supplementation with a combination of fish oil, bilberry extract, and lutein on subjective symptoms of asthenopia in humans
- Results:
 - Symptoms like stiff shoulder, low back pain, frustration, dry eye, and stuffy head improved in the active group.
 - Mental fatigue was reduced in the active group.
- Conclusion
 - These results suggest that dietary supplementation with the combination of omega-3 fatty acid-rich fish oil, bilberry extract, and lutein may safely improve subjective symptoms of asthenopia and mental fatigue in humans.

Light and Eye Damage

(Gregory W. Good, OD, PhD – *American Optometric Association*, 2014)

- This paper is intended to answer common questions about light, specifically short-wavelength visible light known as blue light, and how it can incite eye damage.
- Blue light was positively associated with damage to the retina with both acute and chronic exposure.
 - Blue light shows the greatest effects on eye health possibly due to photochemical or photooxidative damage in the retinal pigment epithelium.
 - Age is less of a factor for damage/effect than overall exposure.
 - Children are especially sensitive to light and should be given proper protection.
- The Beaver Dam Study linked early signs of AMD with excessive exposure to sunlight (5+ hours a day) as a teenager and beyond.
- The Chesapeake Bay Watermen Study linked late AMD with cumulative sun exposure.

DIABETES VISUAL FUNCTION IMPROVEMENT

Diabetes Visual Function Supplement Study (DiVFuSS)

(Chous, Richer, Kowluru, Gerson, et. al. – *British Journal of Ophthalmology*, 2015)

- Six-month clinical research study
- Randomized, placebo controlled
- Subjects with type 1 or type 2 diabetes > 5 years duration
- 67 subjects
 - No significant inter-group differences at baseline.
 - Some with no retinopathy or mild to moderate non-proliferative retinopathy.
- Objective: Determine if patients benefit from a novel, multi-component oral supplement (DiVFuSS Formula = EyePromise DVS)
- Supplement results:
 - MPOD Increase of 31%
 - Color vision improvement of 21%*
 - Contrast sensitivity increase of 19%*
 - Macular visual field (5-2) improvement of 12%*
 - All P values were highly statistically significant
- The supplement achieved the aforementioned results without significantly affecting blood sugar control (A1c)

*Averaged between the two eyes



DRY EYE AND OCULAR NUTRITION

Report of the International Dry Eye Workshop (DEWS)

(Foulks, et. al. - *The Ocular Surface*, 2007)

- Level 2 dry eye patient care recommendations: If Level 1 treatments are inadequate, add: Anti-inflammatories (Omega-3 fatty acids, topical CsA and corticosteroids), Tetracyclines (for meibomianitis, rosacea), Punctal plugs, Secretagogues, Moisture chamber spectacles.
- Omega-3 fatty acid supplementation beginning at level 2 dry eye is standard of care.

The International Workshop on Meibomian Gland Dysfunction

(Nichols, et. al. *Investigative Ophthalmology and Visual Science*, 2011)

- Level 2 MGD Workshop patient care recommendation: Advise patient on improving ambient humidity; optimizing workstations and increasing dietary omega-3 fatty acid intake.
- Omega-3 fatty acid supplementation beginning at level 2 dry eye is standard of care.

Report of the TFOS International Dry Eye Workshop II

(Nelson, et al. - *Tear Film & Ocular Surface Society*, July 2017)

- 12 subcommittees of 150 experts from 23 countries
- 2-year effort
- Objective: better define and classify dry eye disease and formalize a protocol since the last report in 2007.
- Results:
 - Updated definition
 - Updated identification method suggestions
 - 5-item Dry Eye Questionnaire (DEQ-5)
 - Ocular Surface Disease Index (OSDI)
 - Tear break-up time
 - Tear film osmolarity determination
 - Ocular surface staining with fluorescein and lissamine green (cornea, conjunctiva, lid margin)
 - Updated management suggestion – each patient's individual needs dictate the treatment
 - Ocular nutrition is now considered a “first step” in dry eye patient care.

Ocular Nutrition Impact on Tear Film Study (ONIT)

(Mulqueeny, Townsend, Davis, Koffler, et. al. – *Advances in Ophthalmology and Visual System*, 2015)

- Multi-center, clinic-based dry eye study
- 67 subjects
- Eight week study duration
- Objective: To determine if subjects presenting with dry eye, confirmed by diagnostic markers and symptoms (Ocular Surface Disease Index or OSDI), responded to a multi-component, Omega-3 based anti-inflammatory nutritional oral supplement (EyePromise EZ Tears).
- Protocol required patients to meet minimum of 4 dry eye diagnostic inclusion criteria.
- Study Results:
 - OSDI Improved 38%
 - TBUT Improved 45%
 - Conjunctival Staining Improved 50%
 - Corneal Staining Improved 33%
 - Tear meniscus height Improved 50%
 - Lid Inflammation Improved 40%
 - Phenol Red Thread Improved
 - Osmolarity scores Variable and inconclusive
- Rapid Onset of relief: Patients began demonstrating symptom improvement (OSDI) after one week of EyePromise EZ Tears supplementation.
- Improvements continued over the course of the study. (Rationale to keep supplementing beyond 8 weeks.)





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