**Drug treatment**

**Ophthalmology. 2017 Aug 8. [Epub ahead of print]**

**Incidence and Outcomes of Infectious and Noninfectious Endophthalmitis after Intravitreal Injections for Age-Related Macular Degeneration.**


**PURPOSE:** To assess the incidence, cumulative rate, and long-term outcomes of infectious and noninfectious endophthalmitis after intravitreal injections (IVTs) of anti-vascular endothelial growth factor (VEGF) agents.

**DESIGN:** Database study, prospectively designed.

**PARTICIPANTS:** Treatment-naïve eyes with neovascular age-related macular degeneration (nAMD) tracked by the Fight Retinal Blindness! (FRB!) registry that commenced anti-VEGF therapy between January 1, 2006, and November 30, 2016.

**METHODS:** Cumulative rate of endophthalmitis and survival curves were measured using Cox-proportional hazards models. Locally weighted scatterplot smoothing curves were used to display visual acuity (VA).

**MAIN OUTCOME MEASURES:** Incidence and cumulative rate of endophthalmitis, and change in VA 12 months after endophthalmitis.

**RESULTS:** Infectious endophthalmitis developed in 18 of 88,150 injections (1/4897 injections [0.020%]; 95% confidence interval [CI], 0.012-0.032) with no difference found between types of anti-VEGF medications (P = 0.896). The cumulative rate of infectious endophthalmitis per patient was 0.055%, 0.183%, 0.360%, 0.555%, and 0.843% after 10, 20, 30, 40, 50, and 60 IVTs, respectively. However, the "risk" of infectious endophthalmitis did not increase with each successive injection (P = 0.202). Noninfectious endophthalmitis developed in 11 of 88,150 injections (1/8013 injections [0.012%]; 95% CI, 0.006-0.022). The cumulative rate of noninfectious endophthalmitis per patient was 0.087% and 0.228% after 10 and 20 IVTs, respectively, and then remained stable up to 60 IVTs. The incidence of noninfectious endophthalmitis was higher for bevacizumab (8/9931, 0.081%) compared with ranibizumab (3/54,776, 0.005%; P = 0.005) and aflibercept (0/23,425; P = 0.016), and no differences were observed between ranibizumab and aflibercept (P = 1.0). The 12-month VA in infectious and noninfectious endophthalmitis was within ±2 lines of before endophthalmitis in 53% and 75% of eyes, respectively; a loss >2 lines was observed in 31% and 25% of eyes, respectively.

**CONCLUSIONS:** The incidences of infectious and noninfectious endophthalmitis after IVT were low, and the risk did not increase with each successive injection. We found higher rates of noninfectious endophthalmitis with bevacizumab compared with ranibizumab or aflibercept. Three quarters of cases with infectious and two thirds of cases with noninfectious endophthalmitis retained vision within 10 letters of the
pre-endophthalmitis level.

PMID: 28801117

Klin Monbl Augenheilkd. 2017 Aug 11. [Epub ahead of print]

[Eye Drops Instead of Intravitreal Injections? The Dream of Treating Macular Diseases by Topically Administered Drugs]. [Article in German]

Zeitz O, Joussen AM.

Background: The introduction of VEGF inhibitors revolutionized treatment for age-related macular degeneration. However, it requires regular intravitreal (IVT) injections. Hence, replacement of IVT injections by topical, non-invasive eye drop treatment is subject to intensive research.

Material and Methods: Literature and database research on topical therapies for neovascular AMD.

Results: Several clinical projects with topical inhibitors of the VEGF pathway were initiated recently. Several candidate molecules were investigated and should have an efficacy potential in neovascular AMD given their ability to block the VEGF pathway. Preclinical experiments were quite promising. Still, translation into the clinical application has not been successful thus far. Differences in preclinical and clinical pharmacokinetics are assumed to be the major barrier to successful translation. In addition, specific algorithms for monitoring of disease activity are required for successful clinical implementation; otherwise, a topical therapy may reduce the IVT injection number, but patients would not gain independence through fewer office visits.

Discussion: It is required to refine the scientific basis including preclinical models and screening cascades. This will enable targeted selection of future candidates for clinical development.

PMID: 28800660


Two-year outcome of an observe-and-plan regimen for neovascular age-related macular degeneration treated with Aflibercept.


PURPOSE: The purpose of our study was to investigate the two-year outcome of Aflibercept treatment for neovascular age-related macular degeneration (nAMD), using the Observe-and-Plan regimen, an individually planned treatment regimen, based on the predictability of an individual's need for retreatment, aiming to reduce the clinical burden.

METHODS: Our prospective study used the Observe-and-Plan regimen with Aflibercept to treat nAMD: Three loading doses, followed by monthly observation visits until the disease-recurrence interval was determined, which then was shortened by 2 weeks in a treatment plan for the next three injections without intermediate monitoring visits. The subsequent treatment plans were adjusted according to periodically assessed disease activity. The primary outcome measures were visual acuity changes, number of injections, and number of monitoring visits.

RESULTS: The study included 112 eyes of 102 patients with a mean age of 80.7 years (SD 7.6). Mean visual acuity (VA) improved from 61.8 ETDRS letters (20/60+2) at baseline, by 8.5, 8.0, and 6.2 letters at months 3, 12 and 24, respectively. Mean central retinal thickness was 438um at baseline, and reduced by 152um, 155um, and 150um at months 3, 12 and 24, respectively. The mean number of injections was 8.7 and 6.5 in the first and second year, respectively. The mean number of monitoring visits after baseline was 3.8 and 2.8 during the first and second year, respectively.
CONCLUSIONS: The Observe-and-Plan regimen significantly improved VA, while fewer monitoring visits were needed as compared to other variable dosing regimens, thus reducing the workload for chronic care management of nAMD.

PMID: 28798980

Ophthalmic Res. 2017 Aug 11. [Epub ahead of print]

Dynamics of Inflammatory Factors in Aqueous Humor during Ranibizumab or Aflibercept Treatment for Age-Related Macular Degeneration.


PURPOSE: To evaluate the dynamic changes of the aqueous humor levels of inflammatory factors between patients receiving intravitreal ranibizumab injection (IRI) and aflibercept injection (IAI) in patients with exudative age-related macular degeneration (AMD).

METHODS: The study was performed on 30 eyes with AMD that were scheduled to receive 3 doses of IRI (15 eyes) or IAI (15 eyes) at monthly intervals. Aqueous humor samples were collected when injection was done. The concentrations of VEGF, monocyte chemoattractant protein 1 (MCP-1), platelet-derived growth factor (PDGF)-AA, interleukin (IL)-6, and IL-8 were measured in aqueous humor samples from the 30 AMD patients and 10 cataract patients (as controls) by the suspension array method.

RESULTS: Aqueous levels of the inflammatory factors (MCP-1, PDGF-AA, IL-6, and IL-8) were significantly correlated with each other. In both the IRI-treated eyes and the IAI-treated eyes, visual acuity and central macular thickness improved significantly, and the aqueous level of VEGF showed a significant decrease. In IAI-treated eyes, the aqueous levels of MCP-1 and PDGF-AA were significantly decreased at 2 months.

CONCLUSIONS: These findings suggest that the inflammatory factors are involved in the pathogenesis of AMD and also the possibility that the interaction between these inflammatory factors and IRI or IAI is different.

PMID: 28796997


Treat-and-Extend Therapy Using Aflibercept for Neovascular Age-Related Macular Degeneration: A Prospective Clinical Trial.

Călugăru D, Călugăru M.

Author information

PMID: 28800905


High-frequency aflibercept injections in persistent neovascular age-related macular degeneration.

Muftuoglu IK, Freeman WR.

PMID: 28780686

Age-related macular degeneration: current therapeutics for management and promising new drug candidates.

Abd AJ, Kanwar RK, Kanwar JR.

Abstract: Age-related macular degeneration (AMD) is the leading cause of irreversible visual impairment among the aged population. Because the elderly population constitutes a large percentage among society, visual loss due to AMD has become a growing problem. Despite the advances made in developing therapeutics, there is still no satisfactory treatment. The limitations of the available treatments are related to the absence of a potent, noninvasive therapy. Furthermore, some of the available drugs target angiogenesis and create a hypoxic environment that augments further angiogenesis. Therefore, it is reasonable to consider eye integrity and the correlation between hypoxia and angiogenesis before developing successful drugs. This review highlights issues regarding the available therapeutic strategies and explores whether AMD can be managed by employing specific nanoformulations.

PMID: 28782687

Other treatment & diagnosis


Activated Retinal Pigment Epithelium, an Optical Coherence Tomography Biomarker for Progression in Age-Related Macular Degeneration.

Curcio CA, Zanzottera EC, Ach T, Balaratnasingam C, Freund KB.

PURPOSE: To summarize and contextualize recent histology and clinical imaging publications on retinal pigment epithelium (RPE) fate in advanced age-related macular degeneration (AMD); to support RPE activation and migration as important precursors to atrophy, manifest as intraretinal hyperreflective foci in spectral-domain optical coherence tomography (SDOCT).

METHODS: The Project MACULA online resource for AMD histopathology was surveyed systematically to form a catalog of 15 phenotypes of RPE and RPE-derived cells and layer thicknesses in advanced disease. Phenotypes were also sought in correlations with clinical longitudinal eye-tracked SDOCT and with ex vivo imaging-histopathology correlations in geographic atrophy (GA) and pigment epithelium detachments (PED).

RESULTS: The morphology catalog suggested two main pathways of RPE fate: basolateral shedding of intracellular organelles (apparent apoptosis in situ) and activation with anterior migration. Acquired vitelliform lesions may represent a third pathway. Migrated cells are packed with RPE organelles and confirmed as hyperreflective on SDOCT. RPE layer thickening due to cellular dysmorphism and thick basal laminar deposit is observed near the border of GA. Drusenoid PED show a life cycle of slow growth and rapid collapse preceded by RPE layer disruption and anterior migration.

CONCLUSIONS: RPE activation and migration comprise an important precursor to atrophy that can be observed at the cellular level in vivo via validated SDOCT. Collapse of large drusen and drusenoid PED appears to occur when RPE death and migration prevent continued production of druse components. Data implicate excessive diffusion distance from choriocapillaris in RPE death as well as support a potential benefit in targeting drusen in GA.

PMID: 28785769

Tele-ophthalmology for Age-Related Macular Degeneration and Diabetic Retinopathy Screening: A Systematic Review and Meta-analysis.

Kawaguchi A, Sharafeldin N, Sundaram A, Campbell S, Tennant M, Rudnisky C, Weis E, Damji KF.

BACKGROUND: To synthesize high-quality evidence to compare traditional in-person screening and tele-ophthalmology screening.

METHODS: Only randomized controlled trials (RCTs) were included in this systematic review and meta-analysis. The intervention of interest was any type of tele-ophthalmology, including screening of diseases using remote devices. Studies involved patients receiving care from any trained provider via tele-ophthalmology, compared with those receiving equivalent face-to-face care. A search was executed on the following databases: Medline, EMBASE, EBM Reviews, Global Health, EBSCO-CINAHL, SCOPUS, ProQuest Dissertations and Theses Global, OCLC Papers First, and Web of Science Core Collection. Six outcomes of care for age-related macular degeneration (AMD), diabetic retinopathy (DR), or glaucoma were measured and analyzed.

RESULTS: Two hundred thirty-seven records were assessed at the full-text level; six RCTs fulfilled inclusion criteria and were included in this review. Four studies involved participants with diabetes mellitus, and two studies examined choroidal neovascularization in AMD. Only data of detection of disease and participation in the screening program were used for the meta-analysis. Tele-ophthalmology had a 14% higher odds to detect disease than traditional examination; however, the result was not statistically significant (n = 2,012, odds ratio: 1.14, 95% confidence interval (CI): 0.52-2.53, p = 0.74). Meta-analysis results show that odds of having DR screening in the tele-ophthalmology group was 13.15 (95% CI: 8.01-21.61; p < 0.001) compared to the traditional screening program.

CONCLUSIONS: The current evidence suggests that tele-ophthalmology for DR and age-related macular degeneration is as effective as in-person examination and potentially increases patient participation in screening.

PMID: 28783458


Choroidal Remodeling in Age-related Macular Degeneration and Polypoidal Choroidal Vasculopathy: A 12-month Prospective Study.

Ting DSW, Yanagi Y, Agrawal R, Teo HY, Seen S, Yeo IYS, Mathur R, Chan CM, Lee SY, Wong EYM, Wong D, Wong TY, Cheung GCM.

Abstract: Choroid thinning occurs in age-related macular degeneration (AMD). However, it remains unclear whether the reduction is due to reduction in choroidal vessels or shrinkage of choroidal stroma, or both. The purpose of this study was to evaluate the changes of the choroidal vascular and stromal area in 118 patients with typical AMD (t-AMD) and polypoidal choroidal vasculopathy (PCV) over a 12-month period. We used spectral-domain optical coherence tomography (SD-OCT) with enhanced depth imaging (EDI) mode to measure the subfoveal choroidal thickness (CT), central retinal thickness (CRT) and choroidal vascularity index (CVI - ratio of luminal area to total choroidal area). At baseline, PCV eyes had higher CRT (471.6 µm vs 439.1 µm, p = 0.02), but comparable subfoveal CT and CVI, compared to t-AMD. Eyes with high CVI at baseline showed marked reduction in stromal area compared with eyes with average or low CVI. Over 12 months, CRT and subfoveal CT significantly decreased (p < 0.001) in both subtypes. Eyes with high baseline CVI showed significant CVI reduction from baseline to month 12 (p < 0.001), whereas eyes with average to low baseline CVI showed increase in CVI. These differences in choroidal vascularity may reflect different predominant pathogenic processes and remodeling in AMD eyes with varying spectrum.

PMID: 28801615 PMCID: PMC5554201
Pathogenesis


Loss of endothelial planar cell polarity and cellular clearance mechanisms in age-related macular degeneration.

Campos MM, Abu-Asab MS.

Abstract: Apoptosis, autophagosomes, and lysosomes are lacking in the retinal pigment epithelium (RPE) of age-related macular degeneration (AMD) eyes. Necrosis, not apoptosis, appeared to be the prominent type of cell death in RPE, which led to the accumulation of cell debris within and on both sides of Bruch's membrane. The endothelium of the choriocapillaris had an altered planar cell polarity which encompassed the disappearance of fenestrations, the thickening of cytoplasm, and anterior nuclear dislocation. There were no significant differences in RPE and choroidal aberrations between macular and temporal regions. Loss of endothelial polarity could be at the crux of AMD initiation and progression.

PMID: 28796562


An inducible form of Nrf2 confers enhanced protection against acute oxidative stresses in RPE cells.

Vu KT, Hulleman JD.

Abstract: Increasing evidence suggests that overt oxidative stress within the retina plays an important role in the progression of age-related retinal decline, and in particular, in the disease age-related macular degeneration (AMD). Nuclear factor erythroid 2-like 2 (Nrf2) is a master transcription factor that upregulates numerous of antioxidant/detoxification genes. Nrf2-/- mice develop progressive retinal degeneration that includes the formation of drusen-like deposits, lipofuscin, and sub-retinal pigment epithelium (RPE) deposition of inflammatory proteins. Furthermore, strategies that promote Nrf2 activation have shown promise for the treatment of cone/rod dystrophies and other forms of retinal degeneration. Herein we explored whether utilizing a small molecule-inducible version of Nrf2 confers additional protection against oxidative stresses when compared to a constitutively expressed version of Nrf2. Stable populations of human ARPE-19 cells were generated that express either constitutive FLAG-tagged (FT) Nrf2 (FT cNrf2) or doxycycline (dox)-inducible FT Nrf2 (FT iNrf2) at low levels (~4.5 fold vs. endogenous). Expression of either FT cNRF2 or FT iNrf2 upregulated canonical antioxidant genes (e.g., NQO1, GCLC). Both FT cNrf2 and FT iNrf2 ARPE-19 cells were protected from cigarette smoke extract-induced nitric oxide generation to similar extents. However, only FT iNrf2 cells demonstrated enhanced resistance to doxorubicin and cumene hydroperoxide-mediated increases in mitochondrial superoxide and lipid peroxidation, respectively, and did so in a dox-dependent manner. These results suggest that therapeutic approaches which conditionally control Nrf2 activity may provide additional protection against acute oxidative stresses when compared to constitutively expressed Nrf2 strategies.

PMID: 28782506

Genetics


Investigation of associations of ARMS2, CD14, and TLR4 gene polymorphisms with wet age-related macular degeneration in a Greek population.

Moschos MM.

BACKGROUND: Age-related macular degeneration (AMD) is a multifactorial degenerative ocular disease that leads to loss of central vision. Functional gene polymorphisms have already been associated with the disease (for example, ARMS2 A69S, rs10490924).

AIM: The goal of our study was to verify the correlation of the aforementioned ARMS2 variation with the disease, to examine, for the first time, the role of the CD14 C260T variation (rs2569190), and to investigate the association of two TLR4 polymorphisms (Asp299Gly or rs4986790 and Thr399Ile or rs4986791) in a Greek population with the wet form of AMD.

PATIENTS AND METHODS: Genomic DNAs were isolated from blood samples of 103 healthy controls and 120 Greek patients with wet AMD who were age- and sex-matched, and all of whom were clinically evaluated. For the genotyping of all selected polymorphisms, polymerase chain reaction-restriction fragment length polymorphism analysis was performed.

RESULTS AND CONCLUSIONS: This study confirmed the association between the ARMS2 variation and AMD, detecting the T risk allele in a significantly higher frequency in the patient group, compared with the control subjects (45% vs 29.13%, P<0.001, odds ratio [OR] 1.99, confidence interval 1.34-2.95). For the CD14 polymorphism, no statistically significant correlation was observed. As for the TLR4 polymorphisms, the percentage of heterozygotes increased from 2.9% to 11.7% in the patient population for Asp299Gly and from 1.9% to 10% for the Thr399Ile polymorphism (ORs 4.40 [P=0.01] and 5.61 [P=0.0088], respectively). Although our ARMS2 and CD14 results provided definite conclusions, the role of innate immunity TLR4 gene awaits further investigation in larger AMD populations with more clinical data collected on past microbial infections.

PMID: 28794612 PMCID: PMC5538696

**Stem cells**


**Scaffolds for retinal pigment epithelial cell transplantation in age-related macular degeneration.**

White CE, Olabisi RM.

Abstract: In several retinal degenerative diseases, including age-related macular degeneration, the retinal pigment epithelium, a highly functionalized cell monolayer, becomes dysfunctional. These retinal diseases are marked by early retinal pigment epithelium dysfunction reducing its ability to maintain a healthy retina, hence making the retinal pigment epithelium an attractive target for treatment. Cell therapies, including bolus cell injections, have been investigated with mixed results. Since bolus cell injection does not promote the proper monolayer architecture, scaffolds seeded with retinal pigment epithelium cells and then implanted have been increasingly investigated. Such cell-seeded scaffolds address both the dysfunction of the retinal pigment epithelium cells and age-related retinal changes that inhibit the efficacy of cell-only therapies. Currently, several groups are investigating retinal therapies using seeded cells from a number of cell sources on a variety of scaffolds, such as degradable, non-degradable, natural, and artificial substrates. This review describes the variety of scaffolds that have been developed for the implantation of retinal pigment epithelium cells.

PMID: 28794849 PMCID: PMC5524239


**Cellular Reparative Mechanisms of Mesenchymal Stem Cells for Retinal Diseases.**

Ding SLS, Kumar S, Mok PL.
Abstract: The use of multipotent mesenchymal stem cells (MSCs) has been reported as promising for the treatment of numerous degenerative disorders including the eye. In retinal degenerative diseases, MSCs exhibit the potential to regenerate into retinal neurons and retinal pigmented epithelial cells in both in vitro and in vivo studies. Delivery of MSCs was found to improve retinal morphology and function and delay retinal degeneration. In this review, we revisit the therapeutic role of MSCs in the diseased eye. Furthermore, we reveal the possible cellular mechanisms and identify the associated signaling pathways of MSCs in reversing the pathological conditions of various ocular disorders such as age-related macular degeneration (AMD), retinitis pigmentosa, diabetic retinopathy, and glaucoma. Current stem cell treatment can be dispensed as an independent cell treatment format or with the combination of other approaches. Hence, the improvement of the treatment strategy is largely subjected by our understanding of MSCs mechanism of action.

PMID: 28788088

Diet, lifestyle and low vision


Implementing a multi-modal support service model for the family caregivers of persons with age-related macular degeneration: a study protocol for a randomised controlled trial.


INTRODUCTION: Age-related macular degeneration (AMD) is a leading cause of blindness and low vision among older adults. Previous research shows a high prevalence of distress and disruption to the lifestyle of family caregivers of persons with late AMD. This supports existing evidence that caregivers are ‘hidden patients’ at risk of poor health outcomes. There is ample scope for improving the support available to caregivers, and further research should be undertaken into developing services that are tailored to the requirements of family caregivers of persons with AMD. This study aims to implement and evaluate an innovative, multi-modal support service programme that aims to empower family caregivers by improving their coping strategies, enhancing hopeful feelings such as self-efficacy and helping them make the most of available sources of social and financial support.

METHODS AND ANALYSIS: A randomised controlled trial consisting of 360 caregiver-patient pairs (180 in each of the intervention and wait-list control groups). The intervention group will receive the following: (1) mail-delivered cognitive behavioural therapy designed to improve psychological adjustment and adaptive coping skills; (2) telephone-delivered group counselling sessions allowing caregivers to explore the impacts of caring and share their experiences; and (3) education on available community services/resources, financial benefits and respite services. The cognitive behavioural therapy embedded in this programme is the best evaluated and widely used psychosocial intervention. The primary outcome is a reduction in caregiver burden. Secondary outcomes include improvements in caregiver mental well-being, quality of life, fatigue and self-efficacy. Economic analysis will inform whether this intervention is cost-effective and if it is feasible to roll out this service on a larger scale.

ETHICS AND DISSEMINATION: The study was approved by the University of Sydney human research ethics committee. Study findings will be disseminated via presentations at national/international conferences and peer-reviewed journal articles.

TRIAL REGISTRATION NUMBER: The trial registration number is ACTRN12616001461482; pre-results.

PMID: 28780563
Gait Characteristics of Age-Related Macular Degeneration Patients.

Varadaraj V, Mihailovic A, Ehrenkranz R, Lesche S, Ramulu PY, Swenor BK.

PURPOSE: To identify potential differences between age-related macular degeneration (AMD) patients and controls in fall-relevant gait characteristics.

METHODS: Spatiotemporal gait characteristics using the GAITRite walkway were collected from 29 AMD patients and 20 controls, aged 60 to 90 years, at the Wilmer Eye Institute. Multiple linear regressions, controlling for age, sex, body mass index (BMI), and comorbidities were used to assess associations between gait characteristics and AMD.

RESULTS: Study participants were predominantly white (86%) and female (55%). Mean age of the full study population was 73.51 (SD: 8.14) years, and mean BMI was 27.80 (SD: 5.44) kg/m². Median better-eye acuity (logMAR) was 0.23 (interquartile range [IQR] = 0.18, 0.36) and -0.02 (IQR = -0.08, 0.02), while median binocular log contrast sensitivity was 1.44 (IQR = 1.32, 1.56) and 1.76 (IQR = 1.76, 1.80) for the AMD and control groups, respectively. In multivariable regression models, AMD patients had significantly slower walking speeds ($\beta = -0.118$ m/sec [95% confidence interval (CI): -0.229, -0.007], $P = 0.038$) and stride velocities ($\beta = -0.119$ m/sec [95% CI: -0.232, -0.007], $P = 0.038$), and greater double support time ($\beta = 3.381$% of the walk cycle, 95% CI = 1.006, 5.757, $P = 0.006$) than controls. There were no group differences in base of support, step length, stride length, or gait variability measures.

CONCLUSION: AMD patients exhibited many fall-relevant gait characteristics.

TRANSLATIONAL RELEVANCE:

The finding of fall-relevant gait characteristics suggests that AMD patients may be at a greater risk of falls during ambulation than those without AMD.

PMID: 28781927 PMCID: PMC5539799

Lakartidningen. 2017 Aug 4;114.

Bakom blå ögon … svagt evidensläge för kosttillskott för ögonhälsa.[Article in Swedish]

Bro T, Karlsson M.

Abstract: Behind blue eyes - the evidence for ocular nutritional supplements on the Swedish market Health claims for food are harmonized in the European Union by the European Food Safety Authority (EFSA). Nutritional supplements containing vitamin A or B, docosahexaenoic acid or zinc are allowed to state in their marketing that they preserve vision. This decision is based only on studies of cell metabolism and deficiency diseases and not on clinical interventions. A preventive effect on progression of age-related macular degeneration has however been proven with the AREDS-formula, with an absolute risk reduction for severe visual loss of 6% in certain groups. This treatment may however be associated with considerable side effects. Only 2 of the 25 nutritional supplements for preserved vision available on the Swedish market today follows the AREDS-formula. The present marking of ocular nutritional supplements might therefore be misleading for the customer.

PMID: 28787084

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