STATE BOARD OF OPTOMETRY
2450 DEL PASO ROAD, SUITE 105, SACRAMENTO, CA 95834
P (916) 575-7170 F (916) 575-7292 www.optometry .ca.gov

Continuing Education Course Approval Checklist

Title: Age-Related Macular Degeneration

Provider Name: Dr. Joseph Pruitt

☑Completed Application
Open to all Optometrists? ☑Yes ☐No
Maintain Record Agreement? ☑Yes ☐No

☑Correct Application Fee

☐Detailed Course Summary

☑Detailed Course Outline

☑PowerPoint and/or other Presentation Materials

☐Advertising (optional)

☑CV for EACH Course Instructor

☑License Verification for Each Course Instructor
Disciplinary History? ☐Yes ☑No

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY — GOVERNOR EDMUND G. BROWN JR.

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CONTINUING EDUCATION COURSE APPROVAL APPLICATION

$50 Mandatory Fee

Cashiering and Board Use Only			
Receipt #	Payor ID	Beneficiary ID	Amount
1-3323	439594	439594	50

Pursuant to California Code of Regulations (CCR) § 1536, the Board will approve continuing education (CE) courses after receiving the applicable fee, the requested information below and it has been determined that the course meets criteria specified in CCR § 1536(g).

In addition to the information requested below, please attach a copy of the course schedule, a detailed course outline and presentation materials (e.g., PowerPoint presentation). Applications must be submitted 45 days prior to the course presentation date.

Please type or print clearly.

Course Title	**Course Presentation Date**
Age-Related Macular Degeneration	08/18/2017

Course Provider Contact Information

Provider Name

Joseph	Pruitt	Allan
(First)	(Last)	(Middle)

Provider Mailing Address

Street 11980 Mt Vernon Ave. **City** Grand Terrace **State** CA **Zip** 92313

Provider Email Address pruitt.joseph@gmail.com

Will the proposed course be open to all California licensed optometrists?	☑ YES ☐ NO
Do you agree to maintain and furnish to the Board and/or attending licensee such records of course content and attendance as the Board requires, for a period of at least three years from the date of course presentation?	☑ YES ☐ NO

Course Instructor Information

Please provide the information below and attach the curriculum vitae for each instructor or lecturer involved in the course. If there are more instructors in the course, please provide the requested information on a separate sheet of paper.

Instructor Name

Joseph	Pruitt	Allan
(First)	(Last)	(Middle)

License Number 13429	**License Type** TLG
Phone Number (909) 721-7751	**Email Address** pruitt.joseph@gmail.com

I declare under penalty of perjury under the laws of the State of California that all the information submitted on this form and on any accompanying attachments submitted is true and correct.

Joseph — 3/13/2017

Signature of Course Provider — ***Date***

Form CE-01, Rev. 5/16

1 **AGE-RELATED MACULAR DEGENERATION**

Joseph A. Pruitt, O.D., M.B.A., FAAO
Riverside-San Bernardino County Indian Health, Inc.

2 **Statistics**

- #1 Cause of blindness in US among patients >55 years of age
-
- Disease of the elderly
  - Thus "age-related"
  - Present in 10% of individuals >52 years of age
  - Present up to 33% when >75 years of age

3 **Statistics**

- Approximately 1.7 million Americans >65 years of age have suffered some vision loss from ARMD
-
- As many as 200,000 new cases of wet ARMD are diagnosed every year

4 **Risk Factors**

- Increasing age (peak 75 to 85)
- Positive family history
- Hyperopia
- Whites > Blacks
- Light colored irises and hair
- Associated with solar radiation and retinal damage
- *Smoking...*

5 **Smoking**

- Smoking has consistently been shown to be a risk factor for onset and progression of ARMD in several studies
  - Nurses Health Study
    - 2.5 fold increase in ARMD among current smokers
    - 2 fold increase for past smokers
    - Former smokers did not show decreased risk for ARMD up to 15 years after cessation
    - 29% of all ARMD associated with smoking

6 **Smoking**

  - Pahologies Ocularies Liees a l'Age (POLA) Study
    - Greater than 3 fold increased risk for late ARMD in current and former smokers
    -
  - Blue Mountain Eye Study
    - 4 fold increase in late ARMD among current smokers
    -
    -
- Bottom Line: DO NOT SMOKE!!!

7 **Prevalence**

- Salisbury Eye Evaluation Study
  - 3821 residents of Salisbury, MD
  - Prevalence of blindness (20/200 or worse) among white individuals with ARMD
    - 0.38% in 70-79 year olds
    - Increased to 1.15% in 80-84 year olds
  -

8 **Prevalence**

- Baltimore Eye Study
  - 5308 individuals in east Baltimore
  - The prevalence of ARMD (parameters not defined)
    - 0.32% in white 70-79 year olds
    - 2.9% in white patients > 80 year olds

9 **Prevalence**

- Beaver Dam Study
  - 4711 patients age 43-86
  - Soft drusen in 20% of eyes
  - Pigmentary abnormalities in 13.1% of eyes
  - Dry ARMD in 15.6% of patients
  - Wet in 1.2%
  - Geographic atrophy in 0.6%

10 **Prevalence**

- Framingham Eye Study
  - 5262 eyes
    - Dry ARMD in 3.2% of eyes
    - Wet in 0.2%

11 **Prevalence**

- Chesapeake Bay Waterman Study
  - 777 male Waterman >30 years old
  - 85% had one or more drusen in the macula
    - Only 0.5% had wet ARMD

12 **Pathophysiology**

- Exact cause is unknown
  - Older Theory
    - Degeneration of RPE and formation of drusen as main players
    - RPE cells are responsible for normal degradation of waste products for photoreceptors
    - In older individuals, abnormalities in degradation process leads to accumulation of byproducts within the RPE, which leads to the formation of drusen

13 **Pathophysiology**

- These drusen and damaged RPE can lead to breaks within Bruch's membrane, which can then allow passage of vessels from the choroid into the retina
- Exact stimulus for neovascularization unknown .

14 **Pathophysiology**

- Newer Theory

- Looks at vascular disorder with hemodynamic alteration from atherosclerotic changes as etiology
  - Essentially, thickening and weakening of vessels walls within choroid leads to exudation of proteins and lipids into the macular in the form of drusen, as well as decreased choroidal blood flow
  - Also leads to increased rigidity of eye
  - These factors cause breaks in Bruch's membrane which makes it susceptible for CNVM formation
  - VEGF is released in response to relative ischemia of macula, providing stimulus for neovascularization

15 **Classifications**

- Dry or non-neovascular
  - 80% of all cases
  -
- Wet or neovascular
-
- Geographic atrophy
-
- Choroidal Neovascular Memberanes

16 **Dry ARMD**

- 80% of patients with ARMD have this form
- Characterized by:
  - RPE disruption
  - RPE hyperplasia
  - Drusen to varying degrees
- Typically bilateral and fairly symmetrical
- Variable degree of loss of central vision
  - Rarely reduced to legal blindness
- Color vision may also be compromised

17 **Dry ARMD: Management**

- Primary goal is education and maximizing usable vision
-
  - Education regarding signs of progression to wet
  - Home monitoring (e.g. Amsler grid?)
  - Followed routinely, every 3 to 12 months
  - Maximize vision with best SRx, low vision devices, lighting and eccentric viewing

18 **Dry ARMD: Management**

- Fluorescein Angiography and retina consult if threat of "wet" ARMD
  - Decrease vision
  - Change in metamorphopsia
  -
- UV protection?
  - Very controversial
  - Appears blue light (and perhaps violet) associated with increased risk
    - Slightly higher risk for blonde and red haired individuals
  - Appears sun exposure prior to age 25 is most important
  -
- Stop smoking!
- Supplemental vitamin therapy...

19 **Dry ARMD: Management**

- At present, the mainstay of treatment hinges upon progression prevention via vitamins, nutrition and lifestyle.
-
  - Rheophoresis, laser, anecortave acetate did not prove effective

20 **AREDS: The Age Related Eye Disease Study**

-
- Objective: To evaluate the effect of high-dose vitamins C and E, beta carotene, and zinc supplements on AMD progression and visual acuity
  - 11 center, double-masked study
  - 3640 participants, age 55-80 years of age
  - Average f/u of 6.3 years

21 **AREDS**

- Patients divided into 4 categories based on level of ARMD
-
  - Category I: early ARMD
    - Less than 5 small drusen (<63 microns)
  - Category II: mild ARMD
    - Multiple small drusen
    - Single intermediate size drusen (63-124 microns)
  - Category III: moderate ARMD
    - One large drusen (125 microns)
    - Extensive intermediate drusen
    - Geographic atrophy not centrally
  - Category IV: advance ARMD
    - More than 1 large drusen
    - Geographic atrophy centrally

22 **Categorize the Dry ARMD**

23 **Categorize the Dry ARMD**

24 **Categorize the Dry ARMD**

25 **Categorize the Dry ARMD**

26 **Categorize the Dry ARMD**

27 **Categorize the Dry ARMD**

28 **Categorize the Dry ARMD**

29 **Categorize the Dry ARMD**

30 **Categorize the Dry ARMD**

31 **Categorize the Dry ARMD**

32 **AREDS Results**

- 25% decreased risk reduction in developing advanced ARMD in categories III and IV with antioxidants plus zinc
  - 500 mg vitamin C
  - 400 IU vitamin E
  - 15 mg beta carotene
  - 80 mg zinc
  - 2 mg copper (*to prevent anemia)

33 **AREDS Results**

- @ 5 years in patients in Category III and IV
  - Risk of progression to exudative AMD
    - Placebo 28%

- Antioxidants 23%
- Zinc 22%
- Antioxidants + Zinc 20%

- Risk of ≥ 15 letter vision loss
  - Placebo 29%
  - Antioxidants 26%
  - Zinc 25%
  - Antioxidants + Zinc 23%

34 **AREDS Results**
- Unable to show benefit for categories I + II
  - Already low rate of progression to advance
  - Thus no apparent benefit (approx. 80% fall in this group)
- No statistically significant effect on cataracts
- Unsure how long supplements should be taken
- Beta carotene associated with increased risk of lung cancer in smokers
  - Substitution of other antioxidants (lutein) is unclear
  - Length of being a non-smoker debatable

35 **AREDS Results**
- Did not evaluate the role of lutein
- Overall, the benefit is modest
  - All groups had progression despite treatment

36 **AREDS: 2003 update**
- ARMD or cataract is associated with mortality
- Advance ARMD doubles the risk of death from cardiovascular disease
- Even AREDS participants with a few drusen had significant increased risk of death
- Supplemental zinc lowered the death rates

37 **AREDS: Take Home**
- Reasonable to suggest antioxidants plus zinc in patients in moderate to severe ARMD
- Discuss with all patients with ARMD
- No proven benefit in early to mild ARMD
- Increased risk of lung cancer with beta carotene should be considered in smokers and past smokers

38 **AREDS II**
- Enrollment concluded June 2008
- Study concluded October 2012
- Results released 2013
-
- Specifically looked at the role of omega 3, fatty acids, lutein and zeaxanthin in ARMD

39 **AREDS II**
- Subject Characteristics at baseline
  - Average Age: 73 y/o
  - Sex: 43% Male; 57% Female
  - Race: 96% White
  - Education: 66% some college
  - Diabetes: 13%
  - Smokers: 50% former; 9% current

- AMD Status:
  - Bilateral large drusen – 65%
  - Advance AMD in 1 eye – 35%

40 **AREDS II**

- Formula Modification
-
  - 10 mg lutein and 2 mg zeaxanthin
  - 350 mg DHA and 650 mg EPA
  - No beta-carotene
  - 25 mg zinc
  -

41 **AREDS II RESULTS**

- Adding DHA/EPA or lutein/zeaxanthin to the original AREDS formulation (containing beta-carotene) had no additional overall effect on the risk of advanced AMD
- BUT...Trial participants who took AREDS containing lutein/zeaxanthin (only; not DHA/EPA) and no beta-carotene had a slight reduction in the risk of advanced AMD

42 **AREDS II RESULTS**

- Why...?
-
  - Lutein, zeaxanthin, and beta-carotene, belong to a family of organic pigments known as carotenoids
  -
  - Thus, the thought is betacarotene competes for absorption with lutein and zeaxanthin

43 **AREDS II**

- A subgroup of participants with very low levels of lutein/zeaxanthin in their diet, adding these supplements to the AREDS formulation helped lower their risk of advanced AMD.
- Former smokers who took AREDS with beta-carotene had a higher incidence of lung cancer
- No significant changes in the effectiveness of the formulation when they removed beta-carotene or lowered zinc
-

44 **AREDS II**

- Take Home
  - Lutein/zeaxanthin is an acceptable replacement for betacarotene
  -
  - Lowering levels of Zinc did NOT affect effectiveness
    - Bonus: Given the age-group why else is this good?
      -
      - Link between Zinc and Prostate Cancer
    -
  - Still a ways to go....

45 **Veteran LAST Study**
(Lutein Antioxidant Supplementation Trial)

- 12 month randomized, double-masked, placebo-controlled clinical trial
-
- 90 subjects: 86 men, 4 women
-
- August 1999 to May 2001
-
- North Chicago Dept. of VA Hospital

46 **Veteran LAST Study**
(Lutein Antioxidant Supplementation Trial)

- 3 groups
  - Group I: 10 mg lutein
  - Group II: Lutein + additional antioxidants and nutrients
  - Group III: placebo
- Tested at baseline, 4 months, 8 months, and 12 months
  - Macular Pigment Optical Density (MPOD)
  - Glare Recovery (GR)
  - Visual Acuity in LogMAR
  - Contrast Sensitivity Function (CSF)
  - ADLs, night driving, and glare recovery symptoms were evaluated subjectively

47 **Veteran LAST Study Results**
(Lutein Antioxidant Supplementation Trial)

-
- Promising results, but longer f/u needed
  - Increase in MPOD with both Groups I + II
  - Increase in visual acuities in Groups I + II and a decrease in Group III
  - Decrease in subjective symptoms and increase in ADLs with Groups I + II
  - Progression of ARMD undetermined

48 **Progression of Age Related Macular Degeneration Study**

- Mass Eye and Ear Infirmary
  - Longitudinal study designed to measure multiple risk factors for the progression of ARMD
    - Obesity
    - Physical activity
    - Vascular status
  - 261 patients with BVA 20/200 or better with dry ARMD in at least 1 eye
    - Mean age 72.8 years
    - Average follow-up time was 4.6 years

49 **Progression of Age Related Macular Degeneration Study**

- Body Mass Index is a measure of body fat based on height and weight
  - < 19: underweight
  - 19-24: normal
  - 25-29: overweight
  - >30: obese
-
- Increased risk for ARMD progression with higher BMI (specifically above 25)

50 **Progression of Age Related Macular Degeneration Study**

- Higher waist circumference was associated with an increased risk of progression
- Increased physical activity tended to decrease the risk for progression
  - Vigorous activity at least 3x/week

- Suggested an increase for progression among current and past smokers, but not statistically significant

51 **Progression of Age Related Macular Degeneration Study**

- No apparent association between ARMD progression and systolic blood pressure or CVD
- Higher levels of dietary fat were associated with the progression of ARMD to advance stages and visual loss
  - Specifically higher intake of vegetable fat, and animal fat to a lesser degree, increased rates of progression
  - Saturated, mono, poly and tran-saturated fats were also related to progression of ARMD
    - Food groups with high levels of these fats (especially baked goods,) were also associated with higher rates of progression (except nuts)

52 **Progression of Age Related Macular Degeneration Study**

- Potential benefit of nut food group on progression of ARMD
  - May be related to reservatol, a bio-active ingredient shown to have anti-oxidant, anti-thrombotic, and anti-inflammatory properties
  - May also lower total cholesterol and protect against coronary artery disease (CAD) and atherosclerosis due to doses of vitamin E, copper, magnesium and fiber

53 **Progression of Age Related Macular Degeneration Study**

- Suggests a protective effect of fish intake
  - Especially among individuals with lower linoliec acid intake
    - Related to omega-3 fatty acids
    - Omega-3 fatty acids are found in high concentration in the retina
- Also suggests increased meat intake is associated with increased risk

54 **Progression of Age Related Macular Degeneration Study**

- Fruits, vegetables, vitamins and carotenoids
  - Intake of vitamins or carotenoids, either from diet or supplementation NOT strongly related to ARMD risk
  - NO association between vegetable intake and ARMD risk
  - HOWEVER, fruit intake was inversely related to ARMD risk, particular wet
    - Increased fruit intake = decreased risk of WET ARMD, but NOT early dry ARMD
    - Effects greatest with bananas and oranges

55 **Progression of Age Related Macular Degeneration Study**

- Take home:
  - Statistically significant trend for an increased risk of progression to advance ARMD with:
    - higher BMI
    - larger waist-circumference
    - higher waist-hip ratio
  - Possible benefit with increase physical activity
  - Fatty + processed = Bad
  - Nuts, fish, bananas & Oranges = Good
  -

56 **Other Study Summary: Statins**

- Statin use
  - Data from 2 studies showed an inverse association of statins and ARMD (27 and 28 subjects; very small)
  - Beaver Dam Study: retrospective

- 2780 participants age 48-91 followed for 5 years
- Statin use not statistically associated with the prevalence, incidence, or progression of ARMD
- POLA and Amsterdam study concur

57 **Other Study Summary: Statins**

- American Journal of Ophthalmology: April 2004
  - Looked at 326 patients with ARMD at San Francisco VA Hospital Eye Clinic from 1990 to 2003
  - Found decreased rates of CNVM among patients with ARMD who used statins or aspirin

58 **Other Study Summary: Aspirin**

- Rationale: Laboratory studies show that the choroidal blood flow of eye with ARMD is impaired
-
  - Therefore, if vascular disease is a contributory factor, then aspirin (and the like) decreases ARMD risk, right...?
-

59 **Other Study Summary: Aspirin**

- Physicians Health Study I (PHS1)
  - Results showed a statistically non-significant 23% reduced risk of ARMD during the 5 year period
  - Did find a significant reduced risk of ARMD among men who also reported HTN at baseline
  - Disputed previous studies that associated increased risk of hemorrhage with aspirin use
  - Many shortcomings...
    - Male
    - Health conscience
    - Cardiovascular disease was the focus; thus trial stopped after 5 years due to there being a 44% reduction in 1st MI risk

60 **Other Study Summary: Anti-Inflammatories**

- Many researchers feel inflammation plays a prominent role in ARMD
  - Histochemical evidence suggests an inflammatory component in drusen formation
  -
- Therefore, will oral anti-inflammatories help?
  - Evidence unclear and/or conflicting; further studies indicated

61 **Wet ARMD**

- If left untreated, prognosis is poor
  - One study showed 41-64% of untreated eyes lost 6 or more lines of acuity
    - 20/20→20/70 or worse
    -
  - Average visual acuity ranged from 20/160 to 20/320

62 **Wet ARMD: Treatment**

- Macular Photocoagulation
  - Macular Photocoagulation Study 1986
    - At 3 months 20/320 with treatment vs. 20/200 untreated
    - At 24 months 20/320 treated vs 20/400 untreated

- Treated eyes decreased an average of 3 lines from baseline vs. 4.4 without treatment
  - However, treated eyes decrease was immediate
- Long-term modest benefit must be weighed against immediate loss of vision

63 **Wet ARMD: Treatment**

- Photodynamic Therapy (PDT)
-
  - 2-step procedure
    - IV administration of photosensitizing agent (Visudyne)
    - Activation with a laser light source
      - Power of 600 mW/cm^3
      - Duration of 83 seconds
      -
  - FDA approved late 1999/early 2000

64 **Wet ARMD: Treatment**

- Photodynamic Therapy (PDT)
-
  - Patients still lost vision, but less than observation
  - Marked a step forward in ARMD treatment
  - By and large taken over by VEGF treatments
    - Some specialists still consider PDT a viable individual option, as well as, in conjunction with anti-VEGF or intravitreal steroids
  -

65 **Wet ARMD: Treatment**

- Anti-Angiogenic Agents
  - Latest therapies are looking at inhibiting vascular proliferation while preventing damage to photoreceptors
  - Various agents are used as intravitreal injection
    - Macugen (pegatanib sodium) Dec. 2004
    - Lucentis (ranibizumab) June 2006
    - Avastin (bevacizumab) not FDA approved
    - Elyea (aflibicert) Nov. 2011

66 **Wet ARMD: Treatment**

- Anti-Angiogenic Agents
  - Macugen
    - Anti-vasoactive endothelial growth factor (VEGF) aptamer
    - FDA Approved December 2004
      - Commercially available February 2005
      -
    - VISION Study
      - Intravitreal injections of 0.3 m, 1.0 mg, and 3.0 mg every 6 weeks for 48 weeks (8 total injections)
        - 70% loss < 15 letters compared to only 55% without treatment
        - 33% maintained or loss vision with treatment compared to 23% without treatment

67 **Wet ARMD: Treatment**

- Anti-Angiogenic Agents
  - Macugen
    - No longer the agent of choice due to newer agents

- Most notably Avastin, Lucentis and now Eylea
-
  - Must be injected every 6 weeks for 2 years
    - 8-9 injections/year may be indicated
    - Cost: VA medication = $780; most other places $1200

68 **Wet ARMD: Treatment**

- Anti-Angiogenic Agents
-
  - Lucentis
    - Antibody fragment which blocks VEFG activity
      - Less specific that Macugen; thus likely more efficacious
      -
    - FDA Approved June 30, 2006

69 **Wet ARMD: Treatment**

- Anti-Angiogenic Agents
  - Lucentis
  -
    - ANCHOR Study (classic CNVM)
      - 2 year Phase 3 randomized study
        - 94% of patients treated with 0.3 mg had stable or improved vision compared to 64% with Visudyne
        - 36% had gain of 15 letters or more
        - Average acuity gain was 11.3 letter compared to only 3% with Visudyne

70 **Wet ARMD: Treatment**

- Anti-Angiogenic Agents
  - Lucentis
  -
    - MARINA Study (minimally classic/occult)
      - 95% of treated patients versus 62% of controls had less than 15 letter loss
      - 25% of treated patients versus 4.6% of controls had 3 line gain
      - At 2 years, 6.6 letter gain with treatment versus 14.9 letter lost without

71 **Wet ARMD: Treatment**

- Anti-Angiogenic Agents
  - Lucentis
    - Additional studies, PRONTO and PIER, looking at alternative dosing schedules
      - PRONTO: 1 injection/3 months, then inject based on clinical and/or OCT findings
      - PIER: 1 injection/3 months, then inject every 6 months for 2 years
      -
    - Results were very similar to original studies (especially with PRONTO
    -

72 **Wet ARMD: Treatment**

- Anti-Angiogenic Agents
  - Lucentis
  -
    - Study results better than Macugen
      - First time an improvement of vision was seen (←pun intended)
    - Recommended injection: every 4-6 weeks x 2 years
    - Cost: ~$2500 for medication alone

73 **Wet ARMD: Treatment**
- Anti-Angiogenic Agents
  - Avastin
  -
    - Currently FDA Approved for the treatment of metastatic colorectal cancer and certain lung cancers
      - Parent drug of Lucentis
      - Initially thought to be too large to penetrate the retina

74 **Wet ARMD: Treatment**
- Anti-Angiogenic Agents
  - Avastin
  -
    - First report of intravitreal injection in May 2005
    - First case report published in July 2005
    - Within 6 months, global acceptance and widespread clinical use
      - Despite lack of large scale studies regarding efficacy, safety and dosing

75 **Wet ARMD: Treatment**
- Anti-Angiogenic Agents
  - Avastin
  -
    - #1 advantage is cost
      - ~$15-50 per 0.3 ml injection
      - 1/40 cost of Lucentis
      -
    - The Kicker...?

      Both are made by the same pharmaceutical company!

76 **Wet ARMD: Treatment**
- Anti-Angiogenic Agents
  - Avastin
  -
    - Issue is there are no large prospective study to judge its efficacy and safety
      - Systemically, thrombolytic events are a concern
    -
    - Despite the controversy is widely used

77 **Wet ARMD: Treatment**
- Anti-Angiogenic Agents
  - Avastin
  -
    - No studies yet to determine proper dosing
      - Most often, 1 injection/3 months
      - The repeat FA/OCT and evaluate for additional treatments
      - Also, no history of myocardial infarction or CVA within 6 months
      -
    - Patient must be informed of its off-label use

78 **Avastin or Lucentis?**
- Comparison of Age-Related Macular Degeneration Treatment Trial (CATT)
  - NEI/NIH sponsored trial
  - First year results released May 1, 2011 (NEJM)
  - 1208 patients randomized

- Lucentis with 4 week dosing
- Avastin with 4 week dosing
- Lucentis with variable dosing (PRN)
- Avastin with variable dosing (PRN)

79 **Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 1 Year Results**

- Equivalent effects on visual acuity with same administration
  - Lucentis monthly 8.5 letters gained
  - Avastin monthly 8.0 letters gained
  - Lucentis PRN 6.8 letters gained
  - Avastin PRN 5.9 letters gained
- Lucentis PRN = Lucentis monthly
- Avastin PRN vs. Avastin monthly = inconclusive

80 **Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 1 Year Results**

- Central Retinal Thickness
  - Greater effect in Lucentis monthly group (196 micron decrease) than in other groups
    - 164 micron Avastin monthly
    - 168 microns Lucentis PRN
    - 152 microns Avastin PRN
  - Fluid on OCT
    - At 4 weeks, no fluid in 27.5% of patients with Lucentis vs. 17.3% with Avastin
    - At 1 year, no fluid in 43.7% Lucentis monthly and 19.2% Avastin PRN

81 **Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 1 Year Results**

- Adverse effects
-
  - When dosing regimens combined, slightly more serious adverse events in Avastin group
    - 24.1% for Avastin
    - 19.0% for Lucentis
    - Risk ratio 1.29 for Avastin as compared to Lucentis

82 **Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 1 Year Results**

- Average cost for first year treatment:
-
  - $23,400 for Lucentis monthly
  - $13,800 for Lucentis PRN
  - $595 for Avastin monthly
  - $385 for Avastin PRN

83 **Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 1 Year Results**

- Summary
  - Vision with Lucentis vs. Avastin relatively equal over course of first year
    - Some evidence of more effect with Lucentis on anatomical structure (i.e. greater retinal thickness on OCT, but did NOT correlate with improved visual function)
    - Some hint that less systemic events with Lucentis
    - SIGNIFICANT cost differential

84 **Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 1 Year Results**
- 1 year conclusion:
-
  - Avastin wins most of the time, with select cases benefiting from Lucentis

85 **Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 2 Year Results**
- At the end of 2 years, both had similar effects on vision when the dosing regimen was the same
  - Mean gain in acuity, proportion gaining or losing 3 lines, and percentage better than 20/40 were all equivalent
- Mean gain slightly better for monthly vs. PRN by 2.4 letters
- Rates of death from thrombotic events similar
- Adverse events higher with Avastin (39.9%) than Lucentis (31.7%)

86 **Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 2 Year Results**
- Geographic Atrophy most in Lucentis monthly, but more in both monthly
-
- Less fluid at 1 and 2 years with Lucentis
  - Which resulted to 0.6 more injections with Avastin in 2nd year (1.5 more over the whole 2 years)

87 **Avastin or Lucentis?**
- A randomized controlled trial of alternative treatments to Inhibit VEGF in Age-related choroidal Neovascularization

  - IVAN Study

88 **IVAN Study**
- 1 year
- United Kingdom
- 610 patients
- Avastin vs. Lucentis, monthly vs. PRN
- Looked at:
  - Near visual acuity
  - Reading speed
  - Quality of life
  - Serum samples of VEGF Concentration

89 **IVAN Study: Results**
- Final VA was 2 letters in favor of Lucentis
- Monthly vs. PRN difference was negligible
- No real difference in reading speed or quality of life
- Angiographic and topograpic findings favored monthly administration
- Serum Concentration lower with Avastin
- Safety relatively the same
- Switching all patients from Lucentis to Avastin would save UK approximately $132 million annually

90 **Eylea**
- Eylea (aflibercept)
-
- Latest anti-Vegf agent for treatment of wet AMD

- ⊙
- ⊙ Regeneron Pharmaceuticals
- ⊙
- ⊙ FDA approved November 2011

91 **Eylea**

- ⊙ Approved for:
  - Wet Age-related Macular Degeneration (AMD):
    - ○
  - Macular Edema following Retinal Vein Occlusion (RVO):
- ⊙
  - Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR) in patients with DME:
- ⊙

92 **Eylea**

- ⊙ View 1 Study:
  - •
  - 95% of patients receiving 2 mg every 2 months achieved maintenance of vision vs. 94% with Lucentis monthly
  - •
  - 7.9 letter mean improvement of vision (vs. 8.1 with Lucentis monthly)

93 **Eylea**

- ⊙ View 2 Study:
  - •
  - 95% of patients receiving 2 mg every 2 months achieved maintenance of vision vs. 94% with Lucentis monthly
  - •
  - 8.9 letter mean improvement of vision (versus 9.4 with Lucentis monthly)

94 **Eylea**

- ⊙ Adverse events were minimal with most common conjunctival hemorrhage, eye pain, vitreous floaters, cataract and increase IOP
- ⊙
- ⊙ System events included falls, pneumonia, myocardial infarction, atrial fibrillation, breast cancer, and acute coronary syndrome (no difference between study arms)

95 **Eylea**

- ⊙ Cost
  - •
  - ~$1,850 per injection, with injection every 2 months
  - •
  - Therefore ½ of Lucentis monthly

96 **Other Therapies...?**

- ⊙
- ⊙
- ⊙ As of July 2013, there are 936 studies evaluating AMD
- ⊙

97 **FoVista**

- ⊙ Anti-PDGF agent
  - Platelet Derived Growth Factor
  - •

- Theory is that when used in conjunction with anti-Vegf agents there will be a synergistic effect
-
- Ophthotech
  - Currently in Phase III clinical trial

98 **FoVista**

- Initial phase 1 trial to show safety
  -
  - 59% had improvement of three lines or more
  -
- Phase 2b study: 449 patients
-
  - FoVista/Lucentis combination gained 10.6 letters at 24 weeks, versus 6.5 with Lucentis alone
    - -62% additional benefit

99 **FoVista**

- First study results were BETTER THAN Lucentis'
-
  - FoSho

100 **ARMD/DNA Connection**

- ARMD is a genetic disease with known markers responsible for 70% of the population attributable risk
-
  - The other 30% is environmental/lifestyle

101 **Major Genetic Factors**

- Complement H Factor (CHF)
  - Single most important genetic component
  - CHF Y402H
- $ARMS_2/HTRA_1$
  - Second most important gene in ARMD
- C_3
  - Another component of the complement system
- ND_2
  - Mitochondrial oxidative phosphorylation molecule

102 **Macula Risk Score**

- The Macula Risk genetic test incorporates all the known genetic predictors of AMD progression
-
- The test stratifies individuals into 5 risk groups

103 **Macula Risk Score**

104 **Macula Risk Score**

- Macula Risk testing is recommended based on presenting AREDS ARMD score:
-

105 **Macula Risk Score**

- Management recommendations:
-

106 **VEFG Eye Drops**

- ATG3: a topical eye drop for treatment of wet ARMD

- Phase II trial will enroll 330 patients to receive 2 concentrations of ATG3 bid vs placebo for 48 weeks

⊙ Gate Study by Alcon
- Phase III study evaluating AL-8309B as topical ocular treatment for geographic atrophy secondary to ARMD

107 **VEGF Eye Drops**

⊙ Pazopanib
- FDA Approved for renal cell carcinoma
- Treatment for wet ARMD

⊙ OT-551
- Anti-angiogenic drop being investigated for geographic atrophy
- Recent study showed it to be ineffective

108 **Oral Fenretinide**

⊙ What is Fenretinide?
- Synthetic Retinoid Derivative

⊙ RetinPhase II study underway for treatment of advance geographic atrophy from ARMD

⊙

⊙ Theory is that the medication prevents delivery of retinol to the eye, which reduces retinol derived metabolites (A2E) that are toxic to the RPE and photoreceptors

⊙

⊙ 2 year study which is looking primarily at lesion size
- 300 mg and 100 mg capsules taken once a day after evening meal x 24 months

109 **Oral Fenretinide**

⊙ 2009 American Academy of Ophthalmology Meeting

⊙
- At 18 months, lesions in 300 mg group showed 45% less growth than placebo
  - 100 mg looked most protective against growth of small lesion (< disc diameter) 300 mg against all lesions
  -
- Conversion to wet ARMD occurred less in 100 mg (6%) and 300 mg (7%) groups vs. placebo (13.4%)
-
- Granted "fast-track: designation by FDA

110 **Oral Fenretinide**

⊙ May 2011 Association for Research in Vision and Ophthalmology (ARVO)
- 43% patients on 300 mg had decreased lesion size by 60%
- 30% growth with treatment vs. 50% growth with placebo
- Loss of 6 letters over 2 years vs. 11 letters with placebo
- May also reduce incidence of CNVM
  - 22% with placebo vs. 13% with treatment

111 **Copaxone**

⊙ Copaxone (glatiramer acetate) is a immunomodulary substance which has been proven to be safe and effective in treating neurodegenerative diseases, such as MS

⊙ Phase II study will investigate if a weekly vaccination can stop the progression as well as conversion of dry to wet ARMD
- New York Eye and Ear Infirmary

112 **Ciliary Neurotrophic Factor (CNTF) Intraocular Implant: NT-501**

- Recent study of patient with geographic atrophy
-
  - After 12 months, 96.3% of high-dose group had stable vision vs. 75% with sham/placebo
  -
  - Also showed increase in retinal thickness in treated group at 12 months

113 **Stem Cells**

- Transplantation of fetal RPE cells has been performed in patients with CNVM and geographic atrophy
-
- Promising results, but many researchers feel widespread use may be decades away

114 **Radiation**

- Beta Radiation with Avastin
-
  - CABERNET study
  -
  - Looking at combining local application of epiretinal beta radiation with Avastin
    - 1 year: mean improvement of 19 letters with 39% gaining 3 lines or more
    - 67% of patients were stable after initial treatment only
      - 2 injections plus radiation with vitrectomy

115 **Radiation**

- MERITAGE Study
  -
  - 53 patients with ARMD that required frequent VEGF injections
  -
  - Pars Plana Vitrectomy with single 24-GY dose fEMB (epimacuar brachytherapy)

116 **Radiation**

- Results
  - After 1 treatment, 81% had stable vision
  - Mean of 3.29 treatments in 12 months
    - On average 12.5 injections prior to study
  - Mean change in acuity: -4.0 letters
  - Mean OCT CRT increased by 50 microns
  - Stable VA in most patients and may reduce the need for frequent treatments

117 **Others**

- Effect of Saffron Supplementation on ARMD
-
- Transcorneal Electrical Stimulation Therapy for Retinal Disease
-
- Effect of Lutein-Enriched-Egg Beverage on ARMD

118 **Implantable Miniature Telescope (IMT)**

- FDA Approved July 2010 for patients with end-stage ARMD

- Two Models
  - 2.2x
  - 2.7x
  -

119 **Implantable Miniature Telescope (IMT)**

- Study
  - 219 patients
    - 75% improved from severe or profound impairment to moderate impairment
    - Average visual acuity improvement: 2 lines
  - Complications
    - Corneal Edema (9.2%)
    - Corneal Decompensation (6.9%)
    - Corneal Transplant (4.1%)

120 **Macular Degeneration**

- As stated before....
  -
  - There is still quite a ways to go
  -
  - As of 9/3/2015, # of trials returned on a search for "Macular Degeneration" on clinicaltrials.gov...?
  -
    - 1,212

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AGE-RELATED MACULAR DEGENERATION

Statistics

- #1 Cause of blindness in US among patients >55 years of age
- Disease of the elderly
  - Thus "age-related"
  - Present in 10% of individuals >52 years of age
  - Present up to 33% when >75 years of age

Statistics

- Approximately 1.7 million Americans >65 years of age have suffered some vision loss from ARMD
- As many as 200,000 new cases of wet ARMD are diagnosed every year

Risk Factors

- Increasing age (peak 75 to 85)
- Positive family history
- Hyperopia
- Whites > Blacks
- Light colored irises and hair
- Associated with solar radiation and retinal damage
- ***Smoking...***

Smoking

- Smoking has consistently been shown to be a risk factor for onset and progression of ARMD in several studies
  - Nurses Health Study
    - 2.5 fold increase in ARMD among current smokers
    - 2 fold increase for past smokers
    - Former smokers did not show decreased risk for ARMD up to 15 years after cessation
    - 29% of all ARMD associated with smoking

Smoking

- Pahologies Ocularies Liees a l'Age (POLA) Study
  - Greater than 3 fold increased risk for late ARMD in current and former smokers
- Blue Mountain Eye Study
  - 4 fold increase in late ARMD among current smokers
- **Bottom Line: DO NOT SMOKE!!!**

Prevalence

- Salisbury Eye Evaluation Study
  - 3821 residents of Salisbury, MD
  - Prevalence of blindness (20/200 or worse) among white individuals with ARMD
    - 0.38% in 70-79 year olds
    - Increased to 1.15% in 80-84 year olds

Prevalence

- Baltimore Eye Study
  - 5308 individuals in east Baltimore
  - The prevalence of ARMD (parameters not defined)
    - 0.32% in white 70-79 year olds
    - 2.9% in white patients > 80 year olds

Prevalence

- Beaver Dam Study
  - 4711 patients age 43-86
  - Soft drusen in 20% of eyes
  - Pigmentary abnormalities in 13.1% of eyes
  - Dry ARMD in 15.6% of patients
  - Wet in 1.2%
  - Geographic atrophy in 0.6%

Prevalence

- Framingham Eye Study
  - 5262 eyes
    - Dry ARMD in 3.2% of eyes
    - Wet in 0.2%

Prevalence

- Chesapeake Bay Waterman Study
  - 777 male Waterman >30 years old
    - 85% had one or more drusen in the macula
    - Only 0.5% had wet ARMD

Pathophysiology

- **Exact cause is unknown**
  - Older Theory
    - Degeneration of RPE and formation of drusen as main players
    - RPE cells are responsible for normal degradation of waste products for photoreceptors
    - In older individuals, abnormalities in degradation process leads to accumulation of byproducts within the RPE, which leads to the formation of drusen

Pathophysiology

- These drusen and damaged RPE can lead to breaks within Bruch's membrane, which can then allow passage of vessels from the choroid into the retina
- Exact stimulus for neovascularization unknown

Pathophysiology

- Newer Theory
  - Looks at vascular disorder with hemodynamic alteration from atherosclerotic changes as etiology
    - Essentially, thickening and weakening of vessels walls within choroid leads to exudation of proteins and lipids into the macular in the form of drusen, as well as decreased choroidal blood flow
    - Also leads to increased rigidity of eye
    - These factors cause breaks in Bruch's membrane which makes it susceptible for CNVM formation
    - VEGF is released in response to relative ischemia of macula, providing stimulus for neovascularization

Classifications

- Dry or non-neovascular
  - 80% of all cases
- Wet or neovascular
- Geographic atrophy
- Choroidal Neovascular Memberanes

Dry ARMD

- 80% of patients with ARMD have this form
- Characterized by:
  - RPE disruption
  - RPE hyperplasia
  - Drusen to varying degrees
- Typically bilateral and fairly symmetrical
- Variable degree of loss of central vision
  - Rarely reduced to legal blindness
- Color vision may also be compromised

Dry ARMD: Management

- Primary goal is education and maximizing usable vision
  - Education regarding signs of progression to wet
  - Home monitoring (e.g. Amsler grid?)
  - Followed routinely, every 3 to 12 months
  - Maximize vision with best SRx, low vision devices, lighting and eccentric viewing

Dry ARMD: Management

- Fluorescein Angiography and retina consult if threat of "wet" ARMD
  - Decrease vision
  - Change in metamorphopsia
- UV protection?
  - Very controversial
  - Appears blue light (and perhaps violet) associated with increased risk
    - Slightly higher risk for blonde and red haired individuals
  - Appears sun exposure prior to age 25 is most important
- Stop smoking!
- Supplemental vitamin therapy...

Dry ARMD: Management

- At present, the mainstay of treatment hinges upon progression prevention via vitamins, nutrition and lifestyle.
  - Rheophoresis, laser, anecortave acetate did not prove effective

AREDS: The Age Related Eye Disease Study

- Objective: To evaluate the effect of high-dose vitamins C and E, beta carotene, and zinc supplements on AMD progression and visual acuity
  - 11 center, double-masked study
  - 3640 participants, age 55-80 years of age
  - Average f/u of 6.3 years

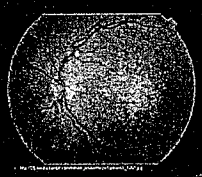
AREDS

- Patients divided into 4 categories based on level of ARMD
  - Category I: early ARMD
    - Less than 5 small drusen (<63 microns)
  - Category II: mild ARMD
    - Multiple small drusen
    - Single intermediate size drusen (63-124 microns)
  - Category III: moderate ARMD
    - One large drusen (125 microns)
    - Extensive intermediate drusen
    - Geographic atrophy not centrally
  - Category IV: advance ARMD
    - More than 1 large drusen
    - Geographic atrophy centrally

Categorize the Dry ARMD

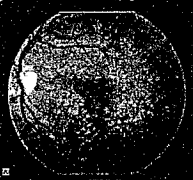
Category II

Categorize the Dry ARMD



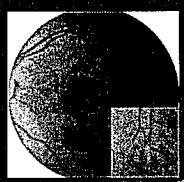
Category IV

Categorize the Dry ARMD



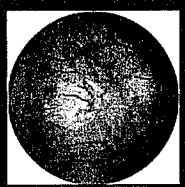
Category III

Categorize the Dry ARMD



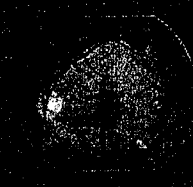
Category II

Categorize the Dry ARMD



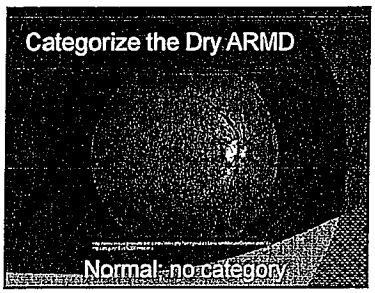
Category IV

Categorize the Dry ARMD



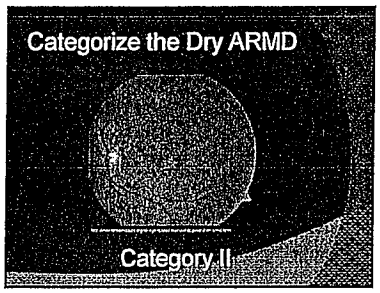
Category I

Categorize the Dry ARMD



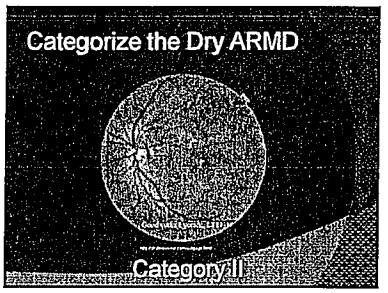
Normal: no category

Categorize the Dry ARMD



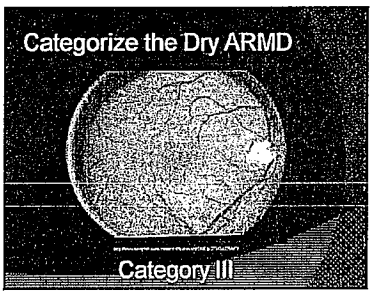
Category II

Categorize the Dry ARMD



Category II

Categorize the Dry ARMD



Category III

AREDS Results

- 25% decreased risk reduction in developing advanced ARMD in categories III and IV with antioxidants plus zinc
  - 500 mg vitamin C
  - 400 IU vitamin E
  - 15 mg beta carotene
  - 80 mg zinc
  - 2 mg copper (*to prevent anemia)

AREDS Results

- @ 5 years in patients in Category III and IV
  - Risk of progression to exudative AMD
    - Placebo 28%
    - Antioxidants 23%
    - Zinc 22%
    - Antioxidants + Zinc 20%
  - Risk of ≥ 15 letter vision loss
    - Placebo 29%
    - Antioxidants 26%
    - Zinc 25%
    - Antioxidants + Zinc 23%

AREDS Results

- Unable to show benefit for categories I + II
  - Already low rate of progression to advance
  - Thus no apparent benefit (approx. 60% fall in this group)
- No statistically significant effect on cataracts
- Unsure how long supplements should be taken
- Beta carotene associated with increased risk of lung cancer in smokers
  - Substitution of other antioxidants (lutein) is unclear
  - Length of being a non-smoker debatable

AREDS Results

- Did not evaluate the role of lutein
- Overall, the benefit is modest
  - All groups had progression despite treatment

AREDS: 2003 update

- ARMD or cataract is associated with mortality
- Advance ARMD doubles the risk of death from cardiovascular disease
- Even AREDS participants with a few drusen had significant increased risk of death
- Supplemental zinc lowered the death rates

AREDS: Take Home

- Reasonable to suggest antioxidants plus zinc in patients in moderate to severe ARMD
- Discuss with all patients with ARMD
- No proven benefit in early to mild ARMD
- Increased risk of lung cancer with beta carotene should be considered in smokers and past smokers

AREDS II

- Enrollment concluded June 2008
- Study concluded October 2012
- Results released 2013
- Specifically looked at the role of omega 3, fatty acids, lutein and zeaxanthin in ARMD

AREDS II

- Subject Characteristics at baseline
  - Average Age: 73 y/o
  - Sex: 43% Male; 57% Female
  - Race: 96% White
  - Education: 66% some college
  - Diabetes: 13%
  - Smokers: 50% former; 9% current
  - AMD Status:
    - Bilateral large drusen – 65%
    - Advance AMD in 1 eye – 35%

AREDS II

- Formula Modification
  - 10 mg lutein and 2 mg zeaxanthin
  - 350 mg DHA and 650 mg EPA
  - No beta-carotene
  - 25 mg zinc

AREDS II RESULTS

- Adding DHA/EPA or lutein/zeaxanthin to the original AREDS formulation (containing beta-carotene) had no additional overall effect on the risk of advanced AMD
- BUT... Trial participants who took AREDS containing lutein/zeaxanthin (only; not DHA/EPA) and no beta-carotene had a slight reduction in the risk of advanced AMD

AREDS II RESULTS

- Why...?
  - Lutein, zeaxanthin, and beta-carotene, belong to a family of organic pigments known as carotenoids
  - Thus, the thought is betacarotene competes for absorption with lutein and zeaxanthin

AREDS II

- A subgroup of participants with very low levels of lutein/zeaxanthin in their diet, adding these supplements to the AREDS formulation helped lower their risk of advanced AMD.
- Former smokers who took AREDS with beta-carotene had a higher incidence of lung cancer
- No significant changes in the effectiveness of the formulation when they removed beta-carotene or lowered zinc

AREDS II

- Take Home
  - Lutein/zeaxanthin is an acceptable replacement for betacarotene
  - Lowering levels of Zinc did NOT affect effectiveness
    - Bonus: Given the age-group why else is this good?
      - Link between Zinc and Prostate Cancer
  - Still a ways to go....

Veteran LAST Study

(Lutein Antioxidant Supplementation Trial)

- 12 month randomized, double-masked, placebo-controlled clinical trial
- 90 subjects: 86 men, 4 women
- August 1999 to May 2001
- North Chicago Dept. of VA Hospital

Veteran LAST Study
(Lutein Antioxidant Supplementation Trial)

- 3 groups
  - Group I: 10 mg lutein
  - Group II: Lutein + additional antioxidants and nutrients
  - Group III: placebo
- Tested at baseline, 4 months, 8 months, and 12 months
  - Macular Pigment Optical Density (MPOD)
  - Glare Recovery (GR)
  - Visual Acuity in LogMAR
  - Contrast Sensitivity Function (CSF)
  - ADLs, night driving, and glare recovery symptoms were evaluated subjectively

Veteran LAST Study Results
(Lutein Antioxidant Supplementation Trial)

- Promising results, but longer f/u needed
  - Increase in MPOD with both Groups I + II
  - Increase in visual acuities in Groups I + II and a decrease in Group III
  - Decrease in subjective symptoms and increase in ADLs with Groups I + II
  - Progression of ARMD undetermined

Progression of Age Related Macular Degeneration Study

- Mass Eye and Ear Infirmary
  - Longitudinal study designed to measure multiple risk factors for the progression of ARMD
    - Obesity
    - Physical activity
    - Vascular status
  - 261 patients with BVA 20/200 or better with dry ARMD in at least 1 eye
    - Mean age 72.8 years
    - Average follow-up time was 4.6 years

Progression of Age Related Macular Degeneration Study

- Body Mass Index is a measure of body fat based on height and weight
  - < 19: underweight
  - 19-24: normal
  - 25-29: overweight
  - >30: obese
- Increased risk for ARMD progression with higher BMI (specifically above 25)

Progression of Age Related Macular Degeneration Study

- Higher waist circumference was associated with an increased risk of progression
- Increased physical activity tended to decrease the risk for progression
  - Vigorous activity at least 3x/week
- Suggested an increase for progression among current and past smokers, but not statistically significant

Progression of Age Related Macular Degeneration Study

- No apparent association between ARMD progression and systolic blood pressure or CVD
- Higher levels of dietary fat were associated with the progression of ARMD to advance stages and visual loss
  - Specifically higher intake of vegetable fat, and animal fat to a lesser degree, increased rates of progression
  - Saturated, mono, poly and tran-saturated fats were also related to progression of ARMD
    - Food groups with high levels of these fats (especially baked goods,) were also associated with higher rates of progression (except nuts)

Progression of Age Related Macular Degeneration Study

- Potential benefit of nut food group on progression of ARMD
  - May be related to reservatol, a bio-active ingredient shown to have anti-oxidant, anti-thrombotic, and anti-inflammatory properties
  - May also lower total cholesterol and protect against coronary artery disease (CAD) and atherosclerosis due to doses of vitamin E, copper, magnesium and fiber

Progression of Age Related Macular Degeneration Study

- Suggests a protective effect of fish intake
  - Especially among individuals with lower linoliec acid intake
    - Related to omega-3 fatty acids
    - Omega-3 fatty acids are found in high concentration in the retina
- Also suggests increased meat intake is associated with increased risk

Progression of Age Related Macular Degeneration Study

- Fruits, vegetables, vitamins and carotenoids
  - Intake of vitamins or carotenoids, either from diet or supplementation NOT strongly related to ARMD risk
  - NO association between vegetable intake and ARMD risk
  - HOWEVER, fruit intake was inversely related to ARMD risk, particular wet
    - Increased fruit intake = decreased risk of WET ARMD, but NOT early dry ARMD
    - Effects greatest with bananas and oranges

Progression of Age Related Macular Degeneration Study

- Take home:
  - Statistically significant trend for an increased risk of progression to advance ARMD with:
    - higher BMI
    - larger waist-circumference
    - higher waist-hip ratio
  - Possible benefit with increase physical activity
  - Fatty + processed = Bad
  - Nuts, fish, bananas & Oranges = Good

Other Study Summary: Statins

- Statin use
  - Data from 2 studies showed an inverse association of statins and ARMD (27 and 28 subjects; very small)
  - Beaver Dam Study: retrospective
    - 2780 participants age 48-91 followed for 5 years
    - Statin use not statistically associated with the prevalence, incidence, or progression of ARMD
    - POLA and Amsterdam study concur

Other Study Summary: Statins

- American Journal of Ophthalmology: April 2004
  - Looked at 326 patients with ARMD at San Francisco VA Hospital Eye Clinic from 1990 to 2003
  - Found decreased rates of CNVM among patients with ARMD who used statins or aspirin

Other Study Summary: Aspirin

- Rationale: Laboratory studies show that the choroidal blood flow of eye with ARMD is impaired
  - Therefore, if vascular disease is a contributory factor, then aspirin (and the like) decreases ARMD risk, right...?

Other Study Summary: Aspirin

- Physicians Health Study I (PHS1)
  - Results showed a statistically non-significant 23% reduced risk of ARMD during the 5 year period
  - Did find a significant reduced risk of ARMD among men who also reported HTN at baseline
  - Disputed previous studies that associated increased risk of hemorrhage with aspirin use
  - Many shortcomings...
    - Male
    - Health conscience
    - Cardiovascular disease was the focus; thus trial stopped after 5 years due to there being a 44% reduction in 1st MI risk

Other Study Summary: Anti-Inflammatories

- Many researchers feel inflammation plays a prominent role in ARMD
  - Histochemical evidence suggests an inflammatory component in drusen formation
- Therefore, will oral anti-inflammatories help?
  - Evidence unclear and/or conflicting; further studies indicated

Wet ARMD

- If left untreated, prognosis is poor
  - One study showed 41-64% of untreated eyes lost 6 or more lines of acuity
    - 20/20→20/70 or worse
  - Average visual acuity ranged from 20/160 to 20/320

Wet ARMD: Treatment

- Macular Photocoagulation
  - Macular Photocoagulation Study 1986
    - At 3 months 20/320 with treatment vs. 20/200 untreated
    - At 24 months 20/320 treated vs 20/400 untreated
  - Treated eyes decreased an average of 3 lines from baseline vs. 4.4 without treatment
    - However, treated eyes decrease was immediate
  - Long-term modest benefit must be weighed against immediate loss of vision

Wet ARMD: Treatment

- Photodynamic Therapy (PDT)
  - 2-step procedure
    - IV administration of photosensitizing agent (Visudyne)
    - Activation with a laser light source
      - Power of 600 mW/cm²
      - Duration of 83 seconds
  - FDA approved late 1999/early 2000

Wet ARMD: Treatment

- Photodynamic Therapy (PDT)
  - Patients still lost vision, but less than observation
  - Marked a step forward in ARMD treatment
  - By and large taken over by VEGF treatments
    - Some specialists still consider PDT a viable individual option, as well as, in conjunction with anti-VEGF or intravitreal steroids

Wet ARMD: Treatment

- Anti-Angiogenic Agents
  - Latest therapies are looking at inhibiting vascular proliferation while preventing damage to photoreceptors
  - Various agents are used as intravitreal injection
    - Macugen (pegatanib sodium) Dec. 2004
    - Lucentis (ranibizumab) June 2006
    - Avastin (bevacizumab) not FDA approved
    - Eiyea (aflibicert) Nov. 2011

Wet ARMD: Treatment

- Anti-Angiogenic Agents
  - Macugen
    - Anti-vasoactive endothelial growth factor (VEGF) aptamer
    - FDA Approved December 2004
      - Commercially available February 2005
    - VISION Study
      - Intravitreal injections of 0.3 m, 1.0 mg, and 3.0 mg every 6 weeks for 48 weeks (8 total injections)
        - 70% loss < 15 letters compared to only 55% without treatment
        - 33% maintained or loss vision with treatment compared to 23% without treatment

Wet ARMD: Treatment

- Anti-Angiogenic Agents
  - Macugen
    - No longer the agent of choice due to newer agents
      - Most notably Avastin, Lucentis and now Eylea
    - Must be injected every 6 weeks for 2 years
      - 8-9 injections/year may be indicated
      - Cost: VA medication = $760; most other places $1200

Wet ARMD: Treatment

- Anti-Angiogenic Agents
  - Lucentis
    - Antibody fragment which blocks VEFG activity
      - Less specific that Macugen; thus likely more efficacious
    - FDA Approved June 30, 2006

Wet ARMD: Treatment

- Anti-Angiogenic Agents
  - Lucentis
    - ANCHOR Study (classic CNVM)
      - 2 year Phase 3 randomized study
        - 94% of patients treated with 0.3 mg had stable or improved vision compared to 64% with Visudyne
        - 36% had gain of 15 letters or more
        - Average acuity gain was 11.3 letter compared to only 3% with Visudyne

Wet ARMD: Treatment

- Anti-Angiogenic Agents
  - Lucentis
    - MARINA Study (minimally classic/occult)
      - 95% of treated patients versus 62% of controls had less than 15 letter loss
      - 25% of treated patients versus 4.6% of controls had 3 line gain
      - At 2 years, 6.6 letter gain with treatment versus 14.9 letter lost without

Wet ARMD: Treatment

- Anti-Angiogenic Agents
  - Lucentis
    - Additional studies, PRONTO and PIER, looking at alternative dosing schedules
      - PRONTO: 1 injection/3 months, then inject based on clinical and/or OCT findings
      - PIER: 1 injection/3 months, then inject every 6 months for 2 years
    - Results were very similar to original studies (especially with PRONTO

Wet ARMD: Treatment

- Anti-Angiogenic Agents
  - Lucentis
    - Study results better than Macugen
      - First time an improvement of vision was seen (<-pun intended)
    - Recommended injection: every 4-6 weeks x 2 years
    - Cost: ~$2500 for medication alone

Wet ARMD: Treatment

- Anti-Angiogenic Agents
  - Avastin
    - Currently FDA Approved for the treatment of metastatic colorectal cancer and certain lung cancers
      - Parent drug of Lucentis
      - Initially thought to be too large to penetrate the retina

Wet ARMD: Treatment

- Anti-Angiogenic Agents
  - Avastin
    - First report of intravitreal injection in May 2005
    - First case report published in July 2005
    - Within 6 months, global acceptance and widespread clinical use
      - Despite lack of large scale studies regarding efficacy, safety and dosing

Wet ARMD: Treatment

- Anti-Angiogenic Agents
  - Avastin
    - #1 advantage is cost
      - ~$15-50 per 0.3 ml injection
      - 1/40 cost of Lucentis
    - The Kicker…?
      Both are made by the same pharmaceutical company!

Wet ARMD: Treatment

- Anti-Angiogenic Agents
  - Avastin
    - Issue is there are no large prospective study to judge its efficacy and safety
      - Systemically, thrombolytic events are a concern
    - Despite the controversy is widely used

Wet ARMD: Treatment

- Anti-Angiogenic Agents
  - Avastin
    - No studies yet to determine proper dosing
      - Most often, 1 injection/3 months
      - The repeat FA/OCT and evaluate for additional treatments
      - Also, no history of myocardial infarction or CVA within 6 months
    - Patient must be informed of its off-label use

Avastin or Lucentis?

- Complications of Age-Related Macular Degeneration Treatment Trial (CATT)
  - NEI/NIH sponsored trial
  - First year results released May 1, 2011 (NEJM)
  - 1208 patients randomized
    - Lucentis with 4 week dosing
    - Avastin with 4 week dosing
    - Lucentis with variable dosing (PRN)
    - Avastin with variable dosing (PRN)

Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 1 Year Results

- Equivalent effects on visual acuity with same administration
  - Lucentis monthly 8.5 letters gained
  - Avastin monthly 8.0 letters gained
  - Lucentis PRN 6.8 letters gained
  - Avastin PRN 5.9 letters gained
- Lucentis PRN = Lucentis monthly
- Avastin PRN vs. Avastin monthly = inconclusive

Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 1 Year Results

- Central Retinal Thickness
  - Greater effect in Lucentis monthly group (196 micron decrease) than in other groups
    - 164 micron Avastin monthly
    - 168 microns Lucentis PRN
    - 152 microns Avastin PRN
  - Fluid on OCT
    - At 4 weeks, no fluid in 27.5% of patients with Lucentis vs. 17.3% with Avastin
    - At 1 year, no fluid in 43.7% Lucentis monthly and 19.2% Avastin PRN

Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 1 Year Results

- Adverse effects
  - When dosing regimens combined, slightly more serious adverse events in Avastin group
    - 24.1% for Avastin
    - 19.0% for Lucentis
    - Risk ratio 1.29 for Avastin as compared to Lucentis

Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 1 Year Results

- Average cost for first year treatment:
  - $23,400 for Lucentis monthly
  - $13,800 for Lucentis PRN
  - $595 for Avastin monthly
  - $385 for Avastin PRN

Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 1 Year Results

- Summary
  - Vision with Lucentis vs. Avastin relatively equal over course of first year
    - Some evidence of more effect with Lucentis on anatomical structure (i.e. greater retinal thickness on OCT, but did NOT correlate with improved visual function)
    - Some hint that less systemic events with Lucentis
    - SIGNIFICANT cost differential

Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 1 Year Results

- 1 year conclusion:
  - Avastin wins most of the time, with select cases benefiting from Lucentis

Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 2 Year Results

- At the end of 2 years, both had similar effects on vision when the dosing regimen was the same
  - Mean gain in acuity, proportion gaining or losing 3 lines, and percentage better than 20/40 were all equivalent
- Mean gain slightly better for monthly vs. PRN by 2.4 letters
- Rates of death from thrombotic events similar
- Adverse events higher with Avastin (39.9%) than Lucentis (31.7%)

Complications of Age-Related Macular Degeneration Treatment Trial (CATT): 2 Year Results

- Geographic Atrophy most in Lucentis monthly, but more in both monthly
- Less fluid at 1 and 2 years with Lucentis
  - Which resulted to 0.6 more injections with Avastin in 2nd year (1.5 more over the whole 2 years)

Avastin or Lucentis?

- A randomized controlled trial of alternative treatments to Inhibit VEGF in Age-related choroidal Neovascularization
  - IVAN Study

IVAN Study

- 1 year
- United Kingdom
- 610 patients
- Avastin vs. Lucentis, monthly vs. PRN
- Looked at:
  - Near visual acuity
  - Reading speed
  - Quality of life
  - Serum samples of VEGF Concentration

IVAN Study: Results

- Final VA was 2 letters in favor of Lucentis
- Monthly vs. PRN difference was negligible
- No real difference in reading speed or quality of life
- Angiographic and topographic findings favored monthly administration
- Serum Concentration lower with Avastin
- Safety relatively the same
- Switching all patients from Lucentis to Avastin would save UK approximately $132 million annually

Eylea

- Eylea (aflibercept)
- Latest anti-Vegf agent for treatment of wet AMD
- Regeneron Pharmaceuticals
- FDA approved November 2011

Eylea

- Approved for:
  - Wet Age-related Macular Degeneration (AMD):
  - Macular Edema following Retinal Vein Occlusion (RVO):
  - Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR) in patients with DME:

Eylea

- View 1 Study:
  - 95% of patients receiving 2 mg every 2 months achieved maintenance of vision vs. 94% with Lucentis monthly
  - 7.9 letter mean improvement of vision (vs. 8.1 with Lucentis monthly)

Eylea

- View 2 Study:
  - 95% of patients receiving 2 mg every 2 months achieved maintenance of vision vs. 94% with Lucentis monthly
  - 8.9 letter mean improvement of vision (versus 9.4 with Lucentis monthly)

Eylea

- Adverse events were minimal with most common conjunctival hemorrhage, eye pain, vitreous floaters, cataract and increase IOP
- System events included falls, pneumonia, myocardial infarction, atrial fibrillation, breast cancer, and acute coronary syndrome (no difference between study arms)

Eylea

- Cost
  - ~$1,850 per injection, with injection every 2 months
  - Therefore ½ of Lucentis monthly

Other Therapies…?

- As of July 2013, there are 936 studies evaluating AMD

FoVista

- Anti-PDGF agent
  - Platelet Derived Growth Factor
- Theory is that when used in conjunction with anti-Vegf agents there will be a synergistic effect
- Ophthotech
  - Currently in Phase III clinical trial

FoVista

- Initial phase 1 trial to show safety
  - 59% had improvement of three lines or more
- Phase 2b study: 449 patients
  - FoVista/Lucentis combination gained 10.6 letters at 24 weeks, versus 6.5 with Lucentis alone
    - -62% additional benefit

FoVista

- First study results were BETTER THAN Lucentis'

- FoSho

ARMD/DNA Connection

- ARMD is a genetic disease with known markers responsible for 70% of the population attributable risk
  - The other 30% is environmental/lifestyle

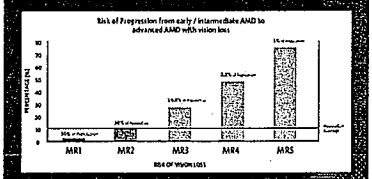
Major Genetic Factors

- Complement H Factor (CHF)
  - Single most important genetic component
  - CHF Y402H
- $ARMS_2/HTRA_1$
  - Second most important gene in ARMD
- C_3
  - Another component of the complement system
- ND_2
  - Mitochondrial oxidative phosphorylation molecule

Macula Risk Score

- The Macula Risk genetic test incorporates all the known genetic predictors of AMD progression
- The test stratifies individuals into 5 risk groups

Macula Risk Score



Those individuals with a Macula Risk score of 1 (MR1) are predicted to have a below average risk of progressing, while those with a MR5 score have over 70% risk of progressive disease. About 20% (MR4/MR5) of the population is predicted to have an elevated risk of AMD progression

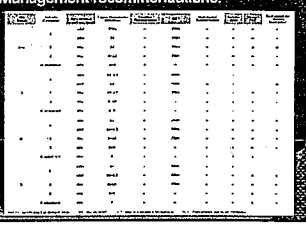
Macula Risk Score

- Macula Risk testing is recommended based on presenting AREDS ARMD score:

AREDS Category	Family History Advanced AMD	Age (years)	Macula Risk Testing
1	-	≤50	-
		>50	
		≤50	
		>50	
2	-	≤50	-
		>50	
3	+	Any	+
4	+	Any	+

Macula Risk Score

- Management recommendations:



VEFG Eye Drops

- ATG3: a topical eye drop for treatment of wet ARMD
  - Phase II trial will enroll 330 patients to receive 2 concentrations of ATG3 bid vs placebo for 48 weeks
- Gate Study by Alcon
  - Phase III study evaluating AL-8309B as topical ocular treatment for geographic atrophy secondary to ARMD

VEGF Eye Drops

- Pazopanib
  - FDA Approved for renal cell carcinoma
  - Treatment for wet ARMD
- OT-551
  - Anti-angiogenic drop being investigated for geographic atrophy
  - Recent study showed it to be ineffective

Oral Fenretinide

- What is Fenretinide?
  - Synthetic Retinoid Derivative
- RetinPhase II study underway for treatment of advance geographic atrophy from ARMD
- Theory is that the medication prevents delivery of retinol to the eye, which reduces retinol derived metabolites (A2E) that are toxic to the RPE and photoreceptors
- 2 year study which is looking primarily at lesion size
  - 300 mg and 100 mg capsules taken once a day after evening meal x 24 months

Oral Fenretinide

- 2009 American Academy of Ophthalmology Meeting
  - At 18 months, lesions in 300 mg group showed 45% less growth than placebo
    - 100 mg looked most protective against growth of small lesion (< disc diameter) 300 mg against all lesions
  - Conversion to wet ARMD occurred less in 100 mg (6%) and 300 mg (7%) groups vs. placebo (13.4%)
  - Granted "fast-track: designation by FDA

Oral Fenretinide

- May 2011 Association for Research in Vision and Ophthalmology (ARVO)
  - 43% patients on 300 mg had decreased lesion size by 60%
  - 30% growth with treatment vs. 50% growth with placebo
  - Loss of 6 letters over 2 years vs. 11 letters with placebo
  - May also reduce incidence of CNVM
    - 22% with placebo vs. 13% with treatment

Copaxone

- Copaxone (glatiramer acetate) is a immunomodulary substance which has been proven to be safe and effective in treating neurodegenerative diseases, such as MS
- Phase II study will investigate if a weekly vaccination can stop the progression as well as conversion of dry to wet ARMD
  - New York Eye and Ear Infirmary

Ciliary Neurotrophic Factor (CNTF) Intraocular Implant: NT-501

- Recent study of patient with geographic atrophy
  - After 12 months, 96.3% of high-dose group had stable vision vs. 75% with sham/placebo
  - Also showed increase in retinal thickness in treated group at 12 months

Stem Cells

- Transplantation of fetal RPE cells has been performed in patients with CNVM and geographic atrophy
- Promising results, but many researchers feel widespread use may be decades away

Radiation

- Beta Radiation with Avastin
  - CABERNET study
  - Looking at combining local application of epiretinal beta radiation with Avastin
    - 1 year: mean improvement of 19 letters with 39% gaining 3 lines or more
    - 67% of patients were stable after initial treatment only
      - 2 injections plus radiation with vitrectomy

Radiation

- MERITAGE Study
  - 53 patients with ARMD that required frequent VEGF injections
  - Pars Plana Vitrectomy with single 24-GY dose fEMB (epimacuar brachytherapy)

Radiation

- Results
  - After 1 treatment, 81% had stable vision
  - Mean of 3.29 treatments in 12 months
    - On average 12.5 injections prior to study
  - Mean change in acuity: -4.0 letters
  - Mean OCT CRT increased by 50 microns
  - Stable VA in most patients and may reduce the need for frequent treatments

Others

- Effect of Saffron Supplementation on ARMD
- Transcorneal Electrical Stimulation Therapy for Retinal Disease
- Effect of Lutein-Enriched-Egg Beverage on ARMD

Implantable Miniature Telescope (IMT)

- FDA Approved July 2010 for patients with end-stage ARMD
- Two Models
  - 2.2x
  - 2.7x

Implantable Miniature Telescope (IMT)

- Study
  - 219 patients
    - 75% improved from severe or profound impairment to moderate impairment
    - Average visual acuity improvement: 2 lines
  - Complications
    - Corneal Edema (9.2%)
    - Corneal Decompensation (6.9%)
    - Corneal Transplant (4.1%)

Macular Degeneration

- As stated before….
  - There is still quite a ways to go
  - As of 9/3/2015, # of trials returned on a search for "Macular Degeneration" on clinicaltrials.gov…?

1,212

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Joseph A. Pruitt, O.D., M.B.A., FAAO

Objective:

Education:

Nova Southeastern University, Fort Lauderdale-Davie, Florida — 2008-2011
Master of Business Administration, 2011

West Los Angeles Veteran Affairs Healthcare Center, Los Angeles, California — 2007-2008
Residency Certificate, Geriatric/Primary Care, 2008

Illinois College of Optometry, Chicago, Illinois — 2003-2007
Doctor of Optometry, 2007

California State Polytechnic University, Pomona, California — 2000-2003
Bachelor of Science, Biology, 2003

University of Memphis, Memphis, Tennessee — 1999-2000
Major in Biology

Licenses:

Tennessee #2753 — Date of Issue: July 10, 2007
- Active
- Injectible Certification
- Therapeutic Certification

California #13429T — Date of Issue: Sept. 28, 2007
- Active
- Therapeutic and Pharmaceutical Agent + Lacrimal Irrigation and Dilation + Glaucoma (TLG) Certified

Georgia #OPT002454 — Date of Issue: June 12, 2008
- Active
- Diagnostic and Therapeutic Pharmaceutical Agent Certified

Minnesota #3130 — Date of Issue: June 17, 2008
- Active
- Diagnostic Pharmaceutical Agent (DPA) Certified
- Therapeutic Pharmaceutical Agent (TPA) Certified

Board Certification:

American Board of Certification in Medical Optometry — Date of recertification: Feb 2018
- Board certified

Certifications:

Drug Enforcement Agency (DEA) Certified — Date of Expiration: Mar 2020

Cardiopulmonary Resuscitation (CPR) & Automated External Defibrillator (AED) — Recommended Renewal: Mar 2017

Bausch & Lomb Overnight Orthokeratology — Date of Issue/Completion: April 6, 2006
- Certification Number: 20060406002

Paragon Corneal Refractive Therapy (CRT) — Date of Issue/Completion: Dec. 28, 2007
- Certification Number: 161000

Advance Competence in Medical Optometry (ACMO) — Date Taken: June 13, 2008
- Administered by the National Board of Examiners in Optometry (NBEO)
- Examination only made available to candidates meeting specific clinical experience requirements/pre-requisites
- Passed examination

Employment:

Riverside San Bernardino County Indian Health, Inc (RSBCIHI) — Oct. 2014- present
- Director of Eye Care
- Staff Optometrist

Riverside San Bernardino County Indian Health, Inc (RSBCIHI) — July 2014- Oct. 2014
- Staff Optometrist

Minneapolis Veteran Affairs Health Care System — Nov 2008- June 2014
- Low Vision/Staff Optometrist
- Optometric Residency Coordinator
  - Spearheaded and implemented program
- Student Externship Coordinator
  - Spearheaded and implemented program

Wal-Mart Vision Center (Red Wing & Rochester, MN) — Jul 2008- Nov 2008
- Associate Optometrist

EyExam of California — Oct 2007- June 2008
- On-call/Fill-in Optometrist

Faculty Appointments:

Western University of Health Science / College of Optometry, Pomona, California — Jan 2015 - present
- Clinical Assistant Professor of Optometry
- RSBCIHI Externship Site Program Director
  - As part of being RSBCIHI Eye Care Director

University of the Incarnate Word-Rosenberg School of Optometry, San Antonio, Texas — May 2012- June 2014
- Clinical Assistant Professor
- Minneapolis VA HCS Externship Site Program Director

Midwestern University-Arizona College of Optometry, Glendale, Arizona — May 2012- June 2014
- Adjunct Clinical Assistant Professor
- Minneapolis VA HCS Externship Site Program Director

Southern College of Optometry, Memphis, Tennessee — Dec 2010- June 2014
- Adjunct Faculty
- Minneapolis VA HCS Externship Site Program Director

University of Missouri, St. Louis College of Optometry, St. Louis, Missouri — Jul 2009- June 2014
- Adjunct Assistant Professor
- Minneapolis VA HCS Externship Site Program Director

Experience:

Riverside-San Bernardino Indian Health, Inc — Oct 2014 - present
- Director of Eye Care
  - Oversee all organizational Eye Care activities

- Staff Optometrist

Riverside-San Bernardino Indian Health, Inc — Jul 2014 – Oct 2014
- Staff Optometrist

Minneapolis Veteran Affairs Medical Center — Nov 2008- June 2014
- Staff Optometrist
  - Primary Eye Care
  - Low Vision
    - Sole low vision eye care provider
  - Polytrauma/Traumatic Brain Injury (TBI) Ocular Health & Vision Assessments

- VISN 23 Low Vision Continuum of Care Conference (May 2009)
  - Faculty
  - Planning committee

- Established Associated Health Education Affiliation Agreement with University of Missouri, St. Louis College of Optometry, Ferris State University Michigan College of Optometry, & Southern College of Optometry for the optometric externship program
  - Externship program director

- Established Associated Health Education Affiliation Agreement with the Illinois College of Optometry for the optometry residency program
  - Residency in Primary Care/Brain Injury and Vision Rehabilitation
  - Residency program director
    - Designed the program's curriculum
    - Secured all necessary approvals and funding
    - After the initial site visit, program received full ACOE accreditation

Wal-Mart Vision Center (Red Wing & Rochester, MN) — Jul 2008- Nov 2008
- Associate Optometrist

Residency:

West Los Angeles Veteran Affairs Healthcare Center — Jul 2007- June 2008
- Geriatrics/Primary Care
  - Primary Care including Diabetic exams
  - Low Vision evaluations/exams
  - Nursing home/in-patient exams
  - Medically justified specialty contact lenses exams/fittings
  - Lecture Internal Medicine's and Endocrinology's Residents & Interns on Diabetic Retinopathy
    - Given during Chief Resident rotation
  - Precept Southern California College of Optometry's interns

Optometric Externships:

Atlantic Eye Institute, Jacksonville Beach, FL — Feb-May 2007
- OD/MD private practice with an emphasis on Contact Lenses and Primary Care
- Observed multiple surgical procedures:
  - Cataract Extraction
  - Blepharoplasty
  - Strabismus recession and resection

Memphis Veterans Affairs Medical Center (VAMC), Memphis, TN — Nov 2006-Feb 2007
- Emphasis on Primary Care
- Assisted in direct care in a high patient volume

medical optometric eye clinic
- Assisted in optometric injections and fluorescence angiographies procedures

Illinois Eye Institute (IEI), Chicago, IL — Aug-Nov 2006
- Emphasis on Pediatrics/Binocular Vision, Advance Care, and Low Vision
- Performed comprehensive eye exams on pediatric patients (infants-11yrs of age)
- Performed comprehensive eye exams on "at risk/2nd chance" children one day a week at Maryville Academy
- Constructed, tailored and performed successful binocular vision/vision therapy treatments to 4 children over a 10 week period
- Assisted in the treatment of advance glaucoma with attending University of Chicago ophthalmologist
- Performed problem specific examinations one day per week in IEI's Emergency/Urgent Care/Walk-in clinic
- Performed full Low Vision examinations including Low Vision device selection and training

Body of Christ Optometry Clinic, Tegucigalpa, Honduras — May-Aug 2006
- Emphasis on Primary and Advance Care
- Performed full-scope optometric care in a high patient volume medical clinic geared towards the underprivileged
- Also worked closely with a local ophthalmologist
  - Observed and assisted in Cataract Extraction and Incision and Curettage procedures
  - Provided pre and post-surgical care

Primary Care Clinical Education
Illinois Eye Institute, Chicago, IL — Aug 2005-May 2006

Volunteer Optometric Assistant
Body of Christ Optometry Clinic, Tegucigalpa, Honduras — Jun-Aug 2004
- Assisted staff optometrist in direct patient care in the clinic and multiple remote satellite outreach locations

Professional Affiliations/Memberships:
- Accreditation Council on Optometric Education
  - Consultant, 2014-present
- American Academy of Optometry (AAO)
  - Fellow; Class of 2009
- American Optometric Association (AOA)
- Armed Forces Optometric Society (AFOS)
- European Academy of Optometry and Optics (EAOO)
  - Candidate for Fellowship
- Fellowship of Christian Optometrists (FCO)
- Minneapolis VAMC Medical Staff Association
  - Steering Committee, member 2010-2014
- National Association of Veteran Affairs Optometrists (NAVAO)
  - Newsletter Committee, member 2010-2014
- National Optometric Association (NOA)
  - Minnesota's NOA State Representative 2010-2012
  - National Optometric Student Association (NOSA)
    - NOSA National Vice-President: 2006-2007
    - NOSA-ICO President: 2005-2006
    - NOSA-ICO Vice-President: 2004-2005

- Volunteer Optometric Service to Humanity (VOSH)
- Journal of Rehabilitation Research and Development
  - Peer Reviewer, 2013-2014

Activities:

- VOSH Medical Mission Trip, Bamenda, Cameroon (May 2010)
- Mayo Medical School/Brighter Tomorrow's Winter Warmth Festival (Jan 2009 & Jan 2010)
  - Fun day of activities for children battling cancer and their families
  - Volunteer
- Veteran Affairs Disaster Emergency Medical Personnel System (DEMPS)
  - Volunteer (Aug 2009-present)
- FCO Optometry Mission Trip, Port Au Prince, Haiti (Feb 2007)
- SVOSH Medical Mission Trip, Addis Addaba, Ethiopia (Mar-Apr 2006)
- FCO Optometry Mission Trip, Tegucigalpa, Honduras (Apr 2003 & Nov 2004)

Honors/Rewards:

- Recognition of Excellence in Teaching as Clinical Assistant Professor, Western University Health Sciences/College of Optometry (2015-2016 Academic Year)
- Nomination for Medical Staff Clinical Excellence Award (2012 & 2013)
- Recognition for Outstanding Dedication and Service as Adjunct Assistant Professor, University of Missouri – St. Louis (2010-2011 Academic Year)
- Journal of the American Optometric Association: Optometry's Eagle Award (Nov 2010)
- Certificate of Appreciation (July 2009)
  - Department of Veterans Affairs – VISN 23
    - Awarded for participation in VISN 23 Blind and Low Vision Continuum of Care Conference
- Recognition for Clinical Excellence (May 2007)
- Derald Taylor Low Vision Award (May 2007)
- Clinical Dean's List (summer 2005; summer & fall 2006, winter & spring 2007)
- Academic Dean's List (fall 2004)
- Wildermuth Leadership Award/Scholarship (Aug 2006)
- Vistakon Acuvue Eye Health Advisor Citizenship Scholarship (Jan 2006)
- NOSA Service Award/Scholarship (Aug 2004)

Publications:

Pruitt JA. The Management of Homonymous Hemianopsia Secondary to Hemispheric Ischemic Cerebral Vascular Accident. Accepted for publication by Review Optometry (July 2010)

Rittenbach TL, Pruitt JA. A Roundup of Recently Approved Ophthalmic Drugs (and their Use in Practice.) Rev Optom. 2014. 151(2):22-28.

Pruitt JA. Management strategies for patients with AION. Rev Optom. 2011. 148(6):57-65.

Pruitt JA. Neuro-Optometric Rehabilitation Association Program Summary. Optimum VA: The Official Newsletter of the National Association of VA Optometrists Summer 2010.

Pruitt JA, Ilsen P. On the frontline: What an optometrist needs to know about myasthenia gravis. Optometry 81(9): 454-460.

Pruitt JA, Sokol T, Maino D. Fragile X Syndrome and the Fragile X-associated Tremor/Ataxia Syndrome. Eye Care Review: Ophthalmology, Optometry, Opticianry 4(2): 17-23

Posters/Presentations

Pruitt JA. The Curious Case of the Functionally Legally Blind Patient with 20/25 (6/7.5) Visual Acuity. *Accepted into American Optometric Association Annual Meeting: Optometry's Meeting (2012) Poster Session.*

Pruitt JA, Prussing N. Successfully Treated Horizontal Diplopia Returns with Subsequent Traumatic Brain Injury. *Accepted into American Optometric Association Annual Meeting: Optometry's Meeting (2012) Poster Session.*

Pruitt JA, Prussing N. The Curious Case of the Functionally Legally Blind Patient with 20/25 (6/7.5) Visual Acuity. European Academy of Optometry and Optics Annual Meeting (2012) Poster Session.

Pruitt JA, Prussing N. Successfully Treated Horizontal Diplopia Returns with Subsequent Traumatic Brain Injury. European Academy of Optometry and Optics Annual Meeting (2012) Case Presentation Session.

Pruitt JA, Prussing N. Traumatic Brain Injury Resulting in Horizontal Diplopia Resolved 5 Years Later with 12 Weeks of Vision Therapy. Minnesota Optometric Association Annual Meeting (2012) Poster Session.

Pruitt JA, Wiley LM. Overcoming Mental Barriers in Visual Rehabilitation. American Optometric Association Annual Meeting: Optometry's Meeting (2011) Poster Session.

Pruitt JA, Prussing N. Traumatic Brain Injury Resulting in Horizontal Diplopia Resolved 5 Years Later with 12 Weeks of Vision Therapy. European Academy of Optometry and Optics Annual Meeting (2011) Poster Session.

Pruitt JA. Overcoming Mental Barriers in Visual Rehabilitation. European Academy of Optometry and Optics Annual Meeting (2011) Case Presentation Session.

Pruitt JA, Wiley LM. Overcoming Mental Barriers in Visual Rehabilitation. Minnesota Optometric Association Annual Meeting's (2011) Poster Session

Pruitt JA, Ilsen P, Yeung C. Ptosis Crutch: Success Treating Myogenic Ptosis Secondary to Myasthenia Gravis. American Optometric Association (AOA) 2008 Optometry Meeting Poster Session

Pruitt JA, Ilsen P. Ptosis Crutch: Success Treating Myogenic Ptosis Secondary To Myasthenia Gravis. Southeastern Congress of Optometry (SECO) 2008 Multimedia Poster Session

Lectures and Other:

Riverside-San Bernardino County Indian Health, Inc.: Eye Care Rounds (Nov 2016)
- Ptosis Crutch: Success Treating Myogenic Ptosis Secndary to Myasthenia Gravis
- CA Board of Optometry-approved CE

Riverside-San Bernardino County Indian Health, Inc.: Eye Care Rounds (Sept 2016)
- Visual Fields
- CA Board of Optometry-approved CE

Riverside-San Bernardino County Indian Health, Inc.: Eye Care Rounds (July 2016)
- Ethical Concerns with Short-term Mission Trips
- CA Board of Optometry-approved CE

Riverside-San Bernardino County Indian Health, Inc.: Eye Care Rounds (July 2016)
- Systemic Urgencies and Emergencies
- CA Board of Optometry-approved CE

Riverside-San Bernardino County Indian Health, Inc.: Eye Care Rounds (Mar 2016)
- Episcleritis, Scleritis, and Iritis
- CA Board of Optometry-approved CE

Illinois College of Optometry: Practice Opportunities Symposium (Mar 2011)
- Represented and presented on VA Optometry
- Participated in panel discussion on "Residency-trained Optometrists"

University of Minnesota: Pre-Optometry Club (Oct. 2010)

- Presentation on the profession of Optometry
- Presented and represented VA Optometry and NOA

Illinois College of Optometry: Capstone Ceremony (May 2010)

- Represented and presented on VA Optometry

Illinois College of Optometry: Practice Opportunities Symposium (Mar 2010)

- Participant in Residency-trained Speaker's Panel
- Represented and presented on VA Optometry

Illinois College of Optometry: White Coat Ceremony/Smart Business Program (Sept 2009)

- Participant on Recent Graduate Speaker's Panel