Optometric Best Practices
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What Happens in the Dark
Early Detection of AMD

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Disclosures
Speaker’s Bureau for:
- Alcon
- Diopsys
- Heidelberg
- MacuLogix
- Optos
- Reichert
- Zeavision

Objectives
Discuss the AMD landscape and gaps in AMD diagnosis
Discuss current management of AMD patients and
unnecessary vision loss
Establish dark adaptation as an indicator of early and
subclinical AMD, and highlight capabilities of AdaptDx®
Explore role of AdaptDx in AMD management, practice
integration models, and ROI
Large Unmet Need

**Prevalence of AMD**
- 9.2 million Americans
- 7 out of every 100 adults over 40 years old
- 1 out of every 7 adults over 60 years old
- 1 out of every 3 adults over 75 years old

**Prevalence of diabetic retinopathy**
- 4.9 million Americans
- 3 out of every 100 adults over 40 years old

**Prevalence of glaucoma**
- 2.7 million Americans
- 2 out of every 100 adults over 40 years old


Gap in Diagnosis of AMD

**Normal**

**Early/Dry AMD**

**Late/Wet AMD**

- Up to 78% of AMD patients have irreversible vision loss at first diagnosis, including 37% who are legally blind in at least one eye
- Early AMD is not adequately detected by current methods


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Call for Early Diagnosis

David Brown, MD, FACS
Retina Consultants of Houston

“Many AMD patients are arriving at our practice with unnecessary vision loss. Ideally these patients would see their primary eye physician and be diagnosed earlier.”

Available Interventions Prior to Advanced AMD
- AREDS2 nutritional supplements lower risk of progression by 25%
- Behavior modification also lowers risk of progression

Available Interventions for Choroidal Neovascularization (CNV)
- Prompt anti-VEGF therapy can save up to 5 lines of visual acuity
- Dramatic loss can occur in as little as 8 weeks

VEGF, vascular endothelial growth factor

Preventing Unnecessary Vision Loss

Available Interventions Prior to Advanced AMD
- AREDS2 nutritional supplements lower risk of progression by 25%
- Behavior modification also lowers risk of progression

AMD Pathogenesis

- Cholesterol accumulation leads to panmacular deposits (Blind and BlinD)
- Peaks in these deposits eventually become clinically visible drusen
- These extracellular cholesterol deposits affect photoreceptor health, causing inflammation and predisposing to CNV
- In addition, they impair normal transport, including that of vitamin A, across Bruch’s membrane

ROLE OF DARK ADAPTATION IN AMD

In effect, AMD causes a localized deficiency of vitamin A, and dark adaptation is the best test to measure this change.

Dark adaptation is the process of adjusting from day vision to night vision.

Easy-to-measure aspect of night vision.

First Symptom of AMD

- Night vision impacted in early disease: 20+ studies
- AMD patients often give up driving at night
- Night vision is impaired before day vision
- Difficult to determine whether night vision is impaired because of AMD or aging

ADAPTDX® OVERVIEW

First dark adaptometer for rapid, routine clinical use

Simple, objective tool to measure dark adaptation as earliest functional correlate of macular dystrophies

Two clinical protocols
- ≤6.5-minute rapid test (for quick assessment)
- ≤20-minute extended test (for benchmarking)

How AdaptDx® Works

Simple, noninvasive test performed in-office by ophthalmic technician

While continuously focusing on fixation light, patient is exposed to a mild bleaching flash and asked to indicate when a progressively dimmer stimulus light appears (randomly timed).
How AdaptDx® Works

Dark Adaptation

Dark Adaptation Is a Major Impairment in AMD

AdaptDx® Diagnostic Study

AdaptDx® Diagnostic Study Results

How Good Is 90%?

- Patients classified as having AMD if dark adaptation >6.5 minutes
- High sensitivity: correctly identified 90.6% of confirmed AMD cases
- High specificity: correctly identified 90.5% of confirmed normal cases
- High overall accuracy of 90.6%
- AMD cases exhibit no rod recovery of dark adaptation
- AdaptDx rapid test – ideal for routine clinical use

Multisite study
Sample consisted of 127 AMD patients and 21 normal adults
Clinical diagnosis confirmed by retina specialist grading fundus photographs

Visual field testing to detect glaucoma is 83% sensitive and 95% specific

Retina specialists using slit lamps to detect AMD are 82% sensitive and 91% specific
Clinically Validated at Leading Institutions

Example of an AdaptDx® Report

Case 1: AMD
- 75 Year old female
- 20/25 OU
- No AMD family Hx
- Nonsmoker
- Large soft drusen
- OCT findings of drusen
- Abnormal dark adaptation

Case 2: Subclinical AMD
- 65 Year old female
- 20/20 OU
- No AMD family Hx
- Nonsmoker
- Subtle drusen
- Unremarkable OCT
- Abnormal dark adaptation

Dark Adaptation Is NOT a Risk Factor for AMD

Genetic testing and macular pigment density (MPOD) can indicate a heightened risk for developing AMD, but neither indicates the actual presence of disease.

Impaired dark adaptation is NOT a risk factor. It is the earliest manifestation of disease.

AdaptDx® Advantages
- No prior adaptation required
- Low patient burden
- Short test duration
- Automated analysis
- Objective output (rod intercept)
- CPT 92284 ($63 avg)
- FDA 510K cleared (K100954)
WHAT DOES A POSITIVE ADAPTDX® TEST MEAN?

Case Example With Positive AdaptDx® Report

You have implemented AdaptDx in your practice and test a patient who has impaired dark adaptation.

NOW WHAT?

What Does a Positive AdaptDx® Report Mean?

Look at the patient’s other characteristics with imaging tools:
1. Are there drusen?
2. Are there pigmentary changes including geographic atrophy?
3. Is there evidence of choroidal neovascularization?

Other characteristics of AMD

No other characteristics of AMD

AMD Patient

Subclinical AMD Patient

AMD Patient – Treatment Protocol

Examination: annual, semi-annual, or more frequent dilated exams (depending on AMD severity)

Testing: BCVA, biomicroscopy, macular function assessment (such as dark adaptation), imaging (fundus photos or other), PHP (preferential hyperacuity perimetry), pERG

Management: consider anti-oxidant supplementation & UV protection, provide counseling on behavior, Amsler grid, PHP (preferential hyperacuity perimetry), pERG

Referral: immediate consultation with retina specialist upon clinical signs or symptoms of choroidal neovascularization


Subclinical AMD Patient – Treatment Protocol

Examination: monitor as appropriate depending on risk factors (age, family history, smoking, weight, genetics)

Testing: BCVA, biomicroscopy, macular function assessment (such as dark adaptation), imaging (fundus photos, OCT), pERG

Management: consider nutraceutical supplementation & UV protection, provide counseling on behavior (diet/exercise)

Co-Manage as Appropriate

Optometrist or General Ophthalmologist

Retina Specialist
PRACTICE INTEGRATION MODELS

Clinical Utilization Case #1

Multispecialty optometry practice

- Insurance reimbursement only
- Primarily tests known AMD patients to benchmark impairment
- Tests night vision complaints to differentiate cataract from AMD

Rapid Test to discriminate night vision impairment due to cataract vs retinal pathology

• Extended Test on both eyes to benchmark dark adaptation time that can be tracked from visit to visit
• Determine patient management program based on results of testing (e.g., quarterly, semi-annual, or annual appointment schedule)

ROI: Conservative use based on known pathologies provides positive investment return with less than 1 test per day

Cataract vs AMD
AMD benchmark testing
Dedicated testing visit

Clinical Utilization Case #2

Two optometrists, comprehensive practice

- Patient-payer initial testing at future dedicated visit with follow-on insurance visits
  - $65 dark adaptation test offered to patients meeting risk profile (over 50, family history of AMD, smoker, overweight, poor night vision, etc)
- 30% decline testing 90% elect to pay for testing

Patients can be asked again at next visit
Previously undiagnosed AMD is discovered in 25% of these patients

ROI: Patients that used to be worth $80 every 18 months are now worth $660 every year. Nutritional sales increased 65% year over year.

Clinical Utilization Case #3

High-volume refractive surgery/cataract practice; multiple ODs/MDs

- Patient-payer initial testing during current visit with follow-on insurance visits
  - $65 dark adaptation test offered to patients meeting risk profile (over 50, family history of AMD, smoker, overweight, poor night vision, etc)
- 40% decline testing 60% elect to pay for testing

Patients can be asked again at next visit

ROI: Practice is generating over $100,000 per year of new revenue from AdaptDx® (including ancillary testing such as OCT and nutritional sales triggered by AdaptDx findings) vs $34,700 AdaptDx list price

OCT, optical coherence tomography

Clinical Utilization: My Practice

Two optometrists, comprehensive practice

- Insurance reimbursement or patient pay if HMO/uninsured
  - Primarily tests known AMD patients to benchmark impairment
  - Tests symptomatic to differentiate early AMD from all other conditions

Other conditions vs sub-clinical AMD

AMC benchmark testing

Dedicated testing visit

Rapid Test to discriminate night vision impairment due to cataract vs retinal pathology

ROI: If AMD is detected early, there are effective interventions that can preserve vision and improve quality of life


Clinical Utilization: My Practice

Two optometrists, comprehensive practice

- Primary tests known AMD patients to benchmark impairment
- Tests symptomatic to differentiate early AMD from all other conditions

Other conditions vs sub-clinical AMD

AMC benchmark testing

Dedicated testing visit

Rapid Test to discriminate night vision impairment due to cataract vs retinal pathology

ROI: An AMD patient is estimated to add from $350 to $600 per year to practice revenue

Good for your practice
• An AMD patient is estimated to add from $350 to $600 per year to practice revenue

How AMD Diagnosis Changes Your Practice
**Proactive Testing Model**

**Initial Assessment**
- AdaptDx Rapid Test based on risk factors
- Discovery of previously undiagnosed early and subclinical AMD
- Benchmark characterization - AdaptDx Extended Test imaging

**Subsequent Management**
- Increased exam frequency (as appropriate) with follow-up testing - AdaptDx Extended Test imaging, etc.
- Early AMD: ICD-9 365.11 - dry AMD
- Subclinical AMD: ICD-9 368.63 - abnormal dark adaptation
- Recommend initiation of nutraceuticals as appropriate

**Return on Investment Calculator**

Enter number of doctors in practice who will use AdaptDx:
1
Enter practice volume (patients per doctor per week):
50

**Practice Volume** | **Total ROI (annual)**
---|---
25 | $33,009
50 | $66,018
75 | $99,027
100 | $132,036

During a typical week, initial testing will be conducted on 13 patients which will find 1.6 new AMD patients.
Total new yearly revenue to the practice is **$66,018**.
Yearly additional revenue from initial AdaptDx testing is **$43,940**.
Yearly additional revenue from semi-annual visits is **$8,896**.
Yearly additional revenue from supplement sales is **$13,182**.
Total yearly revenue from each AMD patient is **$727** not including retail vision.

**Key Takeaways**

**AMD is a highly prevalent condition that causes preventable vision loss**

Proactive detection and management of early and subclinical AMD can transform a practice and ensure better patient outcomes

AdaptDx® can help preserve vision and improve quality of life

**Cases: EG**

- 76yo WM with Hx of macular hole/epiretinal membrane
- 20/40 OD, 20/20 OS BCVA
- Sx's of decreasing vision at night
- Active bowler; needs to maintain sharp VA
- OCT stable OD, negative OS

**Case EG**
Cases: JG

- 67yo WM with Hx of macular drusen
- 20/15 BCVA OU
- Monitored q3-6mos pERG & PHP with no changes over 3 years
- Taking Eyepromise Restore 2 tabs PO QD
- Do I need to monitor so often???

Cases: WK

- 71yo WM with Hx of peripheral drusen
- 20/20 BCVA OU
- Family Hx of AMD with Mother and Sister
- HTN med only
- Genetic testing shows MR1, 75% Genetic Lifetime Risk, AREDS without zinc recommendation

Cases: PS

- 67yo male Pacific Islander with Hx of macular drusen
- Negative family Hx of AMD
- Lipitor med only for Hypercholesterolemia
- pERG function mild decrease magnitude OD, normal sinusoidal curve OU
- No signs of choroidal neovascularization on OCT OU
- BCVA down-2014 noting cataracts 20/60 OD, 20/40 OS
- Successful cataract extraction OU 20/20 OD, 20/25 OS
- Genetic testing shows MR2, 34% Genetic Lifetime Risk, AREDS without zinc recommendation
Coding/billing
Structure/Function

- Fundus imaging/Auto-fluorescence - 92250 - $83.04
- OCT - 92132, 92133, 92134 - $44.76 - $45.88
- PHP - 92083 - $69.13
- Microperimetry - 92083 - $69.13
- pERG - 92275 - $168.59
- Dark adaptation - 92284 - $64.80
- Genetic Testing - No CPT $50 co-pay if insured

THANK YOU!