The AdaptDx Dark Adaptometer — Enabling Earlier Detection of AMD and Better Outcomes for AMD Patients

Diagnosing AMD in its most premature state and managing disease progression

Introduction

Age-related macular degeneration (AMD) is a progressive retinal disease and the leading cause of adult blindness in developed countries. In Europe alone, it is predicted that up to 21.5 million people will be diagnosed with AMD by 2040.[1] Despite the staggering prevalence, eye care professionals are failing to diagnose the disease 25% of the time.[2] Without early detection and proactive monitoring of disease, AMD can quickly and unexpectedly progress to advanced stages of the disease.

Unfortunately, diagnosing AMD at the earliest stages can be a challenge. Patients are often asymptomatic, have good corrected visual acuity, and their retina appears normal upon clinical evaluation. However, research has shown that functional assessment of dark adaptation can improve diagnostic abilities and enable clinicians to intervene before irreversible vision loss occurs.[3]

Much like glaucoma, functional changes are present in AMD prior to clinical presentation of the condition. Often presented as problems driving or reading at night, dark adaptation impairment is evident from the earliest stages of AMD and worsens as the disease progresses.[3] Considering this biomarker[4] is compromised at least three years before structural changes in the macula are observed via clinical examination and imaging, assessing dark adaptation function can be invaluable in detecting AMD in its earliest stages.

'Impaired dark adaptation identifies subclinical AMD at least three years before it can be seen with imaging, OCT or clinical exam. '[3]

Paving the Road to Improved Outcomes

ALSTAR Study

Led by Cynthia Owsley, PhD, researchers at the University of Alabama at Birmingham School of Medicine conducted the Alabama Study on Early Age-Related Macular Degeneration (ALSTAR) to investigate age-related eye disease. A landmark prospective study published in *Ophthalmology,* ALSTAR explored the relationship between dark adaptation and AMD using the AdaptDx automated dark adaptometer (MacuLogix, USA).

The study followed 325 individuals 60 years of age or older with normal retinal health at baseline, as assessed by clinical evaluation and fundus photography, using the AREDS severity classification system. Albeit seeming structurally sound, 24% of them had prolonged dark adaptation times. Three years later, these individuals were twice as likely as those with normal dark adaption results to have AMD and eight times more likely to have advanced beyond the earliest stage of the condition.[3] This ground-breaking study demonstrated that dark adaptation impairment indicates presence of the disease at least three years before structural changes are visible. Subsequent studies confirmed that, indeed, dark adaptation impairment is a biomarker for AMD.[4] Taken as a whole, these results demonstrate that dark adaptation is clinically useful to identify the earliest stages of the disease, when risk reduction strategies are most effective.

The MACUSTAR Study

The first exclusively eye-disease-focused project funded by the Innovative Medicines Initiative (IMI), the MACUSTAR study aims to develop and identify testing options that will lead to future treatments for dry AMD. To achieve this goal, the project is focused on developing clinical endpoints for interventional research for exploring potential treatment options. Additional objectives are to characterize the functional deficit in intermediate AMD (iAMD) and to develop and validate functional, structural, and patient-reported outcome measures for iAMD, as well as identify risk factors for progression to late-stage AMD.[5]

AdaptDx will be used as the functional assessment device for the five-year investigation, which will recruit 750 patients in seven countries across Europe. Coordinated by the University of Bonn, one part of the study concentrates on exploring the different stages of AMD (no AMD, early, intermediate, and late), while the second part examines the progression from intermediate AMD to late-stage AMD against the functional, morphological, and patient-reported changes.

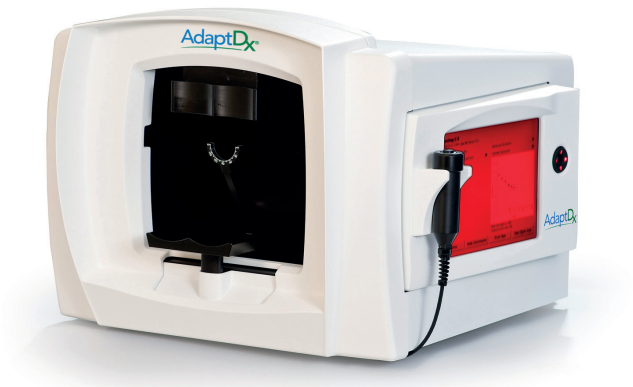
Using the combination of testing modalities to include functional testing is expected to lead to better understanding of this chronic, progressive disease and aid the development of effective treatments for early to intermediate AMD.

AdaptDx® Dark Adaptometer

AdaptDx is a device once developed for clinical investigation to measure the time it takes for eyes to adapt from bright light to darkness, the Rod Intercept™ (RI™). The Rod Intercept provides an objective assessment of retinal function that clearly identifies dark adaptation impairment and makes it possible to monitor disease progression. The simple, automated results generated by the AdaptDx are 90% specific and sensitive to AMD.[6] Unlike traditional dark adaptation testing, the AdaptDx Rapid Test takes less than 6.5 minutes, making it an ideal tool for both investigative use and clinical practice.

Recently launched in the European Union, this instrument can easily be integrated into a clinical workflow to complement structural retinal evaluations and aid early detection of AMD. Detection of pathophysiological abnormalities enables timely intervention, thus increasing the chances of preserving vision and either preventing or delaying advancement to choroidal neovascularization (CNV).

If early intervention is possible, should we not try to detect AMD before vision loss occurs?



AdaptDx® Dark Adaptometer (MacuLogix)

The only objective test for measuring dark adaptation quickly and effectively in a clinical setting.

Conclusion

Understanding structure-function relationships is crucially important in diagnosing and treating AMD. In addition to clinical evaluations, complementing structural imaging with functional dark adaptation assessments helps safeguard against failure to catch clinically detectable AMD. With impaired dark adaptation recognized as an accurate biomarker of AMD pathology, implementing this functional testing should be considered standard of care for detecting and monitoring this disease.

Integration of AdaptDx dark adaptometer into clinical practice expands diagnostic capabilities to accurately detect and effectively manage AMD. With a promising future, adoption of the technology has great potential to improve patient care and clinical outcomes.

Find out how you can help save your patient's vision.

Contact communications@medeuronet.com.

What Experts Say about the AdaptDx Dark Adaptometer

"In my practice I use the AdaptDx to perform an objective assessment of a patient's ability to dark adapt in less than 6.5 minutes. Dark adaptation testing can now be integrated into the clinical setting to quickly and easily assess AMD suspects who present with multiple risk factors and/or a night vision complaint.

Professor Franceso Bandello, MD
University VitaSalute, Scientific Institute San Raffaele
Milan, Italy

"The main advantage of the AdaptDx is its ability to detect early functional impairment in patients whose macula appears anatomically normal."

"In my experience, measuring DA impairment is most useful as a tool to help determine AMD severity, even in eyes that appear to have minor damage. We also use DA to differentiate between subtypes of intermediate AMD; it is a useful way to further characterize phenotypes.

Professor Jordi Monés, MD PhD
Institut de la Màcula
Barcelona Macula Foundation
Barcelona, Spain

"Measuring dark adaptation as a functional test of retinal health (in combination with fundus photography and OCT) to assess a patient's risk for developing AMD could also improve how ophthalmologists approach the condition.

Professor Michael Larsen, MD
Københavns Universitet
Copenhagen, Denmark

> *The device can aid the diagnosis of early stage or subclinical AMD before vision loss occurs, even before structural changes are observed, and adds to the information obtained from retina cameras and OCT imaging.*

Professor David Gaucher, MD
Université de Strasbourg
Nouvel Hôpital Civil Pôle
Strasbourg, France

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