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Monitoring of the fellow eye in nAMD

Based on Vision Academy publication: Wong TY *et al.* Current concepts and modalities for monitoring the fellow eye in neovascular age-related macular degeneration: an expert panel consensus. *Retina* 2020; 40: 599–611.

nAMD, neovascular age-related macular degeneration.

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Objectives

To review the rationale for fellow-eye monitoring in at-risk patients with unilateral nAMD

To provide an overview of the advantages and limitations of current clinic- and home-based detection methods for fellow-eye monitoring

To present Vision Academy guidance on monitoring patients with unilateral nAMD

The Vision Academy provides ophthalmic specialists with a forum to share existing skills and knowledge, build best practice, and lead the wider community in the drive towards optimized, compassionate patient care.

Through their collective expertise, the Vision Academy seeks to provide guidance for best clinical practice in the management of retinal disease, particularly in areas with insufficient conclusive evidence.

?

QUESTION

What is the rationale for monitoring the fellow eyes of patients with unilateral nAMD?

nAMD, neovascular age-related macular degeneration.

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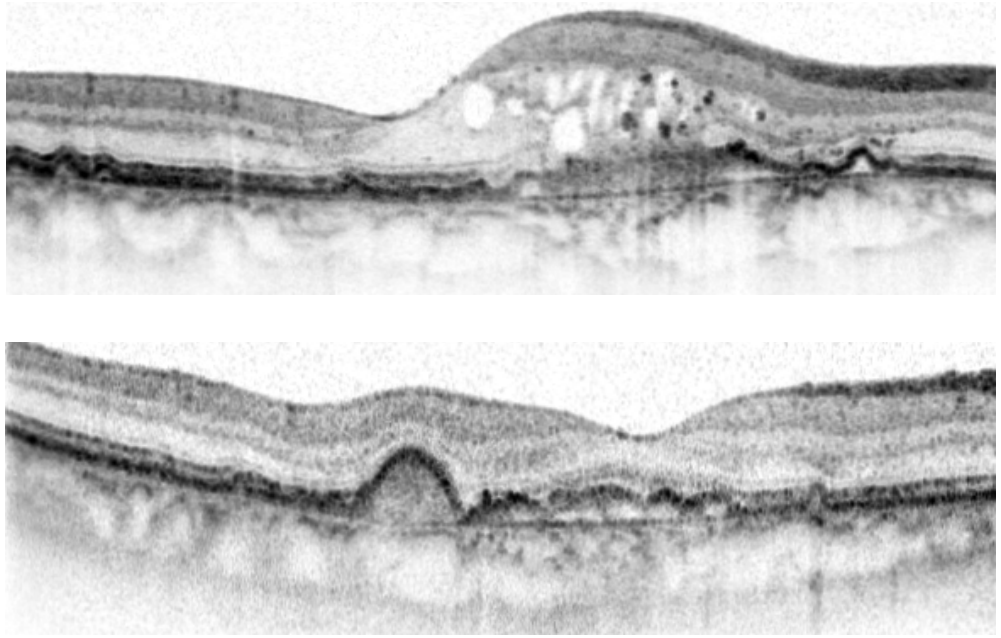
Monitoring of the fellow eye in nAMD: Background

nAMD, neovascular age-related macular degeneration.

Risk to the fellow eye is increased in nAMD



Images courtesy of Professor Anat Loewenstein

- AMD is considered a bilateral disease, but nAMD typically manifests in one eye[1]
- The presence of nAMD in one eye is a strong risk factor for development in the fellow eye[2]
  - CNV has been shown to develop in the fellow eye in 24–39% of patients with nAMD by 2 years[3]
  - nAMD in the fellow eye has been reported in up to 27% of untreated patients after 4 years[3]
  - By 5 years, 27–68% of unilateral late AMD cases progress to bilateral disease[4]

AMD, age-related macular degeneration; CNV, choroidal neovascularization; nAMD, neovascular AMD.

1. Wong TY *et al. Ophthalmology* 2008; 115 (1): 116–126; 2. Al-Zamil WM and Yassin SA. *Clin Interv Aging* 2017; 12: 1313–1330;
3. Barbazetto IA *et al. Am J Ophthalmol* 2010; 149 (6): 939–946.e1; 4. Joachim N *et al. Br J Ophthalmol* 2017; 101 (9): 1185–1192.

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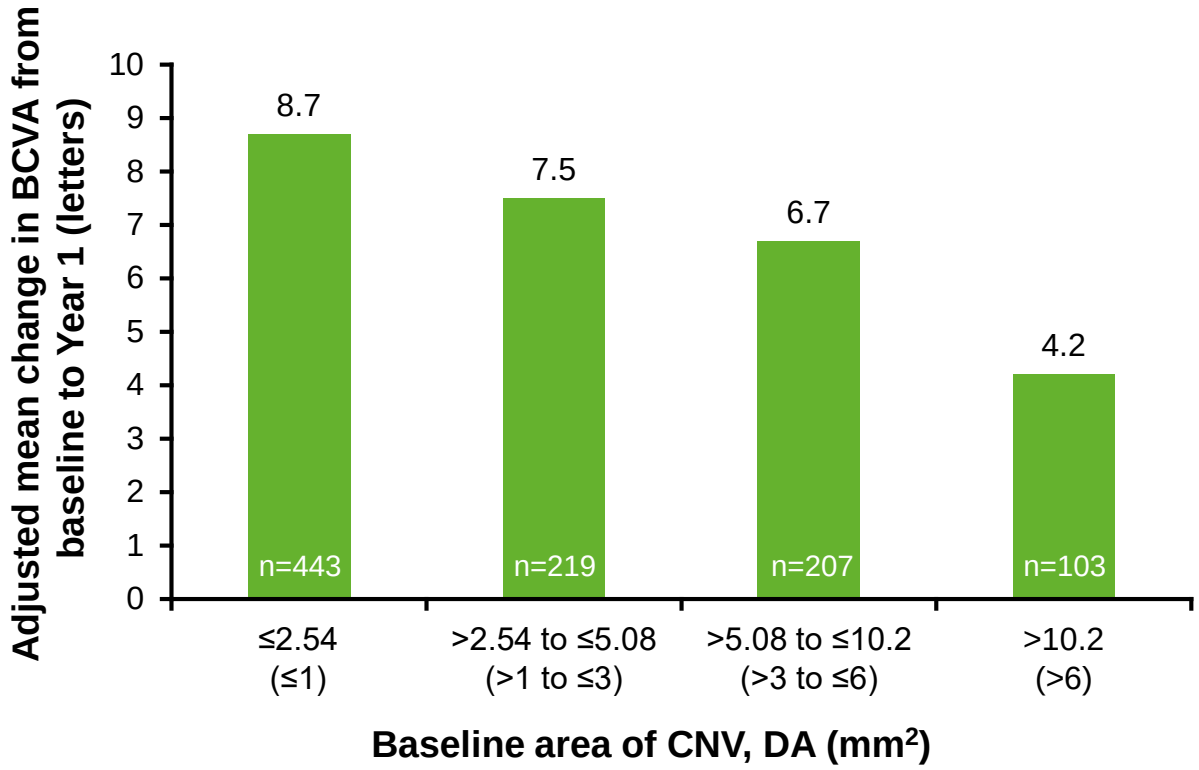
Early detection is critical to maintain visual function

- Graph shows multivariate analysis of patients (N=1068) receiving ranibizumab or bevacizumab in CATT*
- Patients with smaller CNV lesions at baseline had larger VA gains after 1 year of treatment[1]



However, many patients with unilateral nAMD may have already experienced decreased VA by the time CNV lesions are detected in the fellow eye[2,3]

*Missing values: A total of 1068 patients were included in the final multivariate model; 37 were excluded because of missing values for one or more predictors and a further 133 had CNV that could not be measured.

BCVA, best-corrected visual acuity; CATT, Comparison of Age-Related Macular Degeneration Treatments Trials; CNV, choroidal neovascularization; DA, disc areas; nAMD, neovascular age-related macular degeneration; VA, visual acuity.

1. Ying G-S *et al. Ophthalmology* 2013; 120 (1): 122–129; 2. Chew JK *et al. Ophthalmologica* 2017; 238: 23–30; 3. Elshout M *et al. BMC Ophthalmol* 2017; 17 (1): 120.

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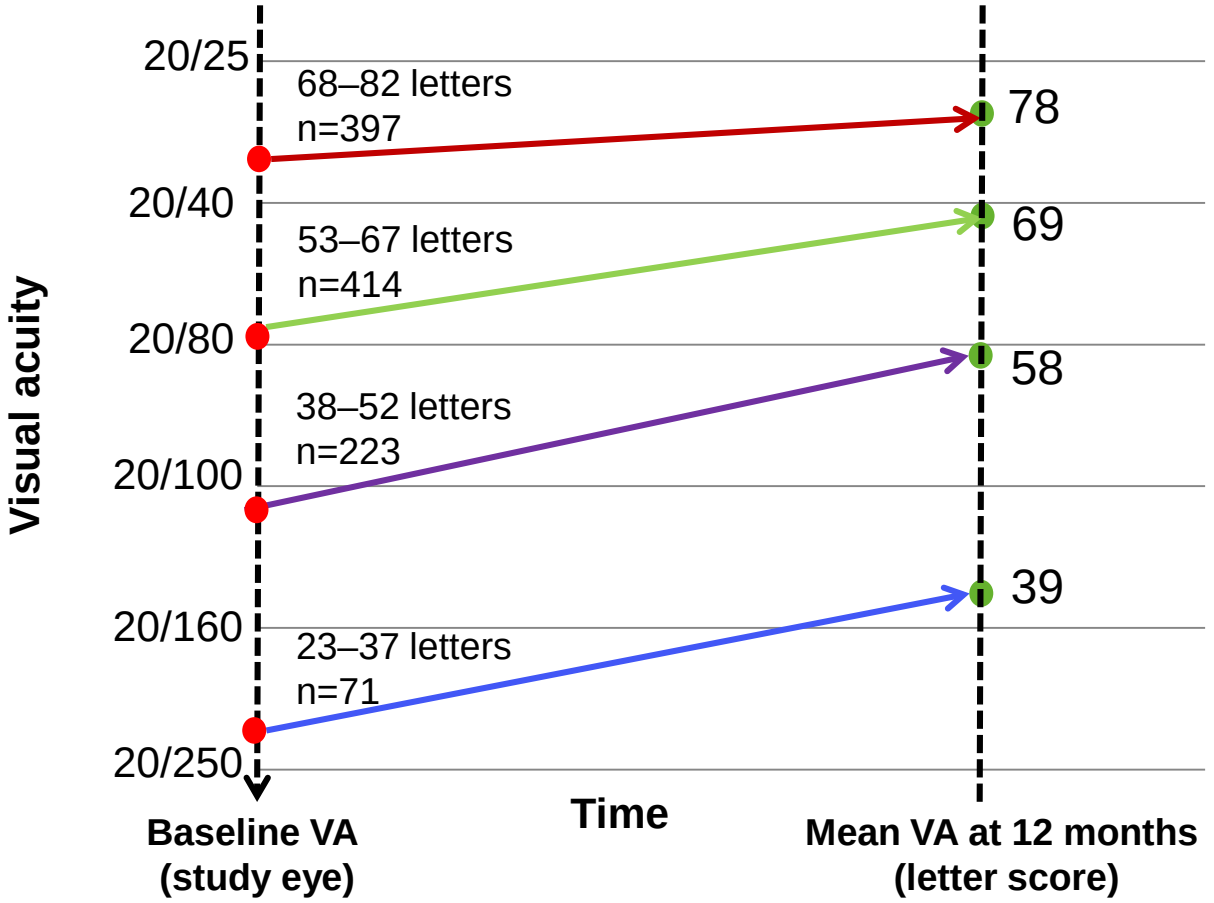
Baseline visual acuity predicts outcomes

Baseline VA predicts outcomes at Year 1: CATT subgroup analysis



Eyes that begin at 20/25–40 have the best mean VA at 1 year[1]

Similar stratification of response by baseline VA is also observed at 2 and 5 years[2,3]

CATT, Comparison of Age-Related Macular Degeneration Treatments Trials; VA, visual acuity.

1. Ying G-S *et al. Ophthalmology* 2013; 120 (1): 122–129; 2. Lee AY *et al. Br J Ophthalmology* 2015; 99 (8): 1045–1050;
3. Gillies MC *et al. Ophthalmology* 2015; 122 (9): 1837–1845.

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Disease detection may be delayed due to difficulty attending appointments or lack of awareness

- Patients delay reporting symptoms to their HCP
  - In a survey of >900 patients with nAMD, 27% of patients waited >1 month before visiting a HCP, primarily due to beliefs that symptoms were part of the aging process or that they would resolve on their own[1]
- A key barrier to treatment is the inability of caregivers to get patients to appointments[1]

HCP, healthcare provider; nAMD, neovascular age-related macular degeneration.

1. Varano M *et al. Clin Ophthalmol* 2015; 9: 2243–2250.

Risk factors for development of CNV in the fellow eye

Development of AMD	Development of bilateral AMD
Age[1]	Age[4]
Cigarette smoking[1,2]	Cigarette smoking[4]
Genetic variants[3] *CFH* *ARMS2* *IL-8* *TIMP3* *SLC16A8* *RAD51B* *VEGF-A* *COL8A1*	Genetic variants[4] *CFH* *ARMS2*
White ethnicity[1]	Presence of unilateral AMD[2,4]
	Large number of drusen or retinal pigmentary abnormalities[4,5]
	PPE[6]
	Subclinical nonexudative neovascularization (subclinical macular neovascularization) detectable by OCT-A[7-9]

AMD, age-related macular degeneration; *ARMS2*, age-related maculopathy susceptibility 2; *CFH*, complement factor H; CNV, choroidal neovascularization; *COL8A1*, collagen alpha-1(VIII) chain; *IL-8*, interleukin-8; OCT-A, optical coherence tomography angiography; PPE, pachychoroid pigment epitheliopathy; *RAD51B*, DNA repair protein RAD51 homolog 2; *SLC16A8*, solute carrier family 16 member 8/monocarboxylate transporter 3; *TIMP3*, metalloproteinase inhibitor 3; *VEGF-A*, vascular endothelial growth factor A.

1. Coleman HR *et al. Lancet* 2008; 372 (9652): 1835–1845; 2. Saunier V *et al. JAMA Ophthalmol* 2018; 136 (5): 473–481; 3. Cascella R *et al. Oncotarget* 2018; 9: 7812–7821; 4. Joachim N *et al. Br J Ophthalmol* 2017; 101 (9): 1185–1192; 5. Cachulo L *et al. Ophthalmologica* 2011; 225 (3): 144–149; 6. Yanagi Y *et al. Invest Ophthalmol Vis Sci* 2017; 58 (9): 3488–3495; 7. Palejwala NV *et al. Retina* 2015; 35 (11): 2204–2211; 8. Roisman L *et al. Ophthalmology* 2016; 123 (6): 1309–1319; 9. de Oliveira Dias JR *et al. Ophthalmology* 2018; 125 (2): 255–266.

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Clinic-based monitoring methods

A range of techniques exist for the early detection of nAMD, including methods that can be used at home

		In clinic	Home-based
Amsler grid	Patient reports distortions, blurriness, or missing lines in a 10x10 cm grid of 400 squares while vision is fixed on a central point[1]	✓	✓
Near visual acuity	Assessed with ETDRS and Snellen charts[2]	✓	✓

ETDRS, Early Treatment Diabetic Retinopathy Study; nAMD, neovascular age-related macular degeneration.

1. Schwartz R and Loewenstein A. *Int J Retina Vitreous* 2015; 1: 20; 2. Nixon DR and Flinn AN. *Clin Ophthalmol* 2017; 11: 715–721; 3. Arden GB. *Br J Ophthalmol* 1978; 62 (4): 198–209; 4. Kara S *et al. Arq Bras Oftalmol* 2016; 79 (5): 323–327; 5. Liutkevičienė R *et al. Medicina (Kaunas)* 2014; 50 (5): 281–286.

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And others only available in the clinic

		In clinic	Home-based
Contrast sensitivity	Measures ability to recognize small differences in luminance or distinguish low-contrast differences between an object and the background[1-4]	✓	
Macular mapping test	Software program that briefly displays letters in central visual field with a wagon wheel-shaped background pattern to help the patient focus on the center of the display[5]	✓	
Microperimetry (MP-1 [Nidek])	Non-invasive technique assessing the sensitivity of the central retina. Allows for correlations of macular anatomy and light sensitivity[6,7]	✓	
Noise field perimetry	Patients report abnormalities in a monochromatic field of high-frequency flickering dots while keeping vision fixed on a central point[8,9]	✓	
OCT / OCT-A	Non-invasive technique for obtaining detailed images of the retina.[8,10-11] OCT-A generates detailed, three-dimensional images of the choroidal vasculature[10,12]	✓	✓ (in development)

MP-1, microperimeter 1; nAMD, neovascular age-related macular degeneration; OCT, optical coherence tomography; OCT-A, OCT angiography.

1. Nixon DR and Flinn AN. *Clin Ophthalmol* 2017; 11: 715–721; 2. Arden GB. *Br J Ophthalmol* 1978; 62 (4): 198–209; 3. Kara S *et al. Arq Bras Oftalmol* 2016; 79 (5): 323–327; 4. Liutkevičienė R *et al. Medicina (Kaunas)* 2014; 50 (5): 281–286; 5. Bartlett H *et al. BMC Ophthalmol* 2005; 5: 18; 6. Laishram M *et al. J Clin Diagn Res* 2017; 11 (7): NC08–NC11; 7. Reinsberg M *et al. Clin Ophthalmol* 2017; 11: 621–629; 8. Schwartz R and Loewenstein A. *Int J Retina Vitreous* 2015; 1: 20; 9. Freeman WR *et al. Arch Ophthalmol* 2004; 122 (11): 1647–1651; 10. Keane PA *et al. Clin Ophthalmol* 2015; 9: 353–366; 11. Wolf S *et al. Ophthalmologica* 2016; 236 (2): 95–99; 12. Wylęgała A *et al. Medicine (Baltimore)* 2016; 95: e4907.

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Summary of clinic-based methods

	Advantages	Disadvantages
Amsler grid	• Suitable for early-stage detection of macular disease[1,2] • Widely used and easily accessible[1,3] • Available as an app[1,3]	• Variable sensitivity[1,2] • Patients may require supervision and instruction[2] • Compensation mechanisms may limit detection of visual field defects[3] • Not suitable for monitoring of progression[1]
Near visual acuity	• Good predictor of reading rate[4] • Suitable for monitoring of disease progression[4] • Charts are easily accessible and suitable for home use[1]	• Efficacy for early detection of AMD not yet thoroughly assessed[1]

AMD, age-related macular degeneration.

1. Schwartz R and Loewenstein A. *Int J Retina Vitreous* 2015; 1: 20; 2. Faes L *et al. Eye (Lond)* 2014; 28 (7): 788–796;
3. Keane PA *et al. Clin Ophthalmol* 2015; 9: 353–366; 4. Lovie-Kitchin J and Feigl B. *Clin Exp Optom* 2005; 88 (5): 292–303.

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Summary of clinic-based methods

	Advantages	Disadvantages
Contrast sensitivity	• Represents an important component of functional vision important for activities of daily living[1,2]	• Requires clinic attendance[3] • Subjective in nature and sensitive to environmental conditions such as lighting, which may affect reliability[2]
Macular mapping test	• Provides rapid assessment of visual defects in patients with macular disease[4-6] • Produces a quantitative score so may be suitable for monitoring disease progression[4-6]	• Requires clinic attendance[4] • Not readily available as computer software, limiting its use in clinical practice[4] • Few reports of use in the literature[4]
Microperimetry (MP-1 [Nidek])	• Provides detailed analysis of macular function in nAMD[7] • Increased sensitivity to changes in macular function due to assessment of large retinal area[8]	• Requires fixation accuracy; therefore may be unsuitable for patients with unstable fixation or excessive head movement[9]

MP-1, microperimeter 1; nAMD, neovascular age-related macular degeneration.

1. Arden GB. *Br J Ophthalmol* 1978; 62 (4): 198–209; 2. Kara S *et al. Arq Bras Oftalmol* 2016; 79 (5): 323–327; 3. Lovie-Kitchin J and Feigl B. *Clin Exp Optom* 2005; 88 (5): 292–303; 4. Schwartz R and Loewenstein A. *Int J Retina Vitreous* 2015; 1: 20. 5. Keane PA *et al. Clin Ophthalmol* 2015; 9: 353–366; 6. Bartlett H *et al. BMC Ophthalmol* 2005; 5: 18; 7. Reinsberg M *et al. Clin Ophthalmol* 2017; 11: 621–629; 8. Okada K *et al. Clin Ophthalmol* 2009; 3: 483–488; 9. Acton JH *et al. Optom Vis Sci* 2011; 88 (11): 1288–1297.

Summary of clinic-based methods

	Advantages	Disadvantages
Noise field perimetry	• Relatively high sensitivity and specificity[1] • Overcomes compensatory mechanisms affecting patient's subjective perception[2] • Device is somewhat portable[1]	• Clinic attendance and patient instruction before use are required[1] • Lacks large-scale trials to support its use[3]
OCT / OCT-A	• OCT demonstrates high sensitivity for the detection of active disease[3] • OCT can detect CNV before patients become symptomatic[2,4] • OCT-A generates three-dimensional images of the choroidal vasculature[2,5]	• Currently requires clinic attendance[3]

AMD, age-related macular degeneration; CNV, choroidal neovascularization; OCT, optical coherence tomography; OCT-A, OCT angiography.

1. Freeman WR *et al. Arch Ophthalmol* 2004; 122 (11): 1647–1651; 2. Keane PA *et al. Clin Ophthalmol* 2015; 9: 353–366; 3. Schwartz R and Loewenstein A. *Int J Retina Vitreous* 2015; 1: 20; 4. Chew JK *et al. Ophthalmologica* 2017; 238: 23–30; 5. Wylęgała A *et al. Medicine (Baltimore)* 2016; 95: e4907.

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Home-based monitoring methods

Home-based monitoring may provide a solution to the delay in detection and treatment

- Monocular vision testing while reading may provide one solution
  - Patient can cover one eye while reading and repeat while covering the opposite eye
- In addition, various tests and tools, including home-based PHP and SDH testing, are available to assist patients with monitoring their vision at home
  - Home-based OCT testing is not currently available
- The widespread adoption of smartphones enables greater opportunities for home-based monitoring applications, which may facilitate the early detection of disease, including:
  - Smartphone-based fundus imaging[1,2]
    - Selfie fundus imaging allows patients to transfer their images to a screening center and has been proposed as an innovative approach to retinopathy screening[3]
  - Smartphone-based applications for:
    - VA testing[4,5]
    - SDH[6]

OCT, optical coherence tomography; PHP, preferential hyperacuity perimetry; SDH, shape discrimination hyperacuity; VA, visual acuity.

1. Bolster NM *et al. J Diabetes Sci Technol* 2015; 10 (2): 318–324; 2. Kim TN *et al. Transl Vis Sci Technol* 2018; 7 (5): 21;
3. Venkatesh P *et al. Natl Med J India* 2018; 31 (6): 345–346; 4. Brady CJ *et al. JAMA* 2015; 314: 2682–2683; 5. Tofigh S *et al. Eye (Lond)* 2015; 29 (11): 1464–1468;
6. Keane PA *et al. Clin Ophthalmol* 2015; 9: 353–366.

In particular, SDH allows patients to monitor their own visual function at home

- SDH involves the use of shape discrimination tasks that test the ability of a patient to detect visual distortion[1-3]
- Early-stage AMD is associated with deficits in performing shape discrimination tasks, without loss of VA[4]

Stimuli used in an SDH test: one radial frequency pattern and two circles[2]

Advantages

- Smartphone app for home-based monitoring is FDA-approved for use by prescription[1,3,4]
- Potential to detect progression from early to advanced stages of disease[4]
  - Patients with AMD exhibit defects in shape discrimination even while maintaining good VA, which may allow for detection before vision loss occurs[5]

AMD, age-related macular degeneration; FDA, US Food and Drug Administration; SDH, shape discrimination hyperacuity; VA, visual acuity.

1. Schwartz R and Loewenstein A. *Int J Retina Vitreous* 2015; 1: 20; 2. Pitrelli Vazquez N and Knox PC. *Br Ir Orthopt J* 2015; 12: 9–15;
3. Keane PA *et al. Clin Ophthalmol* 2015; 9: 353–366; 4. Wang Y-Z *et al. Invest Ophthalmol Vis Sci* 2013; 54 (8): 5497–5505;
5. Wang Y-Z *et al. Invest Ophthalmol Vis Sci* 2002; 43 (6): 2055–2062.

Preferential hyperacuity perimetry can prevent visual decline

- Hyperacuity is the ability to perceive a difference in the relative localization of visual stimuli in space[1]
- PHP testing involves the presentation of artificially distorted stimuli to the patient and the recording of reported distortions, allowing quantification of visual distortions indicative of AMD[1,2]

https://www.foreseehome.com/

Advantages

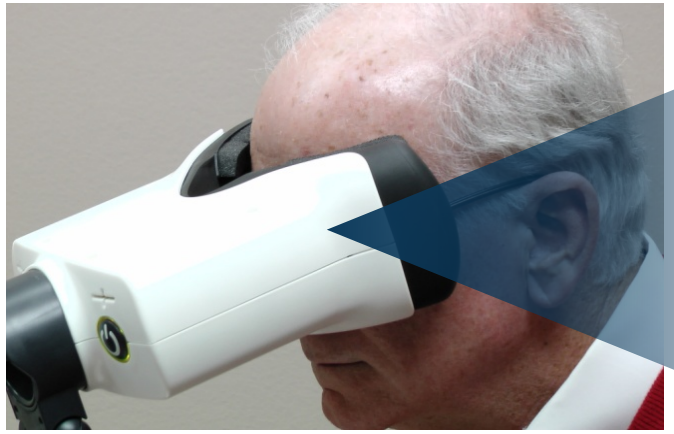
- Home-based testing device (ForeseeHome™) enables simple testing on a daily basis[1,2]
- Test takes <3 minutes[3,4]
- Reports can be sent directly to an ophthalmologist[1]
- Patients are more likely to maintain driving vision[3,4]

AMD, age-related macular degeneration; PHP, preferential hyperacuity perimetry.

1. Schwartz R and Loewenstein A. *Int J Retina Vitreous* 2015; 1: 20; 2. Keane PA *et al. Clin Ophthalmol* 2015; 9: 353–366;
3. ForeseeHome AMD Monitoring Program. NotalVision. 2017. Available at: https://www.foreseehome.com/how-it-works/;
4. Chew EY *et al. Ophthalmology* 2014; 121 (2): 535–544.

How the ForseeHome™ device is used

A patient using the device



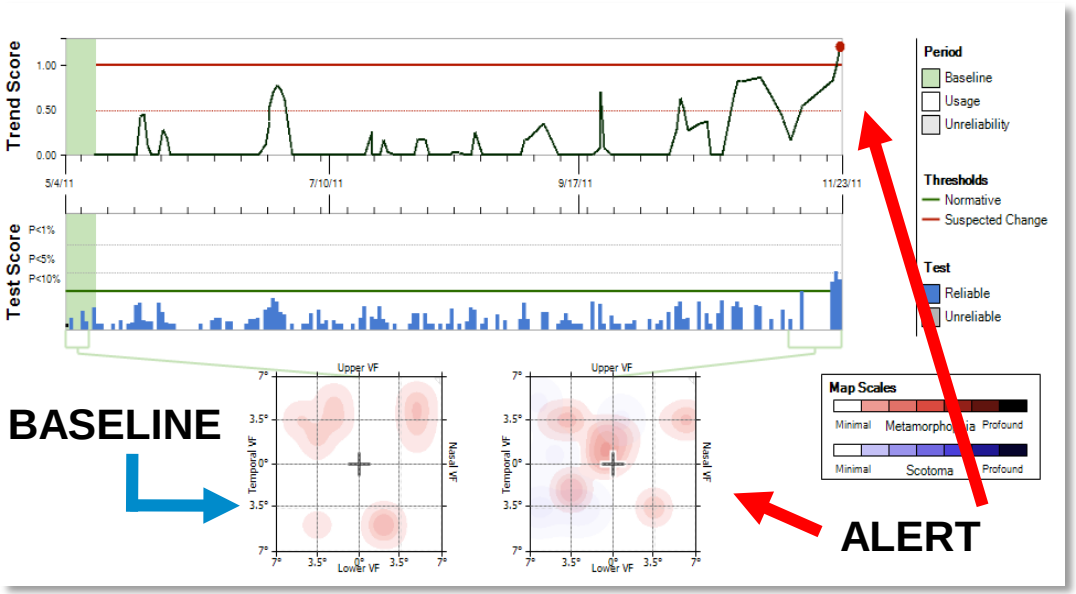
Signaling with mouse when and where distortion in pattern is perceived

https://www.foreseehome.com/

Approx. 3 mins / eye

- Upon referral, a remote diagnostic clinic provides the device to the patient and monitors test compliance
- The referring ophthalmologist is informed by the remote diagnostic clinic when an alert occurs

A report of a patient's test results



- A baseline reference score and map are generated within the first few weeks
- Changes in the score over time may prompt an alert

System FDA-approved and CE marked. Service covered by Medicare and many private insurance companies in the US.
Remote monitoring service provided by Notal Vision Diagnostic Clinic.

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Limitations of the ForseeHome™ device

- Elderly patients often struggle with technology
- Subjective test
- High false-positive rate
- Takes discipline, commitment, and time
- Involves sophisticated infrastructure and costs
- United States is the only country with data monitoring and call centers
- Healthcare system must be able to cope with demands of unscheduled visits
- High cost not affordable in many parts of the world
- Cost-effectiveness not established (US$36,000 per QALY gained)

QALY, quality-adjusted life year.

Home-based OCT testing allows for regular tracking of disease status

- **The Notal Home OCT system**, designed for self-operation, at-home use by vision-impaired elderly patients, has the potential to obtain images with interpretation comparable to those from a commercial in-office OCT
  - 94% of elderly AMD patients (VA ≥20/400; n=45 out of 48) are able to self-operate an OCT and capture gradable images following a 2-minute video tutorial[1]
  - Interpretation of the images can be compared to those from commercial OCTs with high accuracy (Zeiss Cirrus and/or Heidelberg Engineering Spectralis)[1]
- **Notal OCT Analyzer (NOA)** is a validated AI algorithm that identifies,[2] quantifies, and maps IRF and SRF[1]
- **The Notal Home OCT with NOA** was granted breakthrough device designation by the FDA in November 2018

https://notalvision.com/technology/home-oct

System granted FDA breakthrough device designation; not yet approved for clinical use.
AI, artificial intelligence; AMD, age-related macular degeneration; FDA, US Food and Drug Administration; IRF, intraretinal fluid; OCT, optical coherence tomography; SRF, subretinal fluid; VA, visual acuity.
1. Loewenstein A. Oral presentation at Angiogenesis, Exudation, and Degeneration 2019, Miami, Florida, February 9, 2019; 2. Chakravarthy U *et al. Ophthalmology* 2016; 123 (8): 1731–1736.

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Challenge requiring Vision Academy guidance

- A range of clinic- and home-based methods for the early detection of nAMD are available
- The advantages and limitations of each modality vary, especially when considering the accessibility and availability to patients

QUESTION

Should patients with unilateral nAMD be encouraged to monitor their vision at home?

nAMD, neovascular age-related macular degeneration.

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Vision Academy recommendations

Monitoring of the fellow eye should be considered standard of care in most patients with CNV due to nAMD

Examinations should be performed at least every 3 to 4 months after the diagnosis of CNV in the first eye

- Early detection of nAMD in the fellow eye is essential to preventing bilateral vision loss[1]
- Better visual outcomes occur if treatment is started early, before the CNV lesion advances and loss of VA occurs[2-4]
- Patients should be carefully educated on the symptoms associated with disease progression in the fellow eye, as well as on the importance of early access to diagnosis and proper care

Patients examined in the clinic for intravitreal injection should undergo examination of the fellow eye at each visit

Early detection of CNV in the fellow eye may lead to improvements in long-term visual outcomes

General consensus

CNV, choroidal neovascularization; nAMD, neovascular age-related macular degeneration; VA, visual acuity.

1. Schwartz R and Loewenstein A. *Int J Retina Vitreous* 2015; 1: 20; 2. Ying G-S *et al. Ophthalmology* 2013; 120 (1): 122–129; 3. Lee AY *et al. Br J Ophthalmol* 2015; 99 (8): 1045–1050; 4. Writing Committee for the UK Age-Related Macular Degeneration EMR Users Group. *Ophthalmology* 2014; 121 (4): 1092–1101.

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Patients should be monitored by VA examination and appropriate imaging techniques in the clinic

A range of techniques are available for the detection of nAMD, including chart-based methods and specific imaging techniques[1-4]

- Patients are unlikely to notice small changes in their vision during early stages of disease, so VA examination and appropriate imaging techniques are critical aspects of fellow-eye monitoring

Imaging techniques such as OCT can potentially detect asymptomatic CNV

However, many patients with nAMD may have already experienced decreased VA prior to the detection of lesions[5-7]

General consensus

CNV, choroidal neovascularization; nAMD, neovascular age-related macular degeneration; OCT, optical coherence tomography; VA, visual acuity.

1. Schwartz R and Loewenstein A. *Int J Retina Vitreous* 2015; 1: 20; 2. Keane PA *et al. Clin Ophthalmol* 2015; 9: 353–366; 3. Lovie-Kitchin J and Feigl B. *Clin Exp Optom* 2005; 88 (5): 292–303; 4. Laishram M *et al. J Clin Diagn Res* 2017; 11 (7): NC08–NC11; 5. Chew JK *et al. Ophthalmologica* 2017; 238: 23–30; 6. Elshout M *et al. BMC Ophthalmol* 2017; 17 (1): 120; 7. Capuano V *et al. Am J Ophthalmol* 2017; 182: 45–55.

Patients should be encouraged to monitor their vision at home, as possible and appropriate for each patient

Patients should monitor their vision at home through weekly monocular reading tests, and should employ home-based technologies as appropriate for the patient

- Simple tests, including monocular reading of a standardized text at the limit of a patient's reading ability, can be utilized to detect changes in vision
- Patient ability to utilize home-based devices should be determined through in-office trial sessions under clinical supervision, and any comorbid conditions or disabilities should also be considered

Recent advancements have been made in home-based detection and monitoring of nAMD, including smartphones and other personal devices, as well as the development of a home-based OCT system[1-7]

These advancements can help patients overcome barriers and prevent delays in treatment

General consensus

nAMD, neovascular age-related macular degeneration; OCT, optical coherence tomography.

1. Schwartz R and Loewenstein A. *Int J Retina Vitreous* 2015; 1: 20; 2. Chew EY *et al. Ophthalmology* 2014; 12 (2): 535–544; 3. Keane PA *et al. Clin Ophthalmol* 2015; 9: 353–366; 4. Bolster NM *et al. J Diabetes Sci Technol* 2015; 10 (2): 318–324; 5. Tofigh S *et al. Eye (Lond)* 2015; 29 (11): 1464–1468; 6. Dorr M *et al. Invest Ophthalmol Vis Sci* 2013; 54 (12): 7266–7273; 7. Wu Z *et al. Transl Vis Sci Technol* 2015; 4 (3): 13.

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Vision Academy recommendations for monitoring the fellow eye in patients with nAMD

- Monitoring of the fellow eye should be considered standard care in most patients with CNV due to nAMD. Examinations should be performed at least every 3 to 4 months after the diagnosis of CNV in the first eye
- In the clinic, patients should be monitored by VA examination and appropriate imaging techniques
- Patients should be encouraged to monitor their vision at home through weekly monocular reading tests, and should employ home-based technologies as appropriate for the patient

The Viewpoint ‘Monitoring of the fellow eye in nAMD’ can be downloaded from: https://www.visionacademy.org/resource-zone/resources/all

CNV, choroidal neovascularization; nAMD, neovascular age-related macular degeneration; VA, visual acuity.

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Further considerations

Home monitoring tools may not be affordable or available to all patients and may prevent the broad-scale use of these technologies