Real-World Performance of a Self-Operated Home Monitoring System for Early Detection of Neovascular AMD (ForeseeHome device)

Allen C. Ho, MD
Professor of Ophthalmology, Thomas Jefferson University
Director of Retina Research, Wills Eye Hospital
Mid Atlantic Retina

Disclosures

Adverum: C
Aerie: C, G
AGTC: C, G
Alcon Laboratories, Inc.: C, G
Aldeyra: C, G
Allergan: C, G
Apellis: C, G
Asclepix: C
Beaver-Visitec International, Inc.: C
BioTime: C, G
Chengdu Kanghong Biotechnology: C, G
Covalent Medical, LLC.: O
Genentech: C, G
Gemini: G
Graybug: C, G
Gyroscope: C, G
IRIDEX: C
Iveric / Ophthotech: C, G
Johnson & Johnson: C, G
Lineage / BioTime: C, G
Lumithera: G
National Eye Institute: G
Notal: C
Novartis: G
ONL: C, O
Optovue, Inc.: C, G
ProQR: G
Regeneron Pharmaceuticals, Inc.: C, G
RegenXBio: C, G
Sanofi: G

Summary

- Real-world performance of the ForeseeHome Monitoring System is comparable to performance in ARED2 HOME study on early detection nAMD
  - 81% were 20/40 or better VA using FSH detection
  - 34 % were 20/40 or better in IRIS Registry database

- The potential to preserve an additional 3-4 lines of vision at the onset of nAMD as compared to standard-of-care alone leads to better VA prognosis with current anti-VEGF therapy

These results highlight the importance of early detection methodologies and novel intermediate AMD management strategies

Objective

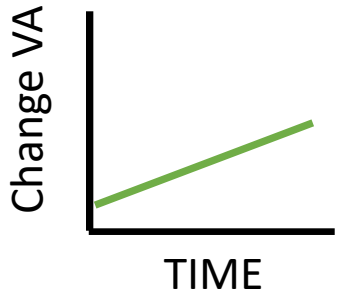
- To evaluate real world performance of a monitoring strategy of intermediate AMD patients for the detection of conversion to NV-AMD

- The strategy includes self-operated a validated tele-connected home monitoring system ForeSee Home (FSH) in conjunction with routine office visits and visits triggered by patient symptoms

Rationale and Background

Visual Acuity at the Time of Wet AMD Diagnosis is the BEST PREDICTOR of Visual Outcomes Following Anti-VEGF Treatments

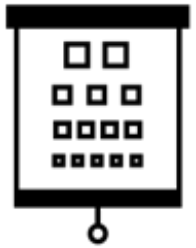
RELATIVE VISION



Improvement from baseline

VS

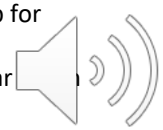
ABSOLUTE VISION



What really matters to patients

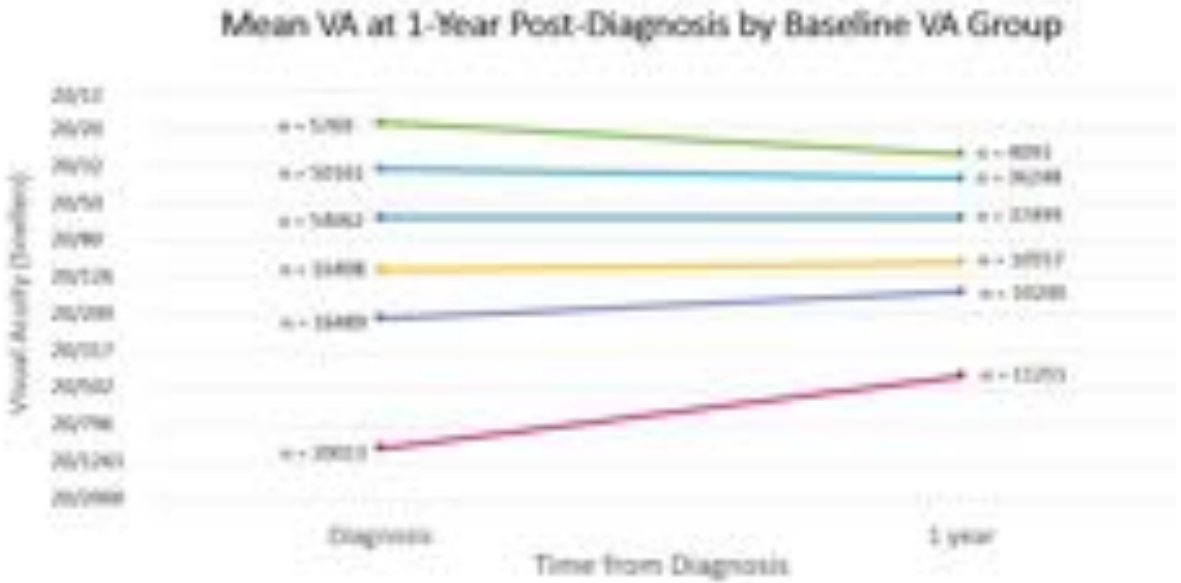
OUR CHALLENGE: CAN WE RETAIN GOOD FUNCTIONAL VISION AT DIAGNOSIS AND THROUGHOUT TREATMENT AS THE GOAL FOR WET AMD MANAGEMENT?

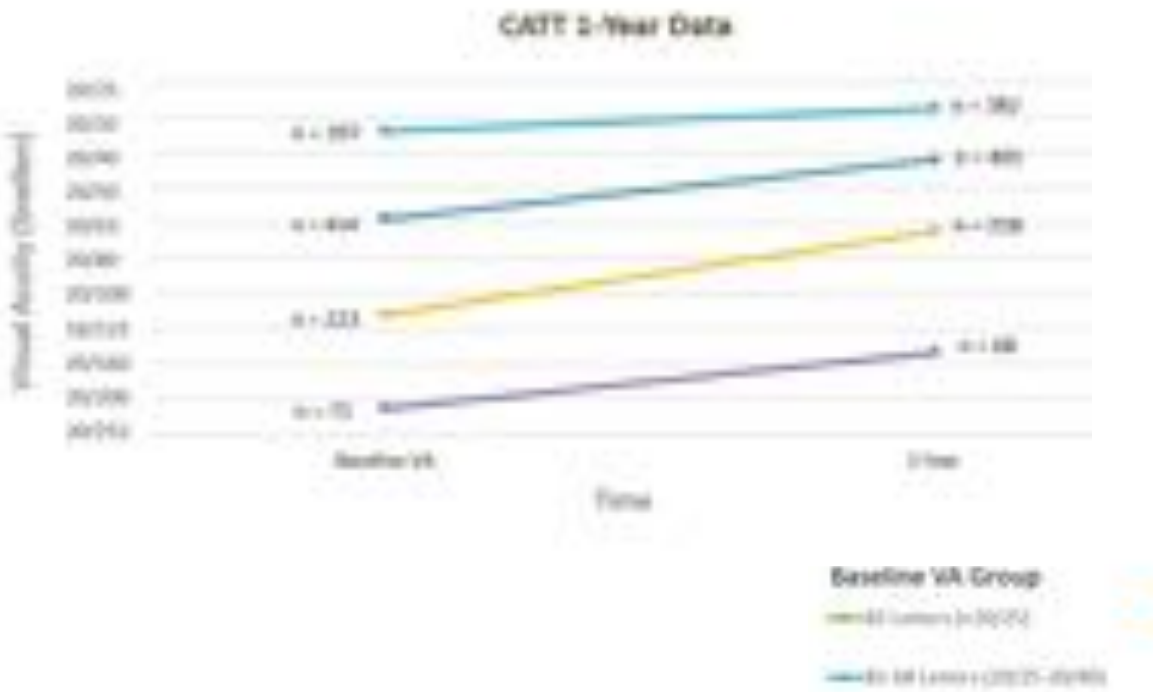
1. Ying GS, Huang J,Maguire MG, et al; Comparison of Age-related Macular Degeneration Treatments Trials Research Group. Baseline predictors for one-year visual outcomes with ranibizumab or bevacizumab for neovascularage-related macular degeneration. Ophthalmology. 2013;120(1):122-129.
2. Ying GS, Maguire MG, Daniel E, et al; Comparison of Age-Related Macular Degeneration Treatments Trials (CATT) Research Group. Association of baseline characteristics and early vision response with 2-year outcomes in the Comparison of AMD Treatment Trials (CATT). Ophthalmology. 2015;122(12):2523-2531.e1.
3. Ho AC, Albini TA, Brown DM, Boyer DS, Regillo CD,Heier JS. The potential importance of detection of neovascular age-related macular degeneration when visual acuity is relatively good. JAMA Ophthalmol 2017;135(3):268–273.



Baseline VA PREDICTS Long-Term Outcomes nAMD

IRIS REGISTRY



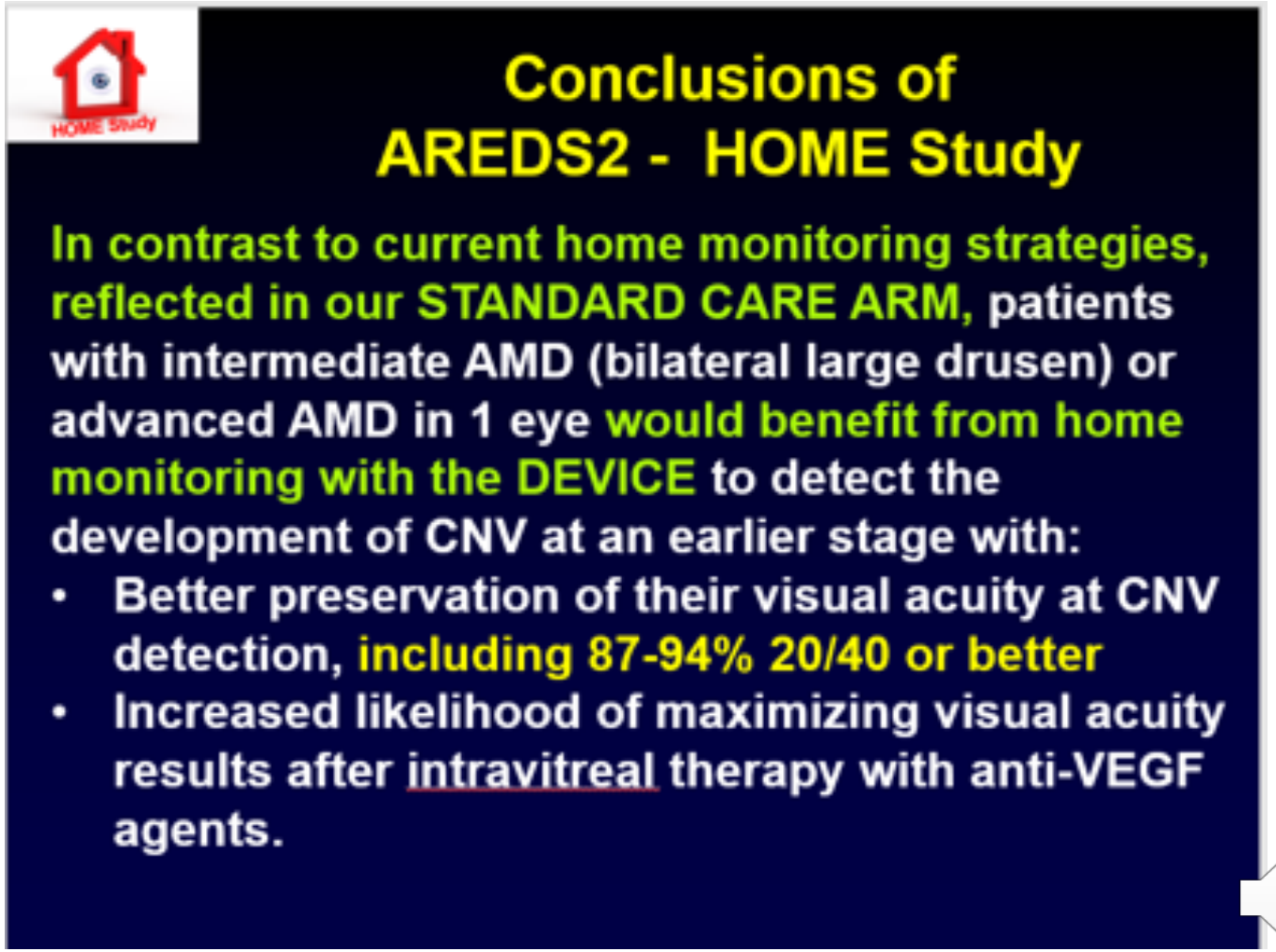


IRIS® Registry Results Correlate with Those Seen in CATT:

Patients with Better VA at Diagnosis had Better VA at 1-Year

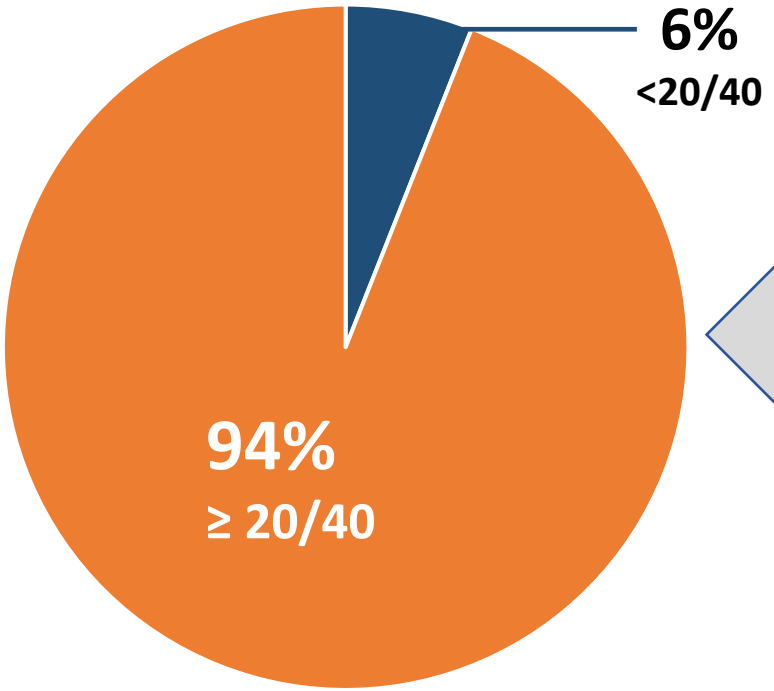
The ForeSee Home system was validated in the AREDS2 HOME study

- DSMC early stop for **efficacy** AREDS2-HOME study
- Medicare coverage and commercial launch of the ForeseeHome AMD Monitoring System
- To date, no real world data on performance



94% of Patients Using ForeseeHome in AREDS2 HOME Study had ≥20/40 VA at Time of CNV Diagnosis

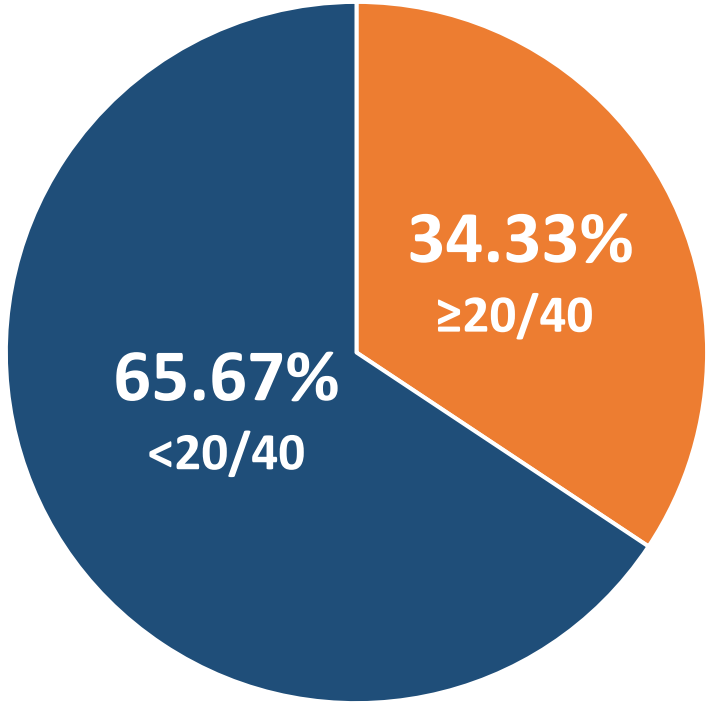
HOME study
ForeseeHome Users*



*FSH patients who used device at least 2x/week (N= 29)

WE'VE LEARNED THAT WE CAN DO BETTER

IRIS Registry®



N = 55,930* wet AMD diagnoses in patients with ≥ 20/40 prior to conversion

*of 162,902 eyes that had a pre-conversion VA and met protocol inclusion/exclusion criteria

Study Design

- Retrospective review of existing real world data collected by the Notal Vision Diagnostics Center (NVDC), an independent diagnostic testing facility responsible for clinical oversight of at-home monitoring system for patients who have been prescribed the home monitoring program
- Inclusion: All de-identified patients who had a confirmed conversion from intermediate AMD to NV-AMD while participating in the program
- Participation was defined as having a FSH device at home with a valid baseline, regardless of the frequency of monitoring
- Time Frame: 9 years (October 2009 to September 2018)

Baseline Demographics and Modality triggering nAMD detection

	Total (n=306)	At-home monitoring alert	During routine visit or by patient symptoms
Modality triggering detection	306	211 (69%)	95 (31%)
Age, yr (mean, [SD])	75 (7.1)	76 [6.9]	73 [7.3]
Gender, n (%): Female	199 (65%)	139 (66%)	60 (63%)

The FSH home monitoring system detected 69% of NV-AMD events

Median VA at baseline, nAMD event, and Change VA

All eyes with known VA				
	Baseline VA	Event VA	Event VA if BL VA available	VA change
# eyes	121	193	121	
Median VA (letters)	79	75	74	-3
Median VA (Snellen)	20/25-2	20/32-1	20/32-2	
Eyes with CNV event detected by FSH with known VA				
	Baseline VA	Event VA	Event VA if BL VA available	VA change
# eyes	95	151	95	
Median VA (letters)	78	75	74	-2
Median VA (Snellen)	20/32+2	20/32-1	20/32-2	
Eyes with CNV event detected by other means with known VA				
	Baseline VA	Event VA	Event VA if BL VA available	VA change
# eyes	26	42	26	
Median VA (letters)	81	76	74	-4.5
Median VA (Snellen)	20/25	20/32	20/32-2	

Median VA at time of conversion 20/32-1 and median change in VA from baseline was 3 letters

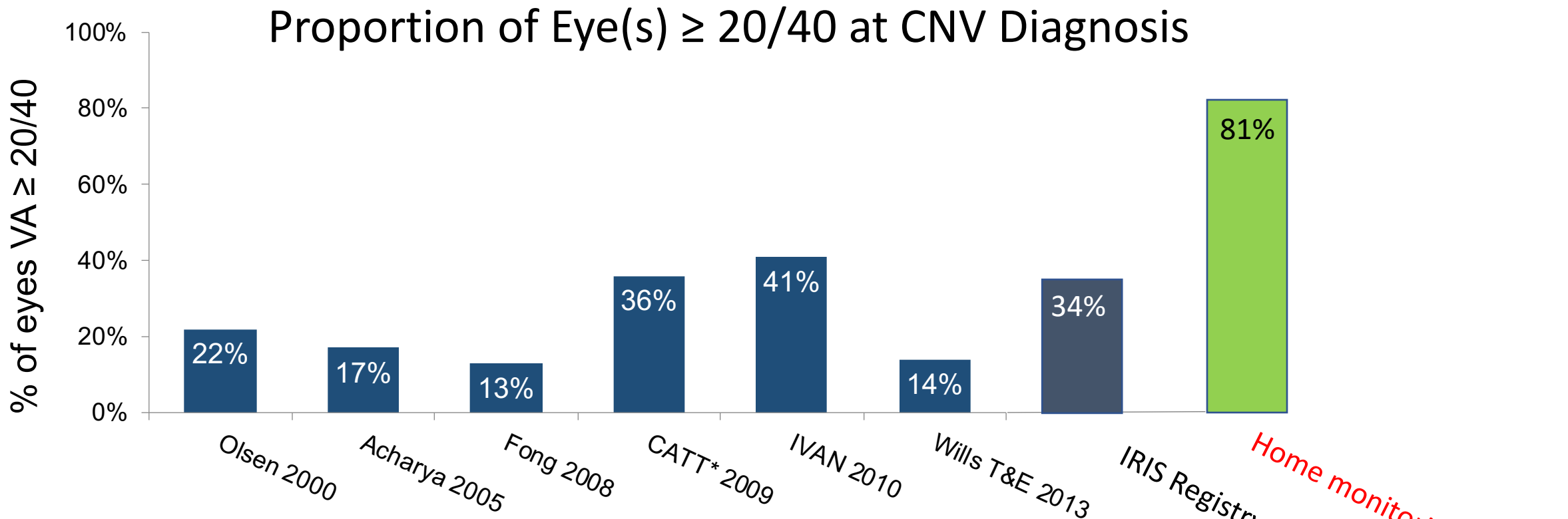
Detection nAMD with VA ≥ 20/40

	Entire cohort	Detected following a device alert	Detected during routine office visit or by patient symptoms
# eyes with VA ≥ 20/40 at baseline	109	86	23
# eyes which retained VA ≥ 20/40 at conversion	88	71	17
% (95% CI) eyes which retained VA ≥ 20/40 at conversion	81% (72%-88%)	83% (73%-90%)	74% (52%-90%)

81% of eyes retained VA ≥ 20/40 at time of diagnosis of conversion to nAMD

VA at New Onset nAMD – Multi-studies comparison

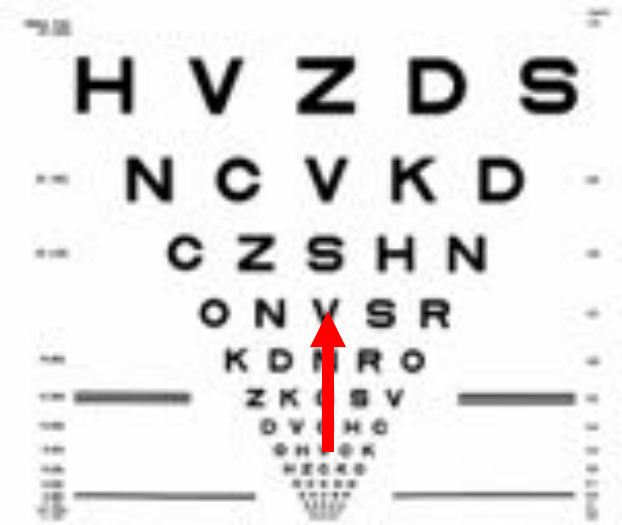
Real-World Data Demonstrates Few Newly Diagnosed CNV Eyes Are Detected Early



*All but CATT included eyes with VA of 20/20 or worse (CATT included ≤20/25)

VA at nAMD Diagnosis – FSH monitoring vs IRIS® Registry

	IRIS registry, Mean VA at Diagnosis	Median VA with Home monitoring	Difference – lines of vision
Patients			
Eyes	**20/83**	**20/32-1**	**Approximately 4 lines**



Significantly better baseline VA with Home monitoring vs IRIS® Registry

1. Rao P, Lum F, Wood K, Salman C, Burugapalli B, Hall R, Singh S, Parke DW 2nd, Williams GA. Real-World Vision in Age-Related Macular Degeneration Patients Treated with Single Anti-VEGF Drug Type for 1 Year in the IRIS Registry. *Ophthalmology*. 2017 Nov 13. pii: S0161-6420(17)31946-2.

Study Limitations

- Retrospective
- Real-world registries do not necessarily reflect best corrected visual acuity (BCVA), but rather corrected VA
- Reliance on the electronic health record (EHR) and the physicians' documentation in the EHR

Discussion

- First study to report on the real-world performance of a monitoring strategy that includes an at-home FSH monitoring for early detection of nAMD in conjunction with routine office visits and response to symptoms realization

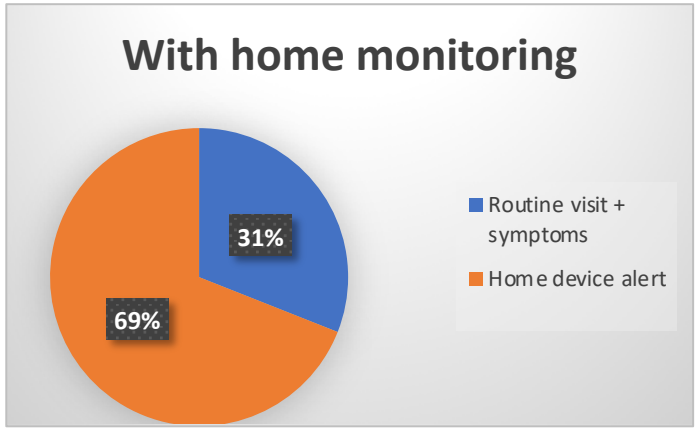
- The dataset of newly diagnosed conversions to nAMD included a large number of 306 eyes

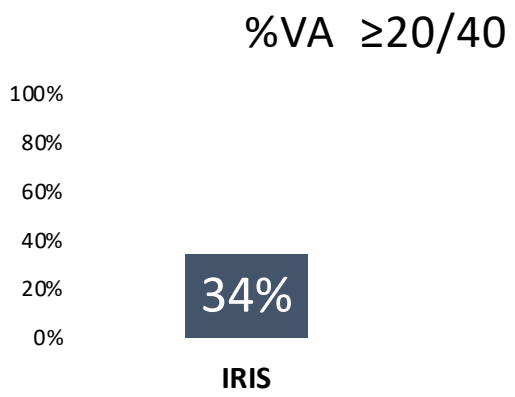
- This same FSH system, hardware, software, support infrastructure and compliance reminder service has been previously evaluated in the AREDS2 HOME study

- The current study provides evidence that the real-world implementation yields similar performance to AREDS2 Home study

Discussion

- 69% of the detection of conversions were triggered by device alerts. AREDS2 HOME study 64% of detections were triggered by the device alerts





- Detection nAMD with baseline VA 20/40 or better was 81% in this study versus 34% in IRIS Registry

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THANK YOU