ForeseeHome AMD home monitoring real-world data analysis compares favorably to HOME study

Notal Vision Diagnostic Clinic chart review shows 83% of patients maintained functional vision

Manassas, VA (July 28, 2020) – Real-world data on the performance of the ForeseeHome® AMD Monitoring Program, which helps detect the conversion from intermediate dry to wet age-related macular degeneration (AMD), was presented at the American Society of Retina Specialist (ASRS) virtual annual meeting on July 26, 2020. The data analysis showed that the use of ForeseeHome provided a significant benefit to patients by helping to detect their wet AMD earlier with better visual acuity, which is known to improve long-term visual outcomes through anti-VEGF treatment.

The retrospective analysis of medical records from the Notal Vision Diagnostic Clinic in Manassas, VA identified 306 eyes that converted to wet AMD between October 2009 and September 2018. The ForeseeHome system identified 69% of the conversions, which confirms the findings of the AREDS2 randomized controlled HOME study, where 64% of the detections were triggered by ForeseeHome alerts in a comparable group.[1] Functional vision (≥20/40) at conversion was maintained in 83% of patients in the real-world ForeseeHome cohort compared to only 34% in the standard of care IRIS registry.[2] The real-world ForeseeHome performance resembles the results of the HOME study, where 94% of patient maintained functional vision at conversion using the same system.

"This real-world data analysis confirms that the use of ForeseeHome provides a significant benefit to patients as a means of increasing the early detection of wet AMD," said Allen C. Ho, MD, the study's principal author and Director of Retina Research of Wills Eye Hospital and Professor of Ophthalmology at the Kimmel School of Medicine at Thomas Jefferson University. "Earlier detection of wet AMD with this FDA-cleared device is a strong predictor of better vision over time with current anti-VEGF therapy. As patients increasingly engage with telehealth tools, ForeseeHome can be a useful strategy to monitor at-risk intermediate AMD and help protect vision."

ForeseeHome is a home-based diagnostic that monitors visual changes in intermediate dry AMD patients at risk of vision loss from undiagnosed wet AMD. Patients perform a short, daily test on an easy-to-use device and their results are automatically transmitted to the Notal Vision Diagnostic Clinic, an independent diagnostic testing facility and medical service provider of ForeseeHome. When a statistically significant change of test patterns is detected, the Notal Vision Diagnostic Clinic alerts the referring physician so they can determine the best course of action for the patient.

"It is remarkable to see ForeseeHome perform as well in the real world as it did in the pivotal HOME study," said Kester Nahen, PhD, CEO of Notal Vision. "In today's COVID-19 pandemic environment, the ability to provide quality care and diagnostics to patients at high risk of converting to wet AMD while limiting their potential exposure cannot be overlooked."

References

1. Chew EY, Clemons TE, Bressler SB, et al. Randomized Trial of the Foreseehome Monitoring Device for Early Detection of Neovascular Age-Related Macular Degeneration. The Home Monitoring of the Eye (Home) Study Design - Home Study Report Number 1. *Contemp Clin Trials* 2014;37:294-300.
2. Ho AC. A Retrospective Analysis of Real-World Disease Detection and Visual Acuity Outcomes in Patients with Dry Amd Converting to Wet Amd Using the AAO Iris Registry Database Paper presented at: American Society of Cataract and Refractive Surgery. Washington, DC, 2018.

About Notal Vision

Notal Vision is a diagnostic services company that operates the Notal Vision Diagnostic Clinic, a medical provider with a proven platform for engaging patients and AI-enabled analyses of high-volume personalized health data that extends disease management from the clinic to the home to improve vision outcomes, reduce treatment burden, and improve health economics. www.notalvision.com

The ForeseeHome AMD Monitoring Program is an FDA-cleared diagnostic that monitors visual changes in intermediate dry AMD patients at risk of vision loss from undiagnosed wet AMD. The clinical utility for ForeseeHome was established in the Home Monitoring of The Eye (HOME) Study, part of the National Eye Institute-sponsored AREDS2 study, in which 94% of patients using ForeseeHome twice weekly who progressed to wet AMD, maintained 20/40 or better vision compared to only 62% of patients whose diagnosis was at a routine eye exam or a visit triggered by symptoms. Based upon the robust level-1 evidence and compelling clinical outcomes demonstrating the ability to detect choroidal neovascularization (CNV) earlier, the ForeseeHome AMD Monitoring Program gained Medicare coverage in 2016. To learn more, visit www.foreseehome.com.

Notal Vision's Home OCT system will enable wet AMD patients to perform technician-free OCT testing at home with rapid and self-guided fixation – critical components, especially for elderly patients frequently with pre-existing vision loss. The Notal OCT Analyzer (NOA™), a proprietary machine learning algorithm, developed in-house, performs automated analysis of the Home OCT scans and generates a report to the physician when a physician specified change in disease activity is detected. The Notal Vision Diagnostic Clinic provides referring physicians patient data via an online portal. In addition, physicians will be provided 24/7 access to all of their patients' B-scan images from each Home OCT test with the location of the fluid annotated on each B-scan. Following physician receipt of an alert report, patients may be brought to the office for evaluation and treatment at the doctor's discretion. NOA can also analyze the output of other commercial OCT devices, and published study data indicate that the performance of NOA in detecting disease activity was similar to that of retina physicians when each was compared to a panel of experts. Notal Vision's Home OCT has the potential to support current and future advances in retinal disease management.

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