

Digital home monitoring shows unique predictive value in disease progression for AMD patients

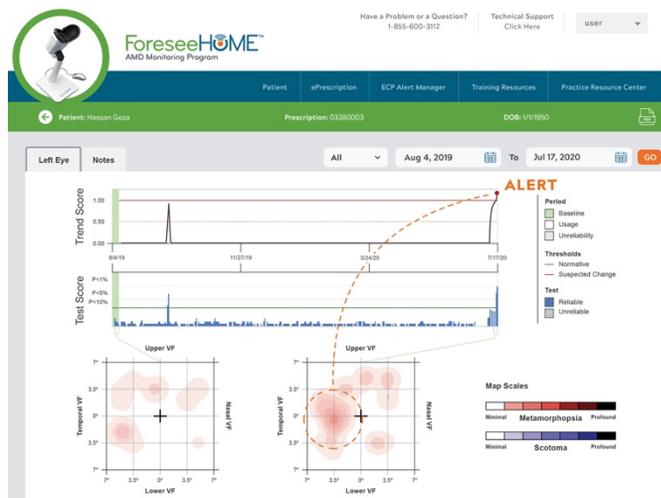
Study shows that ForeseeHome patients with non-exudative alerts warrant closer attention

Manassas, VA (October 25, 2022) Notal Vision, Inc. reported today the publication of the second report of the Analysis of Long-term visual Outcomes of ForeseeHome Remote Telemonitoring (ALOFT) study results in *Ophthalmology Retina*. The 10-year retrospective study details the importance of digital remote monitoring for age-related macular degeneration (AMD) patients.¹ The second report specifically focuses on early management and clinical research capabilities provided by home monitoring technologies.²

AMD is the leading cause of blindness in the developed world. This progressive disease has two stages, dry and wet. All patients begin in the dry stage and are usually able to keep their functional vision. About 10-15% of the patients convert to the vision threatening wet phase. These patients require frequent and expensive therapy, and many are unable to maintain their functional vision.

The first published report of the ALOFT study demonstrated the importance of home monitoring in the early detection of conversion from dry to wet AMD, and consequently showed superior outcomes in long-term vision of patients who converted to wet AMD. The study analyzed data from more than 2,000 patients over 10 years from five clinical sites. As part of the Medicare covered home monitoring program, provided by Notal Vision Monitoring Center, patients tested with the ForeseeHome device, which uses a functional test to detect structural changes, commonly associated with wet AMD, in the retina called preferential hyperacuity perimetry (PHP).

An intrinsic feature of the test detects changes in visual function, which prompts the Monitoring Center to alert the referring physician. The physician then determines if the alert was a conversion to wet AMD through a follow up exam using diagnostic imaging. Researchers in the ALOFT study group further analyzed the data from patients who had alerts that did not result in an immediate wet AMD diagnosis. These patients were twice as likely than other dry AMD patients to convert over the same period. The finding was even more remarkable for patients who had wet AMD in one eye and dry in the other eye, also known as the “fellow eye”. They had a 44% chance of converting to wet AMD over the next two years.

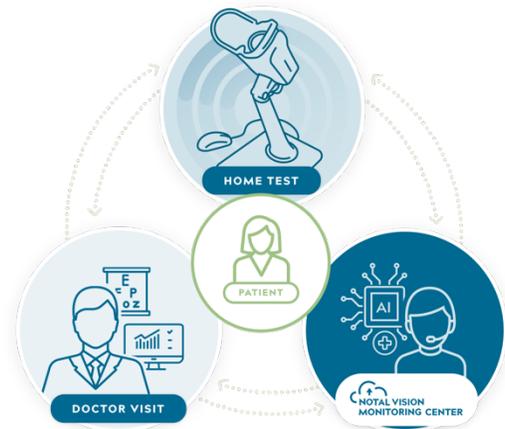


“We placed an increased focus on patients who were seen after a ForeseeHome alert but at the time did not present with wet AMD,” says Allen C. Ho, MD, the report’s principal author and Director of Retina Research of Wills Eye Hospital and Professor of Ophthalmology at the Kimmel School of Medicine at Thomas Jefferson University. “In cases like these, patient management should include more frequent office visits given the elevated risk of conversion the home test indicates.”

Researchers also pointed to the outstanding value of this information for clinical research. There has been great interest in prophylactic treatment for dry AMD patients before wet AMD conversion. However, to study this type of treatment efficacy, a group of patients at high risk of conversion needs to be identified. This is a significant challenge as only a small percentage of patients with dry AMD convert to wet in a given period. The predictive nature of alerts from the AI-enabled ForeseeHome can be invaluable for studying prophylactic treatments for AMD patients.

“Patients identified as high-risk by the ForeseeHome program may be the first to benefit from a prophylactic treatment once approved,” said Michael J. Elman, MD, co-author of the ALOFT study. “The sensitive functional home test may allow us to prevent wet AMD, rather than only treat it.”

The Notal Vision Monitoring Center is the only ophthalmic digital health provider offering remote monitoring for qualified AMD patients. Working closely with their referring doctors, the monitoring center provides patients a comprehensive remote monitoring service that includes an AI-enabled, home-use device. The Monitoring Center services include insurance benefit verification, device provisioning, disease and device education, continuous compliance and data monitoring, and alert management on behalf of the referring doctor. While review is not required, the Monitoring Center also provides doctors with 24/7 access to a secure, web-based portal that provides clinically actionable insights for patient interactions and management.



“Predicting disease progression with the AI-based notifications our ForeseeHome remote monitoring service provides physicians has the potential to expand early management of age-related macular degeneration”, said Kester Nahen, PhD, Chief Executive Officer of Notal Vision, Inc. “Our monitoring center’s advanced digital healthcare data analytics capabilities help us engage with pharmaceutical companies developing new treatment paradigms.”

More details about the ForeseeHome AMD Monitoring program and the Notal Vision Monitoring Center can be obtained at: <https://notalvision.com/technology/foreseehome>

The publication is available at *Ophthalmology Retina*’s website: [https://www.opthalmologyretina.org/article/S2468-6530\(22\)00511-5/fulltext](https://www.opthalmologyretina.org/article/S2468-6530(22)00511-5/fulltext)

References:

1. Mathai M, et al. Analysis of the Long-term Visual Outcomes of ForeseeHome Remote Telemonitoring: The ALOFT Study. *Ophthalmol Retina*. 2022 Apr 26:S2468-6530(22)00193-2. doi: [10.1016/j.oret.2022.04.016](https://doi.org/10.1016/j.oret.2022.04.016)
2. Ho AC, et al. The predictive value of false positive ForeseeHome alerts in the ALOFT study. *Ophthalmol Retina*. 2022. <https://doi.org/10.1016/j.oret.2022.10.009>

About Notal Vision

Notal Vision is a patient-centric ophthalmic remote monitoring services provider extending retinal disease monitoring from the clinic to the home, providing physicians with remote monitoring services to support their patient care between office visits. With a proven approach to home-based, self-operated diagnostics, AI-enabled data analysis, and patient engagement, we help preserve patients' vision.

www.notalvision.com

The Notal Vision Monitoring Center is a remote, Medicare credentialed ophthalmic monitoring center and the epicenter of patient engagement. Led by practicing ophthalmologists and supported by certified ophthalmic professionals, the Monitoring Center offers a comprehensive nationwide age-related macular degeneration (AMD) home monitoring service for referred patients.

The ForeseeHome® AMD Monitoring Program is a comprehensive program, which includes an FDA-cleared device 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 Monitoring Center 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 like 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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