



AI-based OCT analysis of AREDS2 10-Y follow-on study demonstrates superior performance over retina specialists

Publication of study in Ophthalmology shows benefits of Notal OCT Analyzer

Manassas, VA (August XX, 2020) – Data analysis from Age-Related Eye Disease Study 2 10-year Follow-On Study (AREDS2-10Y) participants shows that the Notal Optical Coherence Tomography (OCT) Analyzer, which uses machine learning and image recognition computational techniques to identify, quantify and map intra- and subretinal fluid in wet age-related macular degeneration (AMD), achieved a higher level of accuracy than that of retina specialists, who had imperfect accuracy and low sensitivity in detecting retinal fluid. The study, recently published in *Ophthalmology*, was presented at the American Society of Retina Specialist virtual annual meeting on July 24, 2020.

“The study results show how challenging it is to identify fluid especially when it is not very obvious,” said Michael Elman, MD, a co-author of the article. “In many cases the fluid that was missed was clinically meaningful. The analysis points at the potential benefit of an AI-assisted image review in routine clinical care when the time is limited.”

The study design employed a reading center and masked investigators that graded 1,127 eyes from 651 participants, but were unaware of the planned data analysis. The higher accuracy of NOA versus retina specialists was derived from substantially higher sensitivity (82.2% vs. 46.8%), with only moderately lower specificity (86.5% vs. 97.0%). Retina specialists correctly identified retinal fluid in fewer than half of the cases. The cases where retinal fluid was missed by the human investigators appeared to be more challenging with smaller amounts of fluid, as might be expected. However, these cases might still be clinically relevant, particularly in eyes with intraretinal fluid and a relatively central location. The substantially higher sensitivity of NOA is an important advantage, since the NOA-generated fluid thickness heatmaps drew the physician’s attention to areas of fluid that otherwise might have been missed during volume scan review.

An OCT device is the gold standard for diagnosing and managing the treatment of wet age-related macular degeneration. Review of in-office OCT images, however, is time consuming, slows down workflow, and presents a challenge for retina specialists pressed for time. Emerging home OCT technology will dramatically increase the amount of OCT images that require analysis to assess disease status and need for treatment. The Notal OCT Analyzer (NOA) will assist physicians in identifying, quantifying and mapping intra- and subretinal fluid in wet AMD, as well as automatically provide biomarkers for disease activity in large study data sets.

“We are pleased with the performance of NOA in this large and challenging cohort of OCT scans obtained with two commonly used in-office devices,” said Gidi Benyamini, Notal Vision’s chief technology officer and director of the Notal Vision Innovation Center. “AI-based software could assist physicians in detecting retinal fluid and informing patient management and treatment decisions once confronted with large amounts of images from patients regularly self-imaging on a future home-based OCT device.”

Notal Vision’s home-based OCT pipeline technology received FDA Breakthrough Device designation at the end of 2018, and is in the process of obtaining FDA clearance. In January 2020 the American Medical Association established three category III Current Procedural Terminology (CPT®) codes for reporting patient-initiated remote retinal OCT scans, facilitated by Notal Vision’s home-based OCT. The physician review, interpretation and documentation of AI-based analyses will be billable every 30 days. Results

from a clinic-based trial using the final form factor of the Home OCT presented earlier this year showed that the areas of fluid seen on the system's intra- and subretinal fluid thickness maps correlated with the locations of abnormal vessels seen on OCT angiography, as well as leakage areas on fluorescein angiography, demonstrating the technology's ability to track disease status. In the same study 90% of wet AMD patients self-imaged successfully on the Home OCT device demonstrating the ease of use in an elderly patient population. The image quality was shown to be sufficient for a human grader to identify fluid in one of three consecutive tests with a sensitivity and specificity of 97% and 95%, respectively.

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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