AI-based retinal fluid analytics of serial Notal Vision home OCT images offers insights into retinal disease dynamics

Performance data for NOTAL-OCT V3.0, a patient-operated home-based optical coherence tomography device, presented at international meeting in Miami

Manassas, VA (February 10, 2020) - Longitudinal data on retinal imaging of age-related macular degeneration (AMD) patients using the final form factor of Notal Vision's home OCT (NOTAL-OCT V3.0) was presented at the Angiogenesis, Exudation, and Degeneration meeting in Miami. The pipeline technology is designed to use home-based, patient-initiated retinal OCT scans to support the management of patients with exudative AMD, complementing existing standard of care as well as emerging longer acting drugs and drug delivery systems.

"This is the first time nano-liter scale quantities of intra- and subretinal fluid have been tracked over time based on home OCT images and deep learning retinal fluid analytics from patients receiving anti-VEGF therapy," said Kester Nahen, PhD, CEO of Notal Vision. "The reports generated from the data allow physicians to analyze the temporal dynamics of a patient's retinal fluid, including fluid volume and thickness maps."

The NOTAL-OCT V3.0 trial is recruiting 200 AMD patients at two study sites in Tel Aviv, Israel. The results show that the areas of fluid seen on home OCT based intra- and subretinal fluid thickness maps correlate well with the locations of of abnormal vessels seen on OCT angiography as well as leakage areas on fluorescein angiography, demonstrating the technology's ability to track disease status.

"Home OCT will allow physicians to better-assess retreatment intervals and catch the appearance of retinal fluid as soon as it occurs, rather than at the patient's next clinic visit, which may be far in the future" said Anat Loewenstein, MD, the study's principal investigator and the Director of the Department of Ophthalmology at Tel Aviv Medical Center in Israel. "I foresee the gap in visual outcomes between randomized controlled trials and our real-world experience to shrink with the use of home OCT."

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. Home OCT has the potential to support current and future advances retinal disease management.

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 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, and is covered by most private insurance. To learn more, visit www.foreseehome.com.

Notal Vision's Home OCT will enable exudative AMD patients to perform technician-free OCT testing at home with rapid, 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 sends reports to the treating physician which characterize quantitative changes in fluid. In addition, physicians will be provided 24/7 access to all 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 truly individualize and advance retinal disease management.

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