Notal Vision announces publication of first prospective longitudinal pilot study of daily self-imaging with patient-operated Home OCT in wet AMD patients

The technology is designed to support retina specialists with disease insights between office visits

Manassas, VA (July 13, 2021) – Notal Vision, Inc. announced today that results from the first prospective longitudinal pilot study of daily, home-based self-imaging with their investigational, patient-operated Home OCT for wet age-related macular degeneration (AMD) patients have been published in Ophthalmology Science.[1] The technology is designed to provide retina specialists with remote retinal OCT scans and fluid volume trajectories to support the management of patients with wet AMD, complementing existing standard of care treatments as well as emerging longer acting drugs and drug delivery systems.

The study evaluated the ability of subjects to perform sequential daily self-imaging of their eyes with the user-friendly, tele-connected and self-operated Notal Home OCT device in their homes. Daily OCT images were automatically transmitted to the Notal Health Clould and processed for signs of disease activity by the Notal OCT Analyzer (NOA), an artificial intelligence image processing algorithm that identifies, quantifies and maps fluid in the retina.

“Daily home OCT imaging reveals a high degree of heterogeneity in terms of the dynamics of fluid exudation and resolution,” said Prof. Anat Loewenstein, Director of the Department of Ophthalmology at Tel Aviv Medical Center (Ichilov) in Tel Aviv, Israel. “Typically a clinical decision is inferred from single time points of OCT imaging. With home OCT, we as clinicians will be able to base our decisions on enormous qualitative and quantitative data with greater insights in disease activity between office visits. Home OCT may allow highly personalized retreatment decisions with fewer unnecessary injections and clinic visits.”

Led by Prof. Loewenstein, the pilot study in Israel followed four patients undergoing routine anti-VEGF therapy for wet AMD in one or both eyes for up to three months. Out of 240 self-imaging attempts 87.9% were successful, and of these 97.6% had satisfactory image quality. For fluid presence, NOA agreed with human grading in 94.7% of cases. From a subset of 24 scans with fluid, for agreement between NOA and human fluid volume measurements, the correlation coefficient was 0.996 and mean absolute difference 1.5 nl (vs 0.995 and 1.2 nl, respectively, for inter-human agreement). Graphical plots of fluid volume revealed wide variation in the dynamics of fluid exudation and treatment response.

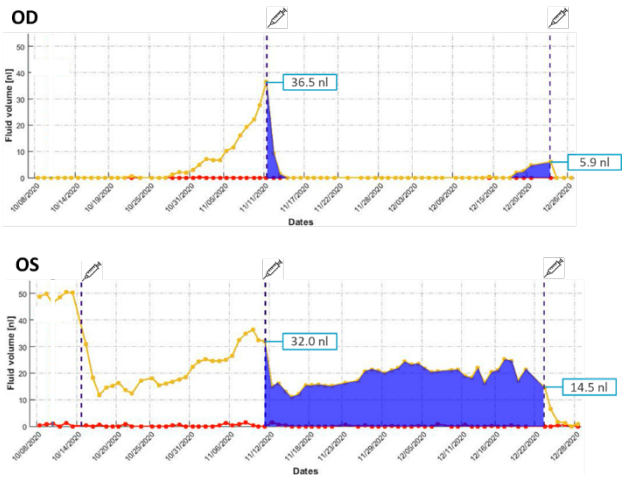

Figure: Intraretinal fluid (red) and subretinal fluid (yellow) volume trajectories from Notal OCT Analyzer (NOA) segmentation of daily home OCT self-images of a patients right and left eye. Retinal fluid exposure described by the area under the curve between treatments (syringe) differs significantly between eyes despite similar fluid volumes measured on the day of office treatment visits illustrating the medical insights gained from daily OCT imaging at home.

“We thank the investigators for their pioneering efforts and laying the foundation for a new paradigm in patient management,” said Dr. Kester Nahen, Chief Executive Officer of Notal Vision, Inc. “The successful demonstration of all elements required for a Home OCT monitoring system in this

longitudinal home-based study has allowed us to embark on several ongoing larger scale trials with pharmaceutical companies that are using our investigational home monitoring service," he added.

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.

Reference:

[1] Keenan TDL, Goldstein M, Goldenberg D, Zur D, Shulman S, Loewenstein A. Prospective longitudinal pilot study: daily self-imaging with patient-operated home OCT in neovascular age-related macular degeneration. Ophthalmology Science 2021 (in press), https://doi.org/10.1016/j.xops.2021.100034

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 a comprehensive platform, 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 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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