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Home Monitoring of Age-Related Macular Degeneration

Utility of the ForeseeHome Device for Detection of Neovascularization

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Purpose: To evaluate the real-world utility of the ForeseeHome monitoring device (Notal Vision, Ltd., Tel Aviv, Israel) for the detection of conversion from intermediate age-related macular degeneration (iAMD) to neovascular AMD (nAMD) and to compare with results published by the Home Monitoring of the Eye (HOME) study.

Design: Retrospective analysis of electronic health records.

Participants: Eyes prescribed use of the ForeseeHome device across 4 retinal practices in the United States.

Methods: Usage information was collected from the online ForeseeHome portal for all eyes prescribed the device. For a predetermined subset of eyes, additional clinical information was collected through chart review and analyzed for clinical utility.

Main Outcome Measures: Frequency and length of use, number of eyes that used the device, number of eyes that established a baseline measurement, number of eyes that converted to nAMD, and number of alerts.

Results: Seven hundred seventy-five eyes of 448 patients were prescribed use of the ForeseeHome device. Six hundred forty-nine eyes (83.7%) used the device at least once; among this population, 478 (73.7%) established a baseline measurement. Patients who established a baseline measurement were significantly younger than those who did not (P < 0.001). Among eyes that established a baseline measurement, 126 (26.4%) had an overall inadequate frequency of use (≥2 tests per week), and 250 (52.3%) did not use the device as frequently as instructed by the manufacturer (≥3 tests per week); 24.7% of eyes discontinued use within 1 year. Of the 136 eyes that established a baseline measurement among 211 eyes prescribed the device at 1 clinical site, 52 alerts were recorded; 3 (6.8%) correctly identified conversion to nAMD and 47 (93.2%) represented false-positive alerts.

Conclusions: Compared with the prospective HOME study, the utility of the ForeseeHome device in the current analysis of clinical practice application was limited. A meaningful proportion of eyes never used the device or could not establish a baseline measurement. Overall frequency of use was low, and continuous use of the device decreased over time. A need exists for improvement in home monitoring technology for eyes with iAMD at risk of conversion to nAMD. Ophthalmology Retina 2020; •:1–9 © 2020 by the American Academy of Ophthalmology

Age-related macular degeneration (AMD) is a leading cause of blindness in individuals 50 years and older in the United States and Europe. In 2010, an estimated 2.07 million people were living with AMD in the United States, with a projected 3.7 million doing so by 2030. Age-related macular degeneration severity typically is classified according to the Age-Related Eye Disease Study (AREDS) AMD categories 1 through 4, dependent on drusen size and area, pigment epithelia state, geographic atrophy, and neovascularization. Two advanced forms of AMD exist (AREDS category 4): geographic atrophy and neovascular AMD (nAMD) characterized by choroidal neovascularization (CNV), more recently termed macular neovascularization. Neovascular AMD occurs in 10% to 15% of all AMD patients and causes an estimated 80% of severe vision loss attributable to AMD. Typically, both forms are preceded by AREDS category 3 AMD, intermediate dry AMD (iAMD), characterized by numerous intermediate drusen, large drusen, and geographic atrophy.

Although aging is the most significant risk factor for development of AMD, modifiable risk factors also have been shown to influence the risk of progression from iAMD to advanced AMD. For example, smoking cessation and optimized cardiovascular risk factors have been correlated with reduced risk of advanced AMD developing. Additionally, the AREDS reported beneficial effects associated with consumption of a specific
A combination of supplements. Nevertheless, no known treatment exists for iAMD. On detection of conversion to nAMD, the standard of care includes intravitreal injections of anti–vascular endothelial growth factor A agents. Multiple studies have demonstrated that better visual acuity (VA) at the time of initiation of nAMD treatment and decreased time between onset of visual symptoms and treatment initiation are correlated positively with better absolute long-term VA outcomes, highlighting the value of early diagnosis and treatment of nAMD.

Historically, monitoring of iAMD patients at risk of conversion included regular in-office examinations in addition to patient reporting of changes in visual symptoms. For monitoring between office visits, patients are advised to use the Amsler grid, a simple pattern of lines to detect scotomas or metamorphopsia, introduced by Marc Amsler in 1947 and validated by the Macular Photocoagulation Study Group. Although this is still a widely used method of self-monitoring, it has shown low levels of sensitivity and poor patient compliance. However, more recent technology has shown promise in the use of daily home telemonitoring of iAMD.

In 2014, the Home Monitoring of the Eye (HOME) study reported beneficial results from a randomized trial using the ForeseeHome device (Notal Vision, Ltd., Tel Aviv, Israel) for early detection of conversion to nAMD. The ForeseeHome device is a home monitoring device that patients use daily for 3 minutes per eye; after establishing a baseline measurement, it monitors for changes in vision suggestive of CNV development. Change in visual function is measured through use of preferential hyperacuity perimetry to detect metamorphopsia or scotoma and results in an alert sent to the patient’s physician and the patient so a clinical appointment can be made to evaluate for signs of exudative disease activity. The main outcome measure of the HOME trial was the change in VA from baseline to detection of CNV between 2 arms: one monitored with standard of care only and another monitored with standard of care plus device use. At the time of CNV detection, the device arm showed a statistically significantly smaller decline in median VA than the standard care arm, at −4 and −9 letters, respectively. Furthermore, the device arm ultimately showed an increased proportion of patients who maintained VA of 20/40 or better, at 87% compared with 62%. Based on these results, the authors concluded that patients at high risk of CNV developing would benefit from use of the ForeseeHome device through increased likelihood of ultimately better VA outcomes. The HOME trial also reported good overall compliance of ForeseeHome use by participants and that performance of the device added minimal burden to patients with an annual false-positive alert rate of 0.24 per year, extrapolating this to 1 false alert every 4.2 years of device use.

The purpose of the current analysis was to determine compliance among prescribed use of the ForeseeHome device, and to describe clinical experience with this home monitoring system in 4 large retina practices across the United States.

Methods

Demographic and clinical information were collected retrospectively from 4 geographically distinct retina practices across the United States: Ophthalmic Consultants of Long Island (New York, New York), Retina Consultants of Houston (Houston, Texas), University Retina and Macula Associates (Chicago, Illinois), and Retina Vitreous Associates of Florida (Tampa, Florida). Institutional review board or ethics committee approval (Houston Methodist Hospital, Houston, TX) was obtained for the retrospective chart review in this Health Insurance Portability and Accountability Act-compliant study, which adhered to the tenets of the Declaration of Helsinki. Date range of data collection was July 25, 2013, through January 3, 2020. Informed consent was not required due to the retrospective nature of the study.

Metrics Collected

For each patient, the eye prescribed, age at first use, length of use, days since last examination, total number of tests, ability to establish a baseline measurement, number of alerts, and types of alerts were collected from the ForeseeHome portal (www.foreseehomeonline.com). Eyes were considered active if they had a test within 30 days of January 3, 2020. Eyes classified as having never used the device included eyes for which a prescription was never filled and eyes for which a prescription was filled but that never used the device. Overall frequency of use over total length of use was calculated from the total number of tests and the length of use.

Each alert was classified as either an unreliable pattern or test score change. Unreliable pattern alerts have been defined by the manufacturer as occurring when a patient consistently overresponds (marking locations far away from light projection) or underresponds (ignoring light projections completely) during testing after a period of reliable results. Test score change alerts have been defined by the manufacturer as occurring when a patient incorrectly marks locations of distortion on the light projections. Both types of alerts may be indicative of CNV onset. For each alert, the frequency of use in the month before the alert also was captured. Two frequencies of use were calculated to investigate compliance: adequate frequency was defined by the HOME study at 2 tests or more per week, and instructed frequency was defined at 3 tests or more per week as specified by the manufacturer to patients. In a predetermined subset of the population (all patients managed at Retina Consultants of Houston, Houston, Texas), a granular analysis was performed by chart review to assess the clinical value of home monitoring with this device; additional clinical information regarding disease state, development of nAMD, and follow-up appointments was collected. In this subpopulation, each alert was classified as positive or false positive. A false-positive result was defined as a test score change alert that did not result in a diagnosis of CNV at the following clinic appointment. Clinical conversions to nAMD that were not identified by ForeseeHome during active device use were classified as false-negative conversions. Diagnoses after alerts were confirmed with spectral-domain optical coherence tomography (SD OCT) and clinical examination and, if clinically warranted, fluorescein angiography (FA). Fluorescein angiography was not performed for all patients who experienced an alert.

Methods of Analysis

Data were analyzed using 2 methods: eye-level data and patient-level data. Eye-level data considered each eye of each patient separately. Patient-level data were used for age correlation. For patients with both eyes prescribed for ForeseeHome use, the patient
was categorized as having established a baseline measurement if at least 1 eye was able to establish a baseline measurement.

Statistical comparisons were performed using RStudio software version 1.2.5019 (www.rstudio.com, Boston, MA). The Shapiro-Wilk test was used to test for normality among the data set. Statistical significance of means was measured using either the parametric Student t test or nonparametric Wilcoxon test when appropriate. Differences between sites were analyzed using the following metrics: proportion of eyes that never used the device, proportion of eyes that could not establish initial baseline measurement, mean frequency of use, mean age, proportion of patients within the HOME study age range, proportion of patients within the HOME study VA range, and proportion of right study eyes. Chi-square tests were performed to test for significant differences among proportions and the 1-way analysis of variance was used to test for significant differences among mean values. A P value of less than 0.05 was considered statistically significant, and a t test distribution was used to calculate 95% confidence intervals.

Results

Initial Baseline Measurement

Among the 4 retina practices evaluated, 775 eyes of 448 patients were prescribed use of the ForeseeHome device. One hundred twenty-six eyes (16.3%) never used the device after prescription. In total, among eyes that attempted to establish a baseline measurement, 478 eyes (73.7%) were able to establish a baseline measurement and 171 eyes (26.3%) were not successful at doing so (Fig 1). Among the patients who used the device at least once, baseline demographics are summarized in Table 1. Among the analyzed factors, the proportion of eyes that never used the device was found to be statistically significantly different among the sites (P = 0.0001); all other comparisons were not statistically significantly different. On prescription of the device, 441 patients (98.4%) had documented medical insurance, 402 patients (89.7%) had Medicare, 35 patients (7.8%) had commercial insurance, and 4 patients (<1%) had other insurance. At first use, the mean age of patients was 76.2 ± 8.4 years. The mean ages of patients who could versus could not establish a baseline measurement were 75.1 ± 7.8 years versus 80.5 ± 9.2 years (P < 0.001, Wilcoxon rank-sum test).

Longitudinal Activity

Among eyes that established a baseline measurement, mean frequency of use over the entire length of use through the end of the current study period was 3.44 ± 1.86 tests per week; 126 eyes (26.4%) and 250 eyes (52.3%) demonstrated an overall frequency of use fewer than 2 and fewer than 3 tests per week (Fig 2). Among this population that established a baseline, the proportion of eyes that continued to be active longitudinally was calculated. Discontinuation of the device was most common within the first year of use: 24.7% of eyes stopped use within the first year, 36.6% stopped within 2 years, and 52.3% stopped within 3 years (Fig 3). More specifically by year, among eyes with the potential to have been tested for 1 year or more, 24.7% stopped before 1 year; among eyes with the potential to have been tested for 2 years or more, 13.8% stopped between 1 and 2 years; and among eyes with the potential to have been tested for 3 years or more, 13.8% stopped between years 2 and 3.

Alerts

Through a mean of 20.35 months of potential total time using the device, 106 eyes (22.2% of eyes that established a baseline measurement) experienced at least 1 alert, and cumulatively, a total of 152 alerts were recorded. Through 6, 12, 24, and 36 months of device use, 9.1%, 14.1%, 15.9%, and 17.3% of active eyes had at least 1 alert cumulatively. One hundred twenty-five alerts (82.2%) were categorized as test score change alerts, and 27 alerts (17.8%) were categorized as unreliable pattern alerts. For each alert, the ForeseeHome portal reported on the frequency of use in the month directly before the alert; 22 alerts (14.4%) and 52 alerts (33.5%) showed an overall frequency of use of fewer than 2 and fewer than 3 tests per week in the month before the alert, respectively. Of the 106 eyes that had at least 1 alert, 44 (41.5%) could not re-establish a baseline measurement after an alert.

Clinical Utility

In a predetermined subset of eyes from 1 clinical site, additional analyses of associated clinical information and conversion to nAMD were performed (Fig 4). All of the following data were collected from this predetermined subset. Of 211 eyes prescribed for 123 patients, 19 (9%) never used the device. Of the 192 patients (91%) who used the device at least once, more than 95% met the ForeseeHome recommendations of VA of 20/60 or better; a total of 18 eyes (9.4%) subsequently converted from iAMD to nAMD over a mean of 8.44 months. Fifty-six eyes (29.2%) could not establish a baseline measurement, with 7 of these eyes subsequently converting to nAMD. Of the 136 eyes (70.8%) that established a baseline measurement, 99 (72.1%) had no alerts and 5 of these eyes subsequently developed nAMD without antecedent detection by the device. Among these 5 eyes, 3 conversions were detected during regularly scheduled

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**Figure 1.** Diagram illustrating use of the ForeseeHome device (Notal Vision, Ltd., Tel Aviv, Israel) for all prescribed eyes.
follow-up appointments, and 2 were detected at appointments scheduled because of subjective change in vision that was noted by the patient. All 5 eyes demonstrated new evidence of exudative fluid on SD OCT evaluation, and 2 eyes underwent concurrent FA demonstrating the presence of new CNV. Overall frequency of use in these 5 eyes was 4.2/C6 1.5 tests per week (range, 2.7–6.3 tests).

The remaining 37 eyes (27.2%) experienced 52 alerts, with a mean of 1.4/C6 0.64 alerts per eye over a mean of 15.0/C6 7.5 months of follow-up. Forty-three of these alerts (82.7%) were categorized as test score changes, and 9 alerts (17.3%) were categorized as unreliable pattern alerts. Seven eyes (14.6%) and 16 eyes (33.3%) showed a frequency of use of fewer than 2 and fewer than 3 tests per week in the month before the alert, respectively. Thirty-five of the alerts (67.3%), experienced by 24 patients, were followed by clinic visits within 4 weeks of notification, with an average of 8.97 days between alert and follow-up.

After an alert, each eye must re-establish a new baseline to continue use of the device. Of the 37 eyes with alerts, 15 (40.5%) could not re-establish a baseline measurement after alerts and continued use of the device. Overall, among eyes that established a baseline measurement, 47 alerts from 33 eyes (88.7%) were false positives, resulting in a mean 1.42/C6 0.61 false-positive alerts per eye over 1.12/C6 0.59 device-use years and 0.43 false-positive alerts per year of device use per patient; on extrapolation, this results in 1 false alert per patient every 2.33 years. Twenty-nine of these eyes (87.9%) did not demonstrate CNV after false-positive alerts with a mean follow-up time of 12.4/C6 6.8 months, and 4 (12.1%) eventually converted to nAMD a mean of 8.1/C6 3.8 months after the first false-positive alert. After the first false-positive alert, eyes underwent a mean of 5.7/C6 4.8 appointments over a mean of 11.9/C6 6.6

Table 1. Patient Demographics*

|                  | Total  | Site 1 | Site 2 | Site 3 | Site 4 |
|------------------|--------|--------|--------|--------|--------|
| Patients, no. (%)| 378    | 46 (12.2) | 23 (6.1) | 112 (29.6) | 197 (52.1) |
| Age (yrs), mean (SD) | 76.2 (8.4) | 75.5 (7.4) | 76.8 (6.7) | 75.9 (6.3) | 76.6 (9.7) |
| 53–90 yrs of age, no. (%) | 361 (95.5) | 46 (100) | 22 (95.7) | 110 (98.2) | 183 (92.9) |
| Female gender, no. (%) | 236 (62.4) | 30 (65.2) | 17 (73.9) | 66 (58.9) | 124 (62.4) |
| Eyes, no. (%) | 649 | 69 (10.6) | 42 (6.5) | 192 (29.6) | 346 (53.3) |
| Right eyes, no. (%) | 325 (50.1) | 33 (47.8) | 20 (52.6) | 101 (52.6) | 171 (49.4) |
| VA 20/60 or better, no. (%) | 616 (94.9) | 64 (92.7) | 40 (95.2) | 185 (96.4) | 327 (94.5) |

SD = standard deviation.
*This table describes the demographic distribution of those who used the device at least once
 Participating in the Home Monitoring of the Eye study were required to be between 53 and 90 years of age with a visual acuity of 20/60 or better.
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Figure 3. Graph illustrating the length of use of the ForeseeHome device (Notal Vision, Ltd., Tel Aviv, Israel) by eyes that established a baseline measurement. Data table with the corresponding number and percentage of active patients every 3 months of use is included at the bottom.

| Month | 0   | 3   | 6   | 9   | 12  | 15  | 18  | 21  | 24  | 27  | 30  | 33  | 36  |
|-------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| N (Eyes) | 478 | 476 | 476 | 453 | 423 | 385 | 337 | 268 | 213 | 169 | 145 | 109 |
| Active | 478 | 462 | 417 | 303 | 341 | 302 | 269 | 227 | 170 | 143 | 95  | 83  | 52  |
| Percent | 100 | 97  | 88  | 83  | 75  | 71  | 70  | 67  | 63  | 67  | 56  | 57  | 48  |

Figure 4. Diagram illustrating a granular analysis of a prespecified subset of eyes. Red boxes indicate eyes that converted to neovascular age-related macular degeneration.
months, resulting in a follow-up rate of 0.57 appointments per month or 1 appointment every 1.75 months until the last follow-up appointment or conversion to nAMD. Among eyes with a fellow eye being treated for nAMD (n = 7), the follow-up rate was 1 appointment every 1.55 months compared with 1 appointment every 1.83 months among eyes with a dry fellow eye (n = 29). Additionally, among all eyes with false-positive alerts, 9 eyes (27.3%) underwent FA at least once in the year after the first false-positive alert; 7 eyes never demonstrated CNV within the follow-up period, and 2 eyes converted within 5.1 and 6.75 months of the false-positive alert.

**Discussion**

At-home telemonitoring is a validated method for monitoring disease states across multiple specialties including cardiology, pulmonology, obstetrics, and ophthalmology. 34,35,37,43 Despite this, use of home monitoring devices in clinical practice can be challenging, as evidenced by the current dataset. The current retrospective study evaluated the clinical application of the ForeseeHome monitoring device among 775 eyes from 4 geographically distinct retina practices across the United States. In total, 83.7% of eyes used the device at least once, and among these, 26.3% were unable to establish an initial baseline measurement to begin monitoring. This challenge was evident in the HOME study, with 15.9% of participants failing the screening because of pre-existing visual field defects, with an additional 8% of randomized eyes reportedly being unable to establish a baseline measurement, smaller proportions than observed in the current study. Multiple factors likely contributed to a larger proportion of eyes being unable to establish a baseline measurement in the current study, including older mean age of the current population at 76.2 ± 8.4 years compared with a mean age of 72.5 ± 7.7 years in the HOME study.

After a baseline measurement is established, consistent long-term use of the device is important to maximize the opportunity to prevent vision loss by early detection of conversion to nAMD. Among eyes that established a baseline measurement within the current analysis, approximately one quarter did not use the device with adequate frequency (≥2 tests per week), and approximately half did not comply with manufacturer instructions for frequency of use (≥3 tests per week). Among 125 patients experiencing test score change alerts, 13.6% had an inadequate frequency of use, and 32% did not use the device as frequently as instructed in the preceding month before the alert. Without an adequate testing frequency, the visual field data and alerts may be less reliable, decreasing the effectiveness of the device. Complete discontinuation of device use was another hurdle: 25% of eyes stopped use of the device within 1 year, nearly 40% stopped within 2 years, and more than half stopped within 3 years. This discontinuation rate is higher than the 20% rate reported in the HOME study through a mean 1.4 years of follow-up. 34 This discrepancy in compliance could be attributed to differences in the populations of the HOME study versus the current retrospective study. The HOME study was a prospective clinical trial including participants who may have been intrinsically more motivated and encouraged by study staff to continue device use. In contrast, the current study retrospectively investigated clinic patients who may not have been as motivated as patients who consent to participate in a clinical trial. Notably, the demographic features of eyes that used the device at least once in the current analysis seemed similar to those reported in the HOME study.

Issues related to patient compliance could have been influenced by several factors. For example, patients may not have had computer experience, making it difficult for them to operate the device or establish a baseline measurement. Patients also may not have understood fully the importance of home telemonitoring and frequent device use. In the current study, across all 4 clinics, it was standard for physicians to encourage continued and consistent use of the ForeseeHome device at each visit. Additionally, patients received monthly reports from ForeseeHome describing their compliance in the past month with recommendations for minimum frequency of use. Issues of compliance may be able to be improved further by screening patients more thoroughly before prescription, ensuring that they are able to use the device effectively, and clinicians could emphasize further the importance of consistent testing and the benefit of early CNV detection on visual outcomes.

The current study demonstrated a higher rate of false-positive alerts per patient per year than did the HOME study. The HOME study reported 0.24 false alerts per person per year, or 1 false alert per person every 4.2 years, compared with 1 false alert per person every 2.28 years in the current series. Preferred practice guidelines recommend follow-up visits for iAMD patients every 6 to 18 months. 34 In the current study, only 12.1% of eyes with false-positive alerts ever demonstrated CNV after the alert, and eyes were followed up clinically a mean of once every 1.75 months, much more frequently than the standard of care for iAMD patients, often related to fellow-eye management needs. Presumably, if these false-positive alerts were attributable to the device identifying CNV conversion earlier than SD OCT or ophthalmic examination were able to, these lesions would be expected to grow and become clinically obvious with subsequent clinical visits. 34

Notably, data from the current study suggested a possible relationship between eyes unable to establish a baseline measurement and eventual conversion to nAMD. Among the subset of eyes analyzed for clinical utility of the device, 12.5% of eyes that could not establish initial baseline later converted to nAMD compared with 8.1% of eyes that could establish a baseline measurement. An additional 20% of eyes that were unable to re-establish a baseline measurement after a false-positive alert also subsequently converted to nAMD. Therefore, patients unable to establish a baseline measurement may indicate a subpopulation at higher risk of converting to nAMD, which may warrant more frequent follow-up visits. Further studies may be warranted to investigate this relationship.

Overall, the results of the current study highlight some of the challenges accompanying home monitoring. 37–43
Telemonitoring strategies range from simple phone calls with health professionals to complex devices like ForeseeHome. Some monitors, like the Holter device and other cardiac monitors, collect data automatically and over short periods.37,39,42 These devices do not have some of the inherent compliance issues associated with long-term monitoring devices such as ForeseeHome because patients do not have to input data manually for the monitoring to be effective, nor do they have to continue monitoring indefinitely. For devices in which patients are required to test themselves manually or input data periodically, ongoing self-motivation is required. Several studies evaluating such devices have described similar compliance challenges as identified in the current study, with patient adherence decreasing over time.40,41,43

Despite the challenges detailed in the current study, the ForeseeHome device remains an important first-generation device that represents the invaluable potentially positive impact that home monitoring could have on improving long-term outcomes when managing not only AMD, but also a host of retinal diseases. The ongoing coronavirus disease 2019 pandemic highlights the importance of advancing our ability to perform home monitoring in ophthalmology. Many ophthalmology clinics have experienced a meaningful decrease in patient volume during this pandemic. At the University of Iowa, for example, patient volume decreased by 85%.35 For patients being monitored for conversion to nAMD, this potential for disruption of routine clinician assessment is concerning and could lead to worse visual outcomes for those who convert to nAMD during this time because of delayed diagnosis. Current methods of home monitoring in ophthalmology, including the Amsler grid and personal device applications such as smartphones and tablets, face similar challenges with patient compliance and also challenges related to reliable use and low sensitivity for visual changes.33,46,47 Nevertheless, technology development is a continuous process, and next-generation devices and new technologies such as incorporation of SD OCT48,49 into home monitoring systems promise to improve on the difficulties encountered with current technology and ultimately may transform the way patients are diagnosed and managed. An important trait of home SD OCT technology is that the assessment of meaningful change will be passive after patient initiation of the at-home test. This would eliminate the limitation of patient data entry that impacts ForeseeHome and many other home monitoring devices. Finally, increased understanding of the reasoning behind patient noncompliance may help aid in the creation of optimal telemonitoring devices.

Strengths of the current study include a large data set from 4 geographically distinct retina centers across the United States. Further, granular data concerning conversion to nAMD in a subset representing 27% of the overall population provided important information on the clinical utility of the ForeseeHome device. Limitations of the study include that VA and other aspects of the disease state were not evaluated uniformly throughout the study, and the follow-up time for device use was limited per eye because of the retrospective nature of the study. The retrospective nature of the study also made it difficult to evaluate how compliance with device use was encouraged by physicians and staff longitudinally. It is also unknown how thoroughly patients were prescreened before prescription of the device for their ability to use a computer mouse. The cost of the device for each patient also was not assessed, and the influence of cost could not be evaluated. Additionally, for eyes that were classified as having never used the device, no distinction was made between whether patients had never filled the prescription or whether they had filled the prescription and never used the device. The current study also was limited in its follow-up of test score change alerts and its confirmation of dry AMD or nAMD diagnosis. In the HOME study, every alert was followed up with clinical examination, FA, and SD OCT, whereas the current study only followed up alerts with SD OCT and clinical examination, with FA being performed only if deemed clinically indicated. Finally, the current study did not evaluate possible reasons for false-positive alerts such as structural changes in eyes not resulting from CNV development.

In summary, the current study investigated the utility of the ForeseeHome device in routine clinical practice. Compared with results from the HOME trial, patient compliance and ability to use the device were more limited because clinically meaningful proportions of patients never used the device or were unable to establish a baseline measurement. Continuous use of the device was low and decreased over time, and the overall false-positive rate was 93.2%, a higher rate than that reported in the HOME trial. These results underscore a need for further refinement of the technologies used for home monitoring for the consideration of iAMD to nAMD with the goal of optimizing long-term visual outcomes for patients.

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Abbreviations and Acronyms:
AMD = age-related macular degeneration; AREDS = Age-Related Eye Disease Study; CNV = choroidal neovascularization; COPD = chronic pulmonary obstructive disease; FA = fluorescein angiography; HOME = Home Monitoring of the Eye; iAMD = intermediate dry age-related macular degeneration; nAMD = neovascular age-related macular degeneration; SD OCT = spectral-domain optical coherence tomography; VA = visual acuity.

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