HOME MONITORING OF DRY AMD PATIENTS

A device used by patients helps detect early signs of CNV so treatment can be started early.

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Patients with dry age-related macular degeneration (AMD) typically see a retina specialist every 6 months or so, at which time they undergo optical coherence tomography (OCT) and a dilated fundus examination. However, neovascular disease can develop between visits, progressing silently and resulting in irreversible pathologic changes and visual acuity loss.

With home monitoring now available, unpredictable and variable disease progression and attendant visual acuity loss can be minimized and even avoided in some cases. The ForeseeHome AMD Monitoring Program (Notal Vision) can detect changes in patients with dry AMD who are at high risk for progressing to choroidal neovascularization (CNV), usually before symptoms develop. ForeseeHome provides a mechanism with which to monitor patients’ AMD every day in their homes without intruding into their lives and without the need to dilate their pupils. The device can serve as a vital safety net, with the potential to catch early development of neovascularization so that treatment can be initiated early enough to preserve vision.

ABOUT FORESEEHOME

ForeseeHome is a self-administered test that takes patients roughly 3 minutes per eye to perform. Ideally, patients should test themselves on a daily basis. The device uses objective preferential hyperacuity perimetry to measure visual field defects using 500 retinal data points over 14° of the patient’s central visual field. Each data point is measured three to five times, with all 500 retinal data points collected in approximately 3 minutes. The test has a sensitivity of more than 80% with a low rate of false positives. Each test consists of a series of dotted lines with an artificial distortion (set of misaligned dots) purposely introduced briefly in various locations of the visual field. The patient is prompted to detect the location of the distortion.

When stimuli are projected over unhealthy portions of the retina, both a real (pathologic) and an artificial wave are delivered to the visual system (Figure 1). When the patient identifies the location of a perceived pathologic wave, it is an indication of both the location and quantity of the underlying pathology. These pattern changes are apparent on testing, often before patients can perceive them visually.

A small percentage of patients will not be able to establish a baseline, but the company makes concerted efforts to help patients get comfortable with performing the test.

The ForeseeHome device automatically transmits test results to Notal Vision’s Monitoring Center, where each test is compared with all previous tests from that patient (Figure 2). Patients who generate an alert on the ForeseeHome test trigger an immediate recall to their eye doctor’s office for additional diagnostic testing and examination. It has been shown that better visual acuity at the time that anti-VEGF injections are initiated correlates with better visual outcomes.

If one of my patients sets off a ForeseeHome alert, Notal Vision contacts my office to inform me, and a follow-up examination is scheduled. If I detect active CNV at that exam, I start him or her on anti-VEGF therapy to increase the likelihood of maintaining vision at a highly functional level.

CLINICAL TRIAL RESULTS

The ability of the ForeseeHome device to effectively detect changes suggestive of disease conversion to CNV was studied in the HOME study. A total of 1520 patients were randomly assigned to test their eyes daily using either the ForeseeHome device with standard testing or standard care.
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alone based on the investigator’s preference (usually Amsler grid testing and/or report of symptoms).

In the primary outcome analysis, patients in the ForeseeHome device group who used the device as instructed at least twice a week showed significantly better outcomes, with a median loss of 3.0 ETDRS letters from baseline to the time of detection of CNV, compared with a loss of 9.0 ETDRS letters in the control group. Additionally, 94% of patients using the ForeseeHome device as directed to detect conversion to CNV maintained 20/40 or better visual acuity at the time of CNV detection, compared with only 62% of patients in the control arm using traditional detection methods. The study was stopped early due to the clinically significant efficacy of the ForeseeHome system, and patients from the control arm were offered use of the device starting at that time.

HOME MONITORING IN CLINICAL PRACTICE

Sometimes what we see in the clinic does not mirror the results obtained in studies, and often adjustments to the use of drugs or devices must be made in real-world settings. In the case of the ForeseeHome device, however, I have employed the same infrastructure and procedures in practice as in the study, and I have witnessed no difference in my own results with the device in clinical practice.

My experience with the device dates back about 5 years, as I was involved in some of the early clinical trials. I have seen patients both under the guise of study protocols and in the clinic, and I can say with confidence that the ForeseeHome device is an excellent tool for early detection of neovascularization in patients with visual acuity of 20/60 or better at risk for disease progression, often before they experience vision loss.

I had a patient several years ago who was being followed for high-risk dry AMD in each eye. During a routine visit, the patient’s visual acuity measured 20/20, and his OCT scan and angiogram were unremarkable. One week later, our office received a ForeseeHome alert, and the patient was immediately contacted to schedule a follow-up visit. When he returned to our office, he remained asymptomatic, and his visual acuity still measured 20/20. However, an occult membrane was easily apparent on OCT and angiogram. Because treatment was initiated before scarring or bleeding occurred and before visual symptoms became apparent, the patient experienced no loss of visual acuity.

I have seen this same scenario with other patients in my practice who use ForeseeHome monitoring. In such cases, had we waited the standard 6 months for patients to return or for them to develop symptoms, there is a good chance that anti-VEGF therapy would have been ineffective. It is...
important to remember that, although anti-VEGF drugs are highly effective at treating newly formed blood vessels, they have no effect on scarring. Treatment must be initiated early in the disease course, preferably at disease onset, for patients to derive maximum benefit.

CONCLUSION

In my mind, ForeseeHome represents a new standard of care, and the recent addition of Medicare coverage for this technology for dry AMD patients at high risk for CNV removes the last barrier to wider implementation: cost. Furthermore, it is likely that the health care system will also recognize cost savings from treatment started early, especially if it leads patients to ultimately require fewer injections. In my opinion, this home monitoring system should be offered to all patients who meet the clinical criteria.