

Monitoring AMD With the ForeseeHome

Teleconnected home-based monitoring system detects early visual changes, often before noticeable symptoms manifest.

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Clinical trials and physician experience have demonstrated that early detection of age-related macular degeneration (AMD) leads to early treatment and saved vision. The ForeseeHome AMD Monitor, manufactured by Notal Vision, Inc. (St. Louis, MO), monitors the progression of AMD and detects conversion to choroidal neovascularization (CNV) before symptoms become evident. Notal Vision received 510(k) clearance for the home-based device from the US Food and Drug Administration (FDA) in December 2009, making it the first ophthalmic device linking patients and doctors between eye exams for ongoing monitoring of AMD. Patients complete a brief exam on their ForeseeHome AMD Monitor each day in the comfort of their home (Figure 1). Data are transmitted to the patients' physician and the Notal Vision Data Monitoring Center.

MONITORING TECHNOLOGY

The ForeseeHome uses a patented technology called preferential hyperacuity perimetry (PHP). Hyperacuity, or vernier acuity, is the human ability to perceive minute differences in the relative localization of two objects in space. The device maps defects within a patient's visual field by analyzing responses to dot deviation signals flashing on a computer screen. A signal, consisting of a series of closely spaced dots in a single straight line with a few dots out of alignment, is displayed on the screen for 160 milliseconds, and then it disappears (Figure 2). The patient uses a computer mouse to identify the most prominent distortion in the line. A typical test measures 500 retinal data points covering the central 14° of the macular visual field. The response patterns are recorded, analyzed, and compared with a normative database, producing a report revealing the relative location of the defects in the macular area.

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As explained by Robert Lowenthal, MD, in the July 2008 issue of *Retina Today*, by utilizing a phenomenon called preferential looking, the device can determine abnormalities that may indicate retinal pigment epithelium (RPE) elevation.¹ Patients' attention will always be drawn to the greatest distortion they see, so if a visual defect causes the patient to see a bend in the line that appears greater than the one presented by the instrument, the patient will select the physiological distortion. The dot deviation signals show differing magnitudes and locations of distortions to measure the extent and location of defects consistent with CNV. In studies, the PHP device has been shown to correctly detect indicators of neovascular AMD more than 80% of the time,² representing a significant improvement over the Amsler grid.

SENSITIVITY

A recent study by Loewenstein et al² showed that the ForeseeHome had good sensitivity and specificity in discriminating between patients with newly diagnosed CNV and intermediate AMD. The study also found that sensitivity was not dependent on lesion characteristics. These findings are consistent with a 2005 study that found the ForeseeHome's PHP technology can detect recent-onset CNV resulting from AMD and can differentiate it from an intermediate stage of AMD with high sensitivity and specificity.³ The authors concluded that



Figure 1. Patients complete a brief exam on their ForeseeHome AMD Monitor each day at home.

monitoring with PHP should detect most cases of CNV of recent onset with few false-positive results at a stage when treatment usually would be beneficial.

The ForeseeHome has also demonstrated greater sensitivity than the Amsler grid.⁴ Among 35 patients with intermediate AMD, 30 were Amsler-grid-negative and 32 were ForeseeHome-negative, yielding a specificity of 85.7% for the Amsler grid and 91.4% for the ForeseeHome. Of 26 patients with CNV, 23 were ForeseeHome-positive compared with only 15 Amsler-grid-positive, yielding a sensitivity of 88.4% for the ForeseeHome and 57.6% for the Amsler grid ($P < .05$).

Howard F. Fine, MD, one of the retina specialists participating in Notal Vision's ForeseeHome prelaunch marketing project, told *Retina Today* that this monitoring technology offers many advantages over the Amsler grid. "The ForeseeHome is highly sensitive for changes in macular function and has detected very early CNV in some of my patients who were asymptomatic, even on Amsler grid testing," Dr. Fine, a retina specialist at the Retina-Vitreous Center in New Brunswick, NJ, said. "The test is objective and reproducible, not subject to patient interpretation. Additionally, patient compliance is always monitored, which is impossible with Amsler grid testing, and patients who are not performing regular home screening tests can be gently reminded to do so."

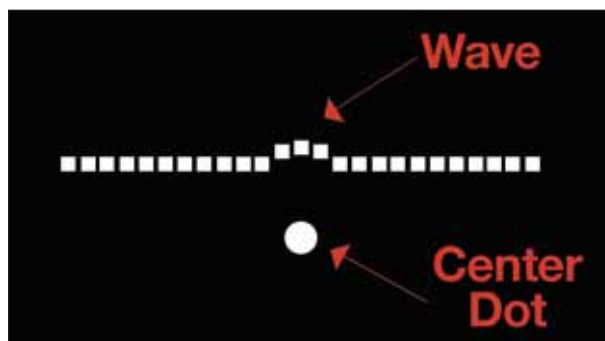


Figure 2. A signal of closely spaced dots in a single straight line with a few dots out of alignment is displayed on the screen for 160 milliseconds, and then it disappears.

PATIENT SELECTION

Carl Awh, MD, a retina specialist at Tennessee Retina in Nashville, TN, and a participant in the prelaunch marketing project for the ForeseeHome, told *Retina Today* that he is still in the early stages of learning how to best use the technology. At the present time, his rule of thumb is to recommend ForeseeHome to patients for whom Amsler grid testing is particularly important. "Monocular patients who have lost vision in one eye to neovascular AMD are ideal candidates," Dr. Awh said. "Patients with high-risk clinical characteristics, particularly those with recognized genetic risk factors, are also reasonable candidates for ForeseeHome."

The patients Dr. Fine encourages most strongly to use the ForeseeHome are those at highest risk for the development of wet AMD, primarily those with wet AMD in the fellow eye. He also discusses the device with patients with dry AMD in both eyes and with patients undergoing therapy with a vascular endothelial growth factor (VEGF) inhibitor to monitor their response to treatment.

USER FRIENDLY

Clinical studies have demonstrated that the design of the ForeseeHome monitor is easy to use for patients at risk of vision loss from wet AMD. Ease of use is important, especially because patients are tested on a daily basis to monitor changes in central macular function. Notal Vision requires users to have a visual acuity of 20/60 or better for stable fixation of the eye being tested. Also, patients must be able to use a computer mouse, a skill that is becoming more familiar in the older patient population, Dr. Fine said. In his experience, many seniors are computer literate and have no significant learning curve for using the mouse. For patients who have never used a computer before, some training may be required to master using a mouse, he said.

"The majority of my patients have been quite pleased

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with the device," Dr. Fine said. "The software for the ForeseeHome is straightforward, and a toll-free number is available if questions arise. My patients have generally been very supportive of home monitoring to ensure their ocular health."

Daily testing also gives patients and doctors a sense of security, Dr. Awh said. For physicians, the internet-based monitoring of the ForeseeHome allows retina specialists to reliably know how often patients perform the test. For patients, the ForeseeHome report gives them a sense of security to know that their tests are continually monitored by the data center and by their doctor's office, and they appreciate the fact that home monitoring may increase their odds of maintaining good vision if they develop neovascular AMD.

According to Notal Vision, this mouse-operated test has several convenient, user-friendly features. "The ForeseeHome test takes just 3 minutes per eye. The small, portable device is easy to set up, requiring the user to simply plug it in and connect to the phone line. A wireless connection will be available later this year," Garrett O'Connell, Vice President of Marketing and Sales, Notal Vision, told *Retina Today*. "The intuitive menu walks the user through each step, and data is automatically transmitted after each test. Live customer support is available if needed."

Currently, the ForeseeHome AMD Monitoring Program is a patient-pay program. Eligible patients pay an initial one-time activation fee plus a monthly monitoring subscription. There is no long-term commitment, and patients may cancel their subscription at any time. Although the US Food and Drug Administration has cleared the device, many insurance companies are not yet willing to cover the cost, which is a limiting factor for many older patients on a fixed income.

EARLY DETECTION SAVED VISION

Dr. Fine's patients test on the ForeseeHome on a daily basis so that he can monitor changes in macular function. If a patient experiences a change between office visits, he is notified promptly. Using a teleconnected home-based monitoring system increases the physician's confidence in treating patients in a timely manner that can potentially save vision. In one such case, dili-

gent monitoring with the ForeseeHome identified a patient that converted to wet AMD.

"One of my patients, with a history of numerous anti-VEGF injections in one eye for wet AMD, was flagged by the ForeseeHome device for recent changes in the fellow eye on home testing," Dr. Fine said. "He was asymptomatic, but angiography demonstrated a small new choroidal neovascular membrane, and I treated him promptly. After several injections he remains 20/20 and is quite grateful that his CNV was detected so early."

LOOKING AHEAD

According to Mr. O'Connell, the response to this teleconnected home monitoring system has been positive. Notal Vision is currently working with a small number of retina practices to introduce the ForeseeHome and refine the company's business model, he explained. Notal Vision is pursuing a limited expansion of this project in 2011 and preparing for a full launch of the ForeseeHome program in the future.

Drs. Awh and Fine are convinced of the value of the ForeseeHome technology. "We are an increasingly wired society, and telemedicine is the way of the future," Dr. Awh said. "This technology can improve patient outcomes while reducing the number of physical office visits. It's better for both the patient and the physician."

The technology has positive implications for the future, too, Dr. Fine said. "I think this represents a paradigm shift in the monitoring of AMD and might be applicable to other chronic retinal diseases in the future like diabetic retinopathy, vein occlusion, and others. ■

1. Lowenthal R. Proactive management for prevention and detection of AMD. *Retina Today*. 2008;3(4):53-55.

2. Loewenstein A, Ferencz JR, Lang Y, et al. Toward earlier detection of choroidal neovascularization secondary to age-related macular degeneration: multicenter evaluation of a preferential hyperacuity perimeter designed as a home device. *Retina*. 2010;30(7):1058-1064.

3. Preferential Hyperacuity Perimeter (PreView PHP) for detecting choroidal neovascularization study. *Ophthalmology*. 2005;112(10):1758-1765.

4. Loewenstein A, Ferencz JR, Yeshurun I, et al. Comparison between the ForeseeHome perimeter and the Amsler grid, in patients with age related macular degeneration. Poster presented at: the American Society of Retina Specialists Annual Meeting; October 11-15, 2008; Maui, Hawaii.

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