

Improving Wet AMD Outcomes With a Fellow Eye Strategy



The importance of detecting early changes in the fellow eye through proactive remote monitoring

By Miguel A. Busquets, MD, FACS

In retina care today, advancing therapies and treat-and-extend regimens have enabled wet AMD patients to extend the time between their anti-VEGF injections, which has served to improve quality of life for those patients under treatment and freed up the retina clinic to see additional patients. While these improvements have positively impacted retina care in many ways, patients with wet AMD may now be seen less frequently than is ideal for following the fellow eye. Some are receiving injections every three or four months, and many are not receiving a bilateral OCT when they present for injections, for a variety of reasons. At the same time, patients may not notice changes that have occurred in their fellow eyes since their last visit. This is concerning because studies reveal that fellow eyes are at higher risk of conversion to wet AMD.^{1,2,3}

These assessment gaps leave a great deal of room to miss conversion. Thankfully, though, advanced remote monitoring solutions make it possible for the patient and specialist to track the fellow eye between office visits, with a goal of catching any structural changes as soon as they occur.

RETINA CLINIC REALITIES

Data has shown us that once a patient begins treatment, the patient tends to be seen less frequently over time. In a paper presented at the American Academy of Ophthalmology Annual Meeting in October 2020, the percentage of patients seen after 8 weeks decreased from 56% (year 1) to 44% (year 2),⁴ meaning in-office imaging frequency of the fellow eye also decreases over time.

I believe retina specialists have the best intentions in putting together comprehensive protocols for patients that include a bilateral exam and OCT with each encounter; however, a number of obstacles exist in retina care today.

One is flow restrictions in clinic. Patient care has become more targeted because of the increasing volume of patients being seen due to an aging population, and an overall shortage of retina specialists. In addition, due to the COVID-19 pandemic, patients may be hesitant to stay at the clinic for a long time. Additionally, unintended delays can be related to logistic hurdles such as bad weather and a lack of transportation, and other variables.

Looking to the future of wet AMD therapy, as longer-acting agents continue to come to market—enabling us to further extend patient treatment intervals—even larger gaps will arise when it comes to following the fellow eye.

These existing and evolving factors prolonging the time between visits make it even more imperative that we adopt available telemedicine technology to overcome these hurdles for patients and clinicians.

TOOLS TO TRACK THE FELLOW EYE

Functional vision is described as 20/40 or better, which is the required driving vision in many states; however, real-world data tells us that fellow eye conversion isn't being caught earlier than 20/79.⁵ An analysis of the IRIS registry found that just 36% of fellow eyes had VA of 20/40 or better at treatment initiation.⁵ At the same time, we know that early diagnosis with good VA is essential to preserving functional vision with anti-VEGF therapy.⁶

Retina specialists have a number of tools available to follow the fellow eye, but they suffer from several limitations. The Amsler grid, which was developed in the 1940s, is rudimentary and not very effective in detecting early wet AMD (20/40); one study showed it was only effective in detecting 9% of such patients.⁷ In addition, we depend on the patient to use it without assistance. While present-day in-office technologies such as simple visual acuity tests, visual acuity charts, OCT imaging, fundus photography, and fluorescein angiography have improved detection of functional or structural changes, they are all subject to the previously mentioned constraints regarding time intervals between patient visits.

Thankfully, the ForeseeHome AMD Monitoring Program provided by the Notal Vision Diagnostic Clinic, a remote ophthalmic monitoring center directed by practicing ophthalmologists and supported by certified ophthalmic professionals, is able to overcome those gaps of time between patient visits. About three years ago, I was introduced to this program, and it has become an invaluable extension of my clinic's services for patients. It is a proven way, via patented Preferential Hyperacuity Perimetry® (PHP) technology developed by Notal Vision, to

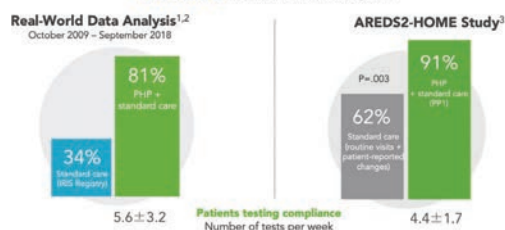
ForeseeHome helps physicians detect wet AMD earlier

ForeseeHome helps physicians detect wet AMD earlier, based on the results of a pivotal clinical trial and real-world results.^{1,2} The HOME study concluded that people at high risk for nAMD benefited from the home monitoring strategy for earlier detection of nAMD development, which increases the likelihood of better visual acuity results after intravitreal anti-VEGF therapy.

More recently, Ho, et al., found that real-world performance of a strategy including the ForeseeHome device monitoring program was comparable to its performance in the HOME study. Coupled with standard of care, its usage demonstrated a substantial benefit to patients by helping preserve an additional three lines of vision at the onset of nAMD, as compared to standard-of-care alone in real-world IRIS data, leading to excellent VA prognosis with current therapy.

ForeseeHome real-world performance resembles pivotal trial results

Percentage of patients maintaining functional vision (20/40 or better) with ForeseeHome at time of wet AMD diagnosis



1. Ho AC, Kleinman DM, Lum FC, et al. Baseline Visual Acuity at Wet AMD Diagnosis Predicts Long-Term Vision Outcomes: An Analysis of the IRIS Registry. *Ophthalmic Surg Lasers Imaging Retina*. 2020;51:633-639.
2. Ho, A.C.; Heier, J.S.; Holekamp, N.M.; Garfinkel, R.A.; Ladd, B.; Awh, C.C.; Singh, R.P.; Sanborn, G.E.; Jacobs, J.H.; Elman, M.J.; et al. Real-World Performance of a Self-Operated Home Monitoring System for Early Detection of Neovascular Age-Related Macular Degeneration. *J. Clin. Med.* 2021;10:1355.
3. Chew EY, Clemons TE, Bressler SB, et al; AREDS2-HOME Study Research Group. Randomized trial of a home monitoring system for early detection of choroidal neovascularization home monitoring of the Eye (HOME) study. *Ophthalmology*. 2014;121(2):535-544.

detect minute vision changes and help catch wet AMD much earlier. In an unmasked, controlled, randomized clinical trial (HOME) of 1,520 subjects with a mean age of 72.5 years at high risk of CNV developing, 91% of patients who progressed to wet AMD maintained functional vision (20/40) upon presentation using ForeseeHome, regardless of test compliance, vs. just 62% of patients using standard detection methods alone.⁸ Real-world performance of the program resembled the pivotal study results in which 81% of patients had 20/40 or better VA at wet AMD diagnosis⁹ compared to only 34% in the IRIS Registry[®] data.⁵

BENEFITS OF A REMOTE MONITORING PROGRAM

The ForeseeHome remote monitoring program is an excellent way to monitor patients remotely for many reasons. The system's ability to detect minute changes in visual distortions means that the system is highly sensitive to detect early changes consistent with a conversion. The HOME study revealed that lesions were approximately three-fold smaller at CNV diagnosis with ForeseeHome vs. standard care alone.⁸ Furthermore, the system's sensitivity and specificity in discriminating between patients with CNV and intermediate AMD has been verified by researchers.¹⁰ Once an alert notification is received from the Notal Vision Diagnostic Clinic, the patient is immediately scheduled to come into our clinic where the change is validated, and, if verified, treatment is initiated. The advantage of this technology is to allow treatment of the patient at the earliest possible time, rather than one, two, or three months after the change has occurred. This is because the patient loses vision every day that a choroidal neovascular membrane is present due to hemorrhage and leakage. Since exudation causes visual loss via cellular damage through these mechanisms, identifying these processes at their inception with the aid of ForeseeHome enables clinicians to minimize retinal damage and, thus, preserve vision. As a result of early detection, patients can experience the full benefit of today's treatment options.

Another benefit of this program is that a team of clinicians at the Notal Vision Diagnostic Clinic monitors the system remotely to ensure that the signals coming through are reliable and that all parties are notified when alerts are issued. In addition, the treating physician obtains regular patient reports from the remote clinic to help them to stay informed about utilization rates, test results, and other relevant information.

Importantly, using ForeseeHome takes little time out of the patient's day and the clinic's workflow. For the patient, the device

is easy to set up and use. The tests take a couple of minutes per eye per day for my patients, and I have them use it daily, with the majority using it 5 times a week. For the physician, the Notal Vision Diagnostic Clinic makes the patient "onboarding" process seamless and prevents it from disrupting my clinic flow. Once the patient agrees to use the system my staff sends an electronic referral to the Notal Vision Diagnostic Clinic which works with the patient directly for setup and assistance over the phone.

AN IMPORTANT EXTENSION OF THE RETINA CLINIC

In my clinic, ForeseeHome has become an important part of the monitoring approach for all eligible patients. When we see a patient receiving intravitreal injections, part of the protocol is that these patients will receive, as part of their workup, a folder with a referral to the Notal Vision Diagnostic Clinic for ForeseeHome. The Diagnostic Clinic provides all educational materials about intermediate AMD and the overall program. One of my technicians, who has been trained by the Notal Vision Diagnostic Clinic, takes a few minutes to educate the patient on the technology and its importance for a comprehensive monitoring strategy. When I come in to do the patient's injection, I simply reinforce the importance of this device and the reasons why it's valuable.

The patient compliance rate with this program is extremely high. I'd say that over 90% of the anti-VEGF patients with whom we have this discussion are not only open to proceeding with the home monitoring, but they're grateful because they know how important monitoring is for their visual outcomes. They've already had one eye under treatment and understand the need to protect the other eye.

The ForeseeHome remote monitoring system administered by the Notal Vision Diagnostic Clinic truly achieves the purpose of telemedicine and remote monitoring technologies, which is to provide an additional branch to our clinical services. It also enables clinicians to treat the eye that has converted while they rest assured that the fellow eye is being properly monitored between office visits as they receive regular reports from the ForeseeHome system. This all comes to fruition when a positive conversion occurs, and the patient is more likely to have vision of 20/25 or 20/30 rather than 20/80 or worse—a much better starting point for me to initiate treatment and preserve vision long-term in what is now a bilateral case under my care.

The ForeseeHome remote monitoring program creates a state-of-the-art model of care that is becoming more and more essential in retina clinics today. I have found it to be a tremendous benefit to my clinic, and my patients have been extremely grateful for it as well.

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Home monitoring is needed to detect fellow eye conversion early

To improve outcomes for patients, home monitoring is needed to detect fellow eye conversion. The ForeseeHome AMD Monitoring Program has been proven to help physicians detect the conversion to wet AMD earlier. The ophthalmologist-led Notal Vision Diagnostic Clinic, provider of the remote monitoring service, helps physicians extend their care between office visits by providing:

- A digital, at-home concierge service from trained engagement specialists and certified ophthalmic professionals
- Benefits verification, disease education, comprehensive device set up assistance and training, and continuous engagement – all done remotely over the phone and via email
- Timely reporting and communications for physicians with information about patients' testing and alerts.

Ongoing patient satisfaction surveys show a 93% approval rating, and 80% of patients test compliantly (as per Medicare guidelines).

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