

## Monitoring AMD With Home-Based OCT

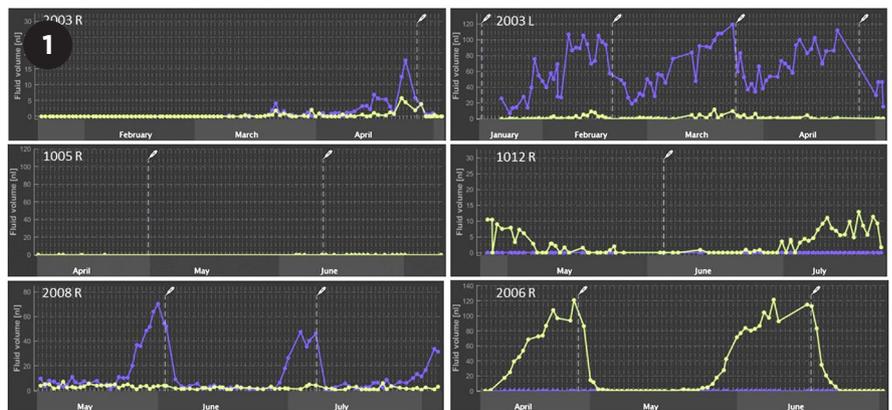
**T**oday, patients with neovascular age-related macular degeneration (AMD) need frequent follow-up. “Our current management of wet AMD is dependent on evaluation of the retina’s fluid status using OCT, which necessitates office visits,” said Judy E. Kim, MD, at the Medical College of Wisconsin in Milwaukee.

Unfortunately, this monitoring and treatment schedule imposes a burden on both doctors and patients. And it has created a dilemma: on one hand, many patients are begging for a little less treatment and a little more balance in their lives, said Claus von der Burchard, MD, at the University of Kiel in Germany. But on the other, if patients miss office visits, they may lose vision, said Diana V. Do, MD, at Stanford University in Palo Alto, California.

Can home-based OCT monitoring help solve this dilemma? It might: if approved and commercialized, home-based OCT could help some patients avoid unnecessary office visits and injections even as it helps ophthalmologists identify those who are most in need of treatment.<sup>1-3</sup> However, significant challenges remain, from the role of artificial intelligence (AI) in the clinic to questions of patient selection and the practicalities of reimbursement.

### Potential Benefits

The concept of home monitoring is not new. For instance, patients with



**FLUID VOLUME TRAJECTORIES.** Data from six eyes, illustrating the intraretinal (purple) and subretinal (green) fluid dynamics over a three-month period.

diabetes regularly measure their own blood sugar, allowing adjustment of treatment as needed, said Dr. von der Burchard. “Doing something similar for AMD patients makes home-based OCT a highly desirable concept.”

**Reduced treatment burden.** A home-based OCT system may help identify patients who have anatomic stability and do not need frequent visits or anti-VEGF injections, said Dr. Do. “Conversely, those who have disease activity on OCT would need frequent injections and be alerted to come in.”

**Individualized treatment.** Studies show that fluid fluctuations of the retina are associated with poorer VA outcomes in neovascular AMD, said Dr. Kim. “However, with frequent gathering of data—which is possible at home—and evaluation with AI, we

can obtain fluid trajectory graphs (Fig. 1). This allows us to see when the fluid resolves after an intravitreal injection and when the fluid reaccumulates over time, requiring another treatment.”

The data derived from home-based OCT can also help detect changes in the retinal fluid volume and location, she said. “These data will help to individualize treatment intervals and minimize fluid fluctuations for each patient or even for each eye, may help us decide when to switch therapies, and may circumvent an office visit if the eye is free of fluid,” she said. “As we develop treatments with longer durability, [such] monitoring will become more important to personalize treatment.”

### Current Challenges

**Image quality.** “When it comes to an imaging device, the image quality is obviously important,” said Dr. Kim. She noted that new home-monitoring devices have been going through clin-

BY ANNIE STUART, CONTRIBUTING WRITER, INTERVIEWING DIANA V. DO, MD, JUDY E. KIM, MD, FARVO, FASRS, AND CLAUS VON DER BURCHARD, MD.

ical trials “to compare their sensitivity, specificity, and reproducibility with that of commercial in-office OCT.”

In addition, any at-home device must be easy to use and be used consistently, she said. “Therefore, we must ask whether it is possible to reliably obtain retinal OCT images with satisfactory quality when the image capture is performed by the patients through undilated pupils and potentially through cataracts or other media opacities.”

**Image analysis and infrastructure.** The OCT images should be analyzed automatically using AI to avoid overburdening the treating ophthalmologist with a large volume of images, said Dr. Do. “And the AI software must be able to reliably detect subretinal and intraretinal fluid.” In addition, any telemedicine infrastructure must be able to securely transmit, store, analyze, and distribute the images and personal health information.<sup>1</sup>

**Coverage and reimbursement.** The health care system should allow coverage for patients who use the device and reimbursement for prescribing physicians who review, interpret, and document the AI-based analyses to manage their patient’s eye condition, said Dr. Do.

Clinicians’ experience with ForeseeHome (Notal Vision) may offer a cautionary lesson. ForeseeHome is a home-based preferential hyperacuity perimetry device that can detect the conversion of intermediate AMD to neovascular AMD. It proved helpful during the initial phase of the pandemic, when patients were reluctant to come in for an office visit, said Dr. Kim. However, she pointed out, there was less uptake than expected, possibly due to the lack of reimbursement to physicians. “A different reimbursement model for home-based OCT evaluation may result in increased adoption.”

**Usability.** Any new home-based system “should be intuitive and easy enough for an elderly patient with vision impairment to use properly at home without any assistance,” said Dr. Do. In some patients, VA may be too poor for the patient to use the machine, said Dr. Kim. “Other patients may not understand how to perform the test,

may be reluctant or fearful of technology, or may be unable to put their head in a certain position or use their hands to perform the necessary function.”

### Closest to FDA Approval

Several home-based OCT devices are under investigation for wet AMD. The one that appears closest to FDA approval is Notal Home OCT (Notal Vision), an AI-enabled program and lightweight, spectral-domain device.<sup>1</sup> It uses a predetermined pattern of 88 B-scans across a 3 mm × 3 mm area at the macula, said Dr. Kim.

**Use.** “Notal Home OCT is currently being investigated to monitor eyes with neovascular AMD only,” said Dr. Kim. “However, where one eye has wet AMD and the fellow eye has intermediate AMD, I speculate that it may be possible to catch conversion of dry AMD to wet AMD in the fellow eye.”

She added, “We may eventually be able to use home OCT to monitor diabetic macular edema [DME] and macular edema due to retinal vein occlusion [RVO]. Each potential indication will require different algorithms and, therefore, will need new clinical trials.”

**Image quality and device algorithm.** “Notal Home OCT’s algorithm has been shown to have high sensitivity and specificity, and the images are quite good,” said Dr. Kim. In particular, she said, the images show “the location of the fluid—whether subretinal or intraretinal, foveal or extrafoveal—as well as the volume of the fluid, even to the picoliter level in each retinal compartment.” A threshold is set for the maximum amount of fluid tolerated before the physician is alerted, she added.

Previous small studies have shown that Notal Home OCT is comparable to the Cirrus-HD (Zeiss) and Spectralis (Heidelberg) commercial OCTs in identifying the presence or absence of retinal fluids, said Dr. Kim. Currently, a larger clinical trial is ongoing.

**Patient selection.** Home OCT studies of patients with a mean age of 78.8 years found that elderly patients can successfully image themselves—but that VA is the biggest determining factor in their ability to do so, said Dr. Do.

“Patients with 20/320 or better VA are good candidates for home monitoring and had an 80% to 90% success rate<sup>1</sup> in self-imaging,” said Dr. Do. “Patients with vision worse than 20/320 were successful less than half the time.”

**Patient guidance.** A proprietary, automatic, visual feedback mechanism instructs patients to move their head for proper positioning and fixation. To date, patient feedback is positive: 96% of patients in one study and 91% of patients in a second study agreed or strongly agreed that the system was simple and comfortable to use.<sup>1</sup> Once the device is commercialized, “someone from the company’s testing facility will contact the patient if a patient doesn’t use the device for several days in a row to inquire about lack of use,” Dr. Kim said, noting that this is a benefit of having a central digital center.

**Access and billing.** Supplied by Notal Vision and connected to a diagnostic testing facility at the company, the OCT machines will be rented by patients, said Dr. Kim. As with ForeseeHome, the usage per month is expected to be billed by Notal Vision and paid for by Medicare. “Unlike ForeseeHome, there will be some compensation for the physicians’ time as long as they review the data at least once a month,” she said.

1 Kim JE et al. *BMC Ophthalmol.* 2022;22(261).

2 Keenan TDL et al. *Ophthalmol Science.* 2021; 1(2):100034.

3 Ho AC et al. *J Clin Med.* 2021;10:1355.

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