



A NEW ERA OF DIAGNOSTIC TECHNOLOGIES



A review of ophthalmic advances that are in development or that are becoming increasingly standard in today's eye care clinic.

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Innovation continues to provide us with opportunities to deliver better care to our patients and improve their visual outcomes, particularly when it comes to diagnostic technologies. In this article, I provide a survey of new diagnostic devices that are helping clinicians detect various posterior segment conditions more effectively and efficiently. *Note: This is not an exhaustive list.*

REMOTE AMD MONITORING

Perimetry

The ForeseeHome AMD Monitoring Program (Notal Vision) is an at-home monitoring service that combines

hyperacuity perimetry, artificial intelligence (AI), and a monitoring center to improve the detection of neovascular age-related macular degeneration (nAMD). Unlike standard visual fields, ForeseeHome uses hyperacuity perimetry, which is particularly sensitive to detecting small distortions. Once the doctor orders ForeseeHome, the Notal Vision Monitoring Center handles the insurance verification, device provision, patient education, and adherence monitoring.

Patients use the small table-top device and mouse that comes with the system (Figure 1) to produce metamorphopsia maps of

the central 14° of the visual field. ForeseeHome generates 500 data points in a few minutes, which are then analyzed remotely by AI. Any significant change from baseline produces an alert that is communicated to the prescribing doctor via encrypted email or phone message. Any alert should prompt the prescribing doctor to evaluate the patient urgently to determine whether there was a conversion to nAMD.

ForeseeHome has been studied in various prospective and retrospective studies and has been shown to improve visual outcomes in those patients who convert to nAMD. The

Image courtesy of Notal Vision.

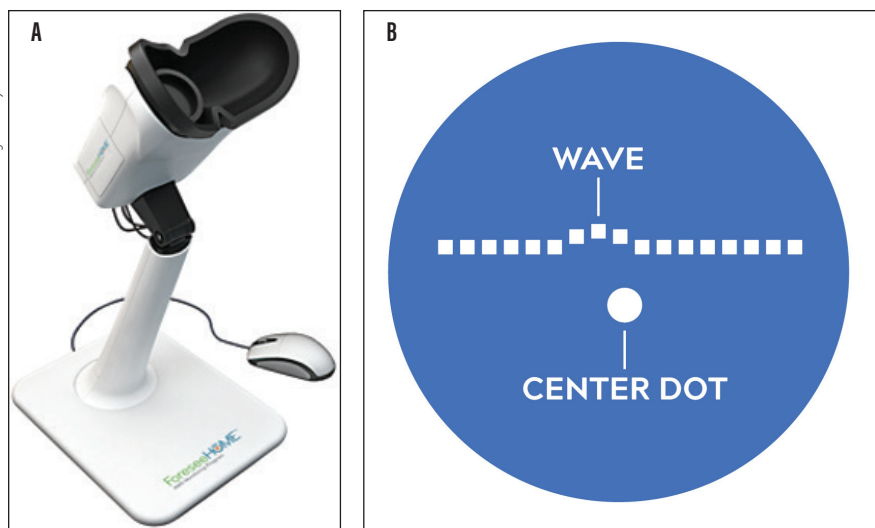


Figure 1. ForeseeHome device on the left (A) and hyperacuity perimetry stimulus used by the ForeseeHome on the right (B).

AREDS2 HOME trial (an arm of the AREDS2 study) was a head-to-head study of 1,520 patients comparing standard-of-care investigator-guided monitoring with use of ForeseeHome plus standard-of-care instructions.¹ It demonstrated that 87% of patients within the ForeseeHome cohort maintained a VA of 20/40 or better at the time of conversion to nAMD, compared with 67% in the standard-of-care cohort.¹ In the ALOFT trial, a longitudinal study that followed

2,123 patients using ForeseeHome, 84% of patients maintained a VA of 20/40 or better at the time of conversion to nAMD. This is a huge improvement over the 34% of patients who maintained the same VA in real-world standard-of-care data drawn from the IRIS registry.²

Home OCT

Although not yet cleared by the FDA, the Notal Home OCT (Notal Vision) (Figure 2) will soon enable

daily monitoring of patients with nAMD to detect changes in subretinal and/or intraretinal fluid. Notal Home OCT will be able to image a 3 mm x 3 mm (10° x 10°) area and acquire 88 B-scans separated by 34 µm in less than 1 minute per eye.² AI will analyze the OCT scans and automatically measure any intraretinal or subretinal fluid volume. Any significant volume changes will generate an alert to the provider.

Having access to such a large OCT dataset will allow clinicians to identify a patient's individual disease process and generate a personalized treatment plan. Using this approach, clinicians should be able to minimize the presence of fluid, while decreasing follow-up burden and improving visual outcomes. As with ForeseeHome, the Notal Vision Monitoring Center will be available to support the patient and doctor with insurance verification, device provision, patient education, and adherence monitoring associated with the Notal Home OCT.

NEW ITERATIONS OF OCT

OCT has been the workhorse of every medical eye care practice for several years, but new iterations of this technology and software updates will improve our ability to accurately detect and manage a variety of ocular conditions.

En Face OCT

Although we are accustomed to analyzing OCT images in cross-sectional views, en face OCT is gaining traction as a powerful adjunct in the detection of geographic atrophy (GA). As GA develops, the retinal pigment epithelium (RPE) thins, allowing greater visualization of the choroid. This same process occurs with OCT imaging, in which the choroid will appear hyperreflective. This phenomenon, known as choroidal hypertransmission (Figure 3), has been used to objectively detect GA

AT A GLANCE

- Once cleared by the FDA, remote monitoring will enable daily observation of patients with age-related macular degeneration to detect changes in subretinal and/or intraretinal fluid.
- Spectral-domain OCT is the most widely used type of OCT in clinical practice and provides high-resolution images of various ocular tissues, thanks to a ~800 nm wavelength light source and rates of 50,000 – 120,000 A-scans per second.
- Genetic testing for inherited retinal degenerations can help with differential diagnosis, prognostication, family planning, and determination of clinical trial qualification, and should be used in conjunction with other diagnostic testing.



Figure 2. Notal Home OCT device.

with software algorithms, such as the Advanced RPE Analysis available with the Cirrus 5000 (Carl Zeiss Meditec). En face OCT analyses can quantify the area of GA and the distance of GA to the fovea, and can detect progression with subsequent scans.

OCT Angiography

OCT angiography (OCTA) has been commercially available for several years, but continues to see increased adoption as more clinical uses for this technology are discovered. OCTA is a noninvasive diagnostic modality for imaging ocular vasculature that uses the movement of red blood cells to generate depth-encoded images of retinal and choroidal vasculature. Unlike dye-based angiography, such as fluorescein angiography and indocyanine green angiography, no injection is required. OCTA images are viewed as en face slabs, where vasculature within separate layers of the retina and choroid can be analyzed using correlated structural OCT data and vascular OCTA data. This combination of angiographic and structural data allows visualization of neovascular lesions, along with resultant structural OCT changes.

In the current era of complement inhibition therapy, en face OCT and OCTA analyses will prove essential in the proper management of GA,

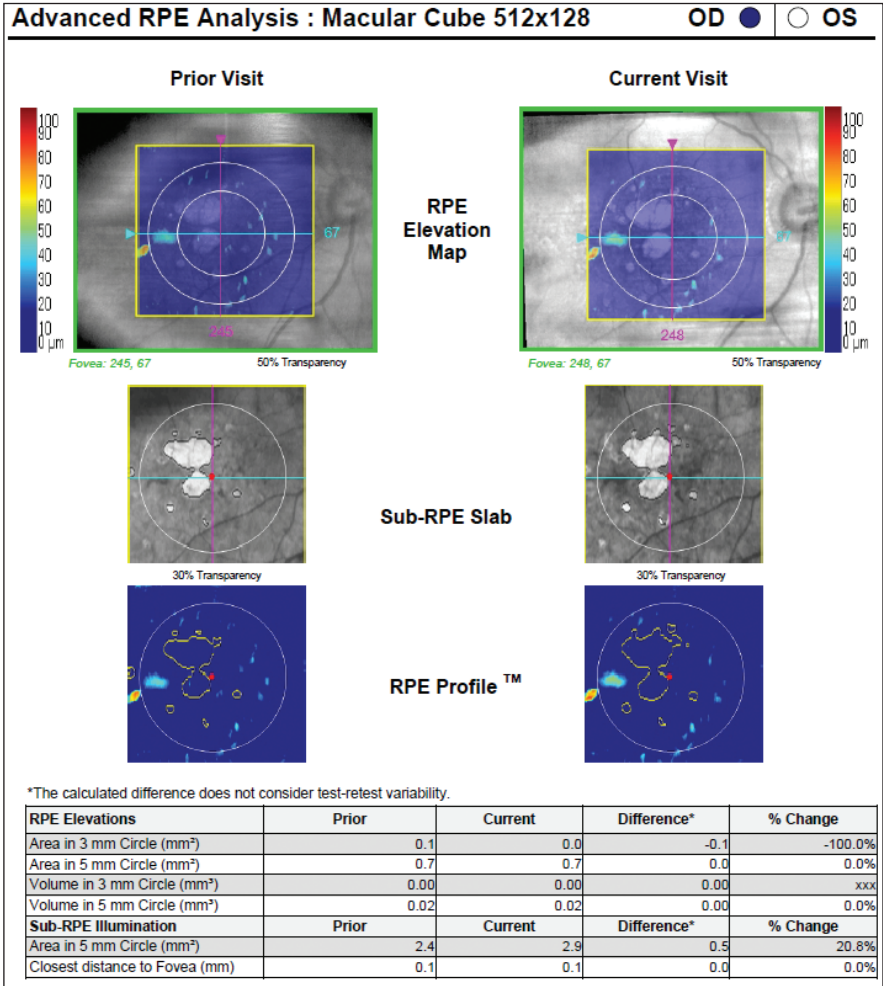


Figure 3. En face OCT automatically detects sub-RPE illumination (ie, choroidal hypertransmission) and reveals GA progression.

allowing objective detection of GA progression and screening for iatrogenic macular neovascularization.

Ultra-Widefield OCT

Ultra-widefield (UWF) OCT allows clinicians to image beyond the posterior pole (Figure 4). Using imaging devices such as Silverstone (Optos), which is a UWF system integrated with a swept-source OCT (SS-OCT) system, clinicians can analyze peripheral lesions without the need for cumbersome (and often impossible) patient steering.

With the ability to analyze the structure of the peripheral retina and choroid, lesion identification should become much more straightforward. Common clinical questions,

such as, “Is this a retinoschisis or a retinal detachment?” and “Does this retinal hole have a fluid cuff?” are muddled by the subjective nature of fundoscopic examination, but can be answered more readily with UWF OCT by analyzing the microstructure of the lesions.

Swept-Source OCT

The most widely used type of OCT in clinical practice is spectral-domain OCT (SD-OCT). Depending on the manufacturer, these units use a ~800 nm wavelength light source, operating at a rate of 50,000 A-scans per second to 120,00 A-scans per second, to provide high-resolution images of various ocular tissues. However, the scans are

Image courtesy of Optos.

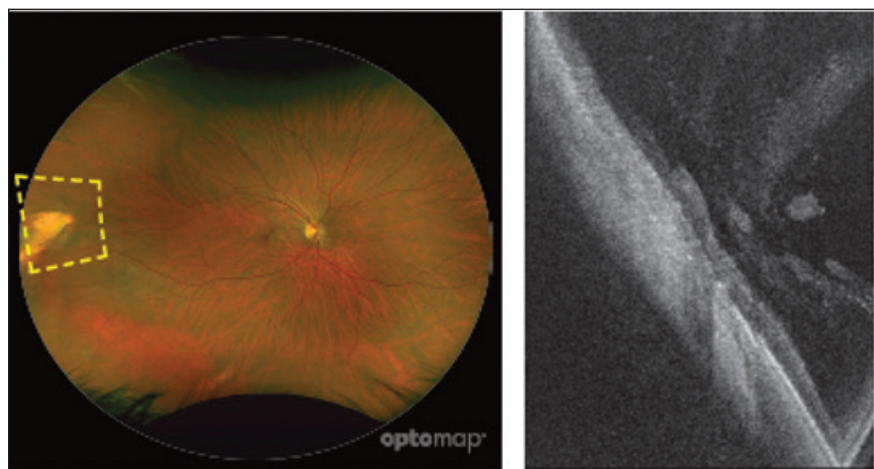


Figure 4. UWF OCT reveals peripheral vitreoretinal traction.

usually limited to a 3 mm depth, which often leaves the vitreous, choroid, and staphylomas poorly visualized.

SS-OCT solves this issue by increasing the scan depth to 6 mm or greater, providing high-resolution imaging of the vitreous, retina, and choroid within a single scan. SS-OCT uses a different type of light source that is capable of faster scan speeds of up to 400,000 A-scans per second, allowing increased scan sampling and noise reduction. These units also use a light source with a longer wavelength (in the range of 1,000 nm), which can more easily penetrate through media opacities and reach deeper into ocular tissues.⁴ This faster scan speed allows wider scan patterns that can capture larger portions of the retina within one scan.

SS-OCT systems are not perfect, however. Due to the longer wavelength of the light source, the axial resolution is lower compared with that which can be attained with SD-OCT. This might seem counterintuitive when looking at side-by-side comparisons of images from the two systems, but the greater visible detail of SS-OCT is due to the higher sampling and improved post-processing systems, rather than an improvement in axial resolution.

As with all newer technologies,

SS-OCT systems are more expensive than SD-OCT systems. Although they provide amazing images and offer several advantages over SD-OCT, it remains to be seen if the increased price tag of SS-OCT systems will be a worthwhile investment for the average clinician.

GENETIC TESTING

Genetic testing has been around for several years, but seems to be coming into its own recently in the retina space. Sponsored programs from Invitae and Blueprint Genetics provide free inherited retinal degeneration testing for patients. The test kits from these companies can be ordered through their respective online portals and contain consent forms, sample collection instructions, supplies for sample collection, and a prepaid label to ship the sample back to the company. Genetic testing for inherited retinal degenerations can help with differential diagnosis, prognostication, family planning, and determination of clinical trial qualification, and should be used in conjunction with other diagnostic testing.

ARTIFICIAL INTELLIGENCE

As wearable technologies and out-of-office diagnostics becomes more commonplace, patients will generate large, personalized data

sets that will require tedious analysis. Multimodal imaging is becoming standard in eye care, and the vast amount of data that need to be analyzed on a daily basis is reaching a point that no human can fully digest. AI, however, is perfectly suited for this task, and will likely do a better job than we can at identifying early diagnostic biomarkers of disease.

Although these new technologies may not provide data as accurate as our gold-standard in-office tests, the sheer amount of data points will likely average out inaccuracies or at least provide information complementary to our in-office tests. For example, continuous glucose monitoring data may be combined with hemoglobin A1C testing, fundus photography, OCT, and OCTA data to generate risk scores—with the help of AI—for the development of vision-threatening diabetic retinopathy. It will then be our job as clinicians to use these data to appropriately manage the patient.

RAISING THE BAR

We are lucky to be a part of a profession that is constantly innovating. Technology will continue to evolve, and we must learn to incorporate these new diagnostic modalities into our practices to increase the standard of care that we can provide to our patients. ■

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