




# Home Optical Coherence Tomography Monitoring for Neovascular Age-Related Macular Degeneration: Transformative Technology or Cool Toy?

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## ABSTRACT

The pending introduction of home-based optical coherence tomography (OCT) in managing neovascular age-related macular degeneration (nAMD) has sparked interesting debates. Advocates assert that home-based OCT will revolutionize care of patients with nAMD, while skeptics question its real-world viability and point out its potential drawbacks. This article delves into the dichotomy, presenting the "pro" argument highlighting the transformative potential of home OCT and the "con" perspective, which

scrutinizes the limitations and challenges to adapting the technology to the real-world setting. By exploring both sides of the discourse, we aim to address the promises and complexities surrounding the role of home OCT in the management of nAMD.

**Keywords:** Neovascular age-related macular degeneration (nAMD); Optical coherence tomography (OCT); Home-based OCT; Anti-VEGF therapy; Telemonitoring

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### Key Summary Points

Advancements in optical coherence tomography (OCT) technology, a vital tool in managing neovascular age-related macular degeneration (nAMD), have allowed the development of home-based OCT systems that patients can use to self-image on a daily basis, providing the potential to impact and transform patient care.

Home OCT offers advantages to traditional in-office OCT, enabling remote detection of anatomical changes, which may reduce treatment burden of patients needing to travel to a physician's office while personalizing treatment intervals.

AI-assisted data analytics can provide valuable insights into disease dynamics, facilitating individualized treatment plans with the potential to improve long-term visual outcomes.

Despite promising potential, studies to date on clinical outcomes associated with the use of home OCT-based treatment protocols are limited to small number of patients.

Obstacles exist which may hinder widespread utilization of home OCT, leaving questions about real-world feasibility and adaptability.

Demographic differences from research participants and potential underutilization by physicians and patients may limit real-world success, while financial disincentives to the physicians may pose adoption challenges.

## INTRODUCTION

Studies have demonstrated that overexpression of vascular endothelial growth factor (VEGF) leads to the development of choroidal neovascularization (CNV), the hallmark of neovascular age-related macular degeneration (nAMD) [1]. Leakage from CNV results in fluid accumulation in the inner retina, outer retina, or under the retinal pigment epithelial layer (RPE), which is best identified on optical coherence tomography (OCT). Therefore, OCT imaging is a vital part of

the diagnosis and management of nAMD. However, OCT imaging is currently performed only in the office due to the size of the equipment and the need for a skilled operator, resulting in an unavoidable treatment burden necessitating frequent office visits. Also, the intermittent nature of OCT image acquisition at office visits provides only a limited snapshot of the treatment response for each patient. The impending introduction of home-based OCT, however, may radically change the current paradigm, providing the possibility of more personalized care and a reduction in treatment burden. While home OCT will have undoubted benefits, we cannot ignore its potential limitations and challenges in real-world use and adaptation of new technology. By exploring both the “pro” and “con” sides of the discourse, we aim to highlight the complexities surrounding the implementation of home-based OCT in the management of nAMD. This article is based on personal experiences and previously conducted studies and does not contain any studies with human participants or animals performed by any of the authors.

### Pro-Home OCT will Shift the Paradigm in the Management of nAMD

Currently, OCT is the primary non-invasive monitoring tool in the management of nAMD through assessment of retinal fluid [2]. A number of commercially available OCT machines are in the market. However, due to their large size and need for expert operators, they are limited to physician offices. To undergo OCT imaging, patients are thus required to schedule an office visit. This places significant burdens on patients and their families.

In recent years, improvements in the size, speed, and cost of OCT device technology have resulted in smaller and more user-friendly devices enabling the development of home-based, patient-operated OCT devices. This will allow patients to self-image their eyes as often as they wish, and the results can be monitored remotely to assess the need for an office visit and possible intravitreal anti-VEGF treatment. Such a device has the potential to dramatically alter the current management paradigm, allowing

patients to present for office visits only when imaging results indicate a need, which may be more or less often than under the current paradigm but personalized for an individual patient's eye. This should allow for more timely treatment with less fluid fluctuation with the potential for better long-term visual outcomes.

### Home Monitoring is a Proven Concept

Home monitoring has a long track record in medical care. Patients with diabetes or hypertension regularly monitor blood glucose or blood pressure at home, allowing for adjustment of treatment as needed. The digital age has ushered improved remote home-monitoring capabilities with devices such as continuous glucose monitors and cardiac implantable electronic devices capable of providing supervising physicians with up-to-date data on patient health status. In retina care specifically, the Foresee Home (Notal Vision Inc., Manassas, VA, USA) has been Food and Drug Administration (FDA)-approved since 2010 for detecting conversion of intermediate dry AMD to nAMD. The device allows patients to perform hyperacuity testing in their home setting with data transferred through telemedicine to a data monitoring center. In a large, prospective randomized clinical trial, use of this device resulted in earlier detection of nAMD with better visual acuity at the time of conversion compared to Amsler grid monitoring [3]. A retrospective review of data from over 8900 patients showed real-world monitoring with the Foresee Home device to be comparable to that seen in clinical trials [4], weakening the argument that clinical trial data may not translate to real-world scenarios.

### Availability of Home OCT

Several home OCT devices are undergoing development, but none are currently cleared for clinical use. The Self-Examination Low-cost Full-field OCT (SELF-OCT) is one such device intended to cost less than \$1000 to produce (Visotec/Heidelberg Engineering, Heidelberg, GER). To date, study reports on this handheld OCT device are limited [5]. A table top home OCT device has

also been developed by a Swiss group, which has published some limited but promising initial safety and feasibility data [6]. The device has not entered commercial development at this time. The Notal Vision Home OCT (NVHO; Notal Vision Inc., Manassas, VA, USA) has more robust clinical data available and is currently pending FDA-approval. Given the greater available clinical data, the subsequent discussion will be limited to published studies and applicability of a home OCT from NVHO.

The NVHO is an artificial intelligence (AI)-enabled digital diagnostic for patients undergoing treatment for nAMD. As per the pending FDA application, the device is to be utilized as part of a home-monitoring program in which eligible patients are referred by evaluating physicians to Notal. In turn, Notal drop-ships devices to patients' homes and remotely assists them with setup and training. The OCT images generated are automatically uploaded to the cloud. The digital monitoring center then analyzes uploaded images using the Notal OCT Analyzer (NOA), an AI-algorithm with demonstrated high sensitivity (92%) and specificity (95%) in the detection of retinal fluid [7]. The NOA has also shown high concordance (91%) with retina specialists' determination of lesion activity. In terms of ongoing monitoring, referring retina specialists set a threshold fluid level to trigger monitoring center alerts and review accumulated image data monthly. A CPT code (0606T) has been established to allow practice reimbursement for image review activities.

Initial clinical trial data has supported the image reliability and feasibility of NVHO home monitoring. A pilot study comparing images obtained with NVHO to those obtained with commercial in-office based OCT found the positive percent agreement and negative percent agreement for detection of fluid, intraretinal fluid, and subretinal fluid in at least one of three consecutive NVHO images to be 97/85%, 96/94% and 100/98% [8]. Two additional small, short-term pilot studies suggested that self-home imaging was highly feasibly. In these studies, NVHO devices were drop-shipped to enrolled patients and setup/install was completed by the patient using only video tutorials. Despite this limited training, the studies found high rates of

successful self-imaging (88–95%) and adequate scan quality (93–98%) in the home setting [9, 10].

### Home-Monitoring Benefits

Integration of home OCT technology into the routine management of nAMD has the potential to revolutionize patient care and ultimately enhance outcomes. Shifting from in-office to remote OCT monitoring has the potential to provide several specific benefits: (1) reduction in treatment burden, (2) increased personalization of care, (3) improved understanding of disease response to treatment, and (4) minimization of undertreatment and associated fluid fluctuations. Collectively, these benefits should improve the patient experience and may result in improved clinical outcomes.

Current anti-VEGF treatment protocols involve a heavy treatment burden on the patient, their caregivers, and the healthcare system. Specifically, patients face challenges related to the arrangement of transportation with caregivers as well as the time and financial commitment required for such frequent in-office visits [11, 12]. Real-world data has revealed associations between these factors and low treatment persistence rates, with some studies reporting up to 60% of patients becoming nonpersistent by 24 months following initiation of treatment, most often occurring within the first 6–12 months of treatment [12]. An analysis of patients undergoing pro re nata (PRN) treatment for nAMD compared treatment adherence of those with access to monitoring visits via telemedicine to a group of patients being monitored in-person at the same clinic without telemedicine access. The results showed that those without access had a significantly lower number of follow-up visits for monitoring and fewer injections compared those with access [13], providing evidence that home OCT should improve long-term adherence and persistence to treatment protocols.

Besides lessening the burden placed on patients, this device also has the potential to greatly reduce physician workload. A recent survey found that 37.8% of the 592 responding ophthalmologists exhibit symptoms of burnout

[14]. A large stressor contributing to this is likely their ever-increasing patient volumes. Lowering unnecessary in-office monitoring visits via the use of home OCT monitoring with AI-assisted image analysis should help reduce patient volumes while hopefully maintaining (or possibly improving) the quality of care provided. Preventable medical errors remain a serious dilemma, substantially increasing healthcare costs and causing significant distress to patients [15]. With a decreased patient volume due to telemonitoring capabilities, physicians will be able to spend more time with each individual patient, possibly leading to lower errors and an improved patient experience.

In addition to establishing the basic framework for the home-monitoring alert system, AI-based data analytics provide an opportunity to gain significant insight into fluid dynamics and the treatment response between office visits. Early experience with the Notal device and its associated image analysis algorithm, NOA, has demonstrated surprising intra-visit fluid fluctuation that, on retrospective review, would have substantively altered physician treatment decisions [16]. These insights imply that solely comparing OCT images from scheduled in-office visits may prove insufficient in appropriately assigning the best-fitting treatment protocol to each patient. Home OCT allows providers to overcome this problem by providing the necessary information to appropriately individualize treatment regimens, resulting in personalized care. Frequent in-home OCT monitoring should provide ample data points to help providers better understand individual patient fluid trajectories and better timely treatments, which should reduce fluid fluctuations that have been shown to have a negative impact on visual outcomes [17]. This accumulation of data points may allow for new ways to assess treatment outcomes such as the “time in range” concept in nAMD management. Under a “time in range” evaluation paradigm, a safe or desirable range of retinal fluid could be designated for patients and treatment “success” could be determined based on the frequency with which daily home-monitoring results fell within this range [18]. Furthermore, home OCT imaging will act as a safety net, allowing clinicians to comfortably extend

treatment intervals and implement longer acting treatment options, which will also reduce treatment burden while not compromising on safety.

Currently, treat-and-extend (T&E) is the preferred treatment regimen among most retina specialists due to its demonstrated superior long-term visual outcomes compared to PRN and similar visual outcomes compared to fixed-interval treatment plans with fewer injections [19–23]. T&E offers the most personalized approach of the three and matches the patient's disease activity. Though PRN therapy has less favorable visual outcomes compared to T&E using traditional in-office monitoring, the implementation of home OCT may allow for detection of early fluid recurrence leading to prompt intervention and less fluid exposure. The potential benefit of home OCT data was observed in a recent study in which retina specialists retrospectively reviewed NVHO data from patients undergoing standard of care treatment with in-office OCT monitoring. In 58% of cases, reviewing retina specialists recommended treatment earlier than was applied during actual care of the patients under a T&E regimen, which would have resulted in the prevention of exposure to substantial amounts of retinal fluid. [16]

Early prospective evidence also shows the potential of home OCT to reduce clinic visits while sustaining favorable long-term visual and anatomical outcomes. A 6-month prospective 15-patient pilot study evaluating home OCT-guided management of nAMD found baseline visual acuity could be maintained ( $p=0.45$ ) despite a significant increase in the treatment interval from 8.0 to 15.3 weeks ( $p<0.01$ ) with the implementation of home OCT monitoring [24]. Adherence rates over this period were measured via testing frequency and did not display a statistically significant change from month 1 through month 6 ( $p=0.226$ ).

The Diabetic Retinopathy Clinical Research network (DRCR) is currently enrolling for protocol AO, which is a large-scale prospective evaluation of home OCT-guided nAMD treatment compared to traditional T&E regimen with in-office monitoring only [25]. The results may be highly compelling if they demonstrate that the

new method achieves similar long-term visual outcomes with fewer required injections.

Home OCT may also benefit patients through provision of a more granular endpoint for clinical trials. Improved endpoint detection could lead to a shortening of trials or allow for less subjects needed, possibly leading to faster and less expensive approvals of new and more powerful medications.

Even in its nascent form, home OCT technology clearly has the ability to bring about a paradigm shift in the treatment of nAMD with numerous benefits. This device can be a significant asset in allowing clinicians to create individualized, adherable treatment plans for each patient while still achieving satisfactory visual and anatomical outcomes. It will notably influence the introduction of longer-lasting treatments (e.g., Port Delivery System, gene therapies, q16-week medications), due to remote telemonitoring now being feasible in the real-world. Providers will gain from the substantial improvement in clinical workflow and the vast data that will now be accessible with home telemonitoring. While the presence of remaining data gaps likely mean home OCT will not immediately become standard of care upon FDA approval, early experience strongly suggests this technology will ultimately reshape nAMD treatment paradigms and improve patient experience and outcomes.

### **Con: Home OCT will NOT Shift the Paradigm in the Management of nAMD**

Although initial pre-approval clinical trial data presented above are encouraging, there remain significant obstacles that hinder the widespread utilization required to transform home OCT into a paradigm-shifting technology for managing nAMD. Specifically, home OCT will need to overcome concerns about the quality and feasibility of at-home imaging in the real world (e.g., outside the setting of clinical trials), adherence to use of the machine, unclear long-term clinical outcomes with home OCT-guided PRN treatment, questions regarding reimbursement, and the presence of significant provider disincentives to adoption.



## Questions Regarding Real-World Applicability

As has been seen with disparity between clinical trial and real-world anti-VEGF treatment outcomes, success in the clinical trial setting does not necessarily translate into real-world success. This may be especially true in the case of a device utilized without direct technician/photographer supervision (e.g., at home). A larger study evaluating NVHO self-imaging in the clinic setting found eyes that were unable to successfully self-image were significantly older (84.3 vs. 78.8 years) and more visually impaired (20/76 vs. 20/45) [26]. In this study, over 25% of eyes with best-corrected visual acuity (BCVA) of 20/80 or worse could not self-image compared to a 94% success rate in those with BCVA better than 20/80. These negative predictive factors for successful self-imaging will likely limit the success of home OCT self-monitoring given the demographics of real-world nAMD patients. Real-world clinical registry data shows that patients undergoing anti-VEGF therapy are generally older (mean age 80.5–80.9 years) and have worse vision (20/63–20/80 Snellen equivalent) compared to those in the NVHO trial [27, 28].

Real-world success may be further depressed due to potential selection bias present in a clinical trial requiring technological aptitude. Patients agreeing to participate in the study are likely more comfortable and, therefore, capable of interfacing with technology. This phenomenon was evidenced previously with the Foresee Home device. In the pivotal HOME study, 5% of enrolled patients never utilized the device and an additional 8% were unable to establish a baseline, which is necessary to enable ongoing monitoring [3]. Real-world data, however, demonstrated much higher rates of non-compliance and technical failure with 16% never utilizing the device and 26% failing to establish a baseline [29]. A similar dichotomy between the clinical trial and real-world settings is likely to be present with the NVHO, which may drive underutilization of home OCT monitoring. Furthermore, patients in more rural/remote areas with limited internet/cellular access may not have adequate connectivity to utilize remote monitoring.

Even if real-world utilization proves to closely mirror that seen in clinical trials, there remain concerns about the clinical outcomes that can be expected with a home OCT-directed treatment paradigm. A home OCT-guided treatment protocol would parallel more traditional PRN treatment, with anti-VEGF administered only after fluid is discovered on OCT. Given that T&E is the dominant treatment protocol used by US retina specialists [30], a shift to home OCT monitoring implies a corresponding shift from T&E to PRN anti-VEGF dosing. This increased utilization of PRN treatment should lead to reduced patient visits but may also lead to worse visual outcomes based on the differing management of fluid under the two different paradigms. Under a PRN strategy, fluid is allowed to recur repeatedly and is only treated once it develops whereas T&E utilizes a maximum tolerated treatment interval with the goal of maintaining a consistently fluid-free macula. Multiple prospective, randomized studies demonstrated inferior visual outcomes with PRN as compared to monthly dosing [31, 32]. In contrast, the prospective TREX study found that T&E and monthly dosing achieved similar visual gains [19]. Taken together, these studies suggest the T&E may provide superior outcomes to PRN. Systematic meta-analyses support this notion with T&E exhibiting superior visual improvement as compared to PRN [20, 21].

## Questions Regarding Assessment of Retinal Fluid

The NOA introduces a new and unfamiliar metric into nAMD management: retinal fluid volume. Many questions remain about how to utilize this measure of nAMD activity. Firstly, there is no data regarding the optimal fluid alert threshold for an individual eye or what is the appropriate fluid volume at which anti-VEGF treatment should be performed. Current clinical trials have used two-dimensional retinal thickness on OCT while NVHO will be assessing fluid volume. The relative utility of volumetric change versus thickness change is yet to be determined. In addition, NVHO assesses intraretinal and sub-retinal fluid but not sub-RPE

fluid. Therefore, it might not be useful in following nAMD with large pigment epithelial detachments. It is also not clear whether the NVHO scan cubes (central 3 × 3 mm), which are smaller compared to commercial in-office devices, might fail to capture functionally important retinal fluid located outside the area imaged.

### Questions Regarding Long-term Visual Acuity Benefit

PRN therapy triggered by early changes on home OCT monitoring may ultimately prove to be superior to a traditional PRN, but a definitive answer to this question will require actual clinical trial and, ultimately, real-world data. The DRCR network recently begun enrollment in Protocol AO, which will compare home OCT-guided AMD-treatment with traditional T&E treatment regimen. Since enrollment has just begun, a definitive answer on the efficacy of home OCT-guided PRN therapy is likely several years off. Considering the concerns about discordant compliance between real-world and clinical trial patients, real-world visual outcome data may be the more important success metric for home OCT. However, real-world outcomes are likely to lag the clinical trial data by 1–2 years. In the absence of solid clinical evidence, providers may fail to embrace the technology.

### Questions Regarding Physician Adoption

Home OCT deployment faces additional hurdles due to the presence of physician work and financial disincentives connected to use of the technology. If they hope to be reimbursed for their role in home monitoring, providers will likely face an outsized work burden relative to the current in-clinic T&E workflow. According to CPT code 606T, which governs physician reimbursement for remote home OCT monitoring, the prescribing physician must “review, interpret, and report” surveillance center data “each 30 days” [33]. To put this into perspective, in a busy practice, a single provider follows upwards of 350 unique nAMD patients. If, for example, said provider spends 3 min reviewing

each patient’s 30 days’ worth of daily OCT data and 60% of provider’s patient adopt home OCT, this provider will spend nearly 10.5 h per month reviewing OCT data. This figure does not factor in the additional time spent by practices discussing/prescribing the device, answering calls/questions from home OCT users, and adding on home OCT-alerted patients into already overloaded clinic schedules.

Despite this added work burden, practices are likely to see downward pressure on reimbursement due to the introduction of home OCT. Firstly, it is expected that, considering the Center for Medicare and Medicaid Services’ budget neutrality mandate, the introduction of a new (and potentially large) expense for home OCT services will result in a corresponding large decrease in the reimbursement for in-office OCT. Secondly, while in-office OCT generates both technical and professional revenue for practices, under the three new codes for home OCT (604T, 605T, and 606T) it appears that only revenue from 606T—which is equivalent to the professional component of in-office OCT—will go to practices while the remaining codes’ revenue—which is equivalent to the technical component—will go to the device manufacturer [33]. It should be noted that without an FDA-approved device, the exact breakdown of payments cannot be confirmed. In sum, the anticipated lower reimbursement for in-office OCT along with the loss of technical revenue associated with a shift to home OCT is likely to be seen as a potential financial loss to practices thus discouraging providers from prescribing the device.

Although some of the specifics—such as actual real-world self-imaging success, clinical outcomes, and anticipated reimbursement changes—will need to be confirmed once an approved device is available, at the current time it appears that adoption and utilization of home OCT may be too limited to bring about a true ‘paradigm shift’ in the management of nAMD. The added work and financial disincentives are likely to discourage retina specialists from prescribing the device particularly in the absence of strong long-term clinical outcome data.

## CONCLUSIONS

The implementation of home OCT technology presents various advantages that could shift the paradigm in the current treatment of nAMD. At home telemonitoring will decrease the heavy treatment burden placed on both patients and physicians and may provide a more cost-effective approach. This device can be a significant asset in allowing clinicians to create individualized, adherable treatment plans for each patient while still achieving satisfactory visual and anatomical outcomes. Providers will gain from the substantial improvement in clinical workflow and the vast data that will now be accessible with home telemonitoring. The data-analyzing algorithms employed by NOA will prove highly effective at capturing large datasets that benefit not only clinical decision-making but will also shape the way future clinical trials are conducted. While remaining data gaps may delay the immediate adoption of home OCT as the standard of care if FDA approved, early experience strongly suggests this technology will ultimately reshape nAMD treatment paradigms and improve patient experience and outcomes.

On the other hand, even though home OCT utilization will allow more timely detection of fluid and carries potential to improve long-term real-world visual outcomes, studies thus far are limited by small sample sizes and short follow-up periods. Longer follow-up with a larger number of subjects and clinical outcomes using home OCT-guided therapy is needed. Use of home OCT will need to overcome concerns about the quality and feasibility of at-home imaging in the real world, adherence to frequent use of the machine by patients, reimbursement barriers, and provider biases relating to the adoption and implementation of new technology. Nevertheless, this is an exciting time to consider the pros and cons of this new technology.

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### Declarations

**Conflict of Interest.** Ethan T. Willis: None. Judy E. Kim: Advisory Board/Consultant – Allergan, Amgen, Apellis, Bausch&Lomb, Clearside Biomedical, Coherus, Dutch Ophthalmic Research Center, Eyepoint, Genentech/Roche, Notal Vision, Outlook Therapeutics, Regeneron. Eric W. Schneider: Consultant – Apellis, Carl Zeiss Meditec, Notal Vision, Iveric Bio.

**Ethical Approval.** This article is based on personal experiences and previously conducted studies and does not contain any studies with human participants or animals performed by any of the authors.

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