COMMENTARY

Perspectives on the Home Monitoring of Macular Disease

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ABSTRACT

Recent advancements in imaging technology have led to increasing interest in home monitoring of macular disease. The prevalence of macular disease is projected to rise considerably over time, leading to a significant burden on hospital services for age-related macular degeneration and diabetic macular edema. Home monitoring has the potential to augment conventional hospital assessment and so enable improved access to clinical care for low- and moderate-risk patients, while also allowing sensitive detection of early signs of disease that may require prompt intervention. Despite this, there are significant considerations before large-scale implementation could be possible. These are related to both the current availability of home monitoring technology and the logistical barriers to its widespread introduction. Access to home monitoring is also likely to be more challenging in lower-income communities and countries, with subsequent implications for health inequality that will need to be considered and addressed appropriately.

Key Summary Points
Home monitoring of macular disease has the potential to improve access to patient care.
Previous studies have focused on visual function metrics including metamorphopsia; however, home OCT assessment of structural features of macular disease has now been developed.
Current barriers to home monitoring include patient selection and uptake, financial implications, logistical issues and patient safety considerations.
Monitoring of patients with macular disease is likely to remain in the outpatient clinic environment currently, but advances in technology and patient care pathways could facilitate future implementation.

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INTRODUCTION

Home monitoring of macular disease has historically involved patient self-reported monitoring of visual symptoms including generalised blurred vision as well as metamorphopsia. Indeed, patients are readily advised to monitor for disease activity, using tools such as the Amsler grid [1]. There have been various technological enhancements to the original Amsler grid, but its limitations in detecting true disease activity in age-related macular degeneration (AMD) have been well reported [2]. The ideal home monitoring solution for macular disease would comprise an easy to use, affordable device with reproducible, sensitive detection of early macular changes.

This article seeks to summarise recent advances in home monitoring of macular disease and provide perspectives on their current and future clinical implementation. Relevant previous publications were identified via the PubMed® database using the following search terms: 'home optical coherence tomography', 'home OCT', 'macula(r) monitoring' 'macula(r) home monitoring' and 'macula(r) remote monitoring'. There were no additional exclusion criteria when conducting the literature search.

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

CURRENT PROGRESS

Recent home monitoring of macular disease has largely focused on new technology that more accurately determines severity of metamorphopsia. For example, the ForeseeHome device (Notal Vision) is available through medical insurance companies in the USA. This system uses preferential hyperacuity perimetry testing to identify metamorphopsia and showed promising results in early trials [3, 4]. Similar technology has been utilised across a range of other devices and smartphone apps designed to detect early surrogate signs of macular neovascularization (MNV) [5–7], for example Home

Vision Monitor (Roche) [8] and Alleye (Oculocare); the latter has been suggested to improve visual outcomes and treatment adherence with a relatively low 'false alarm' rate [7, 9].

The regular use of home optical coherence tomography (OCT) devices would allow patient imaging at home and deliver true anatomical features of disease activity. Kim et al. [10] evaluated a new home OCT device (Notal Home OCT; Notal Vision) and reported that 91% of subjects were able to acquire successful images. Similarly, von der Burchard et al. [11] evaluated a prototype self-examination OCT device in 51 patients with AMD, diabetic macular edema (DME) and retinal vein occlusion and suggested that 77% of subjects could acquire gradable images, in which relevant disease biomarkers could be evaluated. Interestingly, neither age nor visual acuity was an influence on the success of image capture. Additional prototype devices have also shown good compliance with conventional OCT devices when measuring retinal thickness [12]. Liu et al. [13] evaluated the daily use of Notal Home OCT imaging in patients with AMD in a prospective, longitudinal study. Interestingly, the authors utilised artificial intelligence (Notal OCT Analyser) to determine the presence of disease activity, which appeared to have good concordance with human expert graders. Participants were also able to record an average of more than five scans per week, albeit over a limited study duration. Daily home OCT imaging has the potential to deliver new understanding of the temporal metrics in macular disease, particularly in characterising the speed of recurrence after treatment or indeed, the length of time for which disease activity persists after treatment [14].

Home OCT devices necessarily provide lower quality images compared to clinic-based devices, with an example axial resolution of $12\,\mu M$ compared to $3\,\mu M$ for high-resolution Spectralis devices (Heidelberg) [15]. The Notal Home OCT device also scans the central $3\,mm \times 3\,mm$ of the macula compared to the larger $6\,mm \times 6\,mm$ commonly scanned by conventional devices [14]. However, scanning times remain feasible for home imaging at 1 min or less per scan [14, 15], and these more limited

specifications may prove sufficient for use as a screening tool. Longer-term observational studies of wet AMD assessment by home OCT are needed to evaluate success of acquisition of images and determine patient satisfaction with regular home testing.

It should be noted that previous studies have largely focused on AMD, with very limited data available for the home monitoring of DME. DME is perhaps less amenable for home monitoring than AMD. Indeed, patients with DME must also be screened for diabetic retinopathy, and extensive home monitoring for these patients is likely to result in delayed diagnosis of proliferative disease if not combined with regular retinal images or clinical examination. Furthermore, DME progresses more slowly than neovascular AMD, so patients are less likely to suffer severe visual impairment between clinic appointments if changes are left undetected. Patients with diabetes also have systemic medical issues and may gain more benefit from in-person clinical review. Despite this, it is likely that home OCT monitoring could be used in specific cohorts of patients with lower risk DME, for example if combined with regular retinal photographic screening. Further evaluation in patients with diabetic eye disease would be advantageous. The potential to deliver more intensive monitoring with fewer clinic attendances is particularly useful for patients with chronic conditions who are often working-age individuals and have multiple concurrent medical appointments.

BARRIERS AND FUTURE CHALLENGES

Current barriers to home monitoring of macular disease include appropriate patient selection, financial implications, logistical issues and patient safety considerations. Ensuring regular and reliable device usage is essential when implementing home monitoring of disease activity. Although there have been positive reports of long-term compliance [16], large non-proprietary studies of the ForeseeHome device have shown significant underutilisation in the general population compared to the initial study cohorts, with up to a quarter of patients ceasing usage within 1 year [17]. Regular imaging would be essential if home monitoring becomes the primary method of disease surveillance. It is so far unclear how regularly patients might complete home OCT testing in a real-world setting compared to those patients who have proactively enrolled in early-stage clinical trials.

Ensuring equality of access to healthcare will require extensive local support. The populations of patients with AMD and diabetes are diverse, comprising a wide range of ages, performance statuses and prior technological experience. Establishing patient education and community engagement methods to enable large-scale implementation is likely to be complex, requiring regular support for all users. Indeed, while 77% of users were reported to be able to acquire a gradable OCT image [11], the corollary of this is that nearly a quarter of patients were not able to do so; assessment of the ability of individual patients to capture these images successfully will be necessary before relying on this method of monitoring disease activity. One consideration will be visual function, as patients with advanced bilateral disease are unlikely to be able to operate the OCT machines with the same ease as those with early AMD. In contrast, those living with relatives may be more likely to successfully complete home monitoring if they have assistance in performing the scans.

Patient acceptability of this new technology and form of disease monitoring has yet to be determined. It may vary according to factors including specific macular disease, patient location and patient demographics. It will be important to educate patients about its role in clinical care, but there may well be some individuals who decline its use, or feel unable to complete imaging adequately. Alternative care pathways will be necessary unless home monitoring becomes mandatory, otherwise distribution of these devices to individuals who do not use them has the potential to lead to significant financial loss. Comparison with the current trend of virtual clinics using a diagnostic hub will also be required; these have the advantage of utilising the same OCT device on multiple

patients with no dependence on individual operators, but of course necessitate clinic visits and longer monitoring intervals.

It will be necessary to determine the most appropriate patient selection criteria including both the level of disease activity as well as underlying diagnosis. Previous studies have suggested that the monitoring of low-risk patients is not a cost-effective solution for the detection of MNV [18]; it is unlikely to be sensible to distribute home monitoring devices to patients who are relatively unlikely to require treatment, such as those with minimal diabetic maculopathy or early dry AMD. It is also questionable whether patients who are attending outpatient clinics for injection treatment for their other eye require home monitoring if they are already having regular bilateral ocular assessment. However, those individuals having treatment at longer intervals of perhaps 10–12 weeks could benefit from home monitoring to help determine recurrence of disease activity and facilitate access to re-treatment. Newer anti-vascular endothelial growth factor (anti-VEGF) medications promise to enable more sustained treatment intervals, reducing regular attendance and routine assessment of the fellow eye in those with unilateral disease. Home monitoring may therefore ensure continued regular assessment of the fellow eye, while long-term monitoring for possible disease reactivation in those who have previously required anti-VEGF injections facilitates the safe discharge of these patients to the community.

There are significant financial considerations for the widespread introduction of home OCT devices. Most previous studies of the ForeseeHome device and home OCT have been carried out in the USA. Ensuring equality of access to this form of healthcare worldwide will likely be a complex process. In insurance-based medical care systems, negotiation and agreement from medical insurers will be necessary to enable widespread introduction. In publicly-owned and delivered healthcare systems, it may be easier for approval of devices widely but will represent a significant financial outlay when most public services have vast demands. The iCare HOME tonometer for intraocular pressure monitoring may be rented to patients for home use in glaucoma [19], and a similar process could be used for home OCT to reduce financial pressures (and possibly incentivise usage) in healthcare systems where this is acceptable. Regardless, it will be necessary to determine how the cost of home monitoring can be justified compared to current methods of patient assessment. Access to home monitoring is likely to be variable worldwide, and it may be challenging to deliver home OCT monitoring of macular disease on any large scale in lower-income countries.

While there are likely to be savings on multiple device purchases, significant ongoing maintenance and software costs will be required in the long term. The associated workforce expenses will also need to be considered; while initial analysis is likely to be automated, confirmation by trained staff will be required to improve referral accuracy. This is particularly relevant for devices assessing surrogate markers of MNV such as metamorphopsia. For example, the ForeseeHome device has recorded a 93% false positive alert rate on 'real-world' testing [17]. This would likely generate a prohibitive number of unnecessary referrals if applied on any significant scale. Large population-based services for assessment of patients with retinal disease already exist in some countries. Diabetic retinal screening services in Singapore and the UK facilitate a process of patient assessment, review and referral. In the short term, review is likely to be more locally based with the financial costs borne by the hospital services originally responsible for these patients.

The logistical issues relating to the home monitoring of macular disease are considerable. Any OCT images collected must be securely transferable from the patient's home to the monitoring service, as they will include patient identifiable health information. Appropriate data protection measures will therefore need to be put in place, ideally with a minimum of inconvenience to elderly patients who will be transferring scans on a regular basis. Ensuring equality of access will again depend on the individual patient's home and there is significant risk of discrimination against those without access to the required technology and internet connectivity.

Ensuring patient safety is paramount; reliance on home monitoring for disease activity is concerning if false negative results on home testing are significant. Studies of the ForeseeHome device found it to be the first factor detecting MNV in only approximately 50% of patients [3, 4], with symptoms and clinic scans accounting for the remainder. While early studies suggest home OCT will be significantly more sensitive [15], when translated to the population level even modest false negative rates are likely to represent a large number of delayed diagnoses if home monitoring is relied upon alone. Indeed, a previous study found agreement between analysis software and expert graders in only 83% of scans [13]. Future development of analytic tools including artificial intelligence systems are likely to improve sensitivity of disease assessments and reduce false negative rate. Some consideration of regular additional assessment should be made; patients are regularly referred for co-existing ocular conditions such as glaucoma when being assessed for macular disease, and loss of access to face-to-face review may reduce the diagnostic rate of these conditions.

CONCLUSION

Although there are significant concerns regarding widespread implementation of home monitoring of macular disease activity, future advances in the field of telemedicine are likely to facilitate this process. The introduction of home OCT is undoubtedly a more promising option than those devices assessing surrogate measures such as metamorphopsia, as home OCT will provide objective analysis of macular structure which can be accurately reviewed by clinical staff. Appropriate patient selection will be essential, and the logistical and financial considerations outlined in this article will require careful management. However, these novel solutions are important to enable regular patient assessment and ensure access to care in an era of unprecedented clinical demand.

ACKNOWLEDGEMENTS

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