AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

First-Year Visual Acuity Outcomes in the United Kingdom of Providing Aflibercept According to the VIEW Study Protocol for Age-Related Macular Degeneration

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Purpose: Aflibercept has the potential advantage of reducing capacity problems by allowing 2 monthly visits for patients with neovascular macular degeneration (nAMD) compared with monthly pro re nata regimens that are the most commonly used in the United Kingdom. This study aimed to report the visual outcomes achieved in routine clinical practice using the VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW) protocol at 1 year and compare with trials data and other real-world reports.

Design: Retrospective data analysis from an electronic medical record.

Participants: Consecutive series of treatment-naïve patients initiated on aflibercept for nAMD at least 1 year before data extraction.

Methods: Data were anonymized and remotely extracted from 16 centers in the United Kingdom that use the same electronic medical record (EMR) system (Medisoft Ophthalmology; Medisoft Limited, Leeds, UK).

Main Outcome Measures: The minimum data set defined before first data entry and mandated by the EMR included age, gender, visual acuity, injection episodes, and complications.

Results: The mean age was 80.0 years (median, 81.0 years) and 63.7% were women. During the first year of treatment with aflibercept, 1840 treatment-naïve eyes of 1682 patients received a median of 8 (mean, 7.0) injections at a median of 8 (mean, 7.3) visits. The mean baseline visual acuity was 53.7 letters, improving to 58.8 letters (+5.1-letter gain) at 1 year. In first-treated eyes, the respective figures were 52.7 letters at baseline and 58.2 letters at 1 year, a gain of +5.5 letters. The proportion achieving 70 letters or more increased from 16.4% at baseline to 33.7% at 1 year, and 92% avoided moderate visual loss at 1 year.

Conclusions: The visual acuity outcomes are comparable to randomized trials and better than many previous real-world data collections, with a mean +5.1-letter gain at 1 year compared with +8.4 letters in the integrated analysis of the VIEW 1 and VIEW 2 studies. Early visual gains were maintained through the year. Collection of outcomes beyond clinical trials can have limitations but better reflect the full pool of patients actually treated and are important to determine whether a particular treatment is performing as expected. Such data also have the potential to improve services by setting up a mechanism to compare sites. *Ophthalmology 2015;■:1–7* © 2015 by the American Academy of Ophthalmology.

Clinical trial outcomes in neovascular age-related macular degeneration (nAMD) often have not been replicated in routine clinical practice. This is partly because of the difficulty for patients, carers, and health care providers to follow optimum treatment regimens, leading to undertreatment,[1–4] but it is also because real-world cohorts of patients and measurement techniques are different from those in randomized controlled clinical trials. The measurement of outcomes outside clinical trials is important for patients, providers, and payers of therapy. It is important for the assessment of the quality of service delivery that measures are established that allow a fair comparison between centers based on the outcomes that can be achieved in the broader range of patients seen outside clinical trials.

Several treatment regimens are being used, including pro re nata (PRN), treat and extend, fixed, and combinations of the above. The best clinical trial results for ranibizumab and bevacizumab have been obtained when injections were given every 4 weeks.[5–8] It is possible to obtain good visual outcomes with a PRN regimen with these drugs, but

http://dx.doi.org/10.1016/j.ophtha.2015.09.039
ISSN 0161-6420/15

monthly follow-up is required and there needs to be sufficient capacity to give treatment immediately if needed.[7–9] The result of clinical trials using less frequent follow-up regimens have not been as good for maintenance of visual acuity improvements after the loading phase.[10] The treat-and-extend approach increasingly is being used and can produce good results, but it does require careful judgement of treatment intervals and the capacity to deliver appointments to all patients on time, although individual patients may not have fixed recurrence times.[4] On balance, poorer visual acuity outcomes seem to relate largely to undertreatment.[3]

Aflibercept administered every 8 weeks, after a loading phase of 3 injections given at 4-week intervals (the VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD [VIEW] protocol), has been shown to deliver visual acuity results that are as good as administering ranibizumab on a monthly basis over the first year.[11] The biggest challenge in a clinical setting is being able to provide enough capacity to achieve optimal treatment and visual outcomes for the patients. A bimonthly fixed regimen requires fewer monitoring visits and less decision making, and therefore may be a better regimen with less risk of visual compromise than a PRN or treat-and-extend regimen in health services where capacity problems are the dominant issue. This combined with the good outcomes reported in the VIEW trial led several centers in the United Kingdom to apply the VIEW clinical trial protocol to new patients.

The aim of this study was to determine whether a range of centers can provide this regimen in practice and what visual acuity outcomes are achieved, and to compare these with the randomized trial results and previous real-world results of using anti–vascular endothelial growth factor therapy. Such data are important to set a benchmark for outcomes that can be obtained in clinical practice so centers can compare results and potentially look at improvements if outcomes are not as good.

Methods

Study Design

Anonymized data were extracted from 16 UK National Health Service hospitals, (please see the UK Aflibercept Users Group in the footnote section) for all treatment-naïve eyes that were administered aflibercept treatment for nAMD more than 1 year before the data cutoff point. All data were recorded using a single electronic medical record (EMR) system (Medisoft Ophthalmology; Medisoft Limited, Leeds, UK), which mandated collection of a standardized data set throughout the nAMD care pathway. The lead clinician and Caldicott Guardian (nominee responsible for data protection) at each National Health Service hospital gave written approval for anonymized data extraction. Anonymized database analyses of this type do not require ethical permission because they are viewed as audit or service evaluations (see http://www.hra.nhs.uk/research-community/beforeyou-apply/determine-whether-your-study-is-research/). This study was conducted in accordance with the Declaration of Helsinki and the United Kingdom's Data Protection Act. Although this study was retrospective, the data set mandated by the EMR was defined prospectively before first data entry, and hence the study methodology is somewhat closer to an electronic case report form used in clinical trials than a conventional analysis of unstructured data in a retrospective chart review.

Treatment Posology, Dates, and Data Variables

Sites were selected on the basis that they confirmed that they used aflibercept to treat nAMD according to the VIEW protocol (3 monthly loading injections followed by repeated injections every 2 months) and that the EMR system was used to record all visual acuity and injection episodes. Analysis was restricted to treatment-naïve eyes in which aflibercept treatment was initiated between March 2013 and April 2014 to ensure a minimum of 1 year of follow-up.

Optical coherence tomography was used in all patients, and fluorescein angiography, including indocyanine green angiography, was used in most patients to confirm the diagnosis, although treatment was not delayed if this was not possible in a timely manner. At each visit, visual acuity, injection procedure, and follow-up data were entered live into the EMR system by all members of staff as part of routine clinical care. Several centers run entirely paperless clinics, but others print a paper copy to maintain paper notes. The operative and postoperative ocular and systemic complications fields within the EMR system were mandatory at each visit.

Visual Acuity and Missing Value Imputation

Early Treatment Diabetic Retinopathy Study visual acuity letter scores at 2 m were recorded at each visit at all sites. In a few cases, alternative measures were used, but the visual acuity was converted to an Early Treatment Diabetic Retinopathy Study letter score. At each visit, the best-measured visual acuity value was used in analysis. Most visual acuity values were recorded using habitual correction rather than with refraction. Values corresponding to counting fingers, hand movements, light perception, and no light perception were substituted with values of 0 letters.

In clinical practice, it is quite common for patients not to attend at the precisely intended intervals or to have slightly extended gaps in their data because of concurrent illnesses. With the posology of injections every 8 weeks after 3 initial injections at monthly intervals, visual acuity values could be expected to be recorded at 0, 4, 8, 16, 24, 32, 40, and 48 weeks, but in clinical practice, patients in fact become evenly distributed in each 4-week interval by the end of 1 year. It is also of great interest to display the visual acuity changes on a 4-week basis during the loading phase. We therefore chose to analyze the visual acuity data in 4-week intervals, but to ensure that the sample size in each month always reflected all patients who were being followed up continually, any gaps in their visual acuity data were imputed using the mean of the observation before and after the missing period. The impact of this data imputation is explored by reporting visual acuity values with and without data imputation. Unlike in clinical trials, no observations were carried forward beyond the last recorded visual acuity value, because loss to follow-up is more common in clinical practice.

Results

Participants

Data were extracted from 16 National Health Service centers for 1840 treatment-naïve eyes of 1682 patients initiating aflibercept treatment for nAMD between March 2013 and April 2014, to allow a minimum of 1 year of follow-up data potentially to be available. During follow-up, 245 patients (15.4%) required treatment to both eyes. Age and gender information are imported automatically from the hospital administrative system and are not entered directly into the EMR system. Age data were available for 100% of the sample

and sex data were available for all but 1 patient. The mean and median ages at baseline injection were 80.0 and 81.0 years, respectively (interquartile range, 50-102 years; standard deviation, 8.3 years); 63.4% were women.

Visual Acuity

The mean change in visual acuity is shown in Figure 1. The mean baseline vision for the 1840 eyes initiating treatment was 53.7 Early Treatment Diabetic Retinopathy Study letters (standard error, 0.4 letter), improving to 58.8 letters at 1 year (standard error, 0.5 letter; +5.1-letter gain) in the 1321 eyes known to be continually followed up at 1 year and to 58.9 letters (standard error, 0.7 letter; +5.2-letter gain) in the 701 eyes with data in the precise 4-week window at the annual time point (see "Methods"). If analysis was restricted to first-treated eyes (eyes with normal vision in the other eye), the mean baseline visual acuity was 52.7 letters (1388 eyes), improving to 58.2 letters at 1 year (990 eyes; +5.5-letter gain). For second-treated eyes (eyes which had already lost vision in the other eye), the baseline visual acuity was 60.4 letters (245 eyes), improving to 63.7 letters at 1 year (173 eyes; +3.3-letter gain; Fig 2). Eyes were not classified as first or second treated if treatment was initiated in both eyes on the same day (196 eyes from 98 patients) or if there was a different indication in each eye, such as vein occlusion (10 eyes; only data from the nAMD-treated eye were included in this study), or a different drug (1 eye).

Data were missing for 28% of eyes at 1 year, but it was not possible to determine the cause of loss to follow-up within the data extracted from the EMR system. In these eyes, the median visual acuity when last seen was 55 letters (mean, 51.4 letters), with a wide standard deviation of 20.9 and 25% having a visual acuity of 69 letters or better.

The largest visual acuity gains were in eyes that started with the worst vision, as shown in Figure 3. The 209 eyes initiating treatment with a visual acuity less than 35 letters gained a mean of 11.1 letters at 1 year compared with a mean decline of 2.0 letters in the 210 eyes initiating treatment with a baseline visual acuity of more than 70 letters. The proportion of eyes with a visual acuity of 70 letters or more increased from 16.4% at baseline to 33.7% at 12 months (Fig 4).

The proportions of the 1321 eyes with follow-up at 1 year that gained 5, 10, or 15 letters were 48%, 32%, and 18%, respectively, and the proportions losing 5, 10, or 15 letters were 22%, 13%, and 8%, respectively. The use of data imputation at 1 year to analyze a sample known to be followed up at or after 1 year (1321 eyes) compared with the sample of 701 eyes with data at precisely 1 year (±2 weeks) made a maximum difference of 2% to any of these values.

The mean number of injections in all 1840 eyes with potential for follow-up at 1 year was 7.0, with a median of 8 injections. This includes the 28% of eyes that did not have follow-up data at or beyond 1 year. The mean number of visits was 7.3, with a median of 8 visits.

Discussion

The visual acuity outcomes were not quite as good as trial outcomes, but seemed to be better than many previous real-world reports of clinical practice. The mean gain was 5.1 letters, compared with 8.4 letters in the integrated analysis of the VIEW 1 and VIEW 2 studies: 7.9 letters in VIEW 1 and 8.9 letters in VIEW 2. Previous audits of using ranibizumab with an intended PRN regimen in clinical practice achieved mean visual acuity gains at 1 year of 3.8 letters[2] in one of the centers in this audit, 2.4 letters in the AURA (Multi-country real-life experience of anti-vascular endothelial growth factor therapy for wet age-related macular degeneration) study,[3] and 2 letters in a previous multicenter ranibizumab EMR users group report.[1]

Mean letter gain has to be judged in relation to the starting vision. In the VIEW study, the mean baseline vision was 53.6 letters, and the mean 1-year visual acuity was 62 letters, giving a gain of 8.4 letters. The mean starting vision in our group was almost the same at 53.7 letters. In the ranibizumab EMR users group report, the mean starting visual acuity was 55 letters, increasing to 57 letters at 1 year. In the ANCHOR (Treatment of Predominantly Classic Choroidal Neovascularization in Age-Related Macular Degeneration) study, using ranibizumab monthly for only classic choroidal neovascularization, there was a larger mean gain in visual acuity of 11.3 letters, but the mean baseline visual acuity was much lower at 47.1 letters. In the MARINA (The Minimally Classic/Occult Trial of the Anti-VEGF Antibody Ranibizumab in the Treatment of Neovascular Age-Related Macular Degeneration) study, which examined occult choroidal neovascularization, the mean baseline acuity was 53.7 letters, with a mean gain of 7.2 letters.[5,6]

Ranibizumab given PRN, with careful follow-up, achieved similar outcomes compared with monthly treatment, with 7.7 injections in HARBOR (the pHase III, double-masked, multicenter, randomized, Active treatment-controlled study of the efficacy and safety of 0.5 mg and 2.0 mg Ranibizumab administered monthly or on an as-needed Basis [PRN] in patients with subfoveal neOvasculaR age-related macular degeneration) and 6.9 injections in Comparison of AMD Treatments Trials (CATT) in year 1. The baseline visual acuity in the HARBOR study was 54.5 letters for the 275 eyes in the PRN 0.5-mg arm, which gained a mean of 8.2 letters at 1 year. The CATT mean baseline acuity for the PRN arm was higher at 61.5 letters, and this arm gained 6.8 letters at 1 year. In the VIEW studies, the mean number of injections was 7.6. This suggests that a similar number of ranibizumab injections compared with aflibercept injections used in 1 year can produce similar results; however, considerably more monitoring visits were needed when using ranibizumab on a PRN basis. It is unknown whether ranibizumab used bimonthly would produce the same results.

One confounder in real-world data is that visual acuity often is measured with the patients' habitual correction, if any, rather than subjective refractions at each visit. This is likely to underestimate the actual changes in vision; however, it may reflect better what vision patients actually experience.

Visual acuity outcomes may not be expected to be as good as clinical trials because the patient group in clinical practice is likely to be different, with a broader range of lesion type, including a few larger than 12 disc areas; more than 50% of the lesion being hemorrhage; having more atrophy or fibrosis at baseline; having a broader baseline vision; more ocular comorbidities, such as epiretinal membrane or cataract; and the patients having a greater range of other health issues. In this report, the age range at baseline

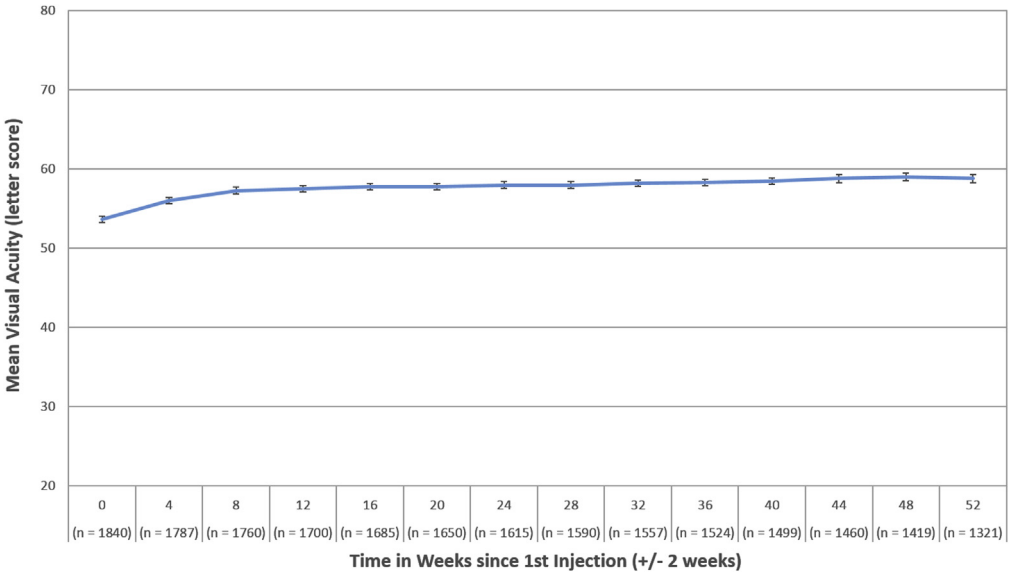

Figure 1. The mean visual acuity over time of patients treated with aflibercept for neovascular age-related macular degeneration who have the potential for 1-year follow-up (n = number of eyes).

went up to 102 years, and the mean age was older than that in the VIEW studies. Older patients are known to achieve less improvement than younger patients. Another major potential difference between clinical trials and the real world is the provision of treatment within tight timelines. This is a particularly important reason for real-world outcomes to be measured; clinical outcomes often are not as good as hoped because of delayed follow-up, undertreatment, or both. If this is found, then it is possible that service adjustments can improve the outcome.

Considering the above factors, our results do seem to compare reasonably with clinical trial results. This is likely because the bimonthly injection regimen was delivered largely as a median of 8 (mean, 7) injections given during the year, with the eighth injection being given at 12 months and the mean not being 8 injections because the 28% of patients for whom we do not have data at the end of the year were included.

The effectiveness of a treatment approach also may be judged by degree to which visual acuity is stabilized in the longer term after initial maximum visual acuity gain. A trend in the real-world ranibizumab data is for an initial visual acuity gain after the first 3 injections, when it is likely that most departments are delivering treatment optimally, followed by a subsequent gradual decline over time, which may be the result of difficulty with delivering optimal

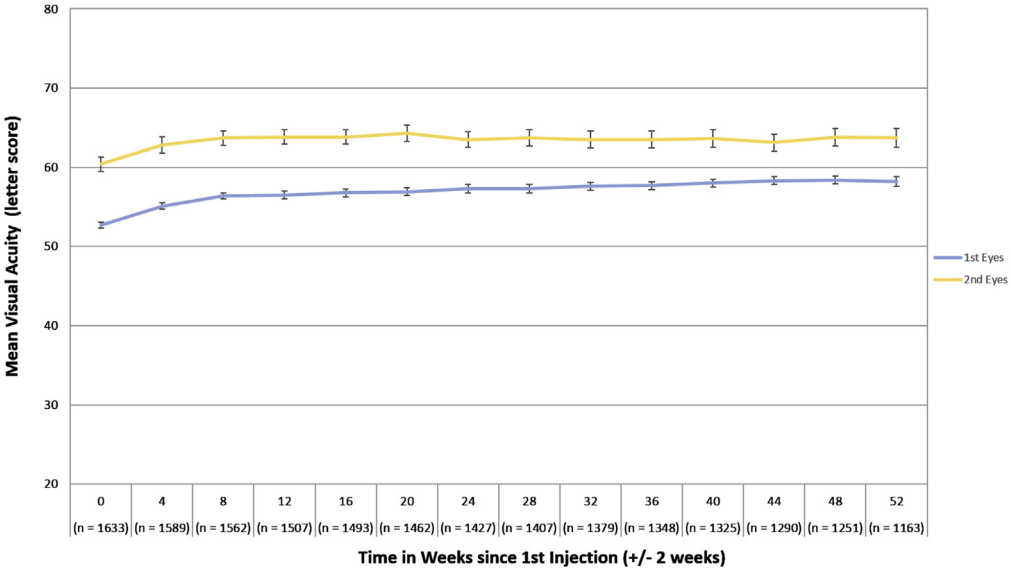

Figure 2. The mean visual acuity over time comparing first-treated and second-treated eyes. n = number of eyes.

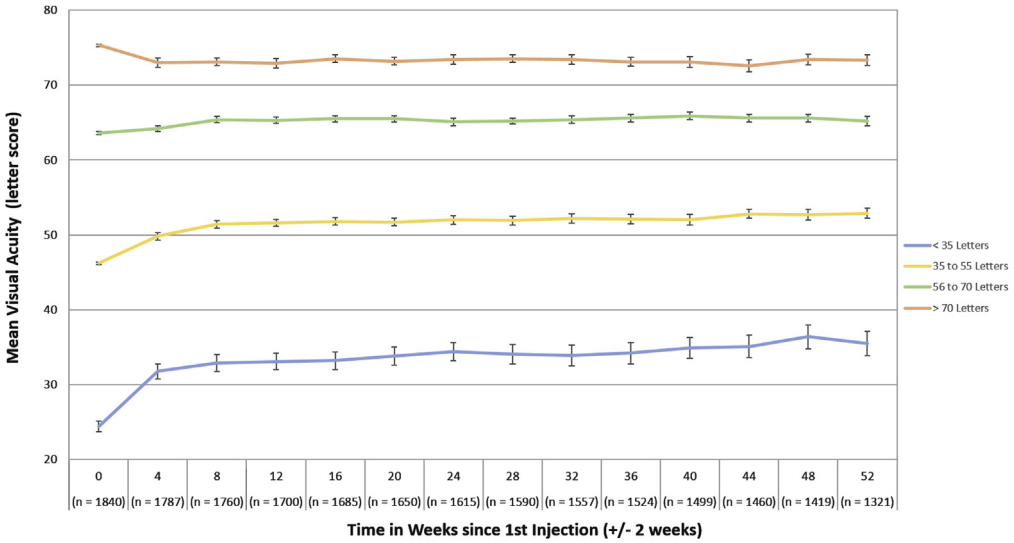

Figure 3. The mean visual acuity of eyes over time stratified by starting visual acuity. n = number of eyes.

therapy. In this study, the initial visual acuity gain after the monthly treatment phase was maintained at the end of 1 year (Fig 1).

Mean gain in visual acuity is only one measure of success, and as the studies presented suggest, a big factor in the magnitude of gain is the baseline vision. Better, more patient-centered measures of success are probably how many patients did not lose vision and how many had useful functional vision, such as 70 letters or more. The number with 70 letters or more increased from 16.4% at baseline to 33.7% at 1 year in our study. In the VIEW study, this number changed from 23% to 45%, and in the HARBOR study, 46% achieved 70 letters or more at 1 year. In the EMR users' group report, 30% of eyes achieved this benchmark at 1 year.

As can be seen on Figure 3, if a patient starts with good vision, they are likely to lose a little but maintain good visual function. However, a patient who starts with poor vision is likely to gain more but have relatively poor vision at 1 year. The comparison of first and second eyes also shows this effect, with second eyes, on average, starting treatment with better vision and maintaining a better visual acuity, but gaining less than first-treated eyes (Fig 2).

Because the data were recorded in an EMR system, all patients accessing therapy at each contributing center should

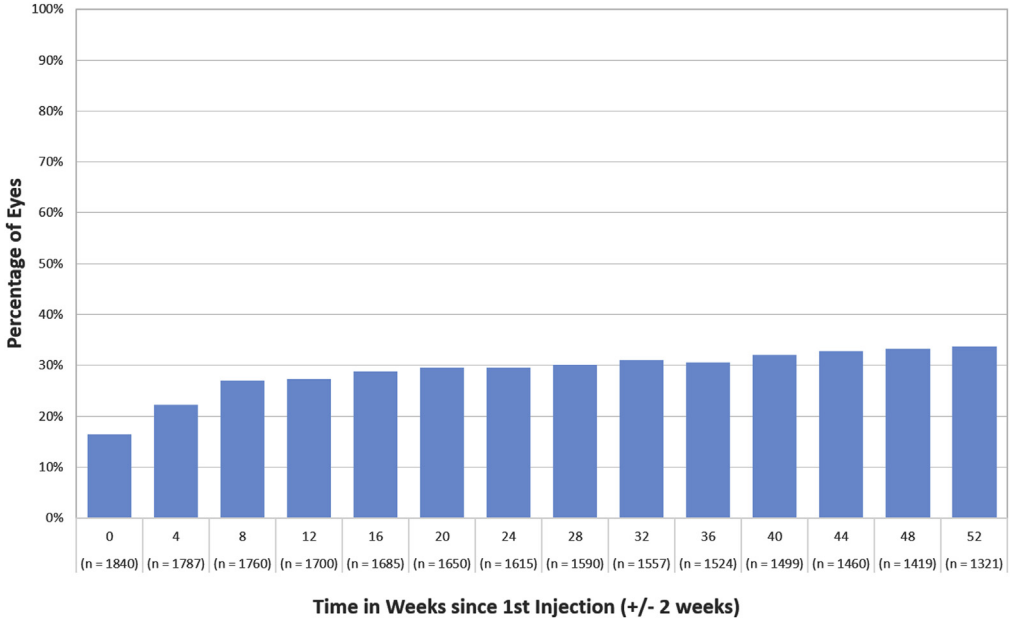

Figure 4. The proportion of eyes achieving 70+ letters of visual acuity. n = number of eyes.

have been recorded, reducing the risk of selection bias. Data were not available for 28% of eyes at 1 year, presumably because of patients moving away, becoming unwell, or dying (unless the EMR system was not, in fact, used at all visits in some centers). The window for analyzing data also may miss patients who have missed an appointment but return later; however, by using a mean of the visual acuity before the missed visit and the visual acuity when they returned, we have attempted to mitigate this by enabling all eyes under continued follow-up to contribute to each time point. Using only the data at a specific time point or including an imputed visual acuity value based on the mean of the vision measurements before and after missed time points made very little difference to the outcome measures. For patients for whom we did not have visual acuity data at or after 1 year, their visual acuity was not carried forward because of the variable nature of follow-up. The mean visual acuity of patients who did not achieve 1 year of follow-up was lower at 51.4 letters, but there was a large standard deviation, so the mean visual acuity can be skewed by a few patients with significant reductions in vision. The median visual acuity of 55 letters in this group gives a clearer measure of how many patients had reasonable vision when last examined.

The similarity of the proportion of missing data in our study, on a fixed regimen and with free access to treatment, versus the that of study by Gilles et al,[4,12] in which patients underwent a treat-and-extend regimen and comprised a mixture of insured, self-pay, and free-access patients, and for whom there was 35% missing data rate, is reassuring in that it is not the treatment regimen, but rather the wider range of patients seen outside trials, that leads to fewer patients maintaining follow-up protocols. Missing data, such as in this instance, are particularly of concern if the purpose of the study is to compare one treatment with another; however, these data are very useful if they are used for capacity planning and cost services. It also may be important for comparing the quality and accessibility of service provision.

The report by Gilles et al[4,12] does suggest that treat and extend is another option for trying to address capacity issues with service provision; however, the best results came later in the period of data collection, when the number of injections went up to 14.2 over 2 years, which is similar to providing injections every 2 months in the first year. The treat-and-extend method does allow a more individualized approach that may have benefits, but it must be performed in a service delivery system that can provide sufficient capacity.

Anti−vascular endothelial growth factor therapy has revolutionized the visual outcome for patients with nAMD. The biggest challenge is providing the treatment effectively for a population of patients within the constraints of finite capacity. Implementing the VIEW protocol leads to the possibility of fewer visits and less monitoring in the first year of treatment and may help with this goal. There is the possibility that some patients have been overtreated and some undertreated with this regimen; however, the data reported here show that this approach is effective and that it can be carried out in multiple centers in the United Kingdom. These data can act as a benchmark for outcomes achieved so far in the United Kingdom with this therapy and can allow intercenter comparisons, which could lead to service improvements. Useful outcome measures for any service and comparing services are mean baseline visual acuity as well as mean actual visual acuity after treatment, rather than just mean visual gain. It is particularly important to improve the number of patients who seek treatment early and can access treatment because the better the starting vision, the more likely a patient is to maintain useful vision. Future research could include assessing whether continued bimonthly treatment, in the second year, maintains the visual acuity gains.

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Footnotes and Financial Disclosures

Originally received: June 26, 2015.
Final revision: September 10, 2015.
Accepted: September 26, 2015.
Available online: ■■■. Manuscript no. 2015-1077.

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Financial Disclosure(s):
The author(s) have made the following disclosure(s): R.L.J.: Employee - Medisoft Limited

The authors have received travel bursaries and attended advisory boards for Bayer, Novartis, and Allergan.

Medisoft and Newcastle Upon Tyne Hospitals NHS Foundation Trust received support for data extraction and analysis from Bayer. Bayer was not involved in the data collection, analysis, or writing of this article.

Other members of the UK Aflibercept Users Group are as follows: Aires Lobo, FRCOphth, FRCS(Ed), Moorfields Eye Unit, Bedford Hospital NHS Trust; Bobby Paul, FRCOphth, Barking, Havering, and Redbridge, University Hospitals NHS Trust; Qureshi Kashif, FRCOphth, East Sussex Hospitals NHS Trust; Cynthia Santiago, FRCOphth, Grampian NHS; Gavin Walters, MRCP, FRCOphth, Harrogate Hospital; Mohamed Tahir, FRCOphth, Berkshire NHS Trust, Bushra Mushtaq, FRCOphth, Sandwell and West Birmingham Hospitals NHS Trust.

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Obtained funding: none

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Abbreviations and Acronyms:
EMR = electronic medical record; **nAMD** = neovascular age-related macular degeneration; **PRN** = pro re nata; **VIEW** = VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD.

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