EXTENDED REPORT

Visual functioning and quality of life in the SubFoveal Radiotherapy Study (SFRADS): SFRADS report 2

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Aims: To determine whether or not self reported visual functioning and quality of life in patients with choroidal neovascularisation caused by age related macular degeneration (AMD) is better in those treated with 12 Gy external beam radiotherapy in comparison with untreated subjects.

Methods: A multicentre single masked randomised controlled trial of 12 Gy of external beam radiation therapy (EBRT) delivered as 6×2 Gy fractions to the macula of an affected eye versus observation. Patients with AMD, aged 60 years or over, in three UK hospital units, who had subfoveal CNV and a visual acuity equal to or better than 6/60 (logMAR 1.0).

Methods: Data from 199 eligible participants who were randomly assigned to 12 Gy teletherapy or observation were available for analysis. Visual function assessment, ophthalmic examination, and fundus fluorescein angiography were undertaken at baseline and at 3, 6, 12, and 24 months after study entry. To assess patient centred outcomes, subjects were asked to complete the Daily Living Tasks Dependent on Vision (DLTV) and the SF-36 questionnaires at baseline, 6, 12, and 24 months after enrolment to the study. Cross sectional and longitudinal analyses were conducted using arm of study as grouping variable. Regression analysis was employed to adjust for the effect of baseline co-variates on outcome at 12 months and 24 months.

Results: Both control and treated subjects had significant losses in visual functioning as seen by a progressive decline in mean scores in the four dimensions of the DLTV. There were no statistically significant differences between treatment and control subjects in any of dimensions of the DLTV at 12 months or 24 months after study entry. Regression analysis confirmed that treatment status had no effect on the change in DLTV dimensional scores.

Conclusions: The small benefits noted in clinical measures of vision in treated eyes did not translate into better self reported visual functioning in patients who received treatment when compared with the control arm. These findings have implications for the design of future clinical trials and studies.

A number of studies have suggested that the most commonly used conventional measure of visual function, distance acuity, does not adequately reflect visual functioning and ability to undertake vision dependent tasks.[1 2] Historically, distance acuity has been measured on a high contrast letter chart containing letters of progressively smaller sizes, which subtend progressively smaller angles at the focal point on the retina, and which serves as a marker for the ability of the eye to resolve objects. It is easily and quickly determined, hence its popularity in the clinical setting. However, there are many other aspects of vision that are important such as contrast sensitivity, colour and binocular vision, reading ability and visual scanning, which are disregarded when high contrast distance acuity alone is measured. As they are time consuming, often requiring the use of complex equipment and an operator with special skills, these other aspects of vision are only likely to be measured in the research setting. Thus, there has been an increase in interest in the use of self reported visual functioning questionnaires, which are performance based and easily administered, in the hope that these will reflect more accurately functional vision in the individual.

A variety of questionnaires have been devised, validated, and used as outcome measures in the evaluation of cataract surgery,[3–6] and a few studies have utilised visual functioning instruments to ascertain the impact of age related macular degeneration (AMD) on vision related quality of life.[7 8] Currently there is much interest in the ability of a variety of therapies to limit or prevent visual decline in wet AMD. Thus far, all of the clinical trials that have tested the effect of interventions in exudative AMD have used ''change in distance visual acuity'' as the primary outcome variable.

Although treatment interventions in exudative AMD have had a limited degree of success in reducing the risk of moderate and severe vision loss, the value of the benefit remains questionable. Thus, for instance, a one line difference in mean acuity between treatment and control groups may not translate into improved visual functioning. The increasing tendency to use dichotomous end points such as the loss of 15 letters of vision presupposes that this difference is significant in terms of lost quality of life. However, this remains unproved.

The Sub Foveal Radiotherapy Study (SFRADS) which examined the effect of 12 Gy of external beam in subfoveal choroidal neovascularisation of AMD included both standard tests of visual function (distance and near acuity, reading speed, and contrast sensitivity) that were described in the first SFRADS report[9] and patient centred variables as outcome measures. There was a difference in favour of treatment in the primary outcome measure (distance visual acuity) at 24 months, which was marginally significant using

Abbreviations: AMD, age related macular degeneration; CS, contrast sensitivity; DLTV, Daily Living Tasks Dependent on Vision; DVA, distance visual acuity; EBRT, external beam radiation therapy; NVA, near visual acuity; SFRADS, SubFoveal Radiotherapy Study

longitudinal modelling techniques. Also, significant differences in the secondary outcomes measures of near acuity and contrast sensitivity were detected at 6 months and 24 months, respectively, which were in favour of treatment. The present analysis and report deals with outcomes in vision related and health related quality of life in treatment and control groups during the 24 month period after enrolment.

METHODS

When the SFRAD trial was under development we considered the existing visual functioning questionnaires that had been designed for studies in ophthalmology. These questionnaires were mainly in the field of cataract surgery in which outcomes are typically perfect or near perfect restoration of vision. A significant proportion of tasks within existing instruments were devoted to extracting information on driving abilities and reading tasks. Because many of the subjects enrolled into studies of neovascular AMD have bilateral involvement, and driving and reading are adversely affected with even small degrees of vision loss in the better seeing eye, we noted a tendency to floor effects when using existing questionnaires. As it is over-optimistic to expect even small improvements following treatment in neovascular AMD and the best outcome envisaged was prevention of further vision loss in the treatment group, it was thought necessary to develop a new instrument that took into account the severe and central nature of the vision loss in neovascular AMD. This instrument which we termed the Daily Living Tasks Dependent on Vision (DLTV) was developed and validated concurrently with the study.

SFRADS inclusion and exclusion criteria, source of participants, intervention, randomisation, and masking have been described in detail.[9] However, a synopsis of the trial design and methods is presented here. Patients were required to be 60 years of age or older and have evidence of subfoveal choroidal neovascularisation on a fundus fluorescein angiogram performed within 1 week of randomisation. Visual acuity at baseline was required to be equal to or better than logMAR 1.0 (6/60 or better) in the study eye. Patients with a presumptive diagnosis of subfoveal choroidal neovascularisation were screened in special study clinics in three UK hospitals in Belfast, London (Moorfields), and Southampton. Enrolment commenced in December 1995 and was completed in September 1998. In all, 203 patients were recruited into the study after giving informed consent and randomised to either the treatment (external beam radiotherapy) or control (observation only) groups. Four patients were subsequently removed from the analysis as they did not fit the entry criteria on grounds of age or visual acuity in the study eye. Patients were examined at baseline, 3, 6, 12, and 24 months after randomisation when standard efficacy and safety parameters were recorded. Visual functioning and quality of life data were collected at all time points except at the 3 month visit. The optometrists who undertook visual assessments and the interviewers who administered the questionnaires were unaware of the treatment status of the patients, although neither the treating physician nor the patient was masked.

Clinical measures of vision

The clinical measures of vision—distance and near acuity and contrast sensitivity—were tested by an optometrist trained to undertake the study protocol that was adapted from the Macular Photocoagulation Study manual of procedures.[10] All measurements were performed on each eye of each patient. Before refraction distance visual acuity (DVA) in each eye was measured with patients wearing their usual glasses if any. The backlit Bailey-Lovie logMAR chart[11] was used for all DVA measurements. Following standardised refraction, DVA was measured again and the line with the smallest letters in which at least three of the letters were correctly identified was entered as the line acuity for that eye. Near visual acuity (NVA) was tested with each eye with a + 4.00 addition on the Bailey-Lovie near reading chart at 25 cm and scored in logMAR notation. Contrast sensitivity (CS) was measured for each eye using the Pelli-Robson chart with the patient seated at the recommended distance of 1 metre.

Visual functioning and quality of life

An interviewer trained for the task in each centre administered the instruments. The visual functioning questionnaire used was the DLTV,[12 13] and information on health related quality of life was obtained using the SF-36.[14–16] We also developed an additional short instrument to assess self reported dependency and the use of social services. The results from this latter aspect of SFRADS are not included in this report.

A full description of the validation of the DLTV and the methods used to assign items to the dimensions is the subject matter of a separate publication.[17] In brief, however, the DLTV was conceived as a 33 item questionnaire covering tasks relating to visual function (with and without the use of magnification aids) and general aspects of visual health. In the majority of instances, each item was scored on a 4 point ordered categorical scale where the minimum possible score was 1 (inability to do the task) and the maximum was 4 (no difficulty with the task). Some items were scored differently, and details of the items and scoring system used have been published previously.[12 13] After the exclusion of items dealing with the use of magnification aids and those on general aspects of visual health, the DLTV contains 22 items that directly pertain to activities of daily living. Validation of the instrument in an independent large dataset of older adults with a clinical diagnosis of AMD in one or both eyes showed that these 22 items formed four dimensions of nine, eight, three, and two items, respectively (table 1). As there was redundancy in dimension 1, two items were omitted. The data from SFRADS for the present report were analysed using the validated domain structure,[17] that is four dimensions containing seven, eight, three, and two items respectively (table 1). The scores from each of the items within a dimension were averaged and converted into a scale between 0 and 100 similar to those used in other studies. Where an individual indicated that a task was not applicable, this item was not scored and the percentage DLTV score was adjusted for the number of items answered.

The SF-36 was the generic instrument of choice which has been validated in older people and used along with visual functioning instruments in other studies. The SF-36 is generally analysed as eight multi-item dimensions of health.[18]

Questionnaire data were unavailable in a small proportion of clinic visits although visual outcome and angiographic data were acquired. This was usually in response to the participant's desire to minimise the length of time spent in the hospital clinics. The flow chart (fig 1) shows the route followed by patients during time on study, number of patients who completed each scheduled study visit and the percentage for whom questionnaire data were available.

Statistical methods

Visual functioning indices have been shown to be most strongly driven by visual acuity in the better seeing eye.[3 5–7 12 13] We examined the effect of treatment in the entire study population and then in a subgroup categorised by the status of the study eye relative to the fellow eye. Each study eye was allocated to the status of better eye or worse eye based on DVA. If DVA was identical in the two eyes, the eye with better

Table 1 Items comprising the original DLTV

Dimension 1	Dimension 2	Dimension 3	Dimension 4
1 Read newsprint	1 Cut fingernails	1 Confidence moving around own neighbourhood	1 Difficulty adapting to bright conditions
2 Read correspondence*	2 Pour a drink	2 Seeing objects off to one side	2 Difficulty adapting to dark conditions
3 Sign documents	3 Cutting food on a plate	3 Seeing steps	
4 Watch TV	4 Use kitchen appliances		
5 Distinguish features at room length	5 Enjoy scenery when out for a drive		
6 Distinguish features across a street	6 Recognise seasonal changes in the garden		
7 Reading road signs and street names	7 Read newspaper headlines		
8 Identify money*	8 Distinguish features at arms length		
9 Confidence moving around unfamiliar neighbourhood			

*Items that were redundant and therefore omitted from dimension 1.

near visual acuity was assigned the status of the better eye. If DVA and NVA were identical, CS was used to determine better eye status. Of the 199 study subjects, only one had identical DVA, NVA, and CS in both eyes and this patient was allocated to the group where the study eye was the better eye. We present summary statistics on the entire study population, and in the subgroup where study eye was the better eye at baseline.

We tested for differences in baseline characteristics between treatment and control groups using the independent samples t test and χ^2 tests.

We then examined the changes in the summary scores for the four dimensions of the DLTV and the eight dimensions of the SF-36 at 12 months and 24 months using the independent samples t test with arm of study as grouping variable. Additionally, regression analysis was employed to test for confounding variables. These analyses were then repeated in the subgroup where the study eye was the better eye. As the data were subjected to multiple testing, only p values below 0.025 were considered as significant.

The DLTV has been previously validated for use in subjects with AMD in cross sectional studies. We exploited the

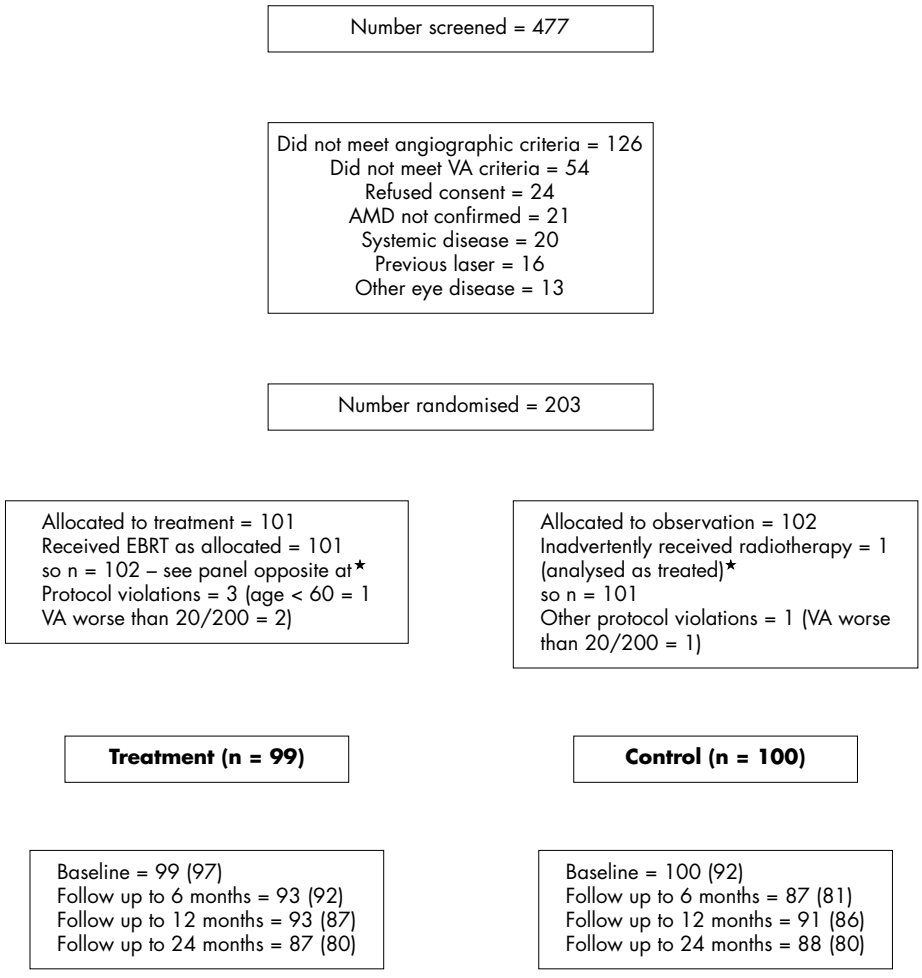

Figure 1 Flow chart. (Figures in parentheses give the numbers of patients for whom self reported outcomes were collected at visit.)

Table 2 SFRADS participant details by sex and centre

	Male	Female
Belfast	30 (36.1%)	53 (63.9%)
London	30 (43.5%)	39 (56.5%)
Southampton	26 (55.3%)	21 (45.7%)
Total	86 (43%)	113 (57%)

longitudinal nature of the dataset to examine the relation between change in DLTV dimension scores and change in distance visual acuity. We included the status of the presenting eye (study eye) and arm of study as co-variates.

The SPSS version 10 was used for the analyses.

RESULTS

In total, there were 199 eligible patients of whom 99 were assigned to the treatment group and 100 to the control group. The mean (SD) age of treated patients was 75.3 (6.4) years and that of the control group was 75.2 (6.4).

Full details of the demography of the SFRAD study population have been reported previously.[9] Sex and centre distribution, which are of relevance to the present report, are shown in table 2.

We have already shown in the first SFRADS report that the treatment and control group were well matched with no significant differences in the clinical measures of vision in the study eye at baseline.[9]Table 3 shows the mean and range of distance and near acuity and contrast sensitivity in the study eye with the study population subdivided by whether the study eye was the better or the worse of the patients two eyes.

Patient centred outcomes

DLTV

Mean scores in dimension 1 were generally lowest compared with those of dimensions 2 and 3 in both treatment and control groups. There were no significant differences in mean scores in any of the dimensions of the DLTV between treatment and control groups (table 4). Reductions in mean scores in dimensions 1–3 of the DLTV were observed during time on study. These were more marked in the first 12 months when compared with the second 12 months of review. In dimension 4 that contained the two items on difficulty with light and dark adaptation, little or no change from baseline mean scores was seen at 12 months and 24 months in both the treatment and control group. Analysis of the change in scores in all dimensions showed that there were no significant differences between treatment and control groups at either 12 months or 24 months (table 4).

Subgroup analysis

In the subgroup in which the study eye was the better eye at baseline (117), the change in mean DLTV dimension scores was not significantly different in treatment and control groups at 12 or 24 months (table 5). Similarly, also in this subgroup, changes in SF-36 dimension scores were not significantly different at 12 and 24 months in treatment and control groups (data not shown).

Factors at baseline influencing DLTV outcomes at 12 months and 24 months

Treatment status did not influence outcome at either 12 months (table 6) or 24 months (table 7) in any dimension of the DLTV. Age and sex also did not influence outcome at 12 months or 24 months. Centre differences were detected solely in dimension 3 at 24 months (table 7). The visual status of the study eye (that is, when it was the better eye at baseline) was associated with a significantly larger change in dimensions 1, 2, and 3 at 12 months and dimension 3 at 24 months.

Relation between DLTV and DVA

Regression analysis showed that only change in distance visual acuity in the better eye was highly significantly associated with change in the three main dimensions of the DLTV (table 8). The change in scores in dimension 4 was not statistically significantly associated with change in visual acuity.

SF-36

Analysis of the eight dimensions of the SF-36 showed that the treatment and control groups were well matched at baseline. The change in SF-36 dimension scores were not significantly different at 12 or 24 months between treatment and control groups (table 9).

Factors at baseline influencing SF-36 outcomes at 12 months and 24 months

As there are eight dimensions in the SF-36 leading to multiple testing, only differences which were significant at the 1% level or less are reported. Treatment status did not influence outcome at 12 months or 24 months. Geographical location impacted on outcomes in three of the dimensions of the SF-36. In these three dimensions (physical functioning, physical role, and energy and vitality) significant differences were seen between centres at both 12 months and 24 months (data not shown).

DISCUSSION

The value of generic quality of life measures as outcomes in clinical trials especially in the realms of cancer and

Table 3 Clinical measures of vision at baseline in SFRADS participants when study eye is better eye or when study eye is worse eye by treatment status (figures in parentheses are standard deviations).

	Treated patients		Control patients	
	Mean	No of patients	Mean	No of patients
Distance acuity (logMAR)				
Study eye is better eye	0.55 (0.22)	65	0.54 (0.22)	52
Study eye is worse eye	0.68 (0.23)	34	0.63 (0.22)	48
Near acuity (logMAR)				
Study eye is better eye	0.82 (0.29)	65	0.83 (0.35)	52
Study eye is worse eye	0.95 (0.35)	34	0.89 (0.36)	48
Contrast sensitivity (log threshold)				
Study eye is better eye	1.16 (0.27)	65	1.12 (0.30)	52
Study eye is worse eye	1.03 (0.34)	34	1.07 (0.36)	48

Table 4 Mean DLTV dimension scores in treatment and control groups at baseline, and mean change in dimensional scores at 12 and 24 months for all study patients (figures in parentheses are standard errors)

DLTV dimension	Baseline			Change at 12 months			Change at 24 months		
	Treatment	Control	p Value	Treatment	Control	p Value	Treatment	Control	p Value
1	50.4 (3.1)	54.9 (3.5)	0.33	−10.6 (2.2)	−9.5 (2.6)	0.74	−13.5 (2.3)	−15.5 (3.3)	0.62
2	80.9 (2.3)	80.1 (2.5)	0.81	−10.6 (2.2)	−7.8 (2.2)	0.37	−10.6 (2.5)	−11.9 (2.6)	0.72
3	82.2 (2.0)	83.1 (2.2)	0.77	−8.4 (2.4)	−6.5 (2.3)	0.55	−8.2 (2.4)	−10.7 (1.7)	0.42
4	66.5 (3.0)	70.0 (2.9)	0.41	−2.0 (3.1)	−3.2 (3.2)	0.79	−3.2 (3.0)	−3.2 (2.4)	0.10

cardiovascular disease are established.[19–21] Disease or organ specific quality of life measures have also gained increasing acceptance. Both are now used extensively when considering the value of an intervention and for the purposes of resource allocation. To date, few published randomised controlled clinical trials in ophthalmology have used such self reported measures.[22 23]

To the best of our knowledge SFRADS is among the first major randomised controlled multicentre clinical trials in the field of AMD to evaluate visual functioning and quality of life as outcome measures.

Our analysis showed no significant differences between treatment and control groups in self reported visual functioning or wellbeing at the two main outcome points. In the initial report from the SFRADS study we described statistically significant differences in some measures of visual outcome (NVA and CS) in favour of radiotherapy treated eyes.[9] However, these differences were small—namely, 0.6 lines of DVA, 1 line of NVA, and 0.3 log units of contrast that equates to two triplets in the Pelli-Robson chart.

An important and frequently asked question is whether or not such small differences in clinical measures of vision between two treatments when observed in trials translates into a meaningful difference in terms of visual functioning. Studies have shown that generic quality of life instruments are not significantly correlated with visual functioning in subjects with AMD.[24] Even when improvements in function are dramatic such as those experienced following cataract surgery, generic instruments demonstrate poor relations with visual functioning.[25 26] This is especially relevant to an elderly population where substantial co-morbidity has the potential to either swamp or drive the responses to an instrument. However, it was unknown whether self reported visual functioning or clinical measures would be more sensitive to change in the visual status. The protocols used to measure clinical measures of vision ensure reproducibility and hence small differences may be reliably detected. However, visual functioning instruments are inherently more prone to greater variation and minor differences may not be detected.

Our experience with SFRADS suggests that there are several factors that have to be taken into account when patient centred outcomes are used to assess the value of an intervention. SFRADS was powered to detect change in the primary outcome variable—namely, DVA. Examination of our data suggested that in order to detect a difference in summary scores of any one of the DLTV dimensions as statistically significant with 90% power, the study would have had to be increased in size to 600 subjects with 300 in each arm. As vision is mediated by a paired organ, it should be recognised that visual functioning is primarily driven by the better eye. This must be taken into account while designing trials with such an outcome measure. In this context, one third of the SFRAD study sample had good visual function in the non-study fellow eye. Therefore,

Table 5 Mean DLTV dimension scores in treatment and control groups at baseline, and mean change in dimensional scores at 12 and 24 months for subgroup where study eye was the better eye at baseline (figures in parenthesis are standard errors)

DLTV dimension	Baseline			12 Months			24 Months		
	Treatment	Control	p Value	Treatment	Control	p Value	Treatment	Control	p Value
1	37.3 (2.9)	33.4 (3.9)	0.42	−14.9 (2.6)	−12.2 (3.5)	0.54	−18.0 (3.0)	−12.0 (4.4)	0.25
2	74.5 (2.9)	69.2 (3.9)	0.27	−14.1 (3.0)	−13.6 (3.6)	0.91	−13.2 (3.5)	−14.1 (3.9)	0.86
3	78.0 (2.9)	69.2 (3.9)	0.83	−10.6 (3.2)	−8.9 (3.8)	0.73	−10.2 (3.1)	−12.4 (2.8)	0.62
4	59.6 (3.8)	64.1 (4.0)	0.42	−0.6 (3.8)	1.9 (5.4)	0.70	3.7 (4.0)	−3.4 (4.0)	0.23

Table 6 Regression model showing effect of baseline co-variates on change at 12 months in the three main dimensions of the DLTV

Baseline covariates	Change in dimension 1			Change in dimension 2			Change in dimension 3		
	B	SE	p Value	B	SE	p Value	B	SE	p Value
Constant	3.07	20.42	0.88	7.15	18.51	0.70	21.97	20.13	0.28
Age	−0.14	0.26	0.59	−0.14	0.24	0.55	−0.34	0.26	0.18
Sex (M = 1, F = 2)	2.29	3.44	0.51	0.30	3.10	0.92	0.90	3.40	0.79
Centre (Belfast)	3.37	3.87	0.39	1.43	3.49	0.68	−3.93	3.82	0.31
Centre (Southampton)	−3.15	4.45	0.48	−3.16	3.98	0.43	−5.37	4.39	0.22
Study eye is better eye	−9.6	3.5	0.007*	−11.1	3.2	0.001*	−5.6	3.5	0.11
Treatment status	−0.86	3.46	0.81	0.36	3.10	0.91	−0.59	3.41	0.86

London was used as the reference centre.

Table 7 Regression model showing effect of baseline covariates on change in the three main dimensions of the DLTV at 24 months

	Change in dimension 1			Change in dimension 2			Change in dimension 3		
Baseline covariates	**B**	**SE**	**p Value**	**B**	**SE**	**p Value**	**B**	**SE**	**p Value**
Constant	0.5	24.8	0.98	30.4	22.3	0.18	35.5	17.9	0.049
Age	−0.16	0.32	0.62	−0.50	0.28	0.08	−0.45	0.23	0.049
Sex (M = 1, F = 2)	1.34	4.19	0.75	1.95	3.75	0.60	−0.48	3.03	0.88
Centre (Belfast)	4.91	4.66	0.29	2.21	4.17	0.60	−1.42	3.37	0.67
Centre (Southampton)	−6.29	5.25	0.23	−4.90	4.67	0.30	−9.98	3.80	0.010*
Study eye is better eye	−4.3	4.2	0.31	−6.0	3.8	0.11	−4.8	3.0	0.12*
Treatment status	−1.96	4.11	0.63	−2.04	3.67	0.58	−2.86	2.98	0.34

London was used as the reference centre.

Table 8 Regression analysis showing relation between change in DLTV dimensions and change in visual acuity in the better eye

	Dimension 1			Dimension 2			Dimension 3			Dimension 4		
Covariate	**B**	**SE**	**p Value**	**B**	**SE**	**p Value**	**B**	**SE**	**p Value**	**B**	**SE**	**p Value**
Constant	−8.85	6.35	0.17	−2.39	2.48	0.34	−1.92	4.72	0.69	8.86	7.04	0.21
Change in DVA better eye	−38.67	5.47	<**0.001**	−35.59	4.79	<**0.001**	−28.39	4.06	<**0.001**	−10.11	6.07	0.09
Arm of study	1.27	3.61	0.73	1.49	3.20	0.64	−0.53	2.69	0.85	−5.20	4.01	0.20
Study eye is better eye	7.03	3.90	0.07	2.98	3.31	0.37	3.05	2.90	0.29	3.37	4.34	0.44
Adjusted R^2 (%)	24.1			26.9			24.6			1.6		

change in the visual status of the study eye in this part of the sample would not have impacted on visual functioning provided that the fellow eye remained the better seeing eye during time on study. Scrutiny of our data showed that change in study eye status relative to the fellow eye occurred in 44 cases (22%) of the sample during the course of the study but the distribution by treatment allocation was not significantly different between groups. To overcome such considerations enrolment criteria would have had to be modified to allow recruitment of subjects whose study eye was the better eye at baseline and remained so for the rest of the study which is clearly impractical. Therefore, we accounted for any potential imbalance in the characteristics of the cohort by adjusting all analyses by the baseline covariates of sex, centre, and study eye status relative to the fellow eye. Finally, it is also possible that the difference between treatment and control groups that was detected in the measures of vision was so small as to be insignificant in patient centred terms.

Although we have used the DLTV in subjects with AMD and shown it to be sensitive to differences in clinical measures of vision,[12 13] these validation studies were undertaken on cross sectional data. We therefore examined the relation between the DLTV and change in visual status in the SFRADS population and extended the scope of the present study to establish concurrent criterion validity in the context of a structured longitudinal study. In the three main dimensions of the DLTV the sensitivity to change in visual status was clearly evident as shown by the regression analysis presented in table 6. Even in dimension 4, where the mean change was small over time, a similar trend was seen. We are therefore confident that any meaningful differences in visual functioning as a result of treatment would have been captured by the DLTV.

The present study also examined changes in quality of life with the SF-36. Although treatment status and sex did not influence SF-36 scores in any of the dimensions, geographical location did have an effect. While the difference by geographical location was unexpected, our studies were generally in accord with previous reports where the SF-36 has been used in older adults.[14–16]

The impact of treatment on visual functioning and quality of life were considered to be important secondary outcome parameters in SFRADS. We were unsure how differences in

Table 9 Mean SF-36 dimension scores in treatment and control groups at baseline, and mean change in dimension scores at 12 months and 24 months for all study patients

	Baseline			12 Months			24 Months		
Dimension	**Treatment**	**Control**	**p Value**	**Treatment**	**Control**	**p Value**	**Treatment**	**Control**	**p Value**
Physical functioning	72.0	73.2	0.74	−9.0	−4.9	0.20	−13.2	−14.9	0.48
Role physical	65.7	64.8	0.88	3.8	−3.6	0.32	−1.9	6.6	0.53
Role emotional	76.4	75.9	0.94	5.6	6.1	0.95	11.8	18.2	0.78
Social functioning	86.0	84.5	0.70	−0.7	−0.3	0.93	5.0	2.9	0.50
Pain	81.9	81.1	0.85	−2.4	−2.8	0.93	−.2	−9.7	0.72
Energy and vitality	78.3	74.4	0.24	−3.9	−.8	0.37	−3.5	5.1	0.11
Mental health	63.9	64.0	0.99	−9.4	−8.2	0.74	−8.7	−7.6	0.32
General health perception	77.0	73.7	0.23	−6.5	−4.1	0.40	−9.4	−3.8	0.051

traditional measures used to describe vision would affect patient centred outcomes especially in a longitudinal analysis. Our results suggest that the small benefit noted in these measures when treating subfoveal choroidal neovascularisation by low dose external beam radiotherapy is too small to impact materially on visual functioning and health related quality of life.

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