Baseline Characteristics, the 25-Item National Eye Institute Visual Functioning Questionnaire, and Their Associations in the Complications of Age-Related Macular Degeneration Prevention Trial (CAPT)

*The Complications of Age-Related Macular Degeneration Prevention Trial Research Group**

Objective: To describe characteristics of participants in the Complications of Age-Related Macular Degeneration Prevention Trial (CAPT) at baseline and to investigate associations among visual function, fundus features, and vision-related quality of life.

Design: Cross-sectional study.

Participants: The 1052 participants in CAPT, a multicenter, randomized clinical trial. Eligibility criteria for CAPT included ≥10 large drusen and visual acuity ≥20/40 in each eye.

Methods: At baseline, the visual acuity, contrast sensitivity, and critical print size for each eye were measured, color stereo photographs of the disc and macula of each eye were taken, and the 25-item National Eye Institute Visual Functioning Questionnaire (NEI-VFQ-25) was self-administered. Graders from a central photograph reading center evaluated the photographs for drusen characteristics and focal hyperpigmentation. All procedures were performed using standardized protocols. Associations among characteristics were assessed by Spearman correlation coefficients and multiple linear regression.

Results: Among CAPT participants at baseline, the mean age was 71.0 years, 60.6% were women, and 99.3% were white. The median visual acuity of the better eye was 20/20 and of the worse eye 20/25. In approximately one third of eyes, drusen covered ≥10% of the retina within 3000 μm of the foveal center, and 67.7% of eyes had focal hyperpigmentation. Drusen area and focal hyperpigmentation were weakly correlated ($r = -0.08$ to -0.18) with the measures of visual function. The measures of visual function were weakly associated with the NEI-VFQ-25 scores. An association of fundus features with NEI-VFQ-25 scores was not found.

Conclusion: At baseline, CAPT participants had good visual function and several risk factors for progression to neovascular age-related macular degeneration. Scores on the NEI-VFQ-25 indicated that participants perceived some problems with their vision. Within this relatively homogeneous group of participants, measures of visual function were only weakly associated with the measures of vision-related quality of life. *Ophthalmology 2004;111:1307–1316 © 2004 by the American Academy of Ophthalmology.*

The Complications of Age-related Macular Degeneration Prevention Trial (CAPT) is a multicenter randomized clinical trial sponsored by the National Eye Institute to evaluate low-intensity laser treatment in preventing vision loss from age-related macular degeneration (AMD). Participants were required to have signs of high risk, early AMD, and relatively good visual acuity in each eye (20/40) to be enrolled in CAPT. Before receiving their randomized treatment assignment, participants had monocular tests of visual function, color stereoscopic photography, and fluorescein angiography to document fundus features, and they completed a self-administered questionnaire on vision-related quality of life. These procedures not only provided the basis for assessing the primary (loss of 15 or more letters of visual acuity) and secondary (incidence of late AMD, change in contrast threshold, and change in critical print size) outcome measures for the comparison of laser treatment with observation, but they also served to describe the participants and eyes enrolled and allowed assessment of the associations among characteristics of participants with early AMD.

Patients with neovascular AMD or geographic atrophy

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typically have severely decreased visual function. Several studies have documented that the severe loss of vision in patients with AMD decreases their quality of life and that the decrease is highly dependent on the degree of visual loss in the better-seeing eye.[1–3] Less is known about vision-related quality of life among patients with early AMD with moderate decreases in visual function and its associations with fundus features.

The purpose of this article is to describe characteristics of the CAPT participants at baseline and to investigate associations among measures of visual function, fundus features, and vision-related quality of life.

Materials and Methods

Details of the design and methods appear elsewhere.[4] Only the major features of CAPT relevant to the status of the participants at the time of the initial visit are addressed here. Participants were enrolled through 23 clinical centers. Each center was granted approval to conduct the study from its local institutional review board. A total of 1052 participants was enrolled between May 1999 and March 2001. Both eyes of the participants were enrolled in CAPT; 1 eye of each participant was randomized to laser treatment with the contralateral eye assigned to observation. CAPT eligibility criteria specified that each eye have ≥10 drusen at least 125 μm in diameter and visual acuity ≥20/40. Neither eye was to have evidence of choroidal neovascularization, serous pigment epithelial detachment, geographic atrophy within 500 μm of foveal center or >1 Macular Photocoagulation Study disc areas, or other ocular conditions that were likely to compromise visual acuity or contraindicate application of laser treatment. An examining CAPT ophthalmologist determined eligibility. After enrollment and randomized treatment assignment, staff of the CAPT Photograph Reading Center and CAPT Coordinating Center (Philadelphia, PA) assessed compliance with the eligibility criteria from stereoscopic color fundus photographs, a bilateral fluorescein angiogram, and the completed data collection forms for the examinations.

After the participant signed a consent statement at the initial visit, information including age; gender; self-reported race; occupation, cigarette smoking status, current use of aspirin, vitamins, and dietary supplements; and history of diabetes mellitus was collected through questioning participants by use of a standardized questionnaire. Blood pressure (BP) was measured once while the patient was sitting. Definite hypertension was defined as systolic BP ≥160 mmHg, diastolic BP ≥95 mmHg, or current use of antihypertensive medications. Suspect hypertension was defined as either systolic BP ≥140 but <160 mmHg or diastolic BP ≥90 but <95 mmHg in participants not taking antihypertensive medications.

During the initial visit, the participant was also asked to complete the 25-item National Eye Institute Visual Functioning Questionnaire (NEI-VFQ-25). The NEI-VFQ-25 includes 25 core items to measure 12 domains of vision function.[5] The NEI-VFQ-25 subscales and overall scores were calculated using the standard algorithm for scoring.[6] Item responses were transformed to a scale of 0 to 100, with higher scores indicating better quality of life. The items within a subscale were averaged together to obtain each of the 12 subscale scores, and the overall score of NEI-VFQ-25 was calculated from the average scores of all 25 items. Overall scores ranged from 0 to 100, with higher scores indicating better quality of life.

The quality-of-life questionnaire was self-administered. The clinic coordinator reviewed the instructions with the participant and answered any questions that arose. On completion, the clinic coordinator immediately reviewed the form to ensure that all questions were answered and the responses were legible. If any problems were identified, the clinic coordinator requested that the participant complete or revise missing or illegible responses.

Monocular visual acuity, contrast sensitivity, and critical print size were measured after refraction was performed under a standardized protocol. For each test, the right eye was measured first. Visual acuity was measured following the procedures developed for the Early Treatment Diabetic Retinopathy Study[7] as adapted for the Age-Related Eye Disease Study (AREDS).[8] Modified Early Treatment Diabetic Retinopathy Study Charts 1 and 2 were used at a distance of 3.2 m. Scoring of the test was based on the number of letters read correctly. The range of possible scores was 0 to 95, representing Snellen visual acuity equivalents of <20/800 to 20/12. Pelli-Robson charts were used at a distance of 1.0 m for testing contrast threshold.[9] Scoring of the test was based on the number of letters read correctly, with the range of possible scores of 0 to 48, representing contrast levels of 100% to 0.05%. MN Read charts were used for determining the critical print size as a measure of reading function.[10] Participants were asked to read aloud "as quickly and accurately as possible" a series of 19 sentences with decreasing print size. CAPT-certified visual function examiners recorded the time to the nearest tenth of a second and the number of words read incorrectly. The Snellen equivalent of the print size corresponding to the first decrease in reading speed was determined by the algorithm of Mansfield.[11]

Graders in the CAPT Photograph Reading Center evaluated the color photographs and fluorescein angiogram for fundus features. The entire retinal area within 3000 μm of the foveal center was considered when grading the percent of area covered by drusen, predominant size of drusen, largest drusen, confluent drusen, and the diameter of the circle that could accommodate all areas of focal hyperpigmentation. Fundus features were also graded considering only the central area within 500 μm of the foveal center, the annulus from 500 μm to 1500 μm, and the annulus from 1500 μm to 3000 μm of the foveal center.

Data Analysis and Statistical Methods

Data from CAPT clinical centers and the CAPT Photograph Reading Center that were entered into the database at the CAPT Coordinating Center by February 28, 2002, are the basis for this report. All analyses were conducted using SAS Version 8.0.[12] Distributions of eye-specific baseline characteristics were summarized for all eyes enrolled in the study and for the "better" and "worse" eye of the participant. The designation of better and worse was made independently for each baseline characteristic, thus the participant's better eye depended on the characteristic being considered. The agreement of scores and gradings between left and right eyes was summarized by intraclass correlation coefficients for continuous measures and by the weighted κ statistic for categorical measures.[13] The reproducibility of the baseline drusen grading by the reading center was evaluated with the percent agreement, the κ statistics, and weighted κ statistics.[14] Agreement between independent gradings was substantial (κ and weighted κ ≥0.60, exact agreement ≥80%) for all the fundus features addressed in this article except for predominant drusen size and focal hyperpigmentation, for which the κ values were moderate (0.42–0.54) and exact agreement was approximately 70%. The descriptive analyses were performed for the overall and subscale scores of NEI-VFQ-25 by calculating mean, standard deviation, median, ceiling (values at the maximum score), and floor (values at the minimum score) percentage. Internal consistency and reliability were assessed with Cronbach's alpha (α)[15] for each multi-item subscale.

Table 1. Demographic Characteristics of Complication of Age-Related Macular Degeneration Prevention Trial Participants at Baseline (N = 1052)

Characteristic	n (%)
Age (yrs)	
50–59	89 (8.5)
60–69	299 (28.4)
70–79	542 (51.5)
80–89	122 (11.6)
Mean (SD)	71.0 (7.6)
Gender	
Female	637 (60.6)
Male	415 (39.4)
Race	
White	1045 (99.3)
Nonwhite	7 (0.7)
Occupation	
Retired	724 (68.8)
Employed with income	241 (22.9)
House-spouse	79 (7.5)
Unemployed	5 (0.5)
Other	3 (0.3)
Hypertension	
Normal	366 (34.8)
Suspected	190 (18.1)
Definite	489 (46.5)
Unknown	7 (0.7)
Vitamin/supplements	
None	202 (19.2)
Multivitamins	670 (63.7)
Zinc supplements	31 (3.0)
Both	146 (13.9)
Unknown	3 (0.3)
Diabetic	
Yes	89 (8.5)
No	958 (91.1)
Unknown	5 (0.5)
Aspirin	
Never	373 (35.5)
<1 tablet per day	350 (33.3)
1 tablet per day	295 (28.0)
>1 tablet per day	34 (3.2)
Cigarette smoking	
Never	477 (45.3)
Quit	517 (49.1)
Current	58 (5.5)

SD = standard deviation.

Correlations between measures were summarized by Spearman correlation coefficients because many of the measures were highly skewed and/or ordinal. To describe the association of measures of visual function and fundus features with NEI-VFQ-25 scores, the means of NEI-VFQ-25 were calculated within categories of visual function measures and fundus features.

Multiple linear regression analyses were performed to assess the association of the baseline characteristics with the overall score of the NEI-VFQ-25. Because of the skewed distribution of NEI-VFQ-25 scores, a logarithmic transformation was performed using the formula TVFQ25 = ln(101-VFQ25), in which TVFQ25 and VFQ25 were the transformed and untransformed values of the overall score, respectively. The adjusted means of the overall score for dichotomized levels of visual acuity, contrast sensitivity, and critical print size were calculated from the multiple regression model with inclusion of demographic characteristics and visual measures. Similarly, the adjusted means of the overall score for dichotomized levels of fundus features were calculated from the multiple regression model with inclusion of demographic characteristics and fundus features. The adjusted means were transformed back to the original scale for easy interpretation.

Table 2. Visual Functions of Complications of Age-Related Macular Degeneration Prevention Trial Participants at Baseline

Visual Function	Better Eye (N = 1052) n (%)	Worse Eye (N = 1052) n (%)	All Eyes (N = 2104) n (%)
Visual acuity			
20/12	68 (6.5)	11 (1.1)	79 (3.8)
20/16	277 (26.3)	103 (9.8)	380 (18.1)
20/20	336 (31.9)	248 (23.6)	584 (27.8)
20/25	261 (24.8)	304 (28.9)	565 (26.9)
20/32	89 (8.5)	256 (24.3)	345 (16.4)
20/40	21 (2.0)	130 (12.4)	151 (7.1)
Contrast threshold (%)			
1–2	493 (46.9)	237 (22.5)	730 (34.7)
3–4	543 (51.6)	733 (69.7)	1276 (60.6)
6–9	16 (1.5)	79 (7.5)	95 (4.5)
≥12	0 (0.0)	3 (0.3)	3 (0.1)
Critical print size (20/X)			
≤20	61 (5.8)	13 (1.2)	74 (3.5)
25–32	476 (45.3)	198 (18.8)	674 (32.0)
40–50	436 (41.4)	528 (50.2)	964 (45.8)
62–80	70 (6.7)	245 (23.3)	315 (15.0)
≥100	9 (0.9)	68 (6.5)	77 (3.7)

For most analyses relating eye-specific characteristics to the quality-of-life measures, the data from the better eye were used except as noted, because previous studies have shown that the visual function in the better eye is more closely associated with subjective assessment of visual performance.[16,17]

Results

Baseline Characteristics

Baseline characteristics of the 1052 participants enrolled in CAPT are displayed in Table 1. The mean age was 71 years, with more than half of the participants between 70 and 79 years (range: 50–89 years). Sixty-one percent were female, 99% were white, and 23% were employed with income. Nearly half of the participants (47%) had definite hypertension. Approximately 80% were taking multivitamins, zinc supplements, or both. Only 6% of enrolled participants were currently smoking cigarettes, although nearly half (49%) were former smokers.

Baseline characteristics of the 2104 eyes included in CAPT are displayed in Tables 2 and 3. Visual acuity was 20/20 or better in 50% of all eyes. When only the eye with better visual acuity was considered, 65% had visual acuity 20/20 or better. When only the eye with the worse visual acuity was considered, 35% had vision 20/20 or better. Two percent or less contrast was required to identify letters on the Pelli-Robson chart for 47% of better eyes and 23% of worse eyes. Critical print sizes (print size associated with a decrease in reading speed) were approximately 0.3 logarithm of the minimum angle of resolution units (3 lines) larger than the letter visual acuities. Approximately 85% of all eyes had between 1 and 9 drusen within 500 μm of the foveal center. Ten or more pairs of confluent drusen were present within 3000 μm of the foveal center in 50% of eyes. The predominant drusen size was ≥125 μm in diameter within 3000 μm of the foveal center in 47% of eyes, whereas the largest drusen was ≥250 μm in diameter in 70% of eyes. Ten percent or more of the retina within 3000 μm of

Table 3. Fundus Features of Eyes of Complications of Age-Related Macular Degeneration Prevention Trial Participants at Baseline

Fundus Feature	Better Eye (N = 1052) *n* (%)	Worse Eye (N = 1052) *n* (%)	All Eyes (N = 2104) *n* (%)
No. of drusen >125 μm in within 500 μm of foveal center			
None	133 (12.6)	32 (3.0)	165 (7.8)
<10	888 (84.4)	903 (85.8)	1791 (85.1)
10–20	16 (1.5)	71 (6.8)	87 (4.1)
Can't determine/grade/missing	15 (1.4)	46 (4.4)	61 (2.9)
Confluent drusen within 3000 μm of foveal center			
None	7 (0.7)	1 (0.1)	8 (0.4)
< 10 pairs	594 (56.5)	347 (33.0)	941 (44.7)
≥ 10 pairs	430 (40.9)	629 (59.8)	1059 (50.3)
Can't determine/grade/missing	21 (2.0)	75 (7.1)	96 (4.6)
Predominant drusen size within 3000 μm of foveal center			
63–< 125μ	635 (60.4)	412 (39.2)	1047 (49.8)
125–< 250μ	394 (37.5)	566 (53.8)	960 (45.6)
≥ 250μ	10 (1.0)	24 (2.3)	34 (1.6)
Can't determine/grade/missing	13 (1.2)	50 (4.8)	63 (3.0)
Largest drusen size within 3000 μm of foveal center			
63–< 125 μm	7 (0.7)	2 (0.2)	9 (0.4)
125–250 μm	378 (35.9)	186 (17.7)	564 (26.8)
≥ 250 μm	655 (62.3)	825 (78.4)	1480 (70.3)
Can't determine/grade/missing	12 (1.1)	39 (3.7)	51 (2.4)
Percent of global area covered by drusen within 3000 μm of foveal center			
< 10%	777 (73.9)	591 (56.2)	1368 (65.0)
10%–24%	227 (21.6)	343 (32.6)	570 (27.1)
≥ 25%	36 (3.4)	78 (7.4)	114 (5.4)
Can't determine/grade/missing	12 (1.1)	40 (3.8)	52 (2.5)
Focal hyperpigmentation within 3000 μm of foveal center			
None/questionable	426 (40.5)	193 (18.3)	619 (29.4)
< 250 μm	538 (51.1)	596 (56.7)	1134 (53.9)
≥ 250 μm	79 (7.5)	212 (20.2)	291 (13.8)
Can't determine/grade/missing	9 (0.9)	51 (4.8)	60 (2.9)

the foveal center was covered with drusen in 33% of eyes. More than two thirds of eyes had focal areas of hyperpigmentation within 3000 μm of the foveal center.

The agreement between right and left eyes in the scores measured on each characteristic was substantial (Table 4). The intraclass correlation coefficient was highest (0.62) for contrast sensitivity and lowest (0.42) for critical print size among the 3 measures of visual function. Among the 6 fundus features examined, the κ statistic was highest (0.70) for the area within 3000 μm of the fovea covered by drusen and lowest (0.36) for the number of drusen ≥125 μm within 500 μm of the foveal center.

The CAPT participants scored relatively high on the NEI-VFQ-25. The mean overall score of the NEI-VFQ-25 was 88, with a median 91 (Table 5). The median score was 90 or greater for the subscales of near vision, distance vision, social functioning, role difficulties, dependency, color vision, and peripheral vision. Restricted to 1007 participants who drive, the mean driving subscale was equal to 85 (median: 88). Scores were lowest in general health. Most of the subscales showed large ceiling effects with a high percentage of participants having the highest possible scores, especially for ocular pain, social functioning, role difficulties, dependency, color vision, and peripheral vision. With the exception of ocular pain, distance vision, and driving subscales (Cronbach's α = 0.69, 0.69, 0.47, respectively), the subscales demonstrated a moderately strong internal consistency and reliability, with estimates of Cronbach's α ranging between 0.76 and 0.81. The distribution of NEI-VFQ-25 scores, both overall and subscales, were right-skewed; however, a logarithm transformation yielded distributions that were approximately gaussian.

Table 4. Agreement of Visual Function and Fundus Features Measurements between Left and Right Eyes

Visual Function/Fundus Feature Measurement	Agreement (95% Confidence Interval)
Visual acuity	0.53 (0.49–0.58)*
Contrast sensitivity	0.62 (0.59–0.66)*
Critical print size	0.42 (0.37–0.47)*
No. of drusen ≥125 μm within central circle	0.36 (0.28–0.44)*
Largest drusen size	0.54 (0.48–0.60)†
Confluent drusen	0.55 (0.49–0.60)†
Predominant drusen size	0.61 (0.56–0.66)†
Percent of global area covered by drusen	0.70 (0.67–0.73)†
Focal hyperpigmentation	0.54 (0.50–0.58)†

*Intraclass correlation coefficient.
†Weighted κ statistic.

Associations among Baseline Characteristics

Visual acuity was modestly correlated with contrast sensitivity and critical print size; the Spearman correlation coefficients for right eyes were 0.43 and 0.55, respectively (Table 6). Correlation coefficients for left eyes were nearly identical to those for right eyes. The correlation between contrast sensitivity and critical print size was 0.32 in right eyes. The correlations between the fundus features and the measures of visual function were considerably weaker and negative (Spearman $r = -0.08$ to -0.18); that is, more severe features of early AMD were associated weakly with decreased visual function scores. Eyes with greater area of retina

Table 5. Twenty-Five Item National Eye Institute Visual Functioning Questionnaire-25 Scores at Baseline in Complications of Age-Related Macular Degeneration Prevention Trial Participants (N = 1052)

Scale	n	Mean ± Standard Deviation	Median	Ceiling n (%)	Floor n (%)	α*
NEI-VFQ-25 overall	1051	88 ± 10	91	14 (1.3)	0 (0.0)	0.92
General health	1048	71 ± 21	75	235 (22.4)	1 (0.1)	NA†
General vision	1047	79 ± 14	80	191 (18.2)	0 (0.0)	NA†
Ocular pain	1051	89 ± 15	88	523 (49.8)	1 (0.1)	0.69
Near vision	1051	85 ± 16	92	326 (31.0)	0 (0.0)	0.78
Distance vision	1051	86 ± 15	92	320 (30.5)	0 (0.0)	0.69
Vision specific:						
Social functioning	1050	97 ± 9	100	911 (86.8)	0 (0.0)	0.76
Mental health	1051	85 ± 15	88	161 (15.3)	0 (0.0)	0.77
Role difficulties	1046	87 ± 19	100	588 (56.2)	6 (0.6)	0.81
Dependency	1049	97 ± 10	100	862 (82.2)	0 (0.0)	0.78
Driving	1007	85 ± 15	88	275 (27.3)	4 (0.4)	0.47
Color vision	1041	95 ± 13	100	870 (83.6)	1 (0.1)	NA†
Peripheral vision	1046	93 ± 15	100	828 (79.2)	1 (0.1)	NA†

*Standardized Cronbach's α.
†NA, correlations are not applicable because only one item in the subscale.
NEI-VFQ-25 = 25-item National Eye Institute Visual Functioning Questionnaire.

covered by drusen were more likely to have areas of focal hyperpigmentation (Spearman $r = 0.26$, 0.29 for left, right eyes).

Descriptive analyses of the NEI-VFQ-25 for the subgroups of visual function and fundus features from the better eye are displayed in Figures 1 and 2. Participants with better visual function had higher scores on all the NEI-VFQ-25 subscales, especially in the subscales of general vision, near vision, and distance vision, where the differences in mean score between 2 subgroups were more than 5 units. However, the scores in the subgroups of drusen coverage and focal hyperpigmentation were similar.

The effects of visual function measures and fundus features in the better eye on the overall score of the NEI-VFQ-25 are summarized in Tables 7 and 8. Better visual function scores were associated with higher scores on the overall NEI-VFQ-25; this relation was true for subgroups on the basis of both the better eye and the worse eye (data not shown), but the association was stronger when the better eye visual function scores were used. With adjustment of other covariates, participants with visual acuity ≥20/20 had mean scores 2 points higher on the overall NEI-VFQ-25 than those with visual acuity worse than 20/20 ($P<0.01$). An association of fundus features with the overall score of the NEI-VFQ-25 was not found.

Discussion

Baseline Characteristics

Most CAPT participants were older than the age of 60 years. Participants having any medical condition who were unlikely to complete 5 years of follow-up were excluded from participation. A high proportion of participants (47%) had definite hypertension, a characteristic that has been associated with increased risk of late AMD in some, but not all, major epidemiologic studies.[18–23] However, current cigarette smoking, accepted as a strong risk factor for AMD,[24] was reported by only 6% of participants. Approximately 80% of participants took multivitamins, zinc supplements, or both. Because the results of the AREDS reporting decreased risk of advanced AMD developing with intake of high daily doses of antioxidant vitamins and zinc had not yet been reported when participants were being enrolled into CAPT, doses at baseline likely were below those used in AREDS.

Although there were no exclusion criteria regarding race, <1% of enrolled participants were nonwhite. Although U. S. population-based studies of early AMD have provided similar estimates for prevalence in white, black, and Hispanic racial groups, the percentage of black and Hispanic participants in CAPT, AREDS, and all the published clinical trials for treatment of neovascular disease have disproportionately fewer black and Hispanic participants.[25] Although the low enrollment of nonwhites in clinical trials may be related to issues of access to care and reluctance to participate in clinical trials, blacks have not been disproportionately underrepresented in clinical trials of other ocular diseases such as glaucoma and diabetic retinopathy. Furthermore, in a population-based survey of blindness and visual impairment, late AMD was responsible for 30% of legal blindness in whites and 0% in blacks. Thus, it may be that whereas nonwhites share the same risk as whites for the minimal level of drusen and pigmentary changes required for classification as early AMD developing, the more advanced stages of early AMD and late AMD may be less common in nonwhite populations.

Participants in CAPT have fundus features in each eye that greatly exceed the minimal levels required for classification as early AMD. Eligibility criteria required that eyes have 10 or more large (≥125 μm) drusen. Inspection of Table 3 shows that most CAPT eyes had at least 1 druse at least 250 μm, confluent drusen, and areas of focal hyperpigmentation. Data from other studies have shown that

Table 6. Correlation between the Visual Function Measurements and Fundus Features of Complications of Age-Related Macular Degeneration Prevention Trial Participants

Correlation in Left Eye (Right Eye)	Visual Acuity	Contrast Sensitivity	Critical Print Size	% Area Covered by Drusen
Contrast sensitivity	0.44 (0.43)			
Critical print size	0.51 (0.55)	0.32 (0.33)		
Percent area covered by drusen	−0.08 (−0.08)	−0.16 (−0.12)	−0.10 (−0.08)	
Focal hyperpigmentation	−0.11 (−0.16)	−0.17 (−0.18)	−0.10 (−0.14)	0.26 (0.29)

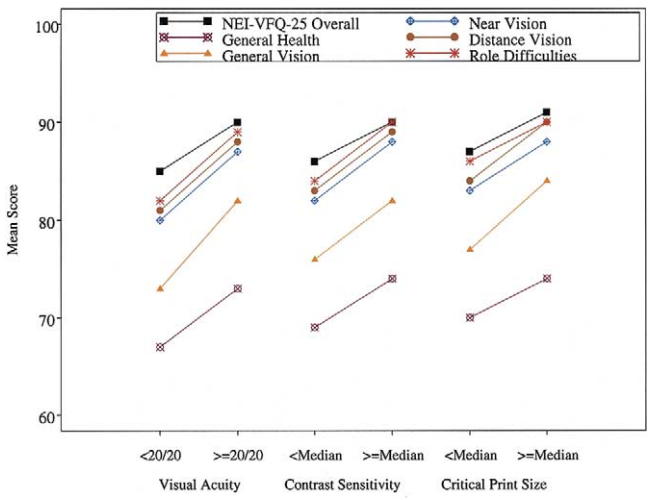

Figure 1. The 25-item National Eye Institute Visual Functioning Questionnaire (NEI-VFQ-25) by visual functions of the better eye. The mean scores of NEI-VFQ-25 overall and its subscales are shown, with subgroups based on visual functions (visual acuity, contrast sensitivity, and critical print size). Each symbol represents a different scale. Lines connect the mean from the participants having eyes with low visual function (left) to the mean from the participants having eyes with higher visual function (right). For all scales, higher visual function was associated with higher score on the scale.

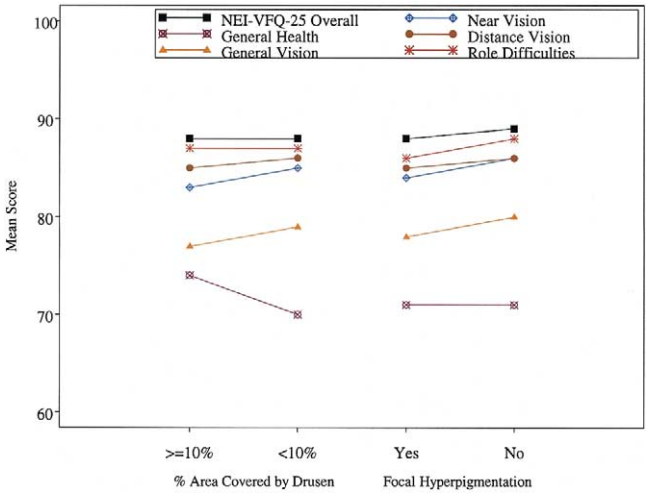

Figure 2. The 25-item National Eye Institute Visual Functioning Questionnaire (NEI-VFQ-25) by fundus features of the better eye. The mean scores of NEI-VFQ-25 overall and its subscales are shown, with subgroups based on fundus features (percent of area covered by drusen and focal hyperpigmentation). Each symbol represents a different scale. Lines connect the mean from the participants having eyes with more severe fundus features (left) to the mean from participants having eyes with less severe fundus features (right). For most scales, mean scores did not vary by severity of fundus features.

these features are associated with increased risk of late AMD and loss of vision.[26–29]

Despite the increased severity of early AMD, the visual acuity of three quarters of the CAPT participants was 20/25 or better. Eligibility criteria required visual acuity 20/40 or better in each eye.

The NEI-VFQ-25 was designed to assess the health-related quality of life of patients with visual impairment. It may be used to evaluate multiple dimensions of vision-related quality of life and has been field tested in populations that included patients with AMD.[6] The overall and subscale scores of the NEI-VFQ-25 among CAPT participants were all lower than those from the field test of NEI-VFQ-25 among normal subjects,[6] especially for the subscales of near vision, distance vision, and role difficulty. However, the older age of CAPT participants may contribute to the lower score in some subscales. In addition, self-administration as in CAPT may result in lower scores than

Table 7. Unadjusted and Adjusted Mean Scores of the Overall 25-Item National Eye Institute Visual Functioning Questionnaire by Visual Function Measurements of the Better Eye

	Overall 25-Item National Eye Institute Visual Functioning Questionnaire*	
Visual Function	*Unadjusted*	*Adjusted*†
Visual acuity		
<20/20	88.5	90.2
≥20/20	92.4	92.3
P value	<0.0001	<0.0001
Contrast sensitivity		
<Median	89.2	90.4
≥Median	92.3	92.2
P value	<0.0001	0.0002
Critical print size		
<Median	89.5	90.5
≥Median	92.6	92.1
P value	<0.0001	0.002

*The overall 25-item National Eye Institute Visual Functioning Questionnaire was log-transformed.
†All models include age, gender, occupation, hypertension, diabetes, smoking status, visual acuity, contrast sensitivity, and critical print size.

Table 8. Unadjusted and Adjusted Mean Scores of the Overall 25-Item National Eye Institute Visual Functioning Questionnaire by Fundus Features Measurements of the Better Eye

	Overall 25-Item National Eye Institute Visual Functioning Questionnaire*	
Fundus Feature	*Unadjusted*	*Adjusted*†
Percent area covered by drusen		
<10%	91.3	92.0
≥10%	91.0	91.6
P value	0.53	0.44
Focal hyperpigmentation		
None/questionable	91.7	92.1
Yes	90.9	91.4
P value	0.10	0.09

*The overall 25-item National Eye Institute Visual Functioning Questionnaire was log-transformed.
†All models include age, gender, occupation, hypertension, diabetes, smoking status, % area covered by drusen, and focal hyperpigmentation.

interviewer administration as used in most other reports of the scores from the NEI-VFQ. The subscale and overall scores from this study were all much higher than those reported by Mangione et al[6] for older AMD patients (mean age: 71 vs. 76 years old), many with late AMD. CAPT participants also had higher NEI-VFQ-25 scores than reported for patients with other ocular disease such as diabetic retinopathy,[6,30] uveitis,[31] optic neuritis,[32] glaucoma, and cataract, [6] despite the fact that participants in those studies were younger.

Examination of the psychometric properties of the NEI-VFQ-25 in the CAPT population showed that the subscales were subject to substantial ceiling effects but not to floor effects (Table 5). With the exception of the driving subscale, the internal consistency for most of the NEI-VFQ-25 subscales was high. Cronbach's α estimates were similar to those reported by the developer[6] and Clemons et al.[33] The exclusion of additional optional items in our study may explain the slightly lower internal consistency in some subscales than those reported by Clemons et al.

By virtue of the extent of drusen in each eye, patients enrolled in CAPT met and exceeded the minimum requirements for Category 3 AMD in AREDS.[33] Although participants in CAPT were on average 3 years younger than participants in AREDS when they completed the NEI-VFQ (mean age: 71 vs. 74), the mean overall score was lower for CAPT patients than AREDS patients (88 vs. 92). There were only small differences (6 points or less) between the mean scores for the CAPT and AREDS patients on the 12 subscales; the greatest difference was for "role difficulties" (87 vs. 93).

Associations among Baseline Characteristics

Visual acuity is widely recognized as a major determinant in vision-related quality of life, so much so that ophthalmologists rely primarily on visual acuity to plan patient management.[34] Diminished visual acuity has been associated with decreased performance of instrumental activities of daily living, poorer cognitive abilities, and ultimately poorer health-related quality of life.[35,36] Many studies have also shown that visual acuity has strong correlations with vision-related quality of life and that visual acuity in the better eye is more strongly correlated to those measures than visual acuity in the worse eye. However, visual acuity can actually be a poor predictor of a number of aspects of visual function.[37,38] Contrast sensitivity has been shown to be correlated with various aspects of activities requiring vision, including orientation and mobility, reading speed, and driving.[39,40] Carta et al[41] reported that contrast sensitivity was strongly associated with vision-related quality of life, even with adjustment for visual acuity among ophthalmic patients with chronic eye conditions including AMD. Hazel et al[16] reported that reading performance is strongly associated with vision-related quality of life among patients with macular disease. Critical print size was found to be correlated independently with high contrast visual acuity[16,42] and contrast sensitivity.[43]

In CAPT, the correlations between the NEI-VFQ-25 subscales and clinical measures of visual function were moderate at best, similar to the findings reported by Cole et al.[32] The weak to modest correlations of visual measures with NEI-VFQ-25 in this study may be due to the restricted range of visual function of participants. Among the 3 visual function measures, visual acuity was most strongly associated with NEI-VFQ-25 in most subscales, except that the driving and color vision subscales were most strongly associated with contrast sensitivity, and the social function subscale was most strongly associated with critical print size. These results suggest that contrast sensitivity and reading speed are complementary to visual acuity in some aspects that affect quality of life.

All participants in CAPT had 20/40 vision or better in each eye, as required by the eligibility criteria. Despite the fairly homogenous visual acuity, differences in the overall NEI-VFQ-25 score and subscale scores were seen when comparing the subgroups of eyes with visual acuity of 20/20 or better to eyes with worse than 20/20 in the better eye (Table 7, Fig 1). Subgroups based on contrast sensitivity and reading speed also yielded differences in the scores.

An association of fundus features in either the better eye or worse eye with the overall and subscales of NEI-VFQ-25 was not found. This may be partially due to the weak correlation of fundus features with visual function (Spearman correlation ≤ -0.18) and to the fact that the area of drusen coverage and focal hyperpigmentation was measured on a relatively coarse scale over a limited range.

In summary, participants with severe early AMD have decreased vision-related quality of life. Worse visual acuity and lower contrast sensitivity and, to a lesser extent, critical print size are weakly associated with lower scores on the overall scale and subscales of the NEI-VFQ-25. The fundus appearance of the participants' eyes does not seem to have direct bearing on vision-related quality of life other than through the weak correlation of the features with visual function measures. The longitudinal follow-up of CAPT participants may help understand how changes in visual function associate with changes in the NEI-VFQ-25.

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