Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ)

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Brody 2005 #260	**Geographical location:** San Diego, CA **Dates:** 1/98 – 9/00 **Context:** X Clinical trial □ Cohort □ Cross sectional □ Other **Inclusion/Exclusion criteria:** AMD, vision ≤ 20/60 in better eye, ≤20/100 in worse eye, no other reason for decreased vision, age>60, no cognitive impairment	**Population size (n):** 232 Group 1: Self management Group 2: Tape-recording Group 3: Waiting list Age: Mean: Group 1 - 80.5 Group 2 - 81.3 Group 3 - 80.3 Eye dx: Not reported **AMD:** 100% **AMD Type:** Mix **Laterality:** □ Unilateral 40% X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Log visual acuity of best eye Group 1: 1.09 Group 2: 1.14 Group 3: 1.11	**Instrument/Technique Name:** NEI-VFQ **Method of administration:** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire X In office questionnaire □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Baseline and every 3 months x 1 yr	**Question 1A: Instrument scores in AMD patients** NEI-VFQ Score / No / Baseline / 6 mos Self-mngmt / 82 / / Depressed / 18 / 49 / 56 Nondepr / 62 / 63 / 62 / / / Control / 131 / / Depressed / 32 / 49 / 49 Nondepr / 99 / 61 / 60	**Quality assessment:** Meaningfully defined study population: + Protection from bias: 0 Consideration of statistical power: - **This article is relevant to:** X Question 1A □ Question 1B □ Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

<table>
<tr><th>Study</th><th>Study Design</th><th>Study Population</th><th>Instrument Characteristics</th><th>Results</th><th>Quality Scoring/Comments</th></tr>
<tr>
<td>Cahill 2005 #120</td>
<td>Geographical location:
Durham, NC

Dates: 2/99-8/02

Context:
□ Clinical trial
□ Cohort
X Cross sectional
□ Other

Inclusion/Exclusion criteria:
Patients with bilateral severe neovascular MD scheduled to undergo MT360.

Inclusion criteria:
Age ≥ 50 yrs.
AMD with subfoveal CNV

Best-corrected Snellen visual acuity between 20/50 and 20/400 in the operative eye;
Maximum 6 mos.
Central vision loss reported by patient;
No light perception in either eye;
Visual acuity of 20/50 or better in the fellow eye;
Previous laser treatment of the center of the fovea in the operative eye;
Previous submacular surgery in the treated eye;</td>
<td>Population size (n): 70

Age: Mean age 76.4 yrs
38.6% male

Eye dx: Not reported

AMD: 100%

AMD Type: 100% wet

Laterality:
□ Unilateral
X Bilateral

Objective Measure(s) of function (e.g., visual acuity):
Mean VA 62.4 letters (SD 16.7); mean fellow eye VA 33.1 letters (SD 23.6)
Mean near VA .81 log MAR (SD .37)
Mean reading speed 74.9 WPM (SD 41.3)
Mean Lesion size 10.0 MPS disc areas (SD, 5.5); all lesions were ≥ 3 MPS disc areas in size.
Duration of vision loss in second eye 13.5 weeks (SD, 11.2)

<table>
<tr><td>Mean VA</td><td>62.4</td></tr>
<tr><td>Fellow eye VA</td><td>33.1</td></tr>
<tr><td>Mean near VA</td><td>.81 log MAR</td></tr>
<tr><td>Mean reading speed</td><td>74.9</td></tr>
<tr><td>Mean lesion size</td><td>10.0 MPS</td></tr>
<tr><td>All lesions</td><td>≥ 3</td></tr>
</table>
</td>
<td>Instrument/Technique Name:
VQF-25
SF-12

Method of administration:

By whom:
X Masked
□ Unmasked
□ Unknown

Mode of administration:
□ Phone interview
X Face to face interview
□ Mail questionnaire
□ In office questionnaire
□ Observation
□ Other

Respondent:
□ Only patient
□ Patient or surrogate
□ Only surrogate
X Unknown

Time points of administration: NA (cross sectional)</td>
<td>Question 1A: Instrument scores in AMD patients

<table>
<tr><th>NEI VQF - 25</th><th>Study</th><th>Low Vis. (P value)</th><th>AMD (P value)</th><th>Ref (P value)</th></tr>
<tr><td>General vision</td><td>31.4</td><td>38 (.015)</td><td>53 (<.001)</td><td>83 (<.001)</td></tr>
<tr><td>Distance tasks</td><td>38.8</td><td>38 (.843)</td><td>56 (<.001)</td><td>93 (<.001)</td></tr>
<tr><td>Near tasks</td><td>29.4</td><td>36 (.047)</td><td>54 (<.001)</td><td>9 (<.001)</td></tr>
<tr><td>Peripheral vision</td><td>66.8</td><td>59 (.086)</td><td>77 (.011)</td><td>97 (<.001)</td></tr>
<tr><td>Color vision</td><td>67.5</td><td>71 (.453)</td><td>85 (<.001)</td><td>98 (<.001)</td></tr>
<tr><td>Dependency</td><td>42.7</td><td>51 (.087)</td><td>72 (<.001)</td><td>99 (<.001)</td></tr>
<tr><td>Role difficulties</td><td>38.2</td><td>44 (.195)</td><td>61 (<.001)</td><td>93 (<.001)</td></tr>
<tr><td>Mental health</td><td>34.1</td><td>46 (.005)</td><td>58 (<.001)</td><td>92 (<.001)</td></tr>
<tr><td>Social function</td><td>58.4</td><td>50 (.075)</td><td>73 (.001)</td><td>99 (<.001)</td></tr>
<tr><td>Driving</td><td>16.1</td><td>10 (.174)</td><td>39 (<.001)</td><td>87 (<.001)</td></tr>
<tr><td>Ocular pain</td><td>81.8</td><td>85 (.321)</td><td>87 (.073)</td><td>90 (.004)</td></tr>
<tr><td>SF-12</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Phys. Comp.</td><td>45.1</td><td>35.8 (<.001)</td><td>46 (.532)</td><td>38.7 (<.001)</td></tr>
<tr><td>Ment. Comp.</td><td>48.4</td><td>49 (.636)</td><td>50 (.328)</td><td>50.1 (.239)</td></tr>
</table>

Question 2: Results of above, by major subgroup(s) and/or in a multivariate analysis (e.g., QOL measure = f(objective measure, clinical features))

Question 3: Relationship between QOL measures (s) and objective measure

VQF 25 subscales</td>
<td>Quality assessment:
Meaningfully defined study population: +
Protection from bias: +
Consideration of statistical power: -

This article is relevant to:
X Question 1A
□ Question 1B
□ Question 1C
X Question 2
X Question 3</td>
</tr>
</table>

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments

Severe diabetic retinopathy or previous lazer treatment for diabetic macular edema or proliferative diabetic retinopathy in the operative eye; Intraocular pressure of ≥ 30 mm-Hg in the operative eye; Ocular disease other than macular degeneration that would prevent the recovery of visual acuity after surgery (e.g., amblyopia, vascular occlusion); ocular disease causing severe peripheral visual field loss in the fellow eye 9e.g., severe glaucoma).

	MPS
Duration vision loss second eye	13.5 weeks

	Gen vision	Diff dist. task	Diff near task	Periph vision	Color vision
Age	.12	-.15	-.24	-.12	-.07
Dur. visionLoss	-.32	-.14	-.23	-.14	-.02
Lesion size	-.18	-.18	-.14	-.19	-.26
Near VA	-.34	-.21	-.34	-.17	-.26
Distant VA	.42	.31	.33	.23	.17
Read speed	.29	.23	.23	.18	.27

VQF 25 subscales

	Depen-dency	Role limits	Ment. Hlth.	Soc. Funct. Limits	Driving diff.	Ocular pain
Age	-.26	-.23	-.3	-.06	-.15	-.13
Dur. Vision loss	-.32	-.3	-.27	-.27	-.24	.01
Lesion size	-.2	-.2	-.12	-.13	-.19	-.05
Near VA	-.36	-.31	-.4	-.26	-.31	-.32
Distant VA	.39	.29	.38	.32	.2	.19
Read speed	.44	.3	.33	.34	.25	.12

SF-12

	Phys comp.	Mental comp.
Age	-.31	-.49
Dur. Vision Loss	.01	-.09
Lesion size	.15	-.08
Near VA	-.05	-.15
Distant VA	.08	.1
Read speed	<.01	.24

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

<table>
<tr><th>Study</th><th>Study Design</th><th>Study Population</th><th>Instrument Characteristics</th><th>Results</th><th>Quality Scoring/Comments</th></tr>
<tr>
<td>Cahill 2005 #130</td>
<td>Geographical location:
Durham, NC

Dates: 2/99-8/02

Context:
□ Clinical trial
□ Cohort
X Cross sectional
□ Other

Inclusion/Exclusion criteria:
Patients who met the inclusion criteria below and who underwent MT 360 with either silicone oil or gas tamponade.

Patients with bilateral severe neo-vascular MD scheduled to undergo MT360.
Inclusion criteria:
Age ≥ 50 yrs.

AMD with subfoveal CNV
Best-corrected Snellen visual acuity between 20/50 and 20/400 in the operative eye;

Maximum 6 mos.
Central vision loss reported by patient;
No light perception in either eye;
Visual acuity of 20/50 or better in the fellow eye;
Previous laser treatment of the center</td>
<td>Population size (n): 50

Age: Mean age 76.9 yrs
32% male

Eye dx: Not reported

AMD: 100%

AMD Type: 100% wet

Laterality:
□ Unilateral
X Bilateral

Objective Measure(s) of function (e.g., visual acuity):
<table>
<tr><th></th><th>Pre-op</th><th>Post-op</th><th>P value</th></tr>
<tr><td>Dist. VA</td><td>60.9</td><td>63</td><td>.278</td></tr>
<tr><td>Mean near VA</td><td>.84</td><td>.61</td><td><.001</td></tr>
<tr><td>Mean reading speed</td><td>74.5</td><td>89.3</td><td>.045</td></tr>
</table>
</td>
<td>Instrument/Technique Name:
VQF-25
SF-12

Method of administration:

By whom:
X Masked
□ Unmasked
□ Unknown

Mode of administration:
□ Phone interview
X Face to face interview
□ Mail questionnaire
□ In office questionnaire
□ Observation
□ Other

Respondent:
□ Only patient
□ Patient or surrogate
□ Only surrogate
X Unknown

Time points of administrationn: NA</td>
<td>Question 1A: Instrument scores in AMD patients
<table>
<tr><th>NEI VQF -25</th><th>Pre-op</th><th>Post-op</th><th>P value</th></tr>
<tr><td>Genl vision</td><td>30</td><td>53.7</td><td><.001</td></tr>
<tr><td>Near tasks</td><td>28</td><td>45.5</td><td><.001</td></tr>
<tr><td>Distance tasks</td><td>34.8</td><td>46.5</td><td>.004</td></tr>
<tr><td>Peripheral vision</td><td>66.5</td><td>66.5</td><td>.98</td></tr>
<tr><td>Color vision</td><td>64.5</td><td>67.5</td><td>.543</td></tr>
<tr><td>Dependency</td><td>38.2</td><td>50.3</td><td>.026</td></tr>
<tr><td>Role difficulties</td><td>38.1</td><td>46.6</td><td>.115</td></tr>
<tr><td>Mental health</td><td>33.9</td><td>50.2</td><td><.001</td></tr>
<tr><td>Social function</td><td>55.7</td><td>67</td><td>.011</td></tr>
<tr><td>Driving</td><td>12.7</td><td>20.1</td><td>.162</td></tr>
<tr><td>Ocular pain</td><td>79.6</td><td>84.4</td><td>.179</td></tr>
<tr><td>Comp. VQF 25</td><td>43.8</td><td>54.4</td><td><.001</td></tr>
<tr><td>SF-12</td><td></td><td></td><td></td></tr>
<tr><td>Phys. Comp.</td><td>44.8</td><td>44.2</td><td>.406</td></tr>
<tr><td>Ment. Comp.</td><td>49.3</td><td>50.8</td><td>.435</td></tr>
</table>
Question 2: Results of above, by major subgroup(s) and/or in a multivariate analysis (e.g., QOL measure = f(objective measure, clinical features))
<table>
<tr><th></th><th>n</th><th>Mean Comp. VFG-25</th><th>P value</th></tr>
<tr><td>Post-op near vision improvement</td><td>33</td><td>16.4</td><td></td></tr>
<tr><td>W/out post-op near vision improvement</td><td>17</td><td>-.79</td><td>.005</td></tr>
<tr><td>Post-op near vision ≥ 20/70</td><td>28</td><td>63.4</td><td></td></tr>
<tr><td>Post-op near vision < 20/70</td><td>22</td><td>43</td><td><.001</td></tr>
<tr><td>Post-op distance improvement</td><td>28</td><td>18.4</td><td></td></tr>
</table>
</td>
<td>Quality assessment:
Meaningfully defined study population: +
Protection from bias: +
Consideration of statistical power: -

This article is relevant to:
X Question 1A
□ Question 1B
□ Question 1C
X Question 2
X Question 3</td>
</tr>
</table>

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments

of the fovea in the operative eye;
Previous submacular surgery in the treated eye;
Severe diabetic retinopathy or previous lazer treatment for diabetic macular edema or proliferative diabetic retinopathy in the operative eye;
Intraocular pressure of ≥ 30 mm-Hg in the operative eye;
Ocular disease other than macular degeneration that would prevent the recovery of visual acuity after surgery (e.g., amblyopia, vascular occlusion); ocular disease causing severe peripheral visual field loss in the fellow eye (e.g., severe glaucoma).

w/out post-op distance improvemnt	22	.55	.002
Post-op distance vision ≥ 69 ETDRS	23	64.4	
Post-op distance vision ≥ 69 ETDRS	27	45.8	<.001
Post-op near vision improvement	29	22	
w/out post-op improvement in reading speed	21	-.28	.005
Post-op reading speed ≥ 90 wwpm	30	62	
Post-op reading speed <90 wpm	20	42.9	<.001

Question 3: Relationship between QOL measures (s) and objective measure

	Chg. QOL (genl. dist. and near vision)	Chg QOL (dep., role limits, MH, social function limits)	Chg QOL (dep., role limits, MH, social function limits0
Chg in VA dist. By 1 ETDRS letter			
Intercept	16.91	11.23	9.9
Slope	.31	.36	.29
P value	.017	.032	.017
Chg in near VA by .1 logMAR unit			
Intercept	14.52	8.44	7.42
Slope	-1.37	-1.59	-1.39
P value	.038	.057	.024
Chg in reading			

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results				Quality Scoring/Comments
				speed by 1 wpm				
				Intercept	15.91	9.82	8.52	
				Slope	.12	.14	.14	
				P value	.055	.048	.013	

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Complications of Age-Related Macular Degeneration Prevention Trial Research Group Maguire 2004 #470	**Geographical location:** Multicenter U.S. **Dates:** 5/99-3/01 **Context:** X Clinical trial □ Cohort □ Cross sectional □ Other **Inclusion/Exclusion criteria:** Inclusion: ≥ 10 drusen at least 125 micron diam Vision ≥ 20/40 Exclusion: CNV, serous RPED, geographic atrophy ≤ 500 microns of foveal center or > 1 MPS disc area, or other conditions that compromise vision/preclude laser	**Population size (n):** 1052 Age: Mean 71 (50-89) 39% male 99% white Eye dx: Not Reported **AMD:** 100% **AMD Type:** 0% wet 100% dry (severe early ARMD) **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Visual acuity ≥ 20/20: 65% Contrast threshold ≤ 2%: 47%	**Instrument/Technique Name:** NEI-VFQ **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire X In office questionnaire □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate **Time points of administration:** Baseline	**Question 1A: Instrument scores in AMD patients** NEI VQF -25 / Mean ± SD / Median / Stdz Cronbach's α Overall: 88 ± 10 / 91 / 0.92 Genl health: 71 ± 21 / 75 / NA Genl vision: 79 ± 14 / 80 / NA Ocular pain: 89 ± 15 / 88 / 0.69 Near vision: 85 ± 16 / 92 / 0.78 Distance vision: 86 ± 15 / 92 / 0.69 Vision specific: Role difficulties: 87 ± 19 / 100 / 0.81 Mental health: 85 ± 15 / 88 / 0.77 Social function: 97 ± 9 / 100 / 0.76 Dependency: 97 ± 10 / 100 / 0.78 Driving: 85 ± 15 / 88 / 0.47 Peripheral vision: 93 ± 15 / 100 / NA **Question 1C: psychometric properties (validity, reliability, responsiveness)** Subject to ceiling effects but not floor effects High internal consistency except driving See above for Cronbach's α **Question 3: Relationship between QOL measures (s) and objective measures** Visual function of better eye: For NEI VFQ overall, general health, general vision, near vision, distance vision, role difficulties, higher visual function (visual acuity,	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: + **This article is relevant to:** X Question 1A □ Question 1B X Question 1C □ Question 2 X Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
				contrast sensitivity, critical print size) was associated with higher score on scale ** Subscales of general vision, near vision, and distance vision more than 5 units difference Fundus Features of better eye: For NEI VFQ overall, general health, general vision, near vision, distance vision, role difficulties, severity of fundus features (%area covered by drusen and focal hyperpigmentation) was not associated with higher score on scale	

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Mangione 2001 #6810	**Geographical location:** 11 university based ophthalmology practices and the NEI Clinical Center **Dates:** Unknown **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Participants had to be 21 years of age and older, English speaking, pass a cognitive test, have one or more of the following: ARMD, diabetic retinopathy, primary open-angle glaucoma, or cytomegalovirus retinitis with one ocular condition only for the field test (pilot study participants could have multiple conditions).	**Population size (n):** 859 Field / Pilot Mean age: 64 / 61 % white: 63 / 81 % AA: 29 / 11 % female: 59 / 54 % employed: 36 / 40 Eye dx: Not reported **AMD:** 21 Other central vision loss (by type): Cataract: 31 Primary open angle glaucoma: 27 Diabetic retinopathy: 22 Cytomegalovirus retinitis: 8 **AMD Type:** Not reported **Laterality:** not reported **Objective Measure(s) of function (e.g., visual acuity):** Visual acuity: Better eye, median (range) 20/30 (20/15 – 20/400) Worse eye, median (range) 20/50 (20/20 – 20/500)	**Instrument/Technique Name:** VFQ-25 **Method of administration:** **By whom:** X Not relevant □ Masked □ Unmasked □ Unknown **Mode of administration:** □ Phone interview □ Face to face interview □ Mail questionnaire X In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** NA	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: Cronbach's alpha ranged from .71 to .85 (13 subscales) Construct validity: Correlations between VFQ-25 subscales and longer-form version of instrument (VFQ-51) exceeded .90. Correlations between VFQ-25 subscales and ETDRS visual acuity ranged from .65-.70. Notes: This study, derived from 2 field tests whose design details are described elsewhere, includes a diverse group of patients including 108 with AMD. Overall, a high-quality cross-sectional validation study. Except for reporting subscale means by condition (manuscript table 4), all analyses were performed on the combined set of patients.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Massof 2001 #8450	**Geographical location:** Baltimore, MD **Dates:** NR **Context:** □ clinical trial □ cohort X cross sectional □ longitudinal **Inclusion/Exclusion criteria:** Diverse convenience sample for focus group	**Population size (n):** 246 Age Median (range): 79 (11 - 94) % female: NR Eye dx: **AMD:** 76% Other central vision loss (by type): Diabetic retinopathy: 9% Glaucoma: 5% Other: 10% **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):** Not reported	**Instrument/Technique Name:** NEI-VFQ **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** □ phone interview X face to face interview □ mail questionnaire □ in office questionnaire □ observation X other (physical exam) **Respondent:** X only patient □ patient or surrogate □ only surrogate □ unknown **Time points of administration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Validity: not evaluated Reliability Rasch analysis indicated that 15 of the 22 items performed better than the others. Responsiveness not evaluated.	**General comments:** Apparently a convenience sample **Quality assessment:** Meaningfully defined study population: - Protection from bias: + Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Tranos 2004 #270	**Geographical location:** .London **Dates:** 1/03-8/03 **Context:** □ Clinical trial □ Cohort X Case series □ Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Patients undergoing macular hole surgery that were a minimum of 17 yrs. old, and had evidence of stage II-IV full thickness macular hole by means of a slip lamp biomicroscopy, speak English, read fluently, and pass a mental health exam. Patients with a history of previous vitreoretinal intervention or those who underwent combined vitrectomy and cataract extraction were excluded. Also excluded were patients with clinically significant coexisting ocular pathology such as glaucoma and ARMD.	**Population size (n):** 30 Age (mean): 70 Sex: 63% male Eye dx:: Not reported **AMD:** 0 Other central vision loss (by type): Macular holes **AMD Type: NA** **Laterality:** X Unilateral □ Bilateral **Objective Measure(s) of function (e.g., visual acuity):**	**Instrument/Technique Name:** VFQ-25 **Method of administration:** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** □ Phone interview □ Face to face interview □ Mail questionnaire X In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** pre operatively and 4 mos. Post.	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Responsiveness: The VFQ-25 general vision subscale and composite score improved post-surgery. Note: This study, performed among patients with macular hole surgery, only provides weak evidence for the validity of the scale, both because of the small sample size and the single validation measure.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: 0 Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Miskala 2005 #520	**Geographical location:** Multi center cites **Dates:** 1998-2000 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Two groups from the SST trials: persons with AMD who were 50 years or older, had subfoveal choroidal neovascularization and VA of 20/100 to 20/800; The subfoveal lesion could be large and well-demarcated or poorly demarcated with no lower limit size. The second group was also 50 and older, had AMD but had large hemorrhagic lesion with a VA of 20/100 or worse but at least light perception.	**Population size (n):** 120 Median age 77 % female 60 % white 98 % retired 78 % employed 12 Eye dx: Not reported **AMD:** 100% **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):** Visual acuity, median (range) Better-seeing eye 20/100 (20/20 – 20/800) Worse-seeing eye 20/500 (20/50 – no light perception)	**Instrument/Technique Name:** VFQ-37 **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** X Phone interview □ Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Construct validity: Ten of 12 VFQ-37 subscales were correlated with visual acuity in the better eye. Notes: This sample of AMD patients from the Submacular Surgery Trials Pilot Study provides a modest degree of support for the validity of the instrument.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Miskala 2003 #820	**Geographical location:** Multi-center trials in US **Dates:** 1998-2000 **Context:** X Clinical trial □ Cohort □ Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Patients receiving QoL and VA measurements at 12 and 24 mos. Of follow up by 12/2000 were included. Patients enrolled in the pilot trials beginning 12/93 and ending 12/97. Also included patients from 3 largest SST trials initiated in 4/97 and 7/98.Patients had large subfoveal hemorrhagic lesions secondary to AMD with VA from 20/100 to light perception in the study eye; A second group included patients with new subfoveal choroidal neovascular lesions secondary to AMD who had 20/100 to 20/800 Va in affected eye; had to be at least 50 yrs. old; and a third group had CNV due to OHS or	**Population size (n):** 218 Median age 73 % male 41 % white 97 % retired 56 % employed 32 Eye dx: Not Reported **AMD:** 100% **AMD Type:** Subfoveal choroidal neovascularization **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Median visual acuity at 12 months follow up (range) Better eye 20/25 (20/20 – 20/800) Worse eye 20/320 (20/20 – light perception)	**Instrument/Technique Name:** VFQ-37 **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** X Phone interview □ Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** 12 and 24 mos. after enrollment.	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Responsiveness: In both bi-variate and multi-variate analyses, changes in visual acuity in the better eye were correlated with changes in the VFQ-37 subscale and overall scores. Notes: This sample of AMD patients from the Submacular Surgery Trials Pilot Study provides a modest degree of support for the validity of the instrument. Although focused on the 37-item version of the instrument, the authors also note that the dimension scores for the VFQ-25 were similar to those of the VFQ-37, and concluded that the shorter version of the instrument could be used as a replacement.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: + **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
	idiopathic causes who were 18 or older with visual acuities between 20/50 and 20/800 in study eye.				

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

<table>
<tr><th>Study</th><th>Study Design</th><th>Study Population</th><th>Instrument Characteristics</th><th>Results</th><th>Quality Scoring/Comments</th></tr>
<tr>
<td>AREDS Research Group 2005 Lindblad #7290</td>
<td>Geographical location:
11 clinical sites in US

Dates: 11/92-1/98

Context:
X Clinical trial
□ Cohort
□ Ccross sectional
□ Longitudinal

Inclusion/Exclusion criteria:
Except for the requirement that all participants have at least one eye with a visual acuity of 20/32 or better and that the media be sufficiently clear for reasonable quality fundus photography, lens opacity status was not considered. Additional exclusions were persons with more than minimal diabetic retinopathy, previous ocular surgery (except for cataract surgery and unilateral photocoagulation for AMD)
or presence of any other eye disease that could complicate assessing the progression of lens opacities or AMD or that could affect visual acuity. Finally persons with illnesses that made long term follow</td>
<td>Population size (n): 4119

Mean age 72
% female 57
% white 96

Eye dx: Not reported

AMD: 100%

AMD Type:
25% wet
75% dry

Laterality:
□ Unilateral
X Bilateral

Objective Measure(s) of function (e.g., visual acuity):
AMD cat 1: 24%
AMD cat 2: 23%
AMD cat 3: 34%
AMD cat 4: 19%</td>
<td>Instrument/Technique Name: NEI-VFQ

Method of administration:

By whom:
X Masked
□ Unmasked
□ Unknown

Mode of administration:
X Phone interview
X Face to face interview
□ Mail questionnaire
□ In office questionnaire
□ Observation
X Other (physical exam)

Respondent:
X Only patient
□ Patient or surrogate
□ Only surrogate
□ Unknown

Time points of administration:
enrollment</td>
<td>Question 1A: Instrument scores in AMD patients:

Question 3: Relationship between QOL measures (s) and objective measure
<table><tr><th>NEI VQF Domains And Progression to Advanced AMD</th><th>Difference</th><th>p</th></tr><tr><td>Genl health</td><td>4.5</td><td><.001</td></tr><tr><td>Genl vision</td><td>11</td><td><.001</td></tr><tr><td>Ocular Pain</td><td>-1.4</td><td>Not sign</td></tr><tr><td>Near Activities</td><td>16</td><td><.001</td></tr><tr><td>Distance Activities</td><td>15</td><td><.001</td></tr><tr><td>Social Functioning</td><td>12</td><td><.001</td></tr><tr><td>Mental Health</td><td>12</td><td><.001</td></tr><tr><td>Role Difficulties</td><td>15</td><td><.001</td></tr><tr><td>Dependency</td><td>15</td><td><.001</td></tr><tr><td>Driving</td><td>25</td><td><.001</td></tr><tr><td>Color Vision</td><td>9</td><td><.001</td></tr><tr><td>Peripheral Vision</td><td>7</td><td><.001</td></tr><tr><td>Global Score</td><td>12</td><td><.001</td></tr></table>
<table><tr><th>NEI VQF Domains And Progression to Signif Vision Loss</th><th>Difference</th><th>p</th></tr><tr><td>Genl health</td><td>6</td><td><.001</td></tr><tr><td>Genl vision</td><td>13</td><td><.001</td></tr><tr><td>Ocular Pain</td><td>-0.1</td><td>Not sign</td></tr><tr><td>Near Activities</td><td>16</td><td><.001</td></tr><tr><td>Distance Activities</td><td>15</td><td><.001</td></tr><tr><td>Social</td><td>11</td><td><.001</td></tr></table></td>
<td>Quality assessment:
Meaningfully defined study population: +
Protection from bias: +
Consideration of statistical power: +

This article is relevant to:
X Question 1A
□ Question 1B
□ Question 1C
□ Question 2
X Question 3</td>
</tr>
</table>

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results			Quality Scoring/Comments
	up unlikely were ineligible.			Functioning			
				Mental Health	11	<.001	
				Role Difficulties	15	<.001	
				Dependency	14	<.001	
				Driving	22	<.001	
				Color Vision	8	<.001	
				Peripheral Vision	6	<.001	
				Global Score	11	<.001	

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Berdeaux 2005 #190	**Geographical location:** 11 centers internationally **Dates:** 5/2000-7/2001 **Context:** X Clinical trial □ Cohort □ Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** 1) willing to give informed consent, able to make required study visits and follow instructions; 2) at least 50 years of age; 3) any race or gender; 4) clinical diagnosis of exudative AMD and primary or recurrent subbfoveal neovascular membrane with lesion area with greatest linear dimenion of ≤ 5400 um, at least 50% total lesion was choroidal neovascularization, best corrected ETDRS VA between 20/40 and 20/400 in studied eye at eligiblity visit and best corrected ETDRS VA in contralateral eye to be 20/800 or best with clinical evidence of macular degeneration;	**Population size (n):** 114 Age: 76.5 (58-91) Eye dx: Not reported **AMD:** 100% **AMD Type:** 100% wet **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Best Eye VA: 0.34 Worst Eye VA: 0.85 AMD affected eye VA: 0.72 Fellow Eye VA: 0.47	**Instrument/Technique Name:** VFQ-39 **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** X Phone interview □ Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** □ Only patient □ Patient or surrogate □ Only surrogate X Unknown **Time points of administration:** Not reported	**Question 1A: Instrument scores in AMD patients:** NEI VQF -39 Domains / Mean / SD Genl health: 72.9 / 18.6 Genl vision: 59.4 / 16.9 Ocular Pain: 87.5 / 14.5 Near Activities: 57.3 / 24.8 Distance Activities: 66.6 / 22.1 Social Functioning: 85.9 / 21.4 Mental Health: 61.1 / 25.4 Role Difficulties: 65.8 / 23.2 Dependency: 75.5 / 27.0 Driving: 53.4 / 34.0 Color Vision: 85.9 / 21.1 Peripheral Vision: 75.9 / 23.0 Global Score: 67.8 / 18.6 **Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: Cronbach's alpha for most domains exceeded .70. Construct validity: Most VFQ-39 subscales, as well as the global score, were correlated with visual activity. Notes: This study, using baseline data from a clinical trial of patients with AMD, provides a modest degree of additional support to the validity of the instrument. **Question 3: Relationship between QOL measures (s) and objective measure** NEI VQF -39 Domains / R-square / P signif in Best Eye / P signif in Worst Eye Genl health: 0.01 / .8468 / .3416	**Quality assessment:** Meaningfully defined study population: + Protection from bias: 0 Consideration of statistical power: +. **This article is relevant to:** X Question 1A □ Question 1B X Question 1C □ Question 2 X Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results				Quality Scoring/Comments
	6) aphakic or pseudophakic eyes could be treated if axial length of eye was 26 mm or less. Patients with history of any medical condition which would preclude scheduled study visits or completion of study,; history of chronic hepatitis; history of ophthalmic disease in the study eye that might compromise its VA during study; angiographic evidence of well defined classical subfoveal < 10%; clinical signs of myopic retinopathy or refraction > -8 diopter in current prescription; clinical evidence of scleral thinning; previous treatment of AMD.			Genl vision	0.31	<.0001	.0123	
				Ocular Pain	0.00	.8887	.7136	
				Near Activities	0.61	<.0001	.0006	
				Distance Activities	0.47	<.0001	.0006	
				Social Functioning	0.36	<.0001	.0108	
				Mental Health	0.27	.0004	.0015	
				Role Difficulties	0.35	<.0001	.1014	
				Dependency	0.36	<.0001	.0011	
				Driving	0.53	<.0001	.0388	
				Color Vision	0.17	.0046	.0254	
				Peripheral Vision	0.12	.0355	.0355	
				Global Score	0.48	<.0001	.0010	

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

<table>
<tr><th>Study</th><th>Study Design</th><th>Study Population</th><th>Instrument Characteristics</th><th>Results</th><th>Quality Scoring/Comments</th></tr>
<tr>
<td>Clemons 2003
#920</td>
<td>Geographical location:
11 clinical sites in US

Dates: 12/97-4/01

Context:
□ Clinical trial
□ Cohort
□ Cross sectional
X Longitudinal

Inclusion/Exclusion criteria:
Except for the requirement that all participants have at least one eye with a visual acuity of 20/32 or better and that the media be sufficiently clear for reasonable quality fundus photography, lens opacity status was not considered. Additional exclusions were persons with more than minimal diabetic retinopathy, previous ocular surgery (except for cataract surgery and unilateral photocoagulation for AMD) or presence of any other eye disease that could complicate assessing the progression of lens opacities or AMD or that could affect visual acuity. Finally persons with illnesses that made long term follow up unlikely were</td>
<td>Population size (n): 4077

<table><tr><td>Mean age</td><td>74</td></tr><tr><td>% female</td><td>57.2</td></tr><tr><td>% white</td><td>96.7</td></tr></table>
Eye dx: Not reported

AMD: Not reported

AMD Type:
25% wet
75% dry

Laterality:
□ Unilateral
X Bilateral

Objective Measure(s) of function (e.g., visual acuity):
IVisual acuity of worse eye; 69 letters

Both eyes 20/20 or better: 28.1%
One eye worse than 20/20: 27.2%
Both eyes worse than 20/20: 44.7%

AMD cat 1: 22.9%
AMD cat 2: 23.9%
AMD cat 3: 28.3%
AMD cat 4: 24.9%</td>
<td>Instrument/Technique Name: VFQ-39

Method of administration:

By whom:
□ Masked
X Unmasked
□ Unknown

Mode of administration:
□ Phone interview
X Face to face interview
□ Mail questionnaire
□ In office questionnaire
□ Observation
X Other (physical exam)

Respondent:
X Only patient
□ Patient or surrogate
□ Only surrogate
□ Unknown

Time points of administration:
Enrollment</td>
<td>Question 1A: Instrument scores in AMD patients:
<table><tr><th>NEI VQF Domains</th><th>Mean</th><th>SE</th></tr><tr><td>Genl health</td><td>72</td><td>.27</td></tr><tr><td>Genl vision</td><td>76</td><td>.27</td></tr><tr><td>Ocular Pain</td><td>90</td><td>.22</td></tr><tr><td>Near Activities</td><td>84</td><td>.32</td></tr><tr><td>Distance Activities</td><td>87</td><td>.29</td></tr><tr><td>Social Functioning</td><td>95</td><td>.21</td></tr><tr><td>Mental Health</td><td>87</td><td>.31</td></tr><tr><td>Role Difficulties</td><td>88</td><td>.32</td></tr><tr><td>Dependency</td><td>94</td><td>.25</td></tr><tr><td>Driving</td><td>77</td><td>.45</td></tr><tr><td>Color Vision</td><td>94</td><td>.25</td></tr><tr><td>Peripheral Vision</td><td>93</td><td>.25</td></tr><tr><td>Global Score</td><td>87</td><td>.22</td></tr></table>
Question 1C: psychometric properties (validity, reliability, responsiveness)
Internal consistency: Cronbach’s alpha for subscales ranged from .58 to .91, .82 for total score. Although individual subscales had numerous patients with ceiling effects, for the overall score only 1% of patients had ceiling effects and 0% had floor effects.

Construct validity: There were significant positive correlations between all subscales and visual acuity (in both better and worse eye). Subscale scores differed when patients were classified by AMD severity; a similar exercise was performed by classifying patients according to current nuclear opacity status, current cortical opacity status, current cataract status, and current visual acuity status.

Notes: These data are derived from the AREDS, a cohort study with a randomized trial embedded within, following patients with AMD. This is a comprehensive cross-sectional validation of the VFQ-39.</td>
<td>Quality assessment:
Meaningfully defined study population: +
Protection from bias: +
Consideration of statistical power: +

This article is relevant to:
X Question 1A
□ Question 1B
X Question 1C
□ Question 2
X Question 3</td>
</tr>
</table>

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
	ineligible.			**Question 3: Relationship between QOL measures (s) and objective measure** Correlation between visual acuity and NEI-VFQ Domain / Visual acuity of better eye / Visual acuity of worse eye Genl health .24 .25 Genl vision .56 .62 Ocular Pain .07 .08 Near Activities .46 .50 Distance Activities .47 .51 Social Functioning .39 .41 Mental Health .40 .47 Role Difficulties .42 .46 Dependency .43 .44 Driving .44 .47 Color Vision .25 .27 Peripheral Vision .25 .31	

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Scilley 2004 #450	**Geographical location:** Birmingham, AL **Dates:** 7/98-6/99 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Other **Inclusion/Exclusion criteria:** Age >55 AMD patients referred to university low-vision clinic AMD primary cause of vision impairment	**Population size (n):** Unknown **Age (mean):** 80 Eye dx: Not reported **AMD:** 100% **AMD Type:** 46% wet 54% dry **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Vision: Better eye: 20/175 Worse eye: 20/600	**Instrument/Technique Name:** NEI-VFQ **Method of administration:** **By whom:** □ Masked X Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation □ Other **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate **Time points of administration:** NA	**Question 1A: Instrument scores in AMD patients:** NEI VQF Domains / Mean / SD / % Floor / % Ceiling Genl health: 50 / 26 / 6 / 11 Genl vision: 39 / 18 / 0 / 0 Ocular Pain: 94 / 16 / 0 / 81 Near Activities: 32 / 22 / 7 / 2 Distance Activities: 38 / 26 / 6 / 2 Social Functioning: 57 / 31 / 3 / 20 Mental Health: 47 / 29 / 9 / 3 Role Difficulties: 45 / 30 / 13 / 9 Dependency: 46 / 33 / 9 / 13 Driving: 11 / 21 / 65 / 1 Color Vision: 67 / 33 / 8 / 38 Peripheral Vision: 83 / 28 / 3 / 66 **Question 3: Relationship between QOL measures (s) and objective measures** NEI VQF Domains / 1 VA> 20/200 both eyes / 2 VA> 20/200 one eye / 3 VA < 20/200 both eyes / p-value Genl health: 37 / 51 / 51 / .676 Genl vision: 52 / 41 / 36 / .003 Ocular Pain: 97 / 93 / 94 / .520 Near Activities: 47 / 38 / 25 / <.001 Distance Activities: 57 / 41 / 32 / <.001 Social Functioning: 79 / 65 / 50 / <.001 Mental Health: 60 / 51 / 42 / .021 Role Difficulties: 32 / 49 / 40 / .005	[Quality assessment: Meaningfully defined study population: + Protection from bias: 0 Consideration of statistical power: - **This article is relevant to:** X Question 1A □ Question 1B □ Question 1C □ Question 2 X Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results					Quality Scoring/Comments
				Dependency	70	42	45	.004	
				Driving	31	16	5	<.001	
				Color Vision	79	71	62	.010	
				Peripheral Vision	90	82	83	.433	

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Submacular Surgery Trials Research Group Childs 2004 #140	**Geographical location:** Multicenter trial, US **Dates:** enrollment began 7/98 **Context:** X Clinical trial □ Cohort □ Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** >50 yo with subfoveal CNV from AMD Vision 20/100 20/1600 and at least LP in one eye Classic cnv >3.5 disk areas Blood > 50% of lesion	**Population size (n):** 336 Group B (subretinal hemorrhage) Mean age: 79 % female: 54 % white: 94 Eye dx: Not reported **AMD:** 100% **AMD Type:** 100% wet **Laterality:** 55% Unilateral 46% Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Mean Visual Acuity: Unilateral: observation: 20/25 better, 20/250 worse eye Unilateral: surgery: 20/32 better, 20/320 worse Bilateral: observation: 20/160 better, 20/500 worse Bilateral: surgery: 20/125 better, 20/400 worse	**Instrument/Technique Name:** NEI-VFQ **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** X Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Enrollment, 6 mos, 12 mos, 24 mos, 36 mos	Median Change in NEI VQF Domains at 24 mos: 20/100 - 20/160 Obser; 20/100 - 20/160 Surg; ≤20/200 Obser; ≤20/200 Surg All patients: -1.4; 3.5; 0.7; -1.7 Unilat: -2.5; 1.5; -1.5; -2.1 Bilat: 2.5; 3.5; 4.1; 0.8 3. Visual acuity outcomes (different report), not statistically significant difference	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: +. **This article is relevant to:** X Question 1A □ Question 1B □ Question 1C □ Question 2 X Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Submacular Surgery Trials Research Group 2004 Dong #480	**Geographical location:** Multicenter trial, US **Dates:** enrollment began 7/98 – 9/01 **Context:** X Clinical trial □ Cohort □ Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** **Criteria** / **Group N** New CNV Age: ≥50 CNV cause: AMD Classic CNV: Required Occult CNV: Optional Foveal center: CNV Lesion size: ≤9 disc areas Area of blood: < 50% lesion Prior laser: Not allowed Best visual acuity, study eye: 20/100 Worst visual acuity, study eye: 20/800 CNV=choroidal	**Population size (n):** Group N=454 Group B (subretinal hemorrhage)=335 Mean age: 78 % female: 54 % white: 98 Eye dx: Not reported **AMD:** 100% **AMD Type:** 100% wet **Laterality:** 55% Unilateral 45% Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Mean Visual Acuity: Unilateral: observation: 20/25 better, 20/250 worse eye Unilateral: surgery: 20/32 better, 20/320 worse Bilateral: observation: 20/160 better, 20/500 worse Bilateral: surgery: 20/125 better, 20/400 worse	**Instrument/Technique Name:** NEI-VFQ **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** X Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Baseline	**3.** Correlation Between Scores on Health-related Quality-of-life Scales and Visual Acuity of Better-seeing Eye at Baseline, SST Group N and Group B Trials (Pearson correlation) Scale / Group N / Group B NEI-VFQ Overall: 0.66 / 0.66 General vision: 0.60 / 0.56 Driving: 0.74 / 0.67 Near activities: 0.69 / 0.69 Distance activities: 0.65 / 0.68 Role difficulties: 0.54 / 0.52 Mental health: 0.45 / 0.41 Dependency: 0.59 / 0.59 Social functioning: 0.57 / 0.51 Peripheral vision: 0.34 / 0.35 Color vision: 0.34 / 0.41 Ocular Pain: 0.09 / 0.12 SF-36 Physical component summary: 0.08 / 0.11 Mental component summary: 0.18 / 0.07 HADS Anxiety: -0.14 / -0.02 Depression: -0.29 / -0.25 HADS = Hospital Anxiety and Depression Scale. NEI–VFQ, National Eye Institute Visual Function Questionnaire. SF-36 = SF-36 Health Survey. Effects of Explanatory Variables on NEI-VFQ Scores: Estimated Coefficients from Multiple Linear Regression Models, SST Group N and Group B Trials **[See Sub-Table #1 on following page]** Comparisons of NEI-VFQ Scores of SST Group N and Group B Patients with Patients with Other Ocular Disorders **[See Sub-Table #2 on following page]**	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: +. **This article is relevant to:** X Question 1A □ Question 1B □ Question 1C □ Question 2 X Question 3

Evidence Table 6: National Eye Institute Visual Functioning Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
	neovascularization **Criteria** / **Group B** (Blood) Age: ≥50 CNV cause: AMD Classic CNV: Optional Occult CNV: Optional Foveal Center: Blood or CNV Lesion size: >3.5 disc areas Area of blood: ≥50% lesion Prior laser: Optional Best visual acuity, study eye: 20/100 Worst visual acuity, study eye: Light per-ception				

Sub-Table #1 Effects of Explanatory Variables on NEI-VFQ Scores

Scale	Better Eye VA (lines)	Bilateral CNV Cases	PCS	MCS	Age (Years)	Gender Male	Model R^2
Group N Trial							
Overall	1.9	-6.4	0.5	0.6	0.07	-1.1	0.62
General Vision	1.8	-5.5	0.4	0.2	0.13	-3.6	0.45
Driving	4.0	-14.2	0.5	0.4	-0.05	6.2	0.60
Near Activities	2.5	-9.4	0.5	0.5	0.20	0.3	0.59
Distance Activities	2.6	-6.8	0.6	0.5	-0.02	-0.2	0.54
Role difficulties	1.5	-10.5	0.8	0.6	-0.11	-5.0	0.49
Mental Health	1.6	-6.1	0.8	1.2	0.34	0.1	0.46
Dependency	1.9	-11.1	0.7	0.8	-0.13	0.7	0.52
Social functioning	2.0	-6.4	0.4	0.7	0.05	-2.0	0.47
Peripheral vision	1.4	-2.6	0.4	0.6	0.10	1.0	0.18
Color vision	1.5	-0.3	0.3	0.3	0.02	-5.2	0.17
Ocular pain	0.01	1.9	0.4	0.6	0.03	1.6	0.16
Group B Trial							
Overall	1.9	-9.9	0.7	0.4	0.41	-1.5	0.65
General Vision	1.7	-9.2	0.5	0.2	0.59	-2.9	0.44
Driving	2.8	-19.5	0.9	0.3	0.28	5.7	0.58
Near Activities	2.3	-16.0	0.7	0.4	0.34	0.7	0.61
Distance Activities	2.8	-11.7	0.7	0.3	0.44	0.2	0.59
Role difficulties	1.8	-9.7	1.0	0.5	0.42	-3.8	0.47
Mental Health	1.2	-13.4	0.8	1.0	0.50	0.01	0.44
Dependency	2.6	-10.5	1.0	0.7	0.24	-0.9	0.52
Social functioning	1.6	-8.4	0.6	0.4	0.48	-1.4	0.39
Peripheral vision	1.7	-3.5	0.6	0.2	0.21	0.3	0.18
Color vision	1.7	-7.3	0.7	0.3	0.51	-8.1	0.29
Ocular pain	-0.1	-1.4	0.6	0.4	0.07	0.6	0.15

All estimates have been adjusted for the reading speed in the better eye.
NEI-VFQ = National Eye Institute Visual Function Questionnaire
PCS = Physical component summary scale from the SF-36
MCS = Mental component summary scale from the SF-36
VA = visual acuity
CNV = choroidal neovascularization

Sub-Table #2 Comparisons of NEI-VFQ Scores of SST Group N and Group B Patients with Patients with Other Ocular Disorders

	SST Patients (means)		Other Ophthalmology Patients (means)		
Condition	**Group N Trial (n=454)**	**Group B Trial (n=335)**	**A (Ref) (n=122)**	**B (AMD) (n=108)**	**C (AMD) (n=151)**
NEI-VFQ					
Overall	65	63	-	-	57
General Vision	52	49	81	54	39
Driving	41	37	89	63	50
Near Activities	55	53	93	55	29
Distance Activities	61	59	95	63	39
Role Difficulties	62	58	96	64	44
Mental Health	59	58	91	63	58
Dependency	70	65	99	74	59
Social Functioning	78	77	99	78	64
Peripheral Vision	72	71	97	77	67
Color Vision	81	78	98	85	73
Ocular Pain	85	84	90	87	87
Mean Age, years (SD)	77 (6)	79 (7)	59 (14)	76 (10)	81 (6)
Women, %	53	54	62	63	68
Median better eye visual acuity	20/40	20/50	20/20	20/63	20/200

A, Mangione et al., 122 patients seen for screening eye examinations or correction of refractive errors.
B, Mangione et al., 108 patients with age-related macular degeneration.
C, Brody et al., 151 patients with age-related macular degeneration.
Best corrected visual acuity in the Submacular Surgery Trials, habitual correction in other three populations.
AMD = age-related macular degeneration

Evidence Table 6: National Eye Institute Visual Function Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Submacular Surgery Trials Research Group 2004 Miskala #150	**Geographical location:** Multicenter trial, US **Dates:** enrollment began 7/98 **Context:** X Clinical trial □ Cohort □ Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** >50 yo with subfoveal CNV from AMD Vision 20/100-20/800 Classic cnv ≤9 MPS disk areas Blood < 50% of lesion	**Population size (n):** 454 Group N (neovascular) Mean age 77 % female 53 % white 98 Eye dx: Not reported **AMD:** 100% **AMD Type:** 100% wet **Laterality:** 55% Unilateral 45% Bilateral **Objective Measure(s) of function (e.g., visual acuity):** Mean Visual Acuity: Unilateral: observation: 20/25 better, 20/200 worse eye Unilateral: surgery: 20/25 better, 20/200 worse Bilateral: observation: 20/100 better, 20/400 worse Bilateral: surgery: 20/125 better, 20/320 worse	**Instrument/Technique Name:** NEI-VFQ **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** X Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration:** Enrollment, 6 mos, 12 mos, 24 mos, 36 mos, 48 mos	Median Change in NEI VQF Domains at 48 mos: Surg / Observ Genl vision 0 / -5 Ocular Pain 0 / 0 Near Activities 0 / 4 Distance Activities -4 / 0 Social Functioning 0 / 0 Mental Health 10 / 2 Role Difficulties 0 / -9 Dependency 0 / -3 Driving 0 / 0 Peripheral Vision 0 / 0 Global Score 2 / 0 3. Visual acuity outcomes (different report), not statistically significant difference	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: + **This article is relevant to:** X Question 1A □ Question 1B □ Question 1C □ Question 2 X Question 3

Evidence Table 6: National Eye Institute Visual Function Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Mangione 1998 #8170	**Geographical location:** Six ophthalmology practices, Bethesda MD **Dates:** 7/95-3/96 **Context:** □ Clinical trial X Cohort □ Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Eligible participants had to have 1 of the following eye conditions: age-related cataracts, age related macular degeneration, diabetic retinopathy, primary open angle glaucoma, cytomegalovirus retinitis, or low vision from any cause. Participants with ARMD had to have evidence of retinal pigment epithelium changes, choroidal neovascular membrane, central foveal drusen 125 um or larger in diameter, or one of the following in each eye: disciform scar, past laser treatment within 500 um of the fovea, RPE detachment or geographic atrophy involving the fovea.	**Population size (n):** 583 (108 with AMD) **AMD** Mean age 76 % female 63 % retired 75 Time since diagnosis > 2 yrs 74 Eye dx: Not Reported **AMD:** 17 Other central vision loss (by type) Diabetic retinopathy: 19 Glaucoma: 12 Cataract: 14 CMV retinitis: 6 Low vision: 14 Reference: 19 **AMD Type:** Not reported **Laterality:** Not reported **Objective Measure(s) of function (e.g., visual acuity):** Snellen visual acuity equivalent, median (range) Better eye 20/63 (NLP – 20) Worse eye 20/252 (NLP – 20) Binocular 20/63 (NLP – 20)	**Instrument/Technique Name:** VFQ - 51 **Method of administration:** **By whom:** X Masked □ Unmasked □ Unknown **Mode of administration:** □ Phone interview X Face to face interview □ Mail questionnaire □ In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of administration** Baseline and 2 weeks later for a convenience sample	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Internal consistency: Cronbach's alphas for subscales ranged from .66 to .94. Between-scale correlations suggest that the subscales represent separate dimensions. Some subscales exhibited ceiling effects, especially for those dimensions that are expected to be unaffected by the condition in question. Reproducibility: Across subscales, test-retest ICCs ranged from .68 to .91. Construct validity: As expected, scales that are likely to be influenced by deficits in central acuity were lowest for those in the low vision group and for AMD. High correlations were observed between VFQ scales that are activity-oriented and other measures that assess vision-related activities (e.g., VF-14, ADVS). The correlations between the VFQ-51 subscales and objective measures of vision were positive, but more modest. Notes: This study, using a diverse sample of patients from tertiary care ophthalmology practices, provides strong evidence of reliability and construct validity.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Function Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
Tranos 2004 #370	**Geographical location:** Three hospitals in London, UK **Dates:** 2//01 – 8/02 **Context:** □ Clinical trial □ Cohort X Cross sectional □ Longitudinal **Inclusion/Exclusion criteria:** Participants had to be at least 17 yrs. old, English speaking, and have evidence of CSMO by means of slit lamp biomicroscopy using a 66 diopter lens requiring laser treatment accord-ing to the ETDRS guidelines. Individuals also had to pass an abbreviated version of the Folstein Mini Mental State exam. Patients with a history of laser photocoagulation for Proliferative Diabetic Retinopathy or CSMO and subjects with vitreous hemorrhage present at the time of recruitment or vitreous hemorrhage which developed after enroll-lment were excluded. Patients were also excluded if there was evidence of clinically significant coexisting	**Population size (n):** 55 Mean age 65.1 Duration of DM 11.6 % male 31 % white 55 Eye dx: Not reported **AMD:** Not reported Other central vision loss% by type Diabetic macular edema **AMD Type:** Not reported **Laterality:** □ Unilateral X Bilateral **Objective Measure(s) of function (e.g., visual** Baseline visual acuity < 45 letters – 26/55 (48%) > 45 letters 29/55 (51%)	**Instrument/Technique Name:** VFQ-51 **Method of administration: self-administration** **By whom:** □ Masked □ Unmasked X Unknown **Mode of administration:** □ Phone interview □ Face to face interview □ Mail questionnaire X In office questionnaire □ Observation X Other (physical exam) **Respondent:** X Only patient □ Patient or surrogate □ Only surrogate □ Unknown **Time points of dministration:** NA (cross sectional)	**Question 1C: psychometric properties (validity, reliability, responsiveness)** Reproducibility: Item-level test-retest correlations ranged from .44 to .96, although it is not clear whether this analysis was limited to those patients whose visual status remained essentially unchanged. Construct validity: Composite scores were higher for moderate-to-severe patients, in comparison with those having mild diabetic retinopathy. Strong associations were observed between VFQ-51 and visual acuity. Responsiveness: Most subscale scores improved with treatment. Notes: This very small study among patients with diabetic macular edema who underwent laser treatment provides little information about validation.	**Quality assessment:** Meaningfully defined study population: + Protection from bias: + Consideration of statistical power: - **This article is relevant to:** □ Question 1A □ Question 1B X Question 1C □ Question 2 □ Question 3

Evidence Table 6: National Eye Institute Visual Function Questionnaire (NEI-VFQ) – continued

Study	Study Design	Study Population	Instrument Characteristics	Results	Quality Scoring/Comments
	ocular pathology such as glaucoma and AMD.				