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Psychometric Properties of the National Eye Institute–Refractive Error Quality of Life Instrument

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Objective: To estimate the psychometric properties of a vision-targeted measure of health-related quality of life, the National Eye Institute–Refractive Error Quality of Life survey (NEI-RQL), which includes 13 scales designed to assess the impact of refractive error and its correction on day-to-day life.

Design: Cross-sectional survey.

Participants: The NEI-RQL was self-administered by 667 myopes, 380 hyperopes, and 114 emmetropes recruited from the practices of 6 medical centers. All participants had near and distance visual acuity of 20/32 or better in the worse eye while benefiting from their current method for correction of refractive error (glasses, contact lens, refractive surgery).

Methods: Mean scores, standard deviations, internal consistency reliability, and test–retest intraclass correlations were estimated for the NEI-RQL scales. Item discrimination was assessed by item–scale correlations. Construct validity was evaluated by assessing the sensitivity of scale scores to type of refractive error, type of refractive error correction, and spherical equivalent. Construct validity of the NEI-RQL was compared to those of the Medical Outcomes Study 36-item short-form health survey (SF-36) and the National Eye Institute Vision Functioning Questionnaire (NEI VFQ-25) in a random subsample of respondents.

Main Outcome Measures: The 13 NEI-RQL scales—clarity of vision, expectations, near vision, far vision, diurnal fluctuations, activity limitations, glare, symptoms, dependence on correction, worry, suboptimal correction, appearance, and satisfaction with correction.

Results: Emmetropes tended to score significantly better on the NEI-RQL scales than myopes and hyperopes. The method of refractive error correction was also associated with NEI-RQL scores. In addition, the NEI-RQL multi-item scales accounted for 29% of the variance in the NEI-RQL satisfaction with correction item beyond that explained by the SF-36 and the NEI VFQ-25.

Conclusion: These results support the reliability and construct validity of the NEI-RQL. The instrument appears to be useful for comparisons of people with different types of correction for refractive error. *Ophthalmology 2003;110:2292–2301 © 2003 by the American Academy of Ophthalmology.*

There is increasing recognition that performance-based clinical measures of vision such as Snellen acuity or visual field fail to capture important aspects of vision-related functioning and well-being or health-related quality of life (HRQOL).[1–10] The limitations of clinical measures led to the development of the National Eye Institute–Visual Functioning Questionnaire (NEI VFQ).[11–13]

The NEI VFQ was designed to capture the effects on daily life of eye diseases representing the major causes of vision impairment and blindness in the United States, including macular degeneration, diabetic retinopathy, glaucoma, cataract, and cytomegalovirus retinitis. The NEI VFQ was not designed, however, to incorporate the impact of type of correction for refractive error on functioning and well-being.

Refractive error affects over half of the adult American

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Table 1. Item Stems Sorted by Scale for the National Eye Institute–Refractive Error Quality of Life Instrument

Clarity of vision
- 23. At this time, how clear is your vision using the correction you normally use, including glasses, contact lenses, a magnifier, surgery, or nothing at all?
- 37. Have you experienced any problems with distorted vision in the last 4 weeks?
- 39. Have you experienced any problems with blurry vision with your eyesight or the type of vision correction you used in the last 4 weeks?
- 40. Have you experienced any problems with trouble seeing in the last 4 weeks?

Expectations
- 1. If you had perfect vision without glasses, contact lenses, or any type of vision correction, how different would your life be?
- 28. If you had perfect vision without glasses, contacts, or any other type of vision correction, how much do you think your life would change?

Near vision
- 2. How much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, fixing things around the house, sewing, using hand tools, or working with a computer?
- 7. How much difficulty do you have reading ordinary print in newspapers?
- 8. How much difficulty do you have reading the small print in a telephone book, on a medicine bottle, or on legal forms?
- 11. Because of your eyesight, how much difficulty do you have with your daily activities?

Far vision
- 4. How much difficulty do you have judging distances, like walking downstairs or parking a car?
- 5. How much difficulty do you have seeing things off to the sides, like cars coming out of driveways or side streets or people coming out of doorways?
- 6. How much difficulty do you have getting used to the dark when you move from a lighted area into a dark place, like walking into a dark movie theater?
- 9. How much difficulty do you have driving at night?
- 10. How much difficulty do you have driving in difficult conditions, such as in bad weather, during rush hour, on the freeway, or in city traffic?

Diurnal fluctuations
- 3. How much difficulty do you have seeing because of changes in the clarity of your vision over the course of the day?
- 20. How often are you bothered by changes in the clarity of your vision over the course of the day?

Activity limitations
- 12. Because of your eyesight, how much difficulty do you have taking part in active sports or other outdoor activities that you enjoy (like hiking, swimming, aerobics, team sports, or jogging)?
- 33. Because of your vision, do you take part less than you would like in active sports or other outdoor activities (like hiking, swimming, aerobics, team sports, or jogging)?
- 34. Are there any recreational or sports activities that you don't do because of your eyesight or the type of vision correction you have?
- 35. Are there daily activities that you would like to do but don't do because of your vision or the type of vision correction you have?

Glare
- 17. How often when you are around bright lights at night do you see starbursts or halos that bother you or make it difficult to see?
- 38. Have you experienced any problems with glare in the last 4 weeks?

Symptoms
- 18. How often do you experience pain or discomfort in and around your eyes (e.g., burning, itching, or aching)?
- 19. How much does dryness in your eyes bother you?
- 24. How much pain or discomfort do you have in and around your eyes (e.g., burning itching, or aching)?
- 25. How often do you have headaches that you think are related to your vision or vision correction?
- 36. Have you experienced any problems with tearing in the last 4 weeks?
- 41. Have you experienced any problems with itching in or around your eyes in the last 4 weeks?
- 42. Have you experienced any problems with soreness or tiredness in your eyes in the last 4 weeks?

Dependence on correction
- 13. Do you need to wear glasses or bifocal lenses or use a magnifier when you are reading something brief, like directions, a menu, or a recipe?
- 14. Do you need to wear glasses or bifocal lenses or use a magnifier when you are reading something long, like a book, a magazine article, or the newspaper?
- 15. When driving at night, do you need to wear glasses or contacts?
- 16. At dusk, when it is just starting to get dark, do you need to wear glasses or contacts for driving?

Worry
- 21. How often do you worry about your eyesight or vision?
- 22. How often do you notice or think about your eyesight or vision?

Suboptimal correction
- 31. How often did you use a type of correction or treatment that was uncomfortable in the last 4 weeks because it made you look better?
- 32. How often did you use a type of correction that did not correct your vision as well as another correction would have in the last 4 weeks because it made you look better?

Appearance
- 27. In terms of your appearance, how satisfied are you with the glasses, contact lenses, magnifier, or other type of correction (including surgery) you have?
- 29. In terms of your appearance, is the type of vision correction you have now the best you have ever had?
- 30. In terms of your appearance, is there a type of vision correction that is better than what you have now?

(*Continued*)

Table 1. (Continued)

Satisfaction with correction
26. How satisfied are you with the glasses, contact lenses, magnifier, or other type of correction (including surgery) you have?

Response options vary by item. No difference; small difference for the better; large difference for the better; I have this already (item 1); no difficulty at all; a little difficulty; moderate difficulty; a lot of difficulty; never try to do these activities because of vision; never do these activities for other reasons (items 2, 12); don't have changes in the clarity of my vision; no difficulty at all; a little difficulty; moderate difficulty; a lot of difficulty (item 3); no difficulty at all; a little difficulty; moderate difficulty; a lot of difficulty (items 4–6, 11); no difficulty at all; a little difficulty; moderate difficulty; a lot of difficulty; never try to do this because of vision (items 7, 8); no difficulty at all; a little difficulty; moderate difficulty; a lot of difficulty; never drive at night because of vision; never do this for other reasons (item 9); no difficulty at all; a little difficulty; moderate difficulty; a lot of difficulty; never drive in these conditions because of vision; never do this for other reasons (item 10); yes, all of the time; yes, some of the time; no (items 13, 14); yes, all of the time; yes, some of the time; no; don't drive at night because of vision; don't drive at night for other reasons (item 15); yes, all of the time; yes, some of the time; no; don't drive at dusk because of vision; don't drive at dusk for other reasons (item 16); all of the time; most of the time; some of the time; a little of the time; none of the time (items 17, 18, 31, 32); don't have dryness; not at all; very little; moderately; quite a bit; a lot (item 19); never; rarely; occasionally; sometimes; all of the time (items 20–22, 25); perfectly clear; pretty clear; somewhat clear; not clear at all (item 23); none; mild; moderate; severe; very severe (item 24); completely satisfied; very satisfied; somewhat satisfied; somewhat dissatisfied; very dissatisfied; completely dissatisfied (items 26, 27); no change; small change for the better; large change for the better; I have this already (item 28); yes; no (items 29, 30, 33); yes, many; yes, a few; no (items 34, 35); no; yes, not at all bothersome; yes, a little bothersome; yes, somewhat bothersome; yes, very bothersome (items 36–42).

population.[14,15] Although spectacles and contact lenses remain the most commonly used methods to treat refractive error in the United States, keratorefractive surgery has been rapidly growing in popularity as an alternative. One early surgical procedure, radial keratotomy, was rigorously evaluated in a comprehensive multicenter study[16,17]; however, in general, the pros and cons of the different methods and options for refractive correction have not been studied using a standardized self-report instrument targeted at vision-related functioning and well-being of persons treated for refractive error.

The NEI VFQ and other functional status instruments such as the Activities of Daily Vision Scale[9] and a 14-item questionnaire that assesses visual function (VF-14)[5] were not designed to distinguish individuals with corrected refractive error from emmetropic individuals who have normal vision without correction. These instruments also are not designed to differentiate the effects of one method of refractive error correction over another. The National Eye Institute–Visual Functioning Questionnaire (NEI-RQI), developed in response to this lacuna, is a self-administered assessment tool designed specifically for those who, through correction of refractive error, have normal visual acuity but, nevertheless, may be experiencing decrements in vision-related functioning and well-being.

Materials and Methods

Subject Recruitment and Eligibility

Subjects for this study were recruited between June 1999 and October 2000 from advertisements and the ophthalmology practices of 6 medical centers (University of Alabama at Birmingham; University of California, San Francisco; Henry Ford Health System, Detroit; The University of Texas Southwestern Medical Center at Dallas; Naval Medical Center, San Diego; and Case Western Reserve University, Cleveland) using clinical records and advertisements. All appropriate institutional review boards approved the study protocol.

To be eligible, subjects were required to sign an informed consent form, be at least 18 years old, be able to read English fluently as a first or second language, and be able to complete a self-administered questionnaire. Participants were required to have visual acuity of 20/32 or better for near and far vision in the worse eye while using their current correction, if any. For participants with monovision, the eye corrected for near acuity must have had near vision of 20/32 or better and the eye corrected for distance must have had far vision of 20/32 or better. Eligible subjects were required to have been using their current method of correction for at least 3 months. Exclusion criteria were chronic ocular disease or

Table 2. Demographic Characteristics of Sample by Refractive Error Subgroup

	(1) Myope (n = 665)	(2) Hyperope (n = 375)	(3) Emmetrope (n = 114)
Age (%)	40 (18–77)*	52 (18–81)*	39 (19–71)*
18–29	23	8	29
30–39	25	14	31
40–49	26	16	18
50–59	21	33	16
60–69	3	18	5
≥70	1	11	1
Gender (% female)	58	65	68
Race (%)			
White	71	69	53
Black	11	21	30
Asian	12	4	11
Hispanic	4	5	5
Other	2	2	2
Educational attainment (%)			
High school degree or less	9	19	20
Some college	29	38	42
Baccalaureate	26	18	20
Postgraduate work	37	25	18
Income (%)			
<$15 000	4	7	9
$15 000–50 000	43	47	60
$50 000–100 000	32	32	22
>$100 000	21	14	9
Work status (% working full-time)	82	65	82

Percentages may not sum to 100% due to rounding error.
*Mean (range).

Table 3. Demographic Characteristics of Sample by Type of Correction

	(1) No Correction (n = 110)	(2) Postsurgery—No Correction (n = 124)	(3) Glasses (n = 482)	(4) Multifocal Glasses (n = 172)	(5) Contacts (n = 253)
Age (%)	38 (19–71)*	42 (19–65)*	43 (18–81)*	58 (33–81)*	39 (18–72)*
18–29	30	13	20	0	29
30–39	32	35	24	1	25
40–49	18	23	25	15	22
50–59	15	24	21	45	21
60–69	4	5	7	24	3
≥70	1	0	4	15	0
Gender (% female)	69	57	58	58	70
Race					
White	51	90	63	73	74
Black	31	2	18	22	8
Asian	11	4	13	1	11
Hispanic	5	3	5	3	5
Other	2	1	2	2	2
Educational attainment					
High school degree or less	21	7	13	21	7
Some college	41	28	35	31	29
Baccalaureate	19	29	19	19	31
Postgraduate work	18	36	33	29	32
Income					
<$15 000	9	1	5	9	5
$15 000–50 000	58	39	46	39	45
$50 000–100 000	23	30	33	33	31
>$100 000	9	30	15	19	20
Work status (% working full-time)	83	82	78	56	82

Group 1 represents those not needing surgery; group 2, those already having surgery; and groups 3–5, potential surgical candidates.
*Mean (range).

keratoconjunctivitis sicca, diabetes, neurological disease that limits everyday activities, inability to walk up a flight of stairs without assistance, and cognitive impairment (based upon clinical judgment). These exclusion criteria were imposed because functional limitations associated with these conditions would make it difficult to estimate the associations of refractive error and its correction with HRQOL.

Enrollment targets were established at each center for 5 clinical subgroups: natural emmetropes (20 per site), myopes with glasses/contacts (60 per site), hyperopes with glasses/contacts (60 per site), myopia before refractive surgery (60 per site), and hyperopia before refractive surgery (30 per site older than 45 years). Recruitment guidelines were also used to ensure an appropriate distribution of cases by age, gender, race, socioeconomic status, and refractive error severity. Specifically, half of the participants in each clinical subgroup were to be ≤45 years of age; with no more

Table 4. Descriptive Statistics and Reliability Estimates for NEI-RQL (n = 1154)

Scale	No. of items	Mean	SD	% Floor	% Ceiling	Internal Consistency Reliability	Test–Retest Intraclass Correlation*
Clarity of vision	4	83.35	18.36	0.1	27.3	0.72	0.63
Expectations	2	43.57	38.22	34.6	22.2	0.90	0.80
Near vision	4	83.94	18.03	0.0	33.5	0.85	0.74
Far vision	5	83.48	15.85	0.0	20.0	0.81	0.79
Diurnal fluctuations	2	74.58	23.13	0.4	30.3	0.73	0.71
Activity limitations	4	85.28	21.92	0.1	53.5	0.76	0.72
Glare	2	76.40	26.41	1.6	40.1	0.75	0.64
Symptoms	7	79.20	16.79	0.0	12.7	0.78	0.83
Dependence on correction	4	42.38	34.75	28.6	15.2	0.74	0.83
Worry	2	61.31	26.04	0.4	9.4	0.80	0.70
Suboptimal correction	2	92.74	17.28	0.8	81.5	0.64	0.55
Appearance	3	79.31	27.00	0.7	31.8	0.66	0.60
Satisfaction with correction	1	74.85	22.55	1.5	28.4	NA	0.64

NA = not applicable; SD = standard deviation.
All scales are scored so that a higher score represents better health.
*Test–retest interval ranged from 7 to 30 days, with a mean of 16 days (n = 278).

Table 5. Health-Related Quality of Life Scores (Standard Errors) by Refractive Error Subgroup

Scale	(1) Myope (n = 665)	(2) Hyperope (n = 375)	(3) Emmetrope (n = 114)	Comparisons	*F* Ratio	*P*
SF-36 PCS*	53.34 (0.55)	52.78 (0.72)	52.01 (1.49)	NS	0.42	0.6584
SF-36 MCS*	53.80 (0.52)	54.22 (0.69)	54.18 (1.42)	NS	0.11	0.8979
NEI VFQ-25*	92.82 (0.64)	91.25 (0.85)	96.16 (1.74)	2 < 3†	3.31	0.0379
NEI-RQL						
Clarity of vision	83.53 (0.73)	80.79 (1.01)	91.10 (1.73)	2 <1‡; 2 <3†; 1 <3†	13.05	<0.0001
Expectations	40.08 (1.47)	40.17 (2.03)	76.35 (3.48)	1 <3†; 2 <3†	48.67	<0.0001
Near vision	85.60 (0.69)	79.15 (0.95)	90.35 (1.63)	2 <1†; 2 <3†; 1 <3†	21.89	<0.0001
Far vision	83.50 (0.62)	81.15 (0.86)	91.01 (1.47)	2 <1‡; 2 <3†; 1 <3†	16.55	<0.0001
Diurnal fluctuations	75.40 (0.92)	70.34 (1.27)	84.36 (2.18)	2 <1†; 2 <3†; 1 <3†	15.51	<0.0001
Activity limitations	83.16 (0.86)	86.10 (1.19)	95.92 (2.04)	1 <3†; 2 <3†	16.74	<0.0001
Glare	74.43 (1.05)	75.66 (1.45)	90.20 (2.49)	1 <3†; 2 <3†	17.28	<0.0001
Symptoms	79.44 (0.67)	77.20 (0.92)	84.87 (1.58)	1 <3†; 2 <3†	8.62	0.0002
Dependence on correction	41.60 (1.20)	32.28 (1.66)	80.56 (2.84)	2 <1†; 1 <3†; 2 <3†	108.14	<0.0001
Worry	60.15 (1.03)	58.79 (1.43)	77.42 (2.44)	1 <3†; 2 <3†	23.92	<0.0001
Suboptimal correction	91.75 (0.71)	92.44 (0.98)	99.38 (1.67)	1 <3†; 2 <3†	8.93	0.0001
Appearance	79.48 (1.09)	77.03 (1.50)	86.27 (2.62)	1 <3‡; 2 <3†	4.59	0.0104
Satisfaction with correction	73.35 (0.89)	73.60 (1.23)	88.60 (2.14)	1 <3†; 2 <3†	22.52	<0.0001

MCS = Mental Component Score; NEI-RQL = National Eye Institute–Refractive Error Quality of Life instrument; NEI VFQ-25 = National Eye Institute Vision Functioning Questionnaire; NS = no significant pairwise comparisons; PCS = Physical Component Score; SF-36 = Medical Outcomes Study 36-item short-form health survey.
Adjusted for age, gender, income, education, race/ethnicity, and work status.
*Sample sizes for these rows are less than the others because only a subset of participants were administered these instruments.
†$P < 0.01$.
‡$P < 0.05$.

than 10% of the group between 40 and 50; half of each group was to have a low income; and at least 40% of the participants were to be female and at least 40% male. No more than 70% of the population was to be white. In the myopia group, 30% were to have a spherical equivalent of <3 diopters (D) and 30% a spherical equivalent of >6 D. In the hyperopia group, 50% were to have ≥2.5 D of spherical equivalent correction. A central coordinating center monitored enrollment progress and adherence to the recruitment guidelines. Sample size estimates for each subgroup were based upon the experience with the development of a previous vision-targeted HRQOL instrument.[2]

Survey and Clinical Measurements

All study participants (n = 1154) self-administered the 42-item NEI-RQL. The NEI-RQL was constructed based on focus groups with 414 persons with myopia or hyperopia[18] and a pilot test of 94 items with 221 individuals with refractive error, corrected with any modality. The NEI-RQL assesses the content deemed important by focus group participants: clarity of vision (4 items), expectations (2 items), near vision (4 items), far vision (5 items), diurnal fluctuations (2 items), activity limitations (4 items), glare (2 items), symptoms (7 items), dependence on correction (4 items), worry (2 items), suboptimal correction (2 items), appearance (3 items), and satisfaction with correction (1 item).

A random subset of 278 nonsurgical participants completed the NEI-RQL a second time from 7 to 30 days later (mean = 16). In addition, a random subset of participants (n = 286) completed both the NEI VFQ-25 and the Medical Outcomes Study 36-item short-form health survey (SF-36).[19] Because of the large correlations among NEI VFQ-25 subscales, we analyze the NEI VFQ-25 summary score here. In addition, we analyzed the 2 major underling components of the SF-36, the physical component score and the mental component score.

Subjects were interviewed with regard to their present and past use of glasses, contacts, and refractive surgery. Corrected near and distance visual acuities (monocular and binocular) were measured using Early Treatment Diabetic Retinopathy Study charts. Refractive error was measured from the subjects' spectacles or contact lenses, or as the preoperative refractive error in individuals who had undergone refractive surgery. Spherical equivalent was calculated by adding the spherical error and 50% of the cylindrical error.

Psychometric Evaluation of the NEI-RQL

The NEI-RQL includes 12 multi-item scales that are constructed using simple summated scoring, and a single-item measure of satisfaction with correction. The questions that comprise each scale and the response options are provided in Table 1. All items are scored so that a higher score represents better health. We estimated internal consistency reliability[20] and item discrimination (the extent to which items correlate most highly with the scale they are designed to measure) by comparing item–scale correlations for hypothesized scales.[21] After confirmation of hypothesized item placement within scales (correlations of item with the hypothesized NEI-RQL scale exceeded correlations of items with other NEI-RQL scales), we averaged items not missing within the same scale together and transformed the average linearly to a 0 to 100 possible range.

Mean scores, standard deviations, and test–retest intraclass correlations were then examined for the NEI-RQL scales. In addition, we estimated construct validity by examining the sensitivity of NEI-RQL scales to the method of refractive correction and compared this with the sensitivity of both the Physical Component Score and the Mental Component Score of the SF-36,[22] as well as the NEI VFQ-25 summary score, using between-group *F* statistics (adjusting for age, gender, income, education, race/ethnicity, and work status) and pairwise comparisons.[23] We investigated the extent to which the NEI-RQL scales account for unique variance in

Table 6. Health-Related Quality of Life Scores (Standard Errors) by Type of Correction

Scale	(1) No Correction (n = 110)	(2) Post-surgery—No Correction (n = 124)	(3) Glasses (n = 482)	(4) Multifocal Glasses (n = 172)	(5) Contacts (n = 253)	Comparisons	*F* Ratio	*P*
SF-36 PCS*	51.42 (1.54)	53.36 (1.24)	53.23 (0.58)	52.79 (0.99)	53.16 (0.88)	NS	0.34	0.8510
SF-36 MCS*	53.99 (1.47)	53.74 (1.19)	53.43 (0.56)	54.42 (0.94)	54.81 (0.84)	NS	0.57	0.6829
NEI VFQ-25*	96.03 (1.79)	95.26 (1.44)	92.45 (0.68)	90.62 (1.15)	91.80 (1.02)	4<1†; 5<1†; 4<2†; 5<2†	2.59	0.0370
NEI-RQL								
Clarity of vision	91.83 (1.76)	86.78 (1.64)	82.64 (0.83)	82.06 (1.53)	80.66 (1.16)	2<1†; 3<1‡; 4<1‡; 5<1‡; 3<2†; 4<2†; 5<2‡	8.78	<0.0001
Expectations	77.46 (3.35)	74.16 (3.13)	36.30 (1.58)	36.77 (2.92)	31.96 (2.22)	3<1‡; 4<1‡; 5<1‡; 3<2‡; 4<2‡; 5<2‡	64.51	<0.0001
Near vision	90.53 (1.66)	88.86 (1.56)	81.97 (0.78)	82.43 (1.45)	84.08 (1.10)	3<1‡; 4<1‡; 5<1‡; 3<2‡; 4<2‡; 5<2†	8.24	<0.0001
Far vision	91.27 (1.50)	86.47 (1.40)	81.82 (0.70)	78.90 (1.30)	84.68 (0.99)	2<1†; 3<1‡; 4<1‡; 5<1‡; 3<2‡; 4<2‡; 3<5†; 4<5‡	12.19	<0.0001
Diurnal fluctuations	84.91 (2.22)	76.65 (2.08)	73.99 (1.04)	76.16 (1.93)	69.76 (1.47)	2<1‡; 3<1‡; 4<1‡; 5<1‡; 5<2‡; 5<3†; 5<4†	8.74	<0.0001
Activity limitations	96.18 (2.04)	98.53 (1.90)	81.34 (0.96)	80.22 (1.77)	84.72 (1.35)	3<1‡; 4<1‡; 5<1‡; 3<2‡; 4<2‡; 5<2‡; 3<5†	25.42	<0.0001
Glare	90.98 (2.54)	67.27 (2.37)	75.97 (1.19)	75.28 (2.21)	75.71 (1.68)	2<1‡; 3<1‡; 4<1‡; 5<1‡; 2<3‡; 2<4†; 2<5‡	11.93	<0.0001
Symptoms	85.72 (1.60)	84.30 (1.50)	78.86 (0.75)	75.17 (1.40)	77.49 (1.06)	3<1‡; 4<1‡; 5<1‡; 3<2‡; 4<2‡; 5<2‡; 4<3†	9.84	<0.0001
Dependence on correction	80.53 (2.46)	84.80 (2.30)	32.07 (1.16)	28.76 (2.14)	33.30 (1.63)	3<1‡; 4<1‡; 5<1‡; 3<2‡; 4<2‡; 5<2‡	185.48	<0.0001
Worry	77.78 (2.48)	66.28 (2.32)	58.94 (1.17)	57.23 (2.16)	59.78 (1.64)	2<1‡; 3<1‡; 4<1‡; 5<1‡; 3<2‡; 4<2‡; 5<2†	14.29	<0.0001
Suboptimal correction	99.38 (1.70)	100.00 (1.59)	90.31 (0.79)	91.76 (1.51)	91.14 (1.10)	3<1‡; 4<1‡; 5<1‡; 3<2‡; 4<2‡; 5<2‡	12.46	<0.0001
Appearance	86.63 (2.54)	94.41 (2.33)	70.70 (1.17)	73.64 (2.17)	89.11 (1.65)	1<2†; 3<1‡; 4<1‡; 3<2‡; 4<2‡; 3<5‡; 4<5‡	35.08	<0.0001
Satisfaction with correction	89.23 (2.13)	87.03 (1.97)	71.24 (0.99)	70.74 (1.82)	72.95 (1.39)	3<1‡; 4<1‡; 5<1‡; 3<2‡; 4<2‡; 5<2‡	26.16	<0.0001

MCS = Mental Component Score; NEI-RQL = National Eye Institute–Refractive Error Quality of Life instrument; NEI VFQ-25 = National Eye Institute Vision Functioning Questionnaire; NS = no significant pairwise comparisons; PCS = Physical Component Score; SF-36 = Medical Outcomes Study 36-item short-form health survey.
Group 1 represents those not needing surgery, group 2 those already having surgery, and groups 3–5 potential surgical candidates.
Adjusted for age, gender, income, education, race/ethnicity, and work status.
*Sample sizes for these rows are less than the others because only a subset of participants were administered these instruments.
†$P<0.05$.
‡$P<0.01$.

satisfaction with correction, controlling for the SF-36 and NEI VFQ-25 scores. We regressed the NEI-RQL satisfaction with correction item on the SF-36 and NEI VFQ-25 initially. Then we allowed any NEI-RQL scales to be entered stepwise into the model that accounted for significant unique variance in satisfaction with correction beyond that explained by the SF-36 and NEI VFQ-25. Finally, we examined associations between NEI-RQL scales and the spherical equivalent refractive error of both better and worse eyes using *F* statistics and pairwise comparisons, as above. Adjustment of standard errors for clustering at the site level yielded results similar to those based on assuming simple random sampling. Therefore, only the latter results are presented here. We also conducted analyses excluding individuals with monovision and found results similar to those for the overall sample (not reported here).

Results

Sample Characteristics

Of the 1161 persons who agreed to be evaluated for eligibility and were eligible (226 from University of Alabama at Birmingham, 203 from University of California, San Francisco; 226 from Henry Ford Health System, Detroit, 262 from University of Texas Southwestern Medical Center, Dallas; 21 from Naval Medical Center, San Diego; and 223 from Case Western Reserve University, Cleveland), 7 refused to participate.

The 1154 study participants included 114 emmetropes, 375 hyperopes, and 665 myopes. The average age of the study sample was 44; 61% were female; 69% were white, 16% black, 9% Asian, 4% Hispanic, and 2% other races or ethnicities. The study population was very educated—87% had completed at least some college courses. Forty-nine percent reported earning above $50,000 per year, and 76% were working full-time. The distribution of myopia was 42% with <3.0 D and 13% with >6.0 D in the better eye. Among hyperopia cases, 72% had <2.5 D in the better eye.

Demographic information by refractive error subgroup is provided in Table 2. Hyperopes tended to be older and less likely to work full-time. Emmetropes were less likely than hyperopes and myopes to be white, and reported a lower income. Myopes reported the highest level of educational attainment and income, and they were most likely to be working full-time. Table 3 provides the same demographic information by type of correction. Those with

Table 7. Health-Related Quality of Life Scores (Standard Errors) by Spherical Equivalent Refractive Error in the Better Eye

Scale	(1) Myopes −0.5 to Less than −3.0 (n = 120)	(2) Myopes −3.0 to −6.0 (n = 126)	(3) Myopes Less than −6.0 (n = 38)	(4) Hyperopes +0.5 to Less than +2.5 (n = 132)	(5) Hyperopes +2.5 or Greater (n = 52)	Comparisons	*F* Ratio	*P*
SF-36 PCS*	52.49 (1.41)	53.44 (1.45)	52.48 (1.98)	51.47 (1.17)	52.58 (1.69)	NS	0.27	0.8964
SF-36 MCS*	53.48 (1.41)	53.03 (1.45)	54.82 (1.98)	54.62 (1.17)	52.40 (1.69)	NS	0.49	0.7453
NEI VFQ-25	90.70 (2.00)	91.46 (2.05)	91.52 (2.81)	91.13 (1.65)	89.23 (2.47)	NS	0.15	0.9606
NEI-RQL								
Clarity of vision	82.62 (1.86)	82.21 (1.85)	83.23 (3.31)	79.00 (1.89)	77.23 (2.87)	NS	0.92	0.4525
Expectations	38.24 (3.17)	25.62 (3.15)	24.53 (5.63)	38.30 (3.22)	33.87 (4.89)	2<1†; 3<1‡; 2<4†; 3<4‡	3.21	0.0130
Near vision	82.59 (1.59)	83.22 (1.58)	85.43 (2.82)	81.18 (1.61)	81.15 (2.45)	NS	0.49	0.7458
Far vision	83.76 (1.47)	78.52 (1.46)	83.11 (2.61)	81.10 (1.49)	83.42 (2.27)	2<1†	2.02	0.0909
Diurnal fluctuations	76.18 (2.17)	75.58 (2.16)	74.88 (3.86)	73.30 (2.20)	68.21 (3.35)	NS	1.04	0.3867
Activity limitations	83.42 (2.18)	75.00 (2.16)	63.78 (3.87)	85.50 (2.21)	80.76 (3.36)	2<1†; 3<1†; 3<2‡; 2<4†; 3<4†; 3<5†	7.48	<0.0001
Glare	81.17 (2.38)	70.93 (2.36)	74.53 (4.22)	78.66 (2.41)	77.71 (3.66)	2<1†; 2<4‡	2.67	0.0318
Symptoms	81.46 (1.57)	77.51 (1.56)	75.81 (2.79)	78.66 (1.60)	79.06 (2.43)	NS	1.22	0.3032
Dependence/correction	34.75 (2.34)	21.57 (2.32)	17.00 (4.16)	27.12 (2.37)	15.08 (3.61)	2<1†; 3<1†; 4<1‡; 5<1†; 3<4‡; 5<4†	8.23	<0.0001
Worry	63.55 (2.42)	56.32 (2.40)	44.92 (4.29)	58.73 (2.45)	55.41 (3.73)	2<1‡; 3<1†; 3<2‡; 3<4‡	4.02	0.0033
Suboptimal correction	91.00 (1.82)	86.94 (1.81)	92.23 (3.21)	92.40 (1.87)	93.11 (2.83)	2<4‡	1.44	0.2204
Appearance	75.06 (2.71)	70.94 (2.69)	69.51 (4.81)	70.77 (2.75)	76.67 (4.18)	NS	0.78	0.5357
Satisfaction/correction	71.30 (2.18)	65.50 (2.16)	67.78 (3.87)	72.43 (2.21)	73.67 (3.39)	2<4‡; 2<5‡	1.68	0.1536

MCS = Mental Component Score; NEI-RQL = National Eye Institute–Refractive Error Quality of Life instrument; NEI VFQ-25 = National Eye Institute Vision Functioning Questionnaire; NS = no significant pairwise comparisons; PCS = Physical Component Score; SF-36 = Medical Outcomes Study 36-item short-form health survey.
Adjusted for age, gender, income, education, race/ethnicity, and work status.
*Sample sizes for these rows are less than the others because only a subset of participants were administered these instruments.
†$P<0.01$.
‡$P<0.05$.

multifocal glasses tended to be older than the other subgroups. The postsurgery group had more white and higher socioeconomic status (education and income) participants than the other subgroups.

Descriptive Statistics and Reliability of the NEI-RQL Scales

Table 4 provides mean scores, standard deviations, percentage of participants scoring 100 (the ceiling), percentage scoring 0 (the floor), and reliability estimates for the NEI-RQL scales. Floor effects were generally not large, but 35% of the sample had the lowest possible score for the expectations scale and 29% for the dependence on correction scale. Ceiling effects were more common, with a range from 9% (worry) to 82% (suboptimal correction) having the highest possible score.

Internal consistency reliability exceeded 0.70 for 10 of the 12 multi-item scales; reliability was 0.64 for the suboptimal correction scale and 0.66 for the appearance scale. Test–retest intraclass coefficients ranged from 0.55 to 0.83. Test–retest coefficients provide a conservative estimate of reliability because of possible changes in HRQOL that may have occurred during the 7- to 30-day retest time interval.[23] These estimates range from *moderate* to *almost perfect,* according to guidelines given by Landis and Koch for the κ statistic, which is equivalent to the intraclass correlation under certain conditions.[23,24] Item discrimination across scales was supported, with 99% of item–scale correlations for hypothesized scales exceeding correlations with other scales.

Table 5 presents mean scores for the SF-36, NEI VFQ-25, and NEI-RQL scales, depending on whether the participant was in the myope, hyperope, or emmetrope subgroup, adjusted for age, gender, education, race/ethnicity, and work status. We hypothesized that these 3 clinical subgroups should differ in HRQOL and that an optimal measure would be sensitive to these differences. There were no differences between groups on the SF-36. Emmetropes scored higher than hyperopes on the NEI VFQ-25, but the difference was not large; myopes did not score significantly differently than emmetropes. However, emmetropes scored significantly better than hyperopes on each of the 13 NEI-RQL scales and better than myopes on 12 of the scales. The dependence on correction scale was the most sensitive to differences between groups, with a between-group *F* statistic of 96.30. Hyperopes scored 58 points worse (>1.5 standard deviations below) than emmetropes on the 0 to 100 possible score range. The differences between groups on the appearance scale were the smallest, with emmetropes significantly different from hyperopes ($P < 0.05$) but not myopes. Hyperopes scored significantly worse than myopes on 4 of the 13 NEI-RQL scales: near vision, far vision, diurnal fluctuations, and dependence on correction.

Table 6 provides HRQOL scores for 5 refractive error correction subgroups (no correction; postsurgery—no correction; glasses; multifocal glasses; contact lenses) adjusted for age, gender, education, race/ethnicity, and work status. Group 1 represents those not needing surgery, group 2 those already having surgery, and groups 3 to 5 potential surgical candidates. Again, we hypothesized that different types of correction should have varying signatures of HRQOL. These subgroups did not differ significantly on the SF-36. However, significant differences were found on the NEI VFQ-25 and for each of the 13 NEI-RQL scales. The biggest differences between groups were observed for the dependence on correction and expectation scales. Those with no correction scored much better than those wearing glasses or contact lenses. Persons

Table 8. Health-Related Quality of Life Scores (Standard Errors) by Spherical Equivalent Refractive Error in the Worse Eye

Scale	(1) Myopes −0.5 to Less than −3.0 (n = 90)	(2) Myopes −3.0 to −6.0 (n = 131)	(3) Myopes Less than −6.0 (n = 63)	(4) Hyperopes +0.5 to Less than +2.5 (n = 114)	(5) Hyperopes +2.5 or Greater (n = 70)	Comparisons	*F* Ratio	*P*
SF-36 PCS*	54.61 (1.68)	51.19 (1.39)	53.49 (1.61)	51.55 (1.18)	52.03 (1.57)	NS	0.84	0.5054
SF-36 MCS*	54.36 (1.68)	52.60 (1.40)	54.33 (1.62)	54.77 (1.19)	52.19 (1.58)	NS	0.76	0.5525
NEI VFQ-25	90.34 (2.39)	91.69 (1.98)	91.33 (2.29)	91.70 (1.69)	88.38 (2.30)	NS	0.45	0.7749
NEI-RQL								
Clarity of vision	83.94 (2.16)	82.02 (1.80)	81.36 (2.59)	80.22 (2.03)	75.92 (2.47)	5<1†	1.51	0.1987
Expectations	40.37 (3.69)	27.72 (3.06)	23.80 (4.41)	38.10 (3.46)	35.17 (4.21)	2<1‡; 3<1‡; 2<4†; 3<4†	3.31	0.0110
Near vision	82.51 (1.84)	82.41 (1.53)	86.08 (2.20)	81.44 (1.73)	80.70 (2.11)	NS	0.86	0.4873
Far vision	84.54 (1.71)	78.57 (1.42)	82.81 (2.04)	81.25 (1.60)	82.37 (1.95)	2<1‡	2.10	0.0804
Diurnal fluctuations	78.23 (2.52)	73.86 (2.09)	75.94 (3.01)	74.56 (2.36)	67.63 (2.88)	5<1‡	2.00	0.0931
Activity limitations	83.97 (2.56)	75.92 (2.12)	69.73 (3.05)	86.10 (2.40)	80.86 (2.92)	2<1†; 1<3‡; 2<4‡; 3<4‡; 3<5†	5.59	0.0002
Glare	80.77 (2.78)	73.20 (2.31)	74.15 (3.32)	78.97 (2.61)	77.21 (3.17)	2<1†	1.44	0.2203
Symptoms	81.93 (1.83)	77.97 (1.52)	76.78 (2.19)	79.98 (1.72)	76.83 (2.09)	NS	1.43	0.2234
Dependence/correction	36.13 (2.75)	23.26 (2.28)	19.86 (3.28)	26.64 (2.58)	18.75 (3.14)	2<1‡; 3<1‡; 4<1†; 5<1‡; 5<4†	6.13	<0.0001
Worry	63.28 (2.82)	57.73 (2.34)	50.35 (3.37)	61.38 (2.64)	52.02 (3.22)	3<1‡; 5<1†; 3<4†; 5<4†	3.63	0.0063
Suboptimal correction	91.87 (2.13)	86.88 (1.75)	91.21 (2.53)	92.81 (1.99)	92.12 (2.46)	2 < 4†	1.57	0.1806
Appearance	76.17 (3.16)	70.33 (2.62)	72.02 (3.77)	70.71 (2.96)	74.96 (3.60)	NS	0.75	0.5600
Satisfaction/correction	73.06 (2.52)	64.28 (2.09)	69.81 (3.01)	74.34 (2.37)	70.10 (2.89)	2<1‡; 2<4‡	3.04	0.0171

MCS = Mental Component Score; NEI-RQL = National Eye Institute–Refractive Error Quality of Life instrument; NEI VFQ-25 = National Eye Institute Vision Functioning Questionnaire; NS = no significant pairwise comparisons; PCS = Physical Component Score; SF-36 = Medical Outcomes Study 36-item short-form health survey.
Adjusted for age, gender, income, education, race/ethnicity, and work status.
*Sample sizes for these rows are less than the others because only a subset of participants were administered these instruments.
†$P<0.05$.
‡$P<0.01$.

with no correction postsurgery scored significantly better than those with glasses or contacts on 8 of the 13 NEI-RQL scales, but scored worse on the glare scale.

Results of the regression of the satisfaction with correction item on the SF-36, NEI VFQ-25, and NEI-RQL multi-item scales show that the NEI-RQL scales (significant unique associations were obtained for clarity of vision, expectations, near vision, activity limitations, and appearance) explained 29% variance in satisfaction with correction beyond that explained by the SF-36 and NEI VFQ-25. This indicates that the NEI-RQL contains a noteworthy degree of information about satisfaction with correction that is not reflected in a generic measure and an eye disease–targeted measure.

The SF-36 and NEI VFQ-25 were not significantly associated with the degree of spherical equivalent refractive error for either the better or the worse eye (Tables 7, 8). In contrast, there were significant associations with refractive error in both better and worse eyes for all of the NEI-RQL scales. Refractive error for myopes tended to be associated with worse HRQOL for several domains. For hyperopes, refractive error was related to more dependence on correction.

Discussion

There are multiple criteria by which the success of correcting refractive error can be indexed. The most commonly cited metric in the clinical literature is Snellen visual acuity. In addition, the magnitude of residual refractive error is used as a measure of efficacy and precision of the correction technique. The use of this information alone, however, fails to distinguish accurately those patients with successful outcomes from those who have limitations in day-to-day functioning and negatively impacted well-being. Some patients with seemingly good outcomes as measured with visual acuity are very dissatisfied with their refractive correction, and may encounter difficulty with a number of tasks, such as driving, reading, or seeing clearly.[25] Adequate assessment of functioning and well-being is essential in evaluating procedures designed to correct refractive error.

The results of this study provide support for the reliability and validity of the NEI-RQL. We found that NEI-RQL scores were associated with having refractive error (myopia and hyperopia) versus not (emmetrope), as well as related to method of correction (with spectacles, contact lenses, and surgery) and the degree of corrected refractive error. The finding that hyperopes scored worse than myopes on near vision, far vision, diurnal fluctuations, and dependence on correction is consistent with the observation that hyperopes suffer at both distance and near without correction, whereas uncorrected myopes tend to have good focus for near vision tasks. In addition, the NEI-RQL accounted for a substantial amount of variation in satisfaction with correction beyond that explained by either a leading generic measure or a measure of HRQOL designed for persons with eye disease, the NEI VFQ-25.

Because patients who were particularly pleased or displeased with their form of correction may have been more likely to participate in this study than other patients, the results reported here may be somewhat biased and not generalized to all patients. It is also possible that treating physicians preferentially encouraged satisfied patients to

participate in the study. In addition, only patients with 20/30 or better visual acuity in their worse eye were included. Patients undergoing surgery are not representative of persons with refractive error. This study is also limited by the cross-sectional design. Hence, this study does not provide a basis for evaluating whether patients are satisfied with refractive surgery or other forms of correction. Nonetheless, the results of this study provide encouraging preliminary support for the reliability and validity of the NEI-RQL.

Another measure of vision-targeted functioning and well-being, the Refractive Status and Vision Profile (RSVP), was recently developed.[26,27] This measure includes 8 scales and 42 items. In their study of 550 patients with refractive error, Vitale et al[26] found initial support for the reliability and validity of the measure. The RSVP scales were more strongly associated with reports of satisfaction with vision than were visual acuity or refractive error. Interestingly, the authors speculated, correctly, that the concerns of people with refractive error might not be reflected adequately in instruments such as the NEI VFQ. However, they did not include the NEI VFQ or a generic HRQOL instrument in their study. Thus, the relationship between the RSVP and other HRQOL measures is unknown.

Additional testing will be needed to demonstrate the range of applications of the NEI-RQL. NEI-RQL scores were largely independent of visual acuity over the limited range of acuities included in this study. Further research is needed to evaluate these relationships in a wider range of visual acuities. Because it provides information that may not be captured by visual acuity and existing clinical tests, the NEI-RQL has potential value in examining the impact of new devices, such as multifocal intraocular lenses and contact lenses, and phakic intraocular lenses, on HRQOL. A recent study of 50 contact lens wearers found no differences in RSVP scores related to wearing daily disposable versus disposable extended-wear contact lenses.[28] Because of the conceptual similarity between the NEI-RQL and the RSVP, it will be important for future studies to include head-to-head comparisons of these 2 instruments.

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