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# Development of the National Eye Institute Refractive Error Correction Quality of Life Questionnaire

## Focus Groups

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for the NEI-RQL Focus Group Investigators

**Objective:** To identify the content area for a questionnaire designed to measure the vision-targeted, health-related quality of life for persons with well-corrected refractive error.

**Design:** Cross-sectional study.

**Participants:** Fifty-two focus groups were conducted with 414 patients from 5 geographically diverse ophthalmic and optometric sites to identify the content area of a questionnaire for use among persons with myopia and hyperopia.

**Methods:** A standard protocol was used to structure each focus group discussion, and groups were led by centrally trained moderators at each participating site. Results were summarized and analyzed using a standard set of codes. Qualitative and quantitative analyses were conducted.

**Main Outcome Measure:** Self-reported observations or comments about vision, vision correction, and other aspects of quality of life.

**Results:** Among the 414 participants, 9262 mentions of comments were recorded. The most frequent comments reported by participants were about types of vision correction, followed by comments with their own vision and vision-related symptoms. The distribution of comments by topic domain was generally similar across types of correction and type of refractive error. The most frequent specific comments about glasses concerned problems with reading, adjustment between near and far vision, and appearance. The most frequent comments about contact lenses included those on symptoms such as dry eyes, itching and tired eyes, and headaches, and negative comments about ease of use. The most frequent comments among patients with surgical correction concerned fewer driving problems; fewer symptoms; and improvement in vision, recreation, and comfort. Participants provided equal numbers of positive and negative comments about glasses. Twice as many positive as negative comments were given by contact lens wearers, and 4 times as many positive comments were provided by patients who had undergone surgical correction.

**Conclusions:** Using focus groups, we were able to identify content areas and aspects of visual functioning in persons with refractive error that are not measured by standard visual acuity testing in the clinic or by other vision-targeted, health-related quality of life instruments such as the 25- or 51-item National Eye Institute-Visual Functioning Questionnaire. The similarity of problems mentioned across refractive error type and correction method suggests it will be possible to develop a single questionnaire with adequate content validity to compare the impact of different modes of correction in vision-targeted, health-related quality of life. *Ophthalmology* 2003; 110:2285-2291 © 2003 by the American Academy of Ophthalmology.

Refractive error affects about 60% of the American population and is the most common problem resulting in visits to eye care professionals.<sup>1-3</sup> Refractive error is usually cor-

rected very well with glasses or contact lenses. However, keratorefractive surgery, in which the corneal curvature is surgically altered in an attempt to eliminate refractive error,

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has gained increasing popularity and viability as an alternative to spectacles and contact lenses during the past decade. Industry estimates were that over 1 million keratorefractive procedures were performed in 2001. These procedures have been carefully studied in multicenter trials, including the National Eye Institute (NEI)-sponsored Prospective Evaluation of Radial Keratotomy Study<sup>4</sup> and the Food and Drug Administration-authorized trials of excimer laser photorefractive keratectomy and LASIK.

Despite the large volume of surgery and the prior studies, there has been no validated patient-centered instrument used in these clinical trials to assess the effects of refractive error on vision-targeted quality of life and functioning. Standard performance-based clinical measures of vision such as Snellen acuity or formal visual field testing often fail to capture important aspects of vision; visual functioning; visual ability or disability; and vision-targeted, health-related quality of life as experienced by patients.<sup>5-18</sup> Recognition of these limitations was the impetus behind the creation of the NEI-Visual Functioning Questionnaire (NEI-VFQ).<sup>19-21</sup> The NEI-VFQ is designed to capture the influences of chronic eye diseases that are the major causes of blindness in the United States on health-related quality of life. Results from the NEI-VFQ field test demonstrate that this measure captures visual disability from macular degeneration, diabetic retinopathy, glaucoma, cataract, and cytomegalovirus retinitis.<sup>20</sup> Because of the nature of uncorrected refractive error and because of the differences in the quality of vision related to the various treatment options for correction, a survey that is specifically targeted toward measuring these more subtle aspects of visual function and its correction, and that is not limited to assessing patient satisfaction with corrective surgery, is needed.

Initial field tests with the NEI-VFQ and other functional status instruments such as the Activities of Daily Vision Scale<sup>16</sup> and VF-14<sup>12</sup> were not designed to test whether it is possible to distinguish individuals with corrected refractive error from those emmetropic individuals with normal vision without correction, because most patients without ophthalmic abnormalities, other than the need for correction, score near the ceiling of these questionnaires' domains. In addition, there is no evidence that these instruments can differentiate the effects of the different techniques for the correction of refractive error. The results of the Prospective Evaluation of Radial Keratotomy study suggest that dimensions of significance (both favorable and adverse) to patients undergoing radial keratotomy surgery include changes in symptoms, vision and functioning under specific environmental conditions, and issues of appearance, convenience, and utility.<sup>22-24</sup> To better capture the effects of current and proposed therapeutic regimens on refractive error, especially surgical ones, the NEI Refractive Error Correction Quality of Life (NEI-RQL) questionnaire development study was initiated. Its purpose is to develop and test an instrument that more appropriately and effectively captures the more subtle aspects of functioning associated with refractive error and its correction in patients with corrected vision of 20/30 or better from the patients' perspective.

The development of the NEI-RQL questionnaire began

with the content identification phase, in which focus groups were conducted to identify constructs that were described by patients as important aspects of vision-targeted functioning. These patients had received a variety of corrections for refractive error. These data were coded and analyzed and the results were used, along with the review of existing instruments, as the basis for development of a draft questionnaire to be pilot and field tested. In particular, the results were used to highlight the differences in experiences and functioning for patients with different types of refractive error and correction methods. A strength of the focus group method is that the constructs and language for the survey are derived from patients with refractive error. This source of information should be a valuable addition to clinical judgment and perceptions of researchers. A subsequent paper will describe the reliability and validity of the NEI-RQL questionnaire.

## Participants and Methods

### Participating Centers

Clinical sites for focus groups and pilot testing were selected in 1997 to insure geographic diversity, participation by both ophthalmologists and optometrists, and ability to recruit patients who met the eligibility criteria. The NEI-RQL focus groups were conducted at the ophthalmic or optometric practices of 5 academic medical centers, including The University of Alabama, Birmingham; The Massachusetts Eye and Ear Infirmary, Boston; The University of Illinois, Chicago; University of California, San Francisco; and University of Southern California, Los Angeles.

### Study Population

An independent Coordinating Center assigned each participating site a list of focus groups to complete in order to obtain focus groups from multiple sites for each refractive error, correction method, and age category. In 1998, clinical center staff identified potential eligible participants for the assigned focus group characteristics via chart reviews and advertisements and invited all eligible persons who were at least 18 years old to participate in focus groups until recruitment objectives were met. Eligibility was determined in relation to a sampling plan developed to ensure that the patients represented the diversity found in an adult population with refractive error. All participants were required to have visual acuity of 20/30 or better for near or far vision in their worse eye using correction or after corrective surgery. Each focus group was constructed so that all members had the same type of refractive error. Exclusion criteria included the presence of other ocular diseases or chronic conditions such as keratoconjunctivitis sicca. Participants were required to have been using their current method of correction for at least the 3 months before participation, and persons in a transitional state of presbyopia (i.e., participants between the ages of 40 and 50) were limited to no more than 10% of the sample population. Participants with English as a second language were included, provided they were fluent in English, as determined by the subjective assessment of the staff member who talked with the prospective participant by telephone about taking part in the group. The staff attempted to have approximately equal male and female representation, to have a range of racial groups and occupations, to include a broad range of ages, and to have persons from both low and high income groups. As shown in Table 1, the sample was recruited according to the following group types:

Table 1. Summary of Number of Focus Groups Conducted and Participants Included

Correction Method	Socioeconomic Status	Myope				Hyperope*			
		≤45 Years Old		>45 Years Old		≤45 Years Old		>45 Years Old	
		Focus Groups	Participants	Focus Groups	Participants	Focus Groups	Participants	Focus Groups	Participants
Glasses/contacts	High	4	31	5	39	3	20	5	37
Glasses/contacts	Low	4	39	3	31	3	25	3	30
Surgery	High	4	26	4	27			2	15
Mixed	High	4	35	5	41			3	18

\*The prevalence of surgical correction for hyperopia in participants ≤45 years old was considered too sparse for inclusion in this study.

- myopia versus hyperopia;
- age under versus over 45 years;
- glasses and/or contacts versus surgery as method of correction; and
- high versus low socioeconomic status (within glasses/contacts groups only).

The target sample size in each focus group was 8 to 10 participants, and the target number of focus groups within each category was ≥2, with a limit of 5. This sampling plan was chosen to provide an across-center range of experiences within logistical constraints. The background information about each participant was captured in a brief questionnaire that was analyzed along with the focus group results. Focus group participants were paid \$25 to \$50 for their participation, depending on standard practice at each location. The study protocol was approved or granted exemption by the institutional review board at each of the participating institutions, and written documentation of informed consent was obtained before each of the focus groups was conducted.

### Data Collection

RAND provided central and on-site demonstrations of moderating techniques and trained staff at each site to be moderators. All moderators were provided with a focus group script, so that the prompts and content areas suggested were uniform across the groups. However, to ensure a relaxed and reasonably natural discussion, moderators were allowed to alter the order of topics to follow the interests of each group. Moderators asked each participant to identify him or herself at the beginning of the session to provide a clear association between voice and identity. Moderators were trained to solicit participation from each group member and to balance the amount of participation across group members during sessions. Each focus group was audiotaped and lasted from 1 to 2 hours. The audiotapes were transcribed on site, and each participant was assigned a unique number that identified him or her on both the focus group transcripts and on a clinical and demographic questionnaire used to determine eligibility. Transcribers were instructed only to associate a comment with an individual when there was clear voice recognition. Because the groups included males and females with diverse characteristics, voice recognition was not difficult. Transcripts and the clinical and demographic questionnaires were submitted to RAND for data entry and analysis.

### Topics Covered in the Focus Groups

A review of the findings of initial focus groups from private industry, the results from the Prospective Evaluation of Radial Keratotomy study and NEI-VFQ field test, and initial interviews

conducted by investigators with patients with myopia who have chosen a variety of corrective techniques provided the initial material for a draft NEI-RQL focus group protocol. The goals of the protocol were to identify the problems with vision; visual functioning; vision-targeted, health-related quality of life; and other problems or symptoms related to refractive error and the techniques for the correction of refractive error. Focus group methods were employed in this study to assure that each of the major content areas of interest were described in the words that patients use. Additionally, the focus groups were designed to determine how problems vary across different demographic, socioeconomic, or geographic strata and to determine how problems vary across refractive error correction methods (i.e., glasses, contact lenses, and surgery). The focus group script was tested with one group of myopes and one of hyperopes (both including presbyopes and those without presbyopic overlay) at the University of Southern California in Los Angeles. The protocol included the following general and specific domains as topics: reading, driving, general vision, adjustment to change, occupation, recreation, vision correction method, general well-being, expectations about future vision, and other comments. Participants were asked first to describe characteristics they associate with their eyes or vision. They then provided answers to open-ended questions about what aspects of their life were most affected by their vision and their vision correction method, and were asked specific questions about how vision affected their day-to-day activities. They also provided their predictions about their visual functioning in the future. Table 2 is an abbreviated version of the focus group script.

Table 2. Refractive Error Focus Groups Topic Listing

Welcome, informed consent, introductions
Introduction of topic of the group
Exercise 1: First thoughts about vision, discussion of initial thoughts about vision
Reading
Driving
General vision quality, adequacy of vision for conditions, symptoms
Adjustment to change in lighting, variation during day
Effects of vision on occupational choice, day-to-day job performance, and safety
Effects of vision on recreational choices, satisfaction with recreation, and safety
Vision correction satisfaction, ease of use
General well-being, appearance, perceptions of others, perceived vulnerability
Expectations about future vision
Additional comments about vision
Advice to others on choices about correction

## Content Analyses of Focus Group Data

A list of codes was developed to capture the detailed comments the participants provided about positive and negative aspects of their vision and vision correction in relation to their usual activities. Initial codes were developed using the focus group protocol and codes from phase I of the NEI-VFQ field test.<sup>19</sup> Additional codes were developed by classifying comments from a representative sample of focus groups conducted as part of this study. New code categories were added as required to capture participants' comments in detail. Participants were also classified by the type of correction they used, age, and type and severity of refractive error. Participants were classified as "surgery" if they had ever had any type of refractive surgery, including surgery for hyperopia in one eye. They were classified as "contact" or "glasses" based on their current (last 3 months) predominant correction. Age was grouped as  $\leq 45$  years versus  $>45$  years as a surrogate for presbyopic status. No more than 10% of the participants were between 40 and 50 years old. Two levels of hyperopia were defined ( $<2.5$  diopters (D) of correction versus  $\geq 2.5$  D of correction), and 3 levels of myopia were defined:  $<3$ D, 3 to 6 D, and  $>6$  D of correction.

The coding was carried out by 6 trained coders at RAND. A supervisor checked all coding and recoded a random sample of 25% of each coder's work to achieve a 95% inter-rater reliability. Each comment in a transcript was assigned a comment code and a code to identify the type of correction to which the patient was referring, based on the content of the discussion, and associated with the identification number of the individual to provide the link to the individual's characteristics. In a few instances (no more than 5%), comments could not be associated with individual identification numbers. In general, most comments were about problems experienced in connection with vision.

The problem codes were aggregated into general groups including difficulty with reading, difficulty with driving, symptoms, quality of vision, lighting, occupation, recreation, types of vision corrections, and comments about emotions related to vision. Some of the codes were categorized in more than one of the major domains, including reading, driving, and types of vision, such as near, far, depth perception, dark adaptation, contrast sensitivity, and glare.

Coded items were analyzed to determine the frequency of comments by domain and in relation to severity of refractive error and type of correction. The analyses suggested constructs that needed to be included in a measure of visual functioning for refractive error correction to capture fully the impact of refractive error and type of correction. Draft items were constructed using the participants' own wording when feasible and using response choices that coincided with the wording of participant perceptions. The items were then placed into a draft questionnaire for initial pilot testing.

## Results

### Study Population

Fifty-two focus groups were conducted from December 1997 through March 1998. Each focus group lasted from 1 to 2 hours. Table 1 provides a summary of the number of groups conducted and participants included in the analyses of focus groups, overall and by participating center. The focus groups consisted of a total of 414 participants, with a mean of 8 participants per group and a range of from 2 (one group only) to 15 participants. Two hundred forty-seven participants (60%) were myopes, 146 persons (35%) had hyperopia, and the remainder had a mixed type of vision problem. Overall, 140 myopes and 112 hyperopes wore glasses

and/or contacts, 53 myopes and 15 hyperopes had undergone refractive error correction surgery without need for further correction for distance or near, and 76 myopes and 18 hyperopes used a mixture of corrections (including use of glasses or contacts after surgery). Sixty-eight percent of the surgery participants had laser surgery, and 85% of all surgeries occurred in 1996 or later. All patients were required to have had surgery at least 3 months previously. Many of the participants had direct experience with several different types of correction. For example, 88% of the participants who were not currently wearing glasses had worn them in the past, and 45% not currently wearing contacts had worn them previously. In this convenience sample, 50% of the patients who had laser surgery were also using some other type of correction for reading or distance vision. For this reason, an individual's comments could cover multiple modes of correction. For example, if a person whose predominant form of correction was glasses made a comment regarding visual functioning while occasionally wearing contact lenses, then that comment was associated with contact lens use.

Clinical and demographic data were available for all of the participants. The majority of participants in the focus groups were female (60%), Caucasian (69%), and college educated (71%); had private insurance (63%); and were classified by clinical staff as being of high socioeconomic status (63%). Fifty-seven percent of the sample was over 45 years old. There were some differences in demographic characteristics across the sites, reflecting the racial and ethnic makeup of the local populations.

Snellen visual acuity for each eye with the habitual means of correction was obtained from the medical record for all participants. Seventy-six percent had visual acuity of 20/20 or better, and all but one person was corrected to 20/30 or better in the worse eye. Myopic participants had mixed severity levels of refractive error in the better eye, including 0.5 to 0.9 D (8%), 1 to 2.9 D (34%), 3 to 5.9 D (44%), and  $\geq 6$  D (14%). The severity levels of refractive error in the better eye of hyperopic participants ranged from 1 to 2.4 D (75%) to  $\geq 2.5$  D (24%). Astigmatism was present in 50% of the participants.

### Content from the Focus Groups

Initial concerns that participants whose refractive errors were considered well corrected would have little to talk about in the focus groups proved unfounded. Participants were readily able to discuss how their vision and the type of correction they used affected their daily activities, both positively and negatively. Among those who used each type of correction (glasses, contacts, surgery), there were people who felt positively and negatively.

Among the 414 participants, 9262 problems or comments were coded. The comments were first grouped by broad categories or domains for preliminary analysis. These broad categories included 89 comments that were counted in more than one category (e.g., comment about driving at dusk coded in both driving and lighting). As shown in Figure 1, the broad categories or domains were reading (7% of comments); driving (7%); symptoms, such as headaches, pain, dry eyes, etc. (15%); vision, including both general vision and specific aspects of vision, such as depth perception (15%); lighting (5%); occupation (3%); recreation (4%); corrections, including glasses, contacts, and surgery (38%); and emotions or feelings (5%). In general, the distribution of comments across these domains was similar across participants by type of correction (Fig 2) and vision problem (Fig 3).

The comments were then examined in terms of more specific categories, in which aspects of vision or function were separated and then classified into positive, negative, and neutral comments. Again, some comments were counted twice (e.g., driving and vision). Comments were grouped by type of correction referenced.

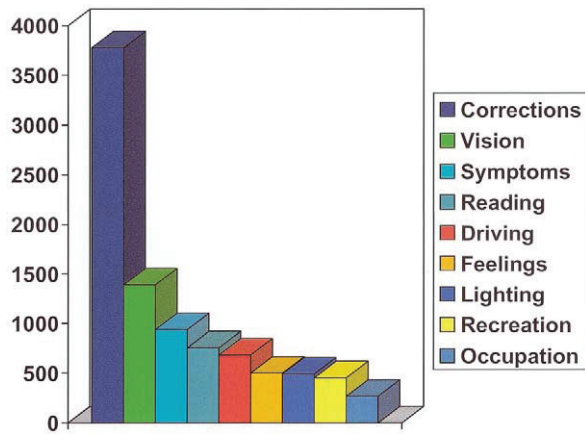


Figure 1. Distribution of comments across general categories.

Of these comments, 4769 comments referred to glasses, 2400 to contacts, and 2181 to surgical correction, and for 683 comments, coders were unable to determine type of correction. Naturally, because almost everyone had used glasses, there were more comments about glasses than about any other method of correction. Of the 4769 comments about glasses, there were approximately equal numbers of positive and negative comments. The most frequently mentioned domains about glasses are listed in Table 3. Of the 2400 comments about contact lenses, there were approximately 2 times as many positive comments about contact lenses as there were negative comments. The most frequent domains about contact lenses are shown in Table 4. Of the 2181 comments about surgery, about 4 times as many positive comments were made than negative comments. The most frequent comments about surgery are located in Table 5.

## Discussion

Although focus groups have been successfully used in the design of the NEI-VFQ, a vision-targeted quality of life

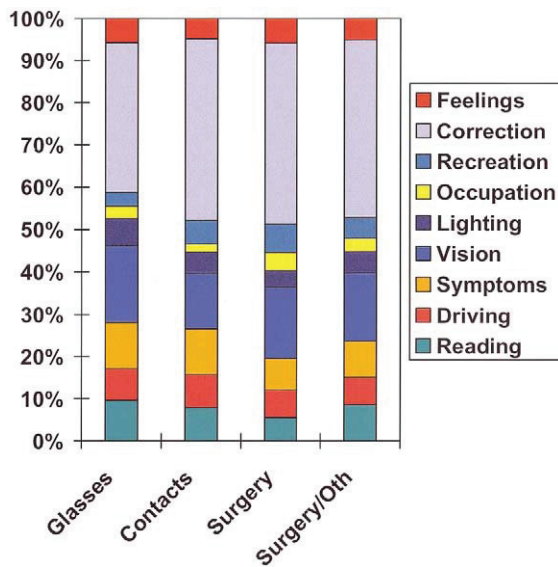


Figure 2. Distribution of comments across general topic categories by type of correction. Oth = other type of correction.

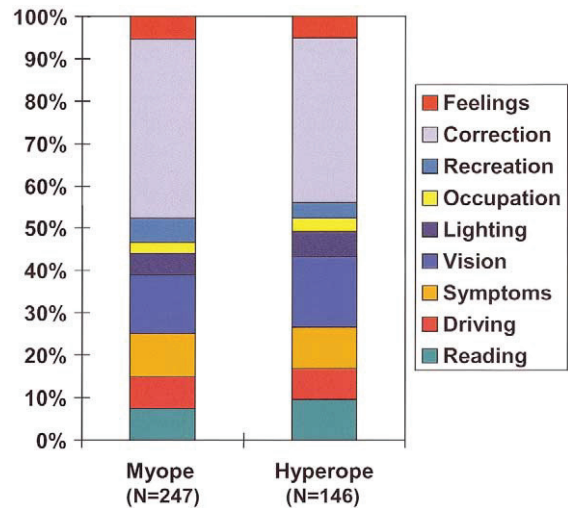


Figure 3. Distribution of comments across general type categories by vision condition of subject.

instrument<sup>16</sup> the study population consisted of individuals with severe ophthalmic pathologies characterized by loss of central acuity, visual field, or both. During planning of this study, it was unknown whether people with eyes corrected to excellent levels of visual acuity as measured by standard tools such as Snellen acuity would experience enough problems related to functioning of everyday life to warrant the development of a vision-targeted, health-related quality of life questionnaire. Moreover, we were uncertain whether a single questionnaire could be developed that would capture problems in functioning across the various correction modalities.

The results of these focus groups amply demonstrated that even when people are corrected to 20/30 or better they still experience a range of problems with vision and with the use of their correction. In this study, the domains that focus group participants described were sufficiently similar across correction modalities and types of refractive error that a single instrument of reasonable length is feasible. Moreover, they were sufficiently different from the domains of the NEI-VFQ that a separate instrument is warranted.

Current clinical tools for measuring visual function (e.g., visual acuity, visual field, dark adaptation) do not ade-

Table 3. Most Frequently Mentioned Domains about Glasses

Domain	N
Negative comments about appearance wearing glasses	310
Negative comments about comfort wearing glasses	286
Negative comments about ability to do activities requiring near vision, including reading	281
Negative comments about symptoms involving vision (e.g., floaters, starbursts, halos, blurring)	276
Negative comments about other symptoms (e.g., headache, pain, dry eyes, itching)	276
Negative comments about problems driving	240
Problems with adjusting between near and far vision	219
Negative comments about reading ability	176
Concerns that vision was getting worse	175

Table 4. Most Frequently Mentioned Domains about Contact Lenses

Domain	N
Negative comments about symptoms (e.g., floaters, starbursts, halos, blurring)	299
Negative comments about ease of use	113
Negative comments about problems with driving	101
Problems with symptoms involving vision	94
Positive comments about comfort wearing contacts	94
Negative problems about ability to do recreational activities	80
Negative comments about comfort wearing contacts	79
Positive comments about appearance	71
Concerns that vision was getting worse	67

quately differentiate patients whose only ophthalmic complaint is the need for refractive error correction. Identification of concerns for this population must come from other sources. The focus group methodology provides empirical information with regard to the type of language that patients use when describing their refractive error-related visual function. The item wordings and response choices for the questions in the NEI-RQL will be strongly influenced by the adjectives that participants used to describe their limitations or problems. The use of language derived from the target population should make it easier to develop questions that are meaningful and readily understood by future respondents.

Recently, another group has published an instrument, the development of which derived from focus group methods.<sup>25</sup> As stated in the publication, their “primary goal was to assess the properties of the [Refractive Status and Vision Profile questionnaire] in a population representative of those considering refractive surgery.” Although this study does not describe or discuss the specific results of the focus groups, both these results and ours suggest that an instrument can be developed to measure important aspects of vision-targeted quality of life.

Limitations of our study include that the population participating in the focus groups was not a probability sample and was derived from chart reviews and persons responding to advertisements. Although representing a range of vision problems and severity levels, focus group

Table 5. Most Frequently Mentioned Domains about Surgery

Domain	N
Positive comments about comfort of surgical correction	148
Positive comments about specific aspects of vision being improved	125
Negative comments about symptoms involving vision (e.g., floaters, starbursts, halos, blurring)	97
Positive comments about vision for recreational activities	89
Negative comments about comfort of surgical correction	88
Negative comments about other symptoms (e.g., headache, pain, dry eyes, itching)	81
Positive comments about general vision	81
Concerns that vision is getting worse	69
Negative comments about bright lights, glare	65
Negative comments about activities involving near vision, including reading	58
Positive comments about reading	57

Table 6. Constructs Selected for Inclusion in Draft Questionnaire

- Reading (as much or as long as desired; specific problems such as computers, small print)
- Driving at night
- Visual symptoms (starbursts, floaters, halos)
- Other symptoms (headaches, dry eyes, pain)
- Near vision activities
- Distance vision
- Depth perception
- Dark adaptation
- Glare, sensitivity to light
- Overall quality of vision
- Whether current correction is best possible correction
- Appearance
- Cost
- Vulnerability to injury
- Ease of use
- Comfort
- Occupational suitability
- Recreational suitability
- Worry and concern about vision

participants were not a representative sample of adults with refractive error. However, we specifically targeted geographically, ethnically, and economically diverse populations. Our sample included the full range of ametropia conditions and correction. Surgery for hyperopia is new relative to myopia, and the number of patients recruited in that category was smaller than those in groups for myopes.

The next steps after the focus groups were to develop and select specific measures to identify the constructs that are important, and to perform psychometric research to test their reliability, validity, and suitability for use in clinical settings. The ultimate goal was to develop an instrument that can be self-administered in a short period of time, that is sensitive to clinically relevant changes, and that can distinguish between different modalities of correction. In its final form, this instrument should be useful as an outcome measure in clinical trials of new and existing methods of refractive error correction.

Based on the focus groups and previous research, we concluded that it would be possible to develop a single set of questions to capture the functional implications of glasses, contacts, and surgery. Table 6 shows the constructs that were recommended for inclusion in the draft questionnaire. Our goal was to produce a standardized, validated instrument to be used by industry, universities, and clinicians, available at no charge. The instrument must be broad enough to measure patient satisfaction with all forms of correction. In addition to its use in research settings where the interest is in aggregate level analysis, it should also be applicable to clinical settings where the goal is to help identify those persons with low quality of visual functioning associated with their current form of correction. As information from studies using this instrument accumulates over time, we may be able to improve physician and patient decision-making about choice among refractive error correction options.

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