THE MEASUREMENT OF PATIENT-REPORTED OUTCOMES OF REFRACTIVE SURGERY: THE REFRACTIVE STATUS AND VISION PROFILE*

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ABSTRACT

Purpose: To develop a questionnaire, the Refractive Status and Vision Profile (RSVP), to assess health-related quality of life associated with refractive error and its correction.

Methods: The published literature on patient report of visual and overall function was reviewed, and the RSVP was self-administered by 550 participants with refractive error. Cross-sectional validation was performed using standard psychometric techniques. The responsiveness of the RSVP to surgical intervention was assessed prospectively in a subset of 176 patients. The principal outcome measures were scores on the overall RSVP scale (*S*) and on 8 RSVP subscales (*functioning, driving, concern, expectations, symptoms, glare, optical problems, problems with corrective lenses*).

Results: The RSVP (S) and its subscales demonstrated very good internal consistency (Cronbach's alpha, 0.70-0.93). *S* and several subscale scores were independently associated with satisfaction with vision and were more correlated with satisfaction with vision than with either visual acuity or refractive error. Higher refractive error was associated with lower scores on *S* and on 5 subscales. In the prospective surgical cohort, 15% of patients had some worsening in their total RSVP score; however, substantial variation was seen in the individual subscales where worsening ranged from 7% (problems with corrective lenses) to 41% (driving). The effect size (measure of responsiveness) of the RSVP and most of its subscales was very high. Approximately 14% of patients had significant worsening in 3 or more subscales, and this outcome was found to be independently associated with being dissatisfied with vision following surgery (OR, 5.84; 95% CI, 1.88, 8.13).

Conclusions: The RSVP has been validated as a questionnaire that measures patient-reported quality of life related to refractive error and its correction. It is responsive to surgical intervention and provides important information regarding patient outcomes not available from standard clinical measurements.

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INTRODUCTION

In 1994, I attended a meeting of the Advisory Panel of the Food and Drug Administration (FDA) when it was presented its first completed data set from a clinical trial of an excimer laser for photorefractive keratectomy (PRK). The panel was under tremendous pressure, since this was the first time it had been asked to consider approval of this new technology. The perceived burden of responsibility was huge, and there was consensus, since validated, that once approved, the technology would explode in popularity. The clinical trial presented all of the standard information required, documenting visual acuity in numerous ways (eg, uncorrected, corrected, stratified by pupil size, with and without glare sources) as well as residual refractive error (eg, with and without cycloplegia, spherical and cylindrical change, accuracy). The results presented were quite straightforward. The targets, measured by these traditional clinical assessments, were met in a reasonably high proportion of cases. However, that FDA panel meeting lasted over 12 hours and was characterized by uncertainty and dispute as to the inferences that one might draw from the clinical data. Specifically, the question lingered as to what the impact of PRK was (and would be) on patient visual and overall function. Isn't it possible, the question was asked, that tolerance of risk and either enjoyment of or dissatisfaction with the outcomes of PRK might vary according to the specific needs, perception, and function of individual patients? The Advisory Panel was clearly frustrated that the data presented could not integrate the standard clinical measurements with patient perception of function in order to produce a composite assessment of how successful the treatment actually was. I shared that frustration and concluded that additional tools needed to be developed to address this gap.

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Over the intervening years, there has, indeed, been an explosion in refractive surgery in the United States. There are a number of competing excimer lasers, each with variations in the profiles of treatment applied. Also, there are a number of evolving refractive procedures in addition to PRK, the most prominent of which are laser-assisted in situ keratomileusis (LASIK), intracorneal rings, and intraocular lenses of various designs designed for phakic patients. There are now approved treatments for hyperopia and astigmatism in addition to those approved earlier for myopia. A variety of other technologies are currently under development. Most strikingly, the population undergoing refractive surgery has increased exponentially since 1996, when approximately 50,000 refractive procedures were performed in the United States. It has recently been estimated that over 1.5 million refractive surgical procedures were performed in the United States in 1999. This proliferation of the technology, its continued evolution, and the array of competing strategies have rendered even more acute the need for assessments that incorporate the patient's perspective in defining the outcomes of refractive surgery procedures.

The underlying hypotheses of the research presented in this thesis are that the systematic assessment of vision-related quality of life in patients undergoing or considering refractive surgery will (1) provide important information that cannot be provided by traditional clinical measurements and (2) provide a tool to optimize patient selection and hence outcome of surgery.

The first section of this thesis reviews the rationale and current status of visual function questionnaires in ophthalmology, emphasizing their application to assessing the outcomes of surgical intervention. This section also indicates why already validated instruments are not suitable to the needs of refractive surgery assessment. The second section describes the development and psychometric validation of the Refractive Status and Vision Profile (RSVP) questionnaire. The third, and most important, section presents RSVP data collected prior to and following refractive surgery on a cohort of patients. These data indicate the responsiveness of the questionnaire to the surgical intervention and confirm that such nonconventional measurements can help to identify those patients most likely to be satisfied with the results of surgery postoperatively. The fourth and final section suggests possible ways in which the patient perspective on refractive error and its correction may be incorporated into future research and practice.

SECTION 1

VALIDATED QUESTIONNAIRES MEASURING PATIENT-REPORTED VISUAL FUNCTION

Although physicians have always tried to understand and be responsive to the impact of diseases and treatments on the overall function of patients, it has become increasingly recognized that the assessment of health-related quality of life (HRQoL) needs to have a significant role in the practice of medicine. HRQoL may have a variety of dimensions, including function (overall, physical, social, psychological), symptoms, health perceptions, and satisfaction. Ideally, if one were able to assess these dimensions for illnesses and their treatments both in individual patients and in populations, then one would have a powerful method to optimize recommendations for individual patients, set policy and priorities for populations (eg, a method to prioritize resources), and compare the effectiveness of alternative treatments based on their perceived impact on patients. Unfortunately, such diverse goals cannot be readily achieved by using off-the-shelf validated questionnaires.

Generic Versus Disease-Specific Questionnaires

Depending on the goals of the evaluation that needs to be made, there are advantages and disadvantages to what are known as "generic" and "disease-specific" measures.[1] Generic measures tend to focus on overall physical, social, and emotional function. Perhaps the 2 most widely used generic measures of HRQoL for the assessment of the impact of chronic diseases and their treatment are the Sickness Impact Profile[2] and the SF-36.[3] These indicators of overall function are particularly valuable when trying to achieve a metric across different disease states. For example, if one wanted to compare the overall health status of 2 populations, then one might choose a generic health status measure as the metric. Alternatively, if one were interested in comparing the effectiveness of different treatments regarding overall patient function over time in the same population (eg, medical versus surgical treatment of coronary artery disease), then such generic measures would be very helpful.

Ophthalmic interventions such as cataract surgery have been shown to have a beneficial effect on overall function and quality of life as measured by generic instruments.[4-6] However, such generic instruments share an important limitation. They are relatively insensitive to the specific benefits of a treatment or to the nuances of progression of a specific disease. This is not surprising, of course, since the content of generic questionnaires is purposely general in nature, while the content of a disease-specific instrument should reflect the special knowledge of patients and physicians who are intimately familiar with the course of the specific disease. Validated, disease-specific questionnaires permit the assessment of the severity of the specific disease, the relationship of the disease to overall function, and the response (or lack thereof) of the

condition to intervention. Disease-specific and generic assessments may also be combined when the particular research or policy question requires information from both perspectives.

Within the field of ophthalmology, one may make still further distinctions. A visual function instrument may be considered generic in that it is said to relate to any condition that affects vision-related quality of life, or it may be disease-specific (eg, cataract). An example of the former is the NEI-VFQ,[7] which was developed as a generic visual function instrument to be used for a wide variety of disorders. Examples of the latter include the VF-14[4,5,9] and the ADVS,[8,9] which were designed specifically for cataract, although both have been subsequently shown to be valid measures of visual function in patients with other visual disorders as well.[10-12] The following discussion is designed to summarize the status of the published literature on visual function instruments that have been validated in a rigorous fashion, including the assessment of surgical outcome. However, before reviewing the published questionnaires, a brief discussion of the term "validation" as it applies to questionnaires is in order.

Assessing the Validity of a Questionnaire

The terminology describing the behavior and performance of questionnaires was developed in the psychometric literature.[13] In its simplest interpretation, a questionnaire that is valid measures what it says it does. Three types of validity are commonly described. *Criterion validity* refers to a comparison (statistical correlation) of the questionnaire with an accepted, external standard. For example, one would expect some association between poor function as measured by a visual function instrument and reduced Snellen visual acuity. *Content validity* refers to whether the questionnaire contains sufficient detail to describe the particular function. For example, one might expect a questionnaire on visual function to contain 1 or more items related to glare, such as night driving. *Construct validity* is a form of "face" validity where the condition studied produces an expected, reasonable response pattern in the questionnaire. For example, persons with macular degeneration would be expected to report more difficulty with reading small print than those without the condition. *Construct validity* is typically assessed by comparing the distribution of scores (eg, means). Finally, *discriminant* and *convergent validity* are terms used to describe the performance of measures that have more than one domain. For example, a questionnaire might contain separate domains covering the areas of social function, psychological well-being, driving, and activities of recreation. For a questionnaire with multiple domains to exhibit *discriminant validity*, each item within the domain should be more highly correlated with a summary measure of that domain than with summary measures of other domains. *Convergent validity* is demonstrated by showing a strong correlation of each item within a domain with its summary measure. *Discriminant* and *convergent validity* may be assessed by a technique known as multitrait analysis.[14]

The *reliability* of an instrument is generally assessed by its ability to yield similar results in a repeatable manner when applied more than once to the same subject or group of subjects. *Reproducibility* refers to the ability of the questionnaire to provide similar responses when applied more than once to the same individuals over a relatively short time. It is usually measured statistically by calculating the intraclasss correlation coefficient. *Reliability* may also be demonstrable across administration techniques (eg, reliable or not for both telephone and in-person interviews) or interviewers (inter-interviewer reliability). *Consistency* refers to the degree to which items measuring the same domain or aspect of function are internally correlated. This is usually assessed by the Cronbach's alpha coefficient, where as values approach 1, they approximate perfect internal consistency, and as they approach 0, they demonstrate no internal consistency.

The *reliability* and *validity* of a questionnaire are usually assessed cross-sectionally (ie, at one point in time) in a cohort of patients with a specific condition. However, not all questionnaires that are validated in such a way are responsive to interventions. *Responsiveness*, which refers to the sensitivity of the questionnaire to change (improvement or worsening) in health status, is the most important form of validation for an instrument whose intended use is the assessment of a surgical intervention. The responsiveness of a questionnaire may be assessed in a variety of ways, including the simple comparison of scores before and after an intervention by using paired analyses or by calculating an effect size.[15-17]

VALIDATED VISUAL FUNCTION QUESTIONNAIRES THAT HAVE BEEN APPLIED TO SURGICAL POPULATIONS

Bernth-Petersen, in Denmark, was perhaps the first ophthalmologist to recognize the need for a systematic evaluation of patient function related to cataract.[18-21] His Visual Functioning Index (VFI) consisted of 11 items, including vision at different distances and settings, driving, social activities, and self-care activities. This Danish questionnaire was validated both cross-sectionally and prospectively in small cohorts of patients undergoing cataract surgery[20,22] and was used to estimate societal costs of visual disability due to cataract and to compare outcomes of intraocular lens implantation versus aphakic contact lens use. The *reliability* of the instrument was not assessed. Subsequent to his own publications, little additional

research was performed with the VFI. Later, Brenner and colleagues[29] compared cataract surgical patients to controls, asking them detailed questions about visual function. Previously validated instruments were used to assess social functioning and mood, but these were not integrated with the questions on visual function for which no validation was performed. The questionnaires used were shown to be responsive to the intervention of cataract surgery.

Mangione and colleagues[9] developed the Activities of Daily Vision Scale (ADVS), which was first validated cross-sectionally in a large cohort of cataract surgical patients. This instrument contains separate subscales for night and day driving, near and distance vision, and glare. It was shown to be responsive to cataract surgery, with the total and all subscales improving following recovery from surgery. Both the ADVS and the SF-36 were applied to the same cohort of cataract surgical patients. Although there was some improvement noted in the generic measure, the disease-specific measure was far more sensitive to change following cataract surgery. The ADVS has also been shown to be useful as a component of a predictive model for outcomes of cataract surgery.[24] It has subsequently been validated in patients with retinal disease.[14] It has not been demonstrated to be responsive in patients with refractive error undergoing refractive surgery.

The VF-14[4,5,5] was specifically designed to measure visual function related to cataract and outcomes of cataract surgery. It is a 14-item questionnaire without subscales that includes items on sports, reading, recreation, driving, household activities, people recognition, and seeing steps. It was first validated cross-sectionally in a large cohort of cataract surgical patients who were also asked to complete the Sickness Impact Profile (SIP)[2] questionnaire as well as answer general questions about trouble and satisfaction with vision. A visual symptoms index consisting of 6 questions about specific visual symptoms was also asked. The VF-14 was found to be internally consistent and to correlate more closely with self-report of satisfaction with vision than did visual acuity in either eye or the SIP. Subsequently, 4-month surgical outcomes of this large cohort were studied. The VF-14 was found to improve in 89% of patients and to be more sensitive to the surgical intervention than the generic measure, the SIP. Change in rating of trouble and satisfaction with vision were more closely correlated with the VF-14 than with change in acuity in the operated eye, indicating that the VF-14 is probably a better measure of the benefit of cataract surgery than change in acuity. Finally, a predictive model was developed[7] which showed that the preoperative VF-14 and cataract symptom score were not only independent predictors of postoperative outcome but were as strong predictors as patient age and ocular comorbidity. The VF-14 was also used to evaluate the benefit to patients of undergoing a second eye cataract surgery, a controversial topic among some health-care payors. The VF-14 showed conclusively that patient-reported function improves significantly following surgery in the second eye.[25] The VF-14 has been translated and used in Finnish, Danish, Catalan, and Canadian-French, and its reliability and responsiveness have been confirmed in these translated versions.[4,26-28] The VF-14 has subsequently been validated in patients undergoing corneal transplantation.[10,29] It has recently been validated cross-sectionally in patients with retinal disease[11] and is currently being evaluated for its responsiveness in a retinal intervention trial by the same investigators. It has not been tested in patients undergoing refractive surgery.

A questionnaire developed in Sweden, the Catquest[30], has also been validated both cross-sectionally and prospectively but is not in active use in English-speaking settings. A visual function questionnaire that has been validated in one setting or country is not necessarily valid universally. For example, to assess the relative benefits in India of intracapsular cataract extraction with aphakic spectacles versus extracapsular surgery with an intraocular lens, a new visual function and vision-related quality-of-life instrument had to be developed and validated.[31] The level of visual disability due to cataract is much more severe in rural India than in developed countries, and the activities and needs of patients are different. The Visual Activities Questionnaire was developed for this purpose and fully validated in India. The use of this questionnaire permitted a very powerful demonstration of the visual and quality-of-life benefits of extracapsular cataract surgery in this setting.[32-34] This important finding would not have been apparent from the traditional comparisons of Snellen visual acuity and the enumeration of operative complications.

The above summary indicates that several visual function questionnaires have been methodologically validated and have been shown to be responsive to the intervention of cataract surgery. The NEI-VFQ[7] has been validated cross-sectionally and is now in use in a variety of studies (retinal disease, glaucoma) where longitudinal and postintervention data are being collected. It is therefore anticipated that data on responsiveness of this questionnaire to a variety of interventions will be forthcoming. A review of the literature on validated visual function questionnaires indicates several common denominators. First, in those settings where generic function and quality-of-life indicators were simultaneously employed, the disease- or vision-specific questionnaires were always more sensitive to both baseline visual disability and change after the intervention. As discussed earlier, this is exactly what one would predict, and this finding again justifies the use of disease-specific

instruments when assessing outcomes of the effectiveness of specific interventions. A second unifying finding is that the various validated visual function questionnaires, although correlated with traditional measures such as Snellen acuity, actually provided valuable information not available using traditional clinical measures. For example, the VF-14[47] was closely associated with patients' self-report of trouble with vision, while Snellen acuity (in the better or worse eye) was not correlated at all.

VISUAL FUNCTION QUESTIONNAIRES, REFRACTIVE ERROR, AND REFRACTIVE SURGERY

Approximately 25% of the world's population is myopic. The rate of refractive surgery has grown exponentially over the past several years. In addition to the improved technology and enormous eligible population, an underlying assumption of refractive surgeons and their patients is that the procedure yields an improvement in patient-perceived quality of life related to vision and its correction. Certainly, industry- and physician-generated marketing would lead one to believe that these issues are paramount. However, no validated methodology for assessing patient function and vision-related quality of life has been developed for this population. Why not use 1 or more of the questionnaires discussed above, such as the ADVS or the VF-14? The principal reason is that these questionnaires focus directly on issues related to loss of central or peripheral vision, which affect one's ability to perform activities. Therefore, an individual with corrected refractive error, even high myopia, would be likely to achieve the same score on such questionnaires as individuals who have no refractive error and who have normal vision. Such questionnaires are therefore insensitive to the limitations (eg, visual, symptoms, quality of life, social) that are experienced by individuals with refractive error who consider refractive surgery. Consequently, such questionnaires would also be insensitive to possible changes (improvement or worsening) that might occur following an intervention. Finally, they would be incapable of detecting differences in the effectiveness of one intervention compared with another for subjects with refractive error. This is the underlying rationale for the development of a vision-targeted quality-of-life questionnaire for individuals with refractive error.

Although no single validated instrument has been previously developed for this purpose, relevant research exists, the most prominent of which is that by Bourque performed in the context of the Prospective Evaluation of Radial Keratotomy Study (PERK).[35-37] In this work, psychological and role-functioning attributes were stressed, and visual function was assessed with only 2 questions (reading newsprint and seeing a friend across the street without glasses). Satisfaction was assessed with a 10-question index that included questions about clarity of vision, comparison of vision with others, and satisfaction with surgical results. Satisfaction was found to be most closely correlated with not needing corrective lenses for distance and lack of fluctuation in daily vision. When the psychosocial characteristics of radial keratotomy candidates was assessed,[36] no evidence of psychological or social deviancy was observed. However, patients did express a fear of being without vision and impatience with current spectacle and contact lens correction as their chief motivation for requesting surgery. The research by Bourque highlighted the importance of the patient perspective in assessing the outcomes of refractive surgery but did not result in a unique or validated instrument to do so.

Other limited attempts to incorporate the patient perspective into the assessment of refractive surgical outcomes have been made. These largely have used a simple 4- or 5-point scale to rate satisfaction with vision or to rate specific symptoms such as glare.[29-31] Of note, in the original cohort of patients undergoing PRK presented to the FDA for approval,[57] 78% of patients indicated that they were satisfied or very satisfied with their vision at 2 years following PRK. The remaining 22% indicated that they were less satisfied. As with radial keratotomy, satisfaction was correlated with final uncorrected acuity. However, the correlation was not strong, indicating that there must be other factors at play. No independent assessment of visual function from the patient perspective was made in these studies. Similarly, visual symptoms such as glare and halo[10,30,33,58] have been commonly reported after excimer laser refractive surgery, and these, too, have been associated with reduced satisfaction with vision. However, such symptoms again have not assessed in a validated fashion nor correlated with overall patient perception of visual function.

Two studies from Europe[27,37] have attempted to evaluate the psychosocial outcomes of excimer laser surgery using standardized questionnaires. McGhee and colleagues[37] found that freedom from spectacles and difficulty with contact lenses were the most common reasons for seeking treatment. Interestingly, they failed to show an association between poor standard clinical outcomes (eg, uncorrected Snellen acuity) and satisfaction, raising the possibility that variation in patient expectations and needs may be important and poorly recognized factors. The most comprehensive assessment of visual and overall function in patients undergoing excimer laser surgery was performed by Freitas[27] in Portugal. Using a variety of existing questionnaires from the medical literature which were translated into Portuguese, she assessed visual function, overall functional status, general well-being, mental status, and satisfaction with surgery and found improvements in

each of the measures used following PRK. The study, however, was performed in a very small sample of only 45 patients and did not result in an independent assessment tool.

The standard for reporting outcomes of refractive surgery is to indicate the proportion of patients achieving various Snellen acuity thresholds without spectacle correction (eg, percent 20/25 or better) and the proportion who achieve accuracy thresholds in final refraction (eg, attempted minus achieved spherical equivalent). Secondary outcome measures that have become standard are also clinical measurements, such as glare disability, corneal topographic irregularity, refractive stability, and astigmatism. These are the assessments by which current and evolving techniques are evaluated by the profession and the FDA. Additional measurements, derived from patient perception of function, are clearly needed.

SECTION 2

DEVELOPMENT OF A QUESTIONNAIRE TO MEASURE VISION-RELATED QUALITY OF LIFE IN PERSONS WITH REFRACTIVE ERROR

Conceptual Framework and Design

Underlying the development of a quality-of-life measure related to refractive error is a broad conceptual model. Figure 1 illustrates such a model, in which a variety of potential external factors (eg, education, preferences, symptoms) impinge on the choice of baseline management of refractive error (eg, spectacles versus contact lenses) as well as on the decision to pursue refractive surgery. In turn, the outcomes of the surgery may be associated with specific symptoms (related to either the underlying refractive error or the subsequent treatment). These symptoms, modified by patient expectations and health perceptions (eg, worry, satisfaction), converge on an overall sense of functional performance (eg, social, physical).

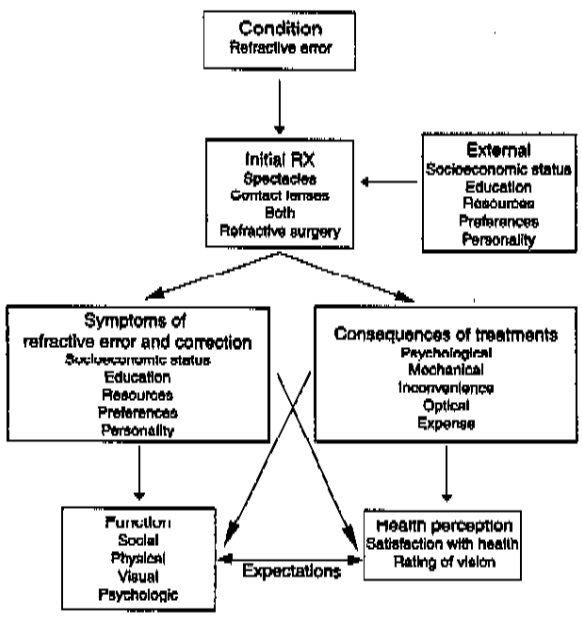


FIGURE 1
Conceptual model of vision-related quality of life related to refractive error.

The model, of course, may be overly simplistic, yet it helps to guide the approach to questionnaire development. Guyatt[15] has clearly outlined the steps that need to be considered in the development of a disease-specific quality-of-life measure. He makes a distinction between a "Rolls Royce" and a "Volkswagen" model. In the former, each step is methodologically rigorous, leading to a valid, clinically relevant, and responsive instrument; in the latter, the questionnaire is created de novo based on existing literature and professional judgment, leading to a questionnaire whose validity and applicability remain uncertain. The plan undertaken for the creation of the RSVP reflects the Rolls Royce framework as outlined by Guyatt. These stages include a rigorous approach to the following: item selection, item reduction, questionnaire format, pretesting, reproducibility, and validity.

Overview of Questionnaire Development

Potential items for the questionnaire were generated from a review of the literature, focus groups with ophthalmologists and optometrists, and interviews and focus groups of individuals with refractive error. The content of the focus groups was transcribed and summarized, and the specific wording of items was retained to the extent possible. An initial version of the questionnaire was pilot-tested in a group of 306 individuals with refractive error, and then statistical analysis of this initial version was performed to shorten and improve it. The revised questionnaire, called the Refractive Status and Vision Profile (RSVP), was then tested in a new population of 550 individuals with refractive error, and the validity of the questionnaire and its subscales was assessed.

Selection and Wording of Items

A review of the relevant published literature (Section 1) and the conceptual model (Fig 1) helped to guide the initial structured interviews with 2 optometrists and 2 ophthalmologists, 1 of whom was a practicing refractive surgeon. These professionals were asked to identify areas of functional difficulty related to refractive error and its correction that patients frequently had reported to them. A focus group of individuals with refractive error was then conducted, in which the voluntary participants identified issues in their own experience and in their own language.

The focus group discussion was recorded and subjected to a content analysis in which items were grouped by domains (eg, symptoms, concern). Domains identified in this fashion were then supplemented by the input of the literature review and the interviews with the eye-care professionals. Items that were clearly redundant were removed, leaving a total of 122 items in the pilot instrument. The items were worded in short, declarative sentences, preserving to the extent possible the vernacular of the patients (eg, "Because of my vision, I have trouble watching TV"). For each question, the subject was asked to indicate how frequently the problem was experienced or how severe it was perceived to be. Additional questions accounted for corrective lens type (ie, spectacle and/or contact lens use). The domains covered included psychological, physical, and social role functioning; symptoms; dependency; and health perceptions.

Pilot Testing

Approval for the pilot study was obtained from the University's Joint Committee for Clinical Investigation. The pilot questionnaire was completed by self-administration by 306 individuals with refractive error. The sample size chosen for questionnaire development and validation is not based on formal hypothesis testing as, for example, is the case for the planning of a clinical trial. The goal for the development of this questionnaire was to assemble a population that was felt to be representative of individuals with refractive error and sufficiently large to permit analyses of subgroups (eg, subjects with various ranges of refractive error). On the basis of previous experience with a similar questionnaire related to visual function, the VF-14, it was estimated that data from at least 250 participants would be necessary. These subjects were derived from 2 optometric practices, 1 general ophthalmologic practice, and 1 refractive surgery practice. The practices also provided data on visual acuity and refractive error. Exploratory analyses of these pilot data were performed to identify items that were rarely experienced or rarely caused difficulty for patients and to indicate areas that were redundant or were nondiscriminatory (ie, could not distinguish groups of subjects from each other). Factor analysis was used to sort item groupings (potential subscales) into the general categories of functioning, symptoms, and health perceptions. The factor solutions were used[60] to exclude certain items from further analyses because of irrelevancy (factor loading <0.1) or redundancy (factor loading >0.9). These analyses yielded a revised questionnaire, the Refractive Status and Vision Profile (RSVP), which contained 42 items covering 8 subscales. Specific global items were added in which subjects were asked to rate their satisfaction (5-point scale) with current vision (distance and near, corrected and uncorrected) and to rate the quality of their vision (10-point scale, again for corrected and uncorrected vision). To assess a possible relationship to overall health issues, 2 "global health" items were also included: concern about health (10-point scale) and general rating of health (5-point scale). Finally, demographic information (eg, age, lens-wearing history) was appended to the questionnaire to provide necessary background information to interpret the patient responses.

PARTICIPANTS IN THE EVALUATION OF THE RSVP

The study was approved by the University's Joint Committee for Clinical Investigation, and all participants gave oral consent to participate. Study coordinators at 6 participating sites, 5 refractive surgery practices, and 1 optometric practice (see Acknowledgments) were asked to give the RSVP to consecutive patients who did not have significant ocular conditions unrelated to refractive error and who had either not undergone refractive surgery at all or who had not undergone such surgery within the 3 months prior to participation. All patients were enrolled between May and December 1997. The questionnaire was self-administered, taking, on average, 10 to 15 minutes to complete. The full questionnaire contained the 42 items of the RSVP plus additional questions relating to satisfaction with and rating of vision and demographic features of interest, such as age, sex, and lens-wearing (spectacle and/or contact lens) history. Clinical data on corrected and uncorrected acuity, refractive error, and ocular medical and surgical history were provided by the coordinators on standardized forms. A copy of the full questionnaire is provided in the Appendix.

Reproducibility

Test-retest assessment was performed on a subset of participants in the months of October and November 1997. The 40 patients who did not have intervening refractive surgery were asked to complete the RSVP questionnaire twice. Twenty-nine of the 40 completed a second RSVP with an interval of 2 days to 3 weeks between completions of the questionnaire. The interval included their clinical evaluation for refractive surgery. A second assessment of reproducibility was performed in a convenience sample of 16 subjects with refractive error who were not being evaluated for refractive surgery. The interval between completions of the RSVP questionnaire in this group ranged from 1 day to 1 week.

Scoring of the Questionnaire

The RSVP responses were coded to values of 1 through 5, with 5 indicating more severe trouble. For subscale and total scale scores, the mean value of non-missing responses was calculated. Subscales for which all the items had

missing responses were coded as missing. To facilitate interpretation of results, the mean score for each subscale was recalibrated to a 0 to 100 metric by subtracting the minimum possible mean score (1) from the mean score for the scale, dividing this difference by the possible range of the mean score (5 minus 1), and multiplying by 100. The total score, *S*, was calculated by taking the sum for all 42 items included in all the subscales of the RSVP and rescaling to a 0 to 100 scale.

RESULTS

Participants

A total of 550 subjects completed the RSVP questionnaire. Table I illustrates the characteristics of the participants. The mean age of participants was 37 years (range, 18 to 71 years), and 59% were female. The mean refractive error was -5.4 (range, -18 to +3.75), and 96% had best corrected acuity of 20/20 or better in at least 1 eye. Approximately 36% wore spectacles only, 19% wore contact lenses only, and 43% wore both. General health was rated very good or excellent by 88% of the participants. While the mean rating of vision was 8.4 (0 to 10 scale, with 10 representing perfect vision), only 56% indicated that they were satisfied or very satisfied with their vision.

Derivation of Subscales

The factor analysis confirmed the subscale structure predicted by the analyses of the pilot testing. Factors were related to physical/social functioning, optical problems, driving, ocular symptoms, concern, glare, expectations, and problems with glasses and contact lenses. These subscale groupings were then evaluated with multitrait scaling methods,[60] and the final results are presented in Table II. Eight subscales composed of a total of 42 items were identified: *concern* (6 items), *driving* (3 items), *expectations* (2 items), *physical/social functioning* (11 items), *symptoms* (5 items), *optical problems* (5 items), *glare* (3 items), and *problems with corrective lenses* (7 items).

PERFORMANCE OF THE OVERALL RSVP

Individual Measure of Validity

The internal consistency of the overall questionnaire was measured by Cronbach's alpha. An alpha of 0.7 (range, 0 to 1) or higher is considered adequate for comparisons of subgroups. The Cronbach's alpha of the entire questionnaire (*S*) was 0.92, with that of the subscales ranging from 0.70 to 0.93. Reproducibility, as assessed by the intraclass correlation coefficient (ICC), differed within the 2 populations studied. In the group that underwent a refractive surgery evaluation in between completions of the questionnaire, the reproducibility was modest (overall ICC, 0.61). In the group not undergoing the intervening evaluation, the reproducibility was very good (overall ICC, 0.88). The average RSVP score (*S*) was 26.6 (0 to 100 scale, with 0 representing no impairment on any item).

Criterion validity was assessed by examining the

TABLE I: CHARACTERISTICS OF PARTICIPANTS (N=550)

CHARACTERISTICS		DESCRIPTION	
Age (mean [SD], range)		37.2 (9.7y)	18 - 71y
Spherical equivalent, worse eye (mean [SD], range)		-5.4D (3.5D)	-18.375 -+3.75D
Health concern* (mean [SD], range)		1.6 (2.4)	0 - 10
Rating of vision† (mean [SD], range)		8.4 (1.4)	0 - 10
Gender (N, %)	Female	325	59.1
Source (practice type) (N, %)	Refractive surgery	508	92.4
	Optometric	42	7.6
Corrective lens status (N,%)	Glasses only	196	35.6
	Contact lenses only	105	19.1
	Glasses and contact lenses	234	42.5
	No lenses‡	13	2.4
History of refractive surgery (N, %)	None	466	84.7
	One eye	71	12.9
	Both eyes	13	2.4
Best corrected VA, both eyes (N, %)	≥20/20 OU	472	86.4
	≥20/20; 20/25 - 20/40	52	9.5
	20/25 - 20/40 OU	22	4.0
Health rating (N, %)	Very good or excellent	480	87.9
Satisfaction with vision	Satisfied or very satisfied	304	56.2

*0=not at all concerned; 10=very concerned.
†0=completely blind; 10=perfect vision.
‡Two additional participants wore glasses for reading only.

TABLE II: PROPERTIES OF THE RSVP AND ITS SUBSCALES

NAME	NO. ITEMS	% CORRECTLY SCALED	α†	ICC‡	ICC§ (IN STABLE GROUP)¶	MEAN‖	RANGE
Concern	6	100	0.83	0.77	0.88	44.0	0 - 100
Driving	3	100	0.93	0.69	0.70	25.9	0 - 100
Expectations	2	100	0.70	0.42	0.91	58.7	0 - 100
Physical/social functioning	11	96.1; 100	0.87	0.84	0.63	17.2	0 - 92.8
Symptoms	5	100	0.84	0.71	0.80	20.8	0 - 100
Optical problems	5	94.3; 100	0.82	0.68	0.91	12.8	0 - 95
Glare	3	90.5; 100	0.75	0.72	0.72	22.3	0 - 100
Problems with corrective lenses	7	100	0.82	0.76	0.78	34.0	0 - 100
S (overall scale)	42	97.6; 100	0.92	0.61	0.88	26.6	0.7 - 100

* If all items within the subscale had significantly higher corrected item-to-total correlations with their own subscale than with any other subscale, this number would be 100%. If some items had higher (but not statistically significantly so) corrected item-to-total correlations with their own subscale than with any other subscale, the first percentage indicates proportion with significantly higher correlations and the second percentage indicates proportion with higher (whether significantly so or not) correlations.

† Cronbach's alpha: a measure of internal consistency. Values of 1.0 indicate perfect internal consistency; values 0 indicate no internal consistency. Values of .7 or higher are considered sufficient for comparing subgroups of persons.

‡ Intraclass correlation coefficient to measure test-retest reliability. Measured in a subgroup of 29 participants who repeated the RSVP questionnaire within 2 days to 3 weeks after the first administration, with an intervening refractive surgery evaluation.

§ Intraclass correlation coefficient to measure test-retest reliability. Measured in a convenience sample of 16 persons not from a refractive surgery practice who repeated the RSVP questionnaire within 1 day to 1 week after the first administration.

‖ All subscale scores were rescaled to 0-100.

association of the overall RSVP score (*S*) (Table III) with the traditional clinical assessments (Snellen acuity and refractive error) and the global measures (rating of vision, satisfaction with vision, general health, and health concern). The correlation between the total RSVP score (*S*) and both satisfaction with vision and rating of vision was found to be much stronger than between any of the traditional clinical markers and these same measures. Therefore, the RSVP score (*S*) is more closely related to an individual's reported satisfaction with vision or rating of vision than are any of the traditional clinical measures, including refractive error (better or worse eye) and Snellen acuity (corrected or uncorrected, better or worse eye). Additionally, the RSVP score (*S*) is more closely associated with an individual's rating of general health and health concern than are the traditional clinical measures, although the association is less strong than with satisfaction with and rating of vision.

Figure 2 illustrates the relationship between the total RSVP score (*S*) and various clinical and demographic variables. Significantly higher scores (more perceived disability) were observed in patients considering refractive

TABLE III: ASSOCIATION* BETWEEN THE RSVP AND DIFFERENT MEASURES OF VISION AND HEALTH STATUS

	S†	VISION SATISFACTION‡	VISION RATING§	GENERAL HEALTH‖	HEALTH CONCERN¶
VA, uncorrected, better eye	-0.12**	0.05	0.15**	-0.05	0.03
VA, uncorrected, worse eye	-0.16**	0.05	0.14**	-0.04	0.06
VA, best corrected, better eye	-0.05	0.09**	0.19**	-0.06	0.02
VA, best corrected, worse eye	-0.10**	0.12**	0.18**	-0.09**	0.00
Spherical equivalent, better eye	-0.19**	0.12**	0.21**	-0.05	0.03
Spherical equivalent, worse eye	-0.21**	0.15**	0.21**	-0.06	0.05
S†		-0.41**	-0.42**	0.20**	0.23**
Vision satisfaction				-0.10**	-0.08
Vision rating				-0.15**	-0.08

* As measured by Spearman correlation coefficient.

† Overall scale.

‡ 1=very dissatisfied; 10=very satisfied.

§ 0=completely blind; 10=perfect vision.

‖ 1=excellent; 5=poor.

¶ 0=not at all concerned; 10=very concerned.

** Correlation coefficient differs significantly from 0 ($P \leq .05$).

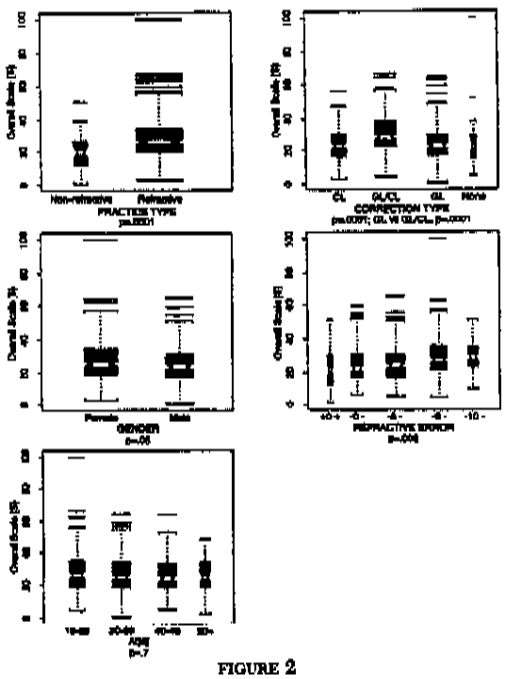


FIGURE 2

Relationship between overall RSVP score (*S*) and clinical and demographic variables. Distribution of scale scores are expressed using box plots. Center white horizontal line represents median. Shaded box extends from 25th to 75th percentiles. Vertical lines extending from box cover extent of data within 1.5 times interquartile range (length of box). Values in data beyond this range are indicated by horizontal solid lines. Indentations in box centered on median, in lighter shading, represent extent of 95% confidence interval for median. Width of each box is proportional to square root of number of observations for that box.

surgery (compared to those not considering it), patients wearing both contact lenses and spectacles (compared to wearing just 1 or the other), females, and those with greater refractive error. No significant age effect on the total RSVP score (*S*) was observed. Using multivariate analysis and adjusting for age, sex, and lens usage, RSVP scores remained independently associated with refractive error and use of both glasses and contact lenses. Associations with individual subscales are also shown (Table IV). A second multivariate analysis was performed (Table V), which confirmed the independent association of the total RSVP score (*S*) and most of the subscales with satisfaction with vision after adjusting for age, sex, lens usage, and refractive error. Finally, an analogous analysis was performed (Table VI), which confirmed an independent association of the total RSVP score (*S*) with patient rating of vision.

PERFORMANCE OF THE RSVP SUBSCALES

The Cronbach's alpha of the individual subscales (Table II), measuring *internal consistency*, ranged from 0.70 to 0.93 (median, 0.82). Mean subscale scores ranged from 12.8 (*optical problems*) to 58.7 (*physical/social functioning*). Although the distribution was somewhat skewed toward fewer problems for some of the subscales (eg, *optical problems*), it was judged that such scales might still be potentially valuable for evaluating potential adverse effects of refractive surgery in some patients and they were there-

TABLE IV: MULTIVARIATE ANALYSIS: FACTORS ASSOCIATED WITH RSVP SCALE SCORES*
REGRESSION COEFFICIENT (STANDARD ERROR)

COVARIATE	CONCERN	EXPECTATIONS	PHYSICAL/SOCIAL FUNCTIONING	DRIVING	SYMPTOMS	OPTICAL PROBLEMS	GLARE	PROBLEMS, CORRECTIVE LENSES	S
Age	-1.34	0.51	-0.11	0.41	-1.34†	1.04	0.12	-0.15	-0.20
per 10 yr	(0.82)	(1.04)	(0.67)	(1.01)	(0.70)	(0.64)	(0.79)	(0.73)	(0.49)
Sex	1.64	5.18‡	-1.73	8.80‡	1.63	3.04‡	5.71‡	-4.19‡	0.96
F vs M	(1.62)	(2.04)	(1.31)	(1.99)	(1.38)	(1.26)	(1.56)	(1.44)	(0.97)
Lens type§	-1.62	0.17	-4.98‡	-5.37‡	11.50‡	-2.72	0.45	-14.60†	-2.04
CL only	(2.21)	(2.78)	(1.78)	(2.72)	(1.87)	(1.72)	(2.12)	(1.97)	(1.32)
CL/CL§	-0.27	0.79	7.16‡	5.08‡	18.96‡	2.74†	5.92†	-10.21‡	4.67‡
	(1.81)	(2.29)	(1.46)	(2.24)	(1.54)	(1.42)	(1.75)	(1.62)	(1.09)
Spherical equivalent per diopter	-1.53‡	-0.76‡	-0.91‡	-1.75‡	-0.01	-0.84‡	-0.72‡	0.32	-0.66‡
	(0.25)	(0.31)	(0.20)	(0.31)	(0.21)	(0.20)	(0.24)	(0.22)	(0.15)

CL, contact lens; GL, glasses

* Higher subscale scores indicate more problems. For age, a positive coefficient means that as age increases, reported problems increase. For a positive coefficient means that females report more trouble than males. For contact lens only, a negative coefficient means fewer problems than reported by glasses wearers only. For glasses/contact lenses, a positive coefficient means more problems than reported by glasses-only wearers. For spherical equivalent, a negative coefficient means those with a greater degree of myopia (toward the negative end of the scale) report more problems than those with a lesser degree of refractive error.

† Borderline significant

‡ statistically significant

§ Glasses only is the reference category. The no-lens group was too small to allow meaningful conclusions to be drawn.

TABLE V: MULTIVARIATE ANALYSIS: ASSOCIATION OF ADJUSTED RSVP SUBSCALE SCORE WITH SATISFACTION WITH VISION ‖
REGRESSION COEFFICIENT* (STANDARD ERROR)

	AGE PER 10 YRS	SEX F VS M	LENS TYPE† CL ONLY	GL/CL	SPHERICAL EQUIVALENT, WORSE EYE PER DIOPTER	SUBSCALE PER 1% INCREASE
Overall RSVP score (S)	-0.17	0.002	0.24	-0.31	0.03	-0.037
	(0.05)‡	(0.097)	(0.13)§	(0.11)‡	(0.02)	(0.004)‡
Subscales	-0.18	-0.012	0.29	-0.48	0.04	-0.012
Concern	(0.05)‡	(0.101)	(0.11)‡	(0.11)‡	(0.02)‡	(0.003)‡
Expectations	0.17	0.003	0.30	-0.48	0.06	-0.004
	(0.05)‡	(0.103)	(0.14)‡	(0.12)‡	(0.02)‡	(0.002)
Physical social function	-0.17	0.093	0.17	-0.29	0.04	-0.021
	(0.05)‡	(0.097)	(0.13)	(0.11)‡	(0.02)‡	(0.003)‡
Driving	-0.17	0.098	0.21	-0.39	0.03	-0.017
	(0.05)‡	(0.099)	(0.13)	(0.11)‡	(0.02)§	(0.002)‡
Symptoms	-0.18	-0.020	0.45	-0.24	0.06	-0.012
	(0.05)‡	(0.102)	(0.14)§	(0.13)‡	(0.02)‡	(0.003)‡
Optical	-0.14	0.054	0.22	-0.40	0.04	-0.028
	(0.05)‡	(0.098)	(0.13)	(0.11)‡	(0.02)‡	(0.003)‡
Glare	-0.16	0.022	0.31	-0.42	0.05	-0.012
	(0.05)‡	(0.103)	(0.14)‡	(0.12)‡	(0.02)‡	(0.003)‡
Problems with corrective lenses	-0.17	-0.055	0.22	-0.54	0.06	-0.006
	(0.05)	(0.103)	(0.15)	(0.12)‡	(0.02)‡	(0.003)§

CL, contact lens; GL, glasses.

* Higher values indicate more satisfaction with vision. A negative coefficient indicates that those who report more problems on subscales (or are older) are less satisfied. A positive coefficient indicates that those who have worse refractive error are less satisfied. For lens type, a positive coefficient means those who wear only contact lenses are more satisfied than those who wear only glasses.

† Only glasses is the reference category.

‡ Statistically significant ($P < .05$)

§ Borderline statistically significant ($P < .07$)

‖ Higher values indicate vision that is closer to perfect.

fore retained. The discriminant and convergent validities of the subscales were strong (Table IV). As observed with the total RSVP score (S), the test-retest reliability was stronger in the stable group than in those undergoing an intervening refractive surgery evaluation. Table VII illustrates the correlations between the various subscales. The correlations are logical, thereby adding to the face validity of the scales. For example, *physical/social functioning* is most strongly correlated with *driving*, as are *glare* and *optical problems*, and *symptoms* were most correlated with *glare* and *optical problems*.

As for the overall RSVP score (S), criterion validity was assessed by calculating the correlations between each of the global measures and each subscale and comparing those correlations to those of the traditional clinical markers and the same global measures (Table VIII). For all subscales except *expectations* and *problems with corrective lenses*, the correlation of the subscales with satisfaction with vision was greater than with corrected or uncorrected Snellen acuity or refractive error. The findings were similar for rating of vision, except that 1 additional subscale, *concern*, was not more correlated with this outcome than the standard clinical measures. Correlation between each of the RSVP subscales and health concern as well as general health were also greater than between these global health measures and the traditional clinical measures. In summary, therefore, the subscales were found to be more correlated with external global measures of vision and general health than Snellen acuity and refractive error.

Figures 3A through 3H illustrate the association of the individual subscales with practice type (refractive surgery versus general practice), corrective lens type (glasses, contact lenses, or both), age, sex, and refractive error. *Concern* was greater among those seen at refractive surgical practices and among those with greater refractive error. Females had lower *expectation* (greater willingness to accept less than perfect vision) scores than males, as were scores from refractive surgical practices. More problems with *physical/social functioning* were reported in persons with greater refractive error and in persons wearing contact lenses. More problems with *driving* were reported among those with greater refractive error, females, and those wearing both contact lenses and glasses. *Symptoms* were reported more frequently by younger subjects, females, and those wearing both spectacles and contact lenses. *Optical problems* were positively associated with degree of refractive error, female sex, and

TABLE VI: FACTORS ASSOCIATED WITH RATING OF VISION
REGRESSION COEFFICIENT* (STANDARD ERROR)

	AGE PER 10 YRS	SEX F VS M	LENS TYPE† CL ONLY	LENS TYPE† GL/CL	SPHERICAL EQUIVALENT, WORSE EYE PER DIOPTER	SUBSCALE PER 1% INCREASE
Overall RSVP score (S)	-0.10	-0.10	0.20	-0.46	0.05	-0.038
	(0.005)‡	(0.11)	(0.15)	(0.12)§	(0.02)§	(0.005)§
Subscales	-0.10	-0.13	0.26	-0.63	0.07	-0.006
Concern	(0.05)‡	(0.11)	(0.15)	(0.13)§	(0.02)§	(0.003)‡
Expectations	-0.10	-0.12	0.26	-0.63	0.08	-0.004
	(0.05)	(0.11)	(0.15)	(0.13)§	(0.02)§	(0.002)‡
Physical social functioning	-0.10	-0.19	0.13	-0.43	0.06	-0.028
	(0.05)‡	(0.11)‡	(0.15)	(0.12)§	(0.02)§	(0.004)§
Driving	-0.10	0.04	0.14	-0.53	0.04	-0.022
	(0.05)‡	(0.11)	(0.14)	(0.12)§	(0.02)§	(0.002)§
Symptoms	-0.12	-0.10	0.49	-0.28	0.08	-0.019
	(0.05)§	(0.11)	(0.16)§	(0.14)‡	(0.02)§	(0.003)§
Optical problems	-0.06	-0.02	0.16	-0.55	0.06	-0.031
	(0.05)	(0.10)	(0.14)	(0.12)§	(0.02)§	(0.003)§
Glare	-0.10	-0.05	0.27	-0.56	0.07	-0.014
	(0.05)	(0.11)	(0.15)	(0.13)§	(0.02)§	(0.003)§
Problems with corrective lenses	-0.10	-0.17	0.22	-0.67	0.08	-0.002
	(0.06)	(0.11)	(0.16)	(0.13)§	(0.02)§	(0.003)

CL, contact lens; GL, glasses.

* Higher values indicate vision that is closer to perfect. A negative coefficient indicates that those who report more problems on subscales (or are older) rate their vision less highly. A positive coefficient indicates that those who have worse refractive error rate their vision less highly. For lens type, a positive coefficient means those who wear only contact lenses rate their vision more highly than those who wear only glasses.

† Only glasses is the reference category.

‡ Statistically significant ($P < .05$)

§ Borderline statistically significant ($P < .07$)

TABLE VII: ASSOCIATION (CORRELATION COEFFICIENTS) OF SUBSCALES OF THE RSVP

SCALE	CONCERN	EXPECTATIONS	PHYSICAL/SOCIAL FUNCTIONING	DRIVING	SYMPTOMS	OPTICAL PROBLEMS	GLARE	PROBLEMS, CORRECTIVE LENSES
Concern	1.00							
Expectations	0.18	1.00						
Physical/social functioning	0.37	0.13	1.00					
Driving	0.32	0.15	0.66	1.00				
Symptoms	0.24	0.10	0.42	0.35	1.00			
Optical problems	0.31	0.10	0.55	0.61	0.43	1.00		
Glare	0.26	0.12	0.37	0.45	0.55	0.49	1.00	
Problems with corrective lenses	0.23	0.02	0.20	0.08	0.17	0.16	0.15	1.00
S*	0.62	0.26	0.82	0.72	0.63	0.71	0.61	0.47

* Overall scale (all items combined)

increasing age. *Glare* was positively associated with increasing refractive error, female sex, and persons wearing both glasses and contact lenses. Finally, *problems with corrective lenses* were associated with increasing age, patients from refractive surgery practices, male sex, and spectacle use.

Multivariate analyses of association between individual subscales and clinical and demographic measures were performed in an analogous fashion to those performed for the overall RSVP score (S). The findings are indicated in Table IV. In summary, these analyses suggest that those who wear both contact lenses and spectacles report more trouble with *physical/social functioning*, *driving*, *symptoms*, *glare*, and *problems with corrective lenses* than do wearers of spectacles only. Those wearing contact lenses only reported more trouble with *symptoms*

TABLE VIII: ASSOCIATION* BETWEEN THE RSVP SUBSCALES AND DIFFERENT MEASURES OF VISION AND HEALTH STATUS

	CONCERN	EXPECTATIONS	PHYSICAL/ SOCIAL FUNCTIONING	DRIVING	SYMPTOMS	OPTICAL PROBLEMS	GLARE	PROBLEMS W/CORRECTIVE LENSES	VISION SATISFACTION†	VISION RATING‡	GENERAL HEALTH§	HEALTH CONCERN‖
Visual acuity, uncorrected, better eye	-0.15¶	-0.07	-0.16¶	-0.13¶	-0.05	-0.12¶	-0.13¶	0.01	0.05	0.15¶	-0.05	0.03
Visual acuity, uncorrected, worse eye	-0.17¶	-0.108	-0.17¶	-0.18¶	-0.08	-0.16¶	-0.16¶	0.02	0.05	0.14¶	-0.04	0.06
Visual acuity, best corrected, better eye	-0.00	-0.07	-0.06	-0.16¶	-0.00	-0.15¶	-0.05	0.14	0.09¶	0.19¶	-0.06	0.02
Visual acuity, best corrected, worse eye	-0.05	-0.10¶	-0.08	-0.18¶	-0.01	-0.15¶	-0.09¶	0.09	0.12¶	0.18¶	0.09¶	-0.00
Spherical equivalent, better	-0.23¶	-0.11¶	-0.19¶	-0.24¶	-0.07	-0.21¶	-0.17¶	0.06	0.12¶	0.21¶	-0.06	0.03
Spherical equivalent, worse	-0.27¶	-0.13¶	-0.20¶	-0.25¶	-0.05	-0.22¶	-0.17¶	0.08	0.15¶	0.21¶	-0.05	0.05
Concern									-0.21¶	-0.16¶	0.13¶	0.21¶
Expectations									-0.09¶	-0.11¶	-0.04	-0.03
Physical social functioning									-0.42¶	-0.44¶	0.13¶	0.16¶
Driving									-0.39¶	-0.47¶	0.19¶	0.13¶
Symptoms									-0.52¶	-0.31¶	0.14¶	0.19¶
Optical problems									-0.39¶	-0.45¶	0.17¶	0.16¶
Glare									-0.32¶	-0.26¶	0.13¶	0.12¶
Problems w/corrective lenses									-0.06	-0.02	0.11¶	0.14¶
Vision satisfaction											-0.10¶	-0.08
Vision rating											-0.15¶	-0.08

* As measured by Spearman correlation coefficient.
† 1=very dissatisfied; 5=very satisfied.
‡ 0=completely blind; 10=perfect vision
§ 1=excellent; 5=poor.
‖ 0=not at all concerned; 10=very concerned.
¶ Correlation coefficient differs significantly from 0 ($P < .05$)

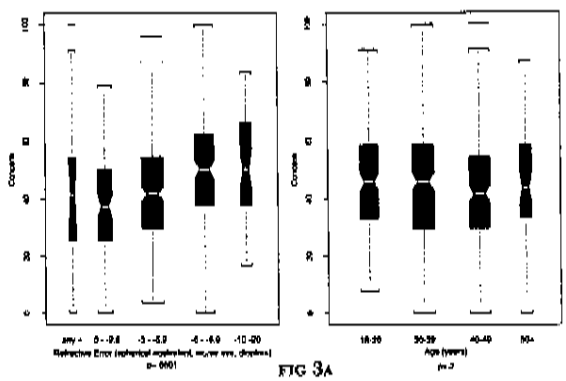


FIG 3A

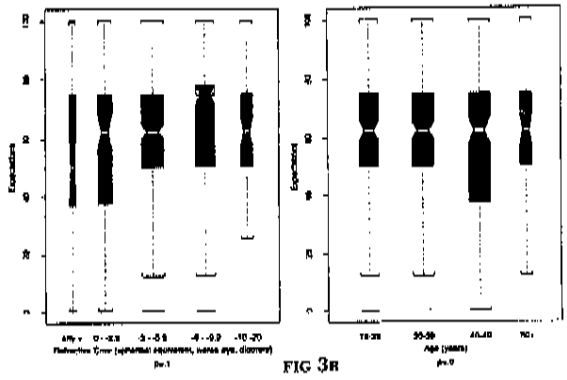
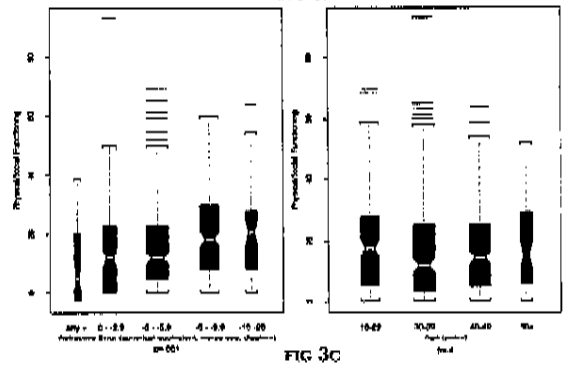


FIG 3B



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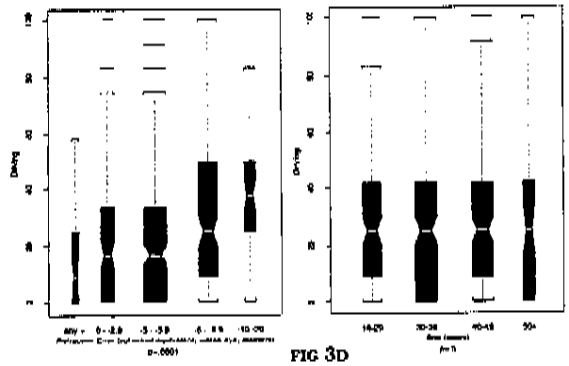

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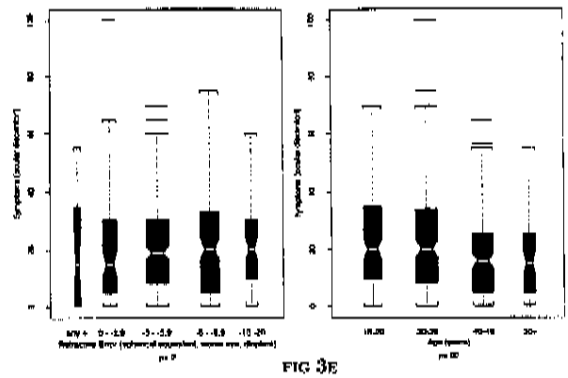

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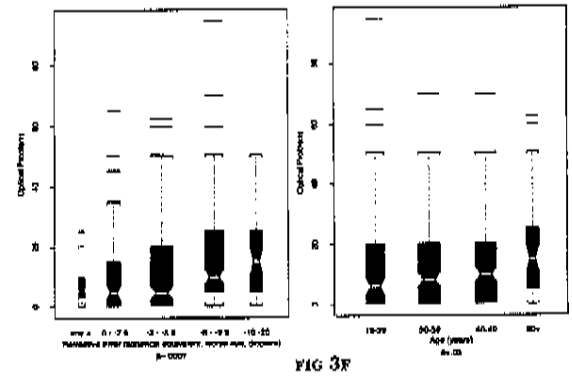

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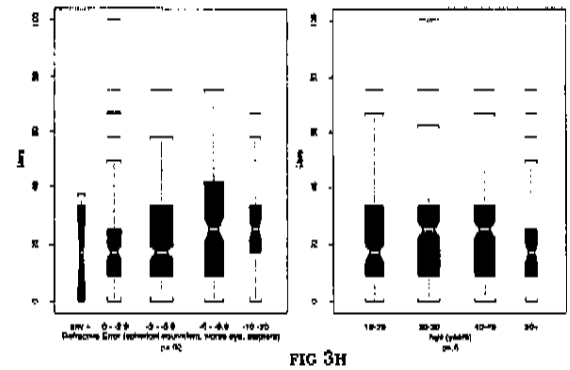

FIG 3H

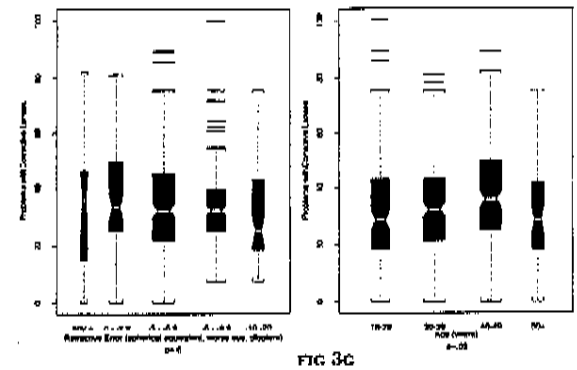

FIG 3G

FIGURE 3A - H

Relationship between individual RSVP subscales and clinical and demographic variables. Distribution of scale scores are expressed using box plots. Center white horizontal line represents median. Shaded box extends from 25th to 75th percentiles. Vertical lines extending from box cover extent of data within 1.5 times interquartile range (length of box). Values in data beyond this range are indicated by horizontal solid lines. Indentations in box centered on median, in lighter shading, represent extent of 95% confidence interval for median. Width of each box is proportional to square root of number of observations for that box.

but significantly less trouble with *physical/social functioning*, *driving*, and *problems with corrective lenses* than did wearers of only glasses. All subscales were significantly associated with greater degrees of refractive error except for *symptoms* and *problems with corrective lenses*. Females reported more trouble with *driving*, *optical problems*, and *glare* than males and were more likely to accept less than perfect vision (*expectations*). Increasing age was marginally associated with reporting of more *symptoms*. Additional multivariate analyses were performed to assess the association of the RSVP subscales with satisfaction with vision (Table V) and with rating of vision (Table VI). After adjustment for age, sex, lens usage, and refractive error, higher (more trouble) scores on the subscales related to *concern*, *physical/social functioning*, *driving*, *symptoms*, *optical problems*, and *glare* were all significantly and independently associated with less satisfaction with vision. A borderline association was observed between *problems with corrective lenses* and less satisfaction with vision. Therefore, the RSVP subscales yield additional information, not related to the traditional clinical assessments, that are related to patients' satisfaction with vision. When comparable analyses were performed for rating of vision (Table VI), the findings were similar. After adjustment for the same demographic and clinical parameters, all of the subscales except for *problems with corrective lenses* were associated with rating of vision. Therefore, the RSVP subscales yield additional information related to patients' rating of vision not contributed by the standard clinical measures.

DISCUSSION

A questionnaire designed to measure HRQoL should reflect the concerns and issues most important to the relevant population of patients. The items of the RSVP were selected on the basis of a cumulative process, which included review of the published literature and focused discussions with experts and patients. The items chosen therefore are likely to reflect the principal areas of concern for patients with refractive error. The *validity* and *reliability* of the RSVP and its subscales were extensively evaluated and documented. Both the overall RSVP score (*S*) and most of the subscales were independently associated with satisfaction with vision and patient rating of vision. Moreover, they were more strongly correlated with satisfaction with vision and rating of vision than were either refractive error or Snellen acuity, even in multivariate analyses. These analyses indicate that the RSVP and its subscales provide additional information about patient perception of visual status and function that is not captured by traditional clinical measurements.

Interestingly, test-retest reliability was lower in a group of patients who had an intervening refractive surgery evaluation than in a group not receiving such an evaluation. It is likely that the evaluation itself, which no doubt contained an appraisal of issues related to visual difficulties and a discussion of the risks and expectations relevant to refractive surgery, had an effect on the responses of the second administration of the RSVP. This hypothesis is supported by the fact that the least reproducible subscale was *expectations*, the area one might anticipate would be most affected by an intervening surgical evaluation. This finding suggests that the timing of the administration of the RSVP (before versus after surgical evaluation) may be important in establishing an accurate baseline for estimating function and vision-related quality of life for individuals considering refractive surgery.

There are several potential methodologic limitations to the development of any functional status questionnaire, which also may apply to the RSVP. First, 1 or more items of concern to patients may have been overlooked. As mentioned above, the use of a multistage process to identify items of interest at least limits that possibility. A second potential limitation is that the population in which the instrument was developed may not be representative of those in which the instrument will likely be used. The primary purpose for developing the RSVP was to create a measure that would be useful in assessing patient outcomes of refractive surgery. Therefore, the population studied was largely composed of individuals considering refractive surgery. A small proportion of individuals who had refractive error but who were not considering surgery was retained to improve the generalizability of the findings. Of course, it is possible that the refractive surgery candidates who participated in the RSVP development might differ in some important way from other populations of patients with refractive error who are considering refractive surgery. This might have occurred either because the centers patients were in some way atypical or because of selection bias within each center. Although coordinators were asked to administer the RSVP to consecutive eligible patients, this was not possible because of coordinator time and other restraints in each practice. The design and resources of the study do not permit a rigorous analysis of representativeness. However, the possibility of selection and related biases is mitigated by including patients from multiple sites in the development of the instrument. In fact, subscale scores did not differ significantly by clinical center, suggesting a certain homogeneity of patients across sites and that variation in practice patterns and geographic locale may not present a significant obstacle to the development of a visual function questionnaire related to refractive error and its correction. Finally, only a small percentage of participating subjects had hyperopia. Although issues related to hyperopia were

specifically addressed in the selection of items for the questionnaire, it is possible that the performance of the RSVP and its subscales might vary depending on the distribution of hyperopes and myopes in a given population.

In conclusion, the RSVP and its subscales were developed in a methodologically rigorous manner and were demonstrated to be valid and reliable.

SECTION 3

PROSPECTIVE EVALUATION OF THE RSVP IN PATIENTS UNDERGOING REFRACTIVE SURGERY

The previous section demonstrated that the RSVP and its subscales exhibit good psychometric validity and suggests that the questionnaire can be used to describe the HRQoL related to vision of individuals and populations with refractive error. This demonstration was performed cross-sectionally. In other words, it was performed at a single moment in time for each subject. The validation did not, however, provide any indication as to whether the questionnaire would be responsive or sensitive to change in visual function that might occur following refractive surgery.[16] In contrast, it is possible that subscales with limited utility in differentiating subgroups cross-sectionally may be valuable in detecting changes that follow a surgical intervention. Finally, a cross-sectional validation cannot provide evidence that an instrument may be useful as a preoperative tool to help predict which patients will have the best outcomes following refractive surgery. To address these important issues, a prospective assessment of the RSVP, administered before and after refractive surgery, was performed.

METHODOLOGY

Patients and Outcomes

Patients were eligible for the prospective assessment of the RSVP if they completed a baseline RSVP and underwent refractive surgery in both eyes. Patients were recruited from the same 5 centers that provided patients for the cross-sectional validation of the RSVP and were recruited between May and December 1997. Eligible patients received a copy of the RSVP questionnaire to complete between 2 and 6 months following surgery on the second eye. If no response was achieved, a second questionnaire was sent. If there was still no response, up to 5 attempts were made by telephone to contact the patient to request participation. In addition to the subscales of the RSVP, patients were asked to rate their satisfaction with vision on a 5-point scale (very dissatisfied, dissatisfied, neither satisfied nor dissatisfied, satisfied, or very satisfied) and to rate their concern about their vision and their overall health. Clinical and demographic data were provided by the study coordinators at each center and included information on baseline and postoperative refractive error and uncorrected vision as well as date and type of operation performed. The study was approved by the Human Studies Committees at the participating sites, and each patient gave verbal consent to participate.

STATISTICAL ANALYSIS

Responsiveness

In the context of the evaluation of a functional status questionnaire or other measurement tool (eg, visual acuity), responsiveness refers to the sensitivity of the instrument to change following an intervention. For example, as discussed previously, 1 of the advantages of disease-specific questionnaires (eg, the VF-14) over a generic health status questionnaire (eg, the SIP) is that it is much more likely to be sensitive to the relevant intervention (eg, cataract surgery). The standard measure of the responsiveness of a questionnaire is to calculate its effect size. This can be most simply performed by incorporating data from all participating patients and dividing the mean change in a measure from baseline to follow-up by the standard deviation of the measure at baseline.[17] This statistic was calculated for the RSVP and its subscales.

A second technique for calculating the effect size is known as the responsiveness statistic of Guyatt.[15] This statistic uses the same numerator as in effect size, but its denominator is the standard deviation of the score changes of patients who appear stable or unchanged over time on the basis of clinical criteria. This technique acknowledges that some patients may have improvement or worsening in certain measurement scores even though they may be clinically unchanged. With this technique, the responsiveness of an instrument is predicated on the notion that greater change should be seen in the measure for improved or worsened compared with stable patients. To assess effect size by this technique, the stable group was defined by the test-retest performance of the 16 myopic subjects who were assessed for reproducibility (see Section 2).

In addition to any intrinsic properties of the measurement itself, it is evident that responsiveness, or sensitivity to change, might vary depending on the baseline status. For example, responsiveness might vary by the severity of disease at baseline. Therefore, responsiveness was also evaluated by stratifying the patients by their degree of preoperative refractive error.

One of the subscales derived in the baseline RSVP was *expectations*. The 2 questions in this subscale relate to patients' projected tolerance of less than perfect vision. Since it does not make sense to include such questions

postoperatively, this domain was dropped from the presurgical versus postsurgical comparisons. A Cronbach's alpha was computed for the 40-item RSVP and was also found to be 0.92 (ie, there was no change in the internal consistency of the questionnaire after removing this subscale). Change in the RSVP and its subscales was first determined by simply calculating the difference between the preoperative and postoperative scores. This method is limited in that improvement, if crudely defined as any change for the better, might include some individuals who only appeared to improve because of "noise" or imprecision of the measurement tool itself. Therefore, a more conservative approach was also taken on the basis of the standard error of the measurement as assessed in the test-retest subjects (see Section 2). In this approach, the pooled standard deviation with 95% confidence intervals is calculated on the basis of measurements repeated on the same individual(s). If the post refractive surgery score differed from the preoperative score by more than 2 times the pooled standard error of measurement in the test-retest subjects, then a statistically significant change was judged to have occurred.

Several bivariate and multivariate analyses also were performed to examine change in the RSVP and its subscales in relation to other variables. Mean changes in the RSVP (*S*) and its subscales were analyzed in relation to preoperative refractive error using analysis of variance (ANOVA) with a test for linear trend. The association of changes in satisfaction with vision or ratings of vision with change in the RSVP (*S*) and its subscales was assessed using Spearman rank correlation coefficients. Multiple logistic regression was used to predict postoperative dissatisfaction with vision using changes in RSVP subscales and postoperative visual status (uncorrected acuity or need for corrective lenses) as predictors. Then a combined outcome was created (postoperative dissatisfaction with vision or significant worsening on 3 or more RSVP subscales), and bivariate associations were examined in relation to preoperative patient characteristics. Finally, multiple logistic regression was used to assess the independent association between preoperative characteristics and the combined outcome to understand further the predictors of a poor outcome from refractive surgery. All analyses were performed with use of SAS (SAS Institute, Cary, NC), version 6.12.

RESULTS

During the study period, 326 patients at the 5 centers were eligible for the study, and 176 (54%) completed a postoperative RSVP. The baseline characteristics of those completing versus not completing the RSVP were compared. Those completing the questionnaire postoperatively were slightly more likely at baseline to have been older and female and to have had better self-reported ion and worse scores for *symptoms* and *trouble with corrective lenses* than those who did not complete the postoperative questionnaire. No differences in preoperative satisfaction with vision, *concern with vision*, *trouble driving*, *corrective lens use*, or best corrected visual acuity were seen between the 2 groups.

Table IX illustrates the baseline clinical characteristics of the study population. The age and sex distribution

TABLE IX: BASELINE CHARACTERISTICS OF PATIENTS PRIOR TO REFRACTIVE SURGERY (N=176)

Age (yr)	18-29	18%
	30-39	33%
	40-49	37%
	50+	12%
Sex	F	64%
Corrective lenses	Contact lenses only	18%
	Glasses and contact lenses	40%
	Glasses only	42%
Refractive error	Hyperopic	3%
	0 to -2.9	10%
	-3 to -5.9	41%
	-6 to -9.9	34%
	-10 or higher	12%
Best corrected visual acuity	20/20 or better	87%

are consistent with other series reporting outcomes of refractive surgery.[37,61,62] Hyperopic patients accounted for only 3% of the total. Of note, there was a significant proportion of patients with moderate to high myopia, 34% with 6 to 9.9 diopters of myopia, and 12% with 10 or more diopters. The type of refractive surgery performed varied by center and degree of myopia. Overall, 47% of patients underwent PRK and 53% LASIK.

Table X summarizes the standard clinical outcomes of uncorrected visual acuity (better and worse eye) and

TABLE X: CLINICAL OUTCOMES OF PATIENTS WHO UNDERWENT REFRACTIVE SURGERY

	UNCORRECTED VISUAL ACUITY (N=151)	
	Worse eye %	Better eye %
20/20 or better	28.5	58.3
20/25 - 20/40	47.7	33.8
20/50 - 20/80	17.2	6.6
20/100 - 20/160	3.3	0.0
20/200 or worse	3.3	1.3
	REFRACTIVE ERROR* (N=152)	
	Worse eye %	Better eye %
±0.5 diopters	44.7	73.7
±0.6 - ±1.0 diopters	27.0	13.8
±1.0 - ±2.0 diopters	19.1	11.2
>2.0 diopters	9.2	1.3

*Spherical equivalent.

TABLE XI: SUMMARY MEASURES OF PATIENT OUTCOMES FOLLOWING REFRACTIVE SURGERY

A. SATISFACTION WITH VISION

	PREOPERATIVE		POSTOPERATIVE		% OF PREOPERATIVE PATIENTS WHO ARE SATISFIED OR VERY SATISFIED W/VISION POSTOPERATIVELY
	N	%	N	%	
Very dissatisfied	8	4.6	11	6.3	62.5
Dissatisfied	49	28.0	15	8.6	66.8
Neither satisfied nor dissatisfied	20	11.4	13	7.4	70.0
Satisfied	71	40.6	61	34.9	87.3
Very satisfied	27	15.4	75	42.9	81.5
Total		100.0		100.0	77.8

B. GLOBAL HEALTH

	PREOPERATIVE		POSTOPERATIVE	
	N	%	N	%
Very good	51	29.0	75	42.9
Good	27	15.3	21	12.0
Fair	0	0.0	6	3.4
Poor	0	0.0	1	0.6
Total		100.0		100.0

C. RATING OF VISION† AND CONCERN ABOUT HEALTH‡

	PREOPERATIVE MEAN (SD)	POSTOPERATIVE MEAN (SD)	% IMPROVED	% WORSENED
Rating of vision with unusual correction	8.5 (1.4)	8.5 (1.9)	45.0	28.7
Rating of uncorrected vision	2.6 (1.6)	8.0 (2.5)	89.8	3.9
Concern about health	1.4 (2.3)	1.8 (2.5)	21.7	31.4

* Response to "In general, would you say your health has been...?"
† 0-10 scale.
‡ Response to "How concerned about your health have you been in the past month?" (0-10 scale).

final refractive error. Overall, 92% of patients saw 20/40 or better at distance in their better eye and 76% in their worse eye. Seventy-two percent of worse eyes were within 1 diopter of emmetropia and 91% within 2 diopters. Table XI summarizes patient report of satisfaction with vision, global health, rating of vision, and concern about health preoperatively and postoperatively. Satisfaction with vision preoperatively was based on the reported level of satisfaction with whichever form of correction (ie, glasses or contact lenses) was used predominantly. If both contact lenses and glasses were habitually worn, then the worse rating of the 2 was used. Postoperative rating of satisfaction was based on satisfaction with uncorrected vision. Thirty-three percent of patients indicated that they were dissatisfied or very dissatisfied with their vision preoperatively and 15% postoperatively. Sixty-eight percent of patients who indicated that they were dissatisfied or very dissatisfied with their vision preoperatively indicated that they were satisfied or very satisfied postoperatively. Patients' report of overall health and concern about health both showed a slight, insignificant trend toward worse scores. Rating of vision showed no change by simple comparisons of means, although more improved than worsened, when vision with corrective lenses was used as the baseline for comparison. A large change in rating of vision was observed when vision without corrective lenses was used as the baseline comparison.

The change in the total RSVP score (S) and change in each individual subscale are illustrated in Table XII. The mean overall RSVP score (S) improved from 24 preoperatively to 13.2 postoperatively. Eighty-five percent of patients had some improvement in total RSVP score. Using the more conservative statistical definition of change, 67% of patients had an improved total RSVP score, 4.5% worsened, and the remaining 28.5% had no change. Substantial variation was observed in both the proportional and absolute change of the individual subscales of the RSVP. By far, the largest proportional change

TABLE XII: RSVP SUBSCALES AND OVERALL S: PREOPERATIVE, POSTOPERATIVE, AND CHANGE STATISTICS

RSVP SUBSCALE	PREOP MEAN* (SD)	PREOP RANGE	POSTOP MEAN (SD)	POSTOP RANGE	% ANY IMPROVEMENT	% ANY WORSENING	% SIGNIFICANT IMPROVEMENT†	% SIGNIFICANT WORSENING†
Concern	45.0 (18.1)	4.2-87.5	26.7 (16.8)	0-75	78.9	14.3	62.9	7.4
Functioning	15.9 (14.2)	0-65	7.4 (14.5)	0-86.4	70.4	19.5	40.2	5.9
Driving	24.3 (22.7)	0-100	23.7 (21.7)	0-100	38.0	41.5	28.3	29.5
Symptoms	19.6 (16.6)	0-75	10.8 (10.7)	0-75	59.0	27.1	44.6	12.7
Optical problems	11.8 (13.6)	0-62.5	10.3 (13.5)	0-87.5	42.8	34.9	27.7	19.9
Glare	22.4 (17.3)	0-75	19.0 (16.1)	0-75	45.2	33.7	28.9	16.3
Trouble w/corrective lenses	35.0 (17.3)	7.1-81.3	7.4 (16.3)	0-75	86.5	7.0	73.7	2.3
Total (S) (40-item)	24.0 (10.6)	3.2-54.5	13.2 (10.5)	0-59.7	84.7	15.3	66.5	4.5

* RSVP and subscale scores may range from 0-100. Lower scores indicate less dysfunction.
† Change greater than 2x standard error of measurement (see methods).

was observed for *trouble with corrective lenses*, where the mean fell from 35 preoperatively to 7.4 postoperatively. Large proportional improvements in mean scores were also observed for *concern* (45.0 preoperative to 26.7 postoperative), *functioning* (15.9 preoperative to 7.4 postoperative), and *symptoms* (19.6 preoperative to 10.8 postoperative). Large variation was also seen in the proportion of those who improved significantly (range, 27.7% to 73.7%) or worsened (2.3% to 29.5%). Of note, despite the good outcomes as reflected by Snellen acuity, significant worsening was reported in the subscale *concern* by 7.4% of patients, *functioning* by 5.9%, *driving* by 29.5%, *symptoms* by 12.7%, *optical problems* by 19.9%, and *glare* by 16.3%. Only 2.3% reported more trouble with corrective lenses. Figure 4 illustrates the preoperative and postoperative distributions of the RSVP and its subscales.

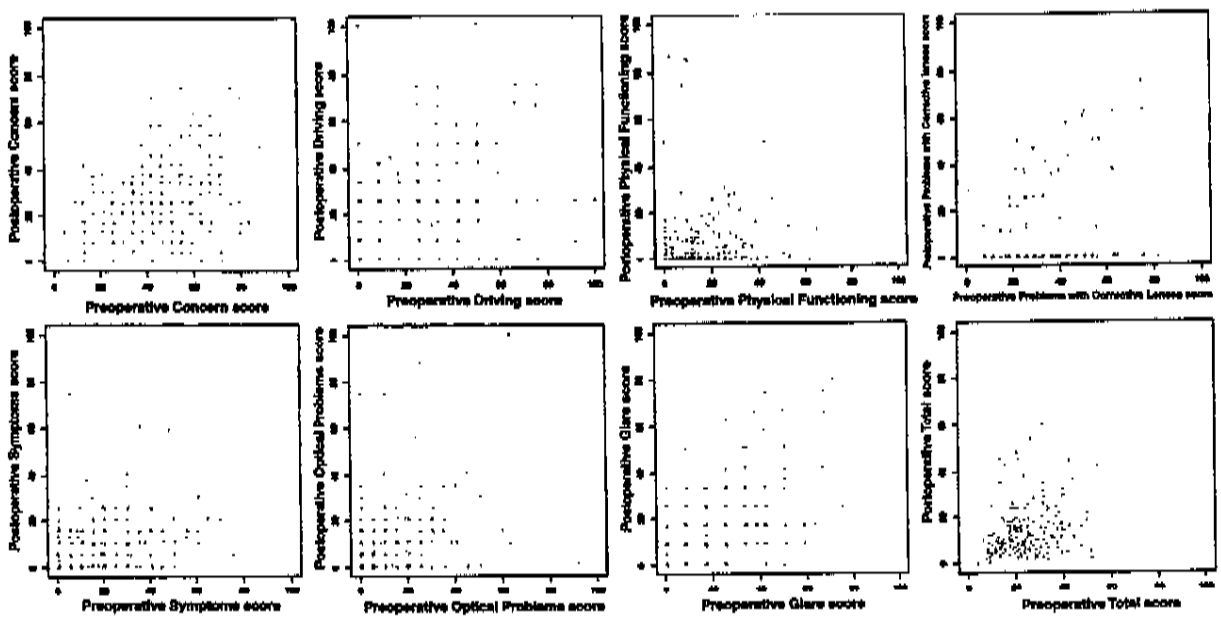

FIG 4
Preoperative and postoperative distribution of RSVP and its subscales scores.

TABLE XIII: PROPORTION OF PATIENTS WORSENING BY NUMBER OF RSVP SUBSCALES

NO. SUBSCALES WITH SIGNIFICANT WORSENING	% PATIENTS
0	52.3
1	25.6
2	8.5
3	9.7
4	2.3
5	1.7
6	0.0
7	0.0

* Change greater than 2x standard error of measurement (see methods)

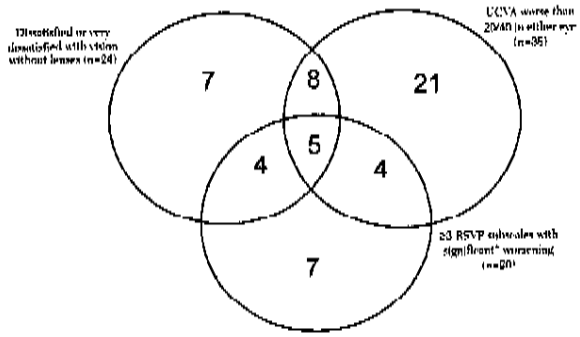

FIG 5
Venn diagram illustrating minimal overlap between 3 different measures of outcomes following refractive surgery. UCVA, uncorrected visual acuity. * 2x SE mean variability (see Methods section).

Since an individual may have improvement or worsening on a number of different subscales, the proportion of individuals reporting up to 7 subscales with significant worsening was calculated, and this information is presented in Table XIII. Approximately 52% of patients had no significant worsening in any of the subscales, 26% had worsening in 1, 22% in 2 or more, and 14.7% of patients had significant worsening in 3 or more subscales.

Figure 5 is a Venn diagram illustrating the relationship between 3 different measures of less than optimal refractive surgery outcome: the traditional outcomes of uncorrected acuity, dissatisfaction with vision, and a new proposed measure, a worsening of 3 or more of the RSVP subscales. As is evident from this diagram, these 3 measures are assessing different outcome domains. Strikingly, only 5 individuals fell into the intersection of the 3 measures.

The relationship between preoperative refractive error in the eye with less refractive error and change in the RSVP and its subscales is shown in Table XIV. (The analysis was repeated using the eye with greater refractive error, and the results were nearly identical.) For the over-

TABLE XIV: ASSOCIATION BETWEEN PREOPERATIVE REFRACTIVE ERROR AND IMPROVEMENT IN RSVP (*S*) AND SUBSCALES FOLLOWING REFRACTIVE SURGERY

PREOPERATIVE REFRACTIVE ERROR IN BETTER EYE	NO. OF PATIENTS*	S†	% PATIENTS IMPROVED IN S	CONCERN‡	% PATIENTS IMPROVED IN CONCERN	PHYSICAL FUNCTIONING§	% PATIENTS IMPROVED IN PHYSICAL FUNCTIONING	DRIVING‖	% PATIENTS IMPROVED IN DRIVING
Hyperopic	7	5.5 (9.0)	85.7	7.9 (14.9)	57.1	-2.0 (6.2)	14.3	-11.9 (9.4)	0.00
0 to -2.9	26	8.4 (12.9)	76.9	14.1 (20.1)	69.2	4.0 (21.1)	63.6	0.4 (23.0)	28.6
-3 to -5.9	82	12.2 (13.2)	87.8	20.7 (19.8)	82.9	8.8 (21.9)	69.1	-0.6 (31.0)	42.5
-6 to -9.9	48	11.2 (12.9)	83.3	19.7 (19.2)	83.0	10.1 (18.2)	80.4	1.6 (22.9)	39.1
-10 or higher	13	8.9 (9.7)	84.6	12.4 (25.9)	69.2	9.0 (9.1)	84.6	9.0 (24.7)	41.7

PREOPERATIVE REFRACTIVE ERROR IN BETTER EYE	NO. OF PATIENTS*	SYMPTOMS¶	% PATIENTS IMPROVED IN SYMPTOMS	OPTICAL PROBLEMS**	% PATIENTS IMPROVED IN OPTICAL PROBLEMS	GLARE††	% PATIENTS IMPROVED IN GLARE	TROUBLE WITH CORRECTIVE LENSES‡‡	% PATIENTS IMPROVED IN TROUBLE W/LENSES
Hyperopic	7	13.2 (19.1)	85.7	1.3 (12.8)	28.6	5.4 (12.9)	57.1	23.3 (20.4)	85.7
0 to -2.9	26	3.4 (17.3)	38.1	0.1 (21.1)	38.1	7.7 (18.4)	57.1	35.8 (25.8)	91.7
-3 to -5.9	82	10.5 (16.9)	63.3	1.2 (17.8)	35.4	3.7 (18.4)	41.8	29.9 (19.5)	90.0
-6 to -9.9	48	9.2 (22.5)	58.7	3.3 (16.0)	56.5	2.2 (16.3)	45.7	21.8 (21.9)	79.2
-10 or higher	13	6.7 (17.7)	53.8	1.9 (9.7)	53.8	2.2 (21.3)	38.5	17.6 (15.7)	83.3

* The number of patients in each category varies for each subscale due to some missing data. The Ns in this table apply to the total *S* score.
† Analysis of variance for difference in means; F=0.86; *P*=.489; Test for linear trend; F=0.61; *P*=.437.
‡ Analysis of variance for difference in means; F=1.39; *P*=.241; Test for linear trend; F=0.58; *P*=.449.
§ Analysis of variance for difference in means; F=0.85; *P*=.496; Test for linear trend; F=2.16; *P*=.144.
‖ Analysis of variance for difference in means; F=0.72; *P*=.578; Test for linear trend; F=2.62; *P*=.108.
¶ Analysis of variance for difference in means, F=0.73, *P*=.573; Test for linear trend; F=0.15; *P*=.698.
** Analysis of variance for difference in means; F=0.16; *P*=.958; Test for linear trend; F=0.07; *P*=.789.
†† Analysis of variance for difference in means; F=0.39; *P*=.817; Test for linear trend; F=0.46; *P*=.500.
‡‡ Analysis of variance for difference in means; F=2.81; *P*=.027; Test for linear trend; F=1.51; *P*=.220.

all RSVP and the individual subscales (except, perhaps, for *trouble with lenses*, where a significant difference in means but not in linear trend was seen), neither the magnitude of change nor the percent of patients showing improvement varied by preoperative refractive error. These findings indicate that the degree of improvement reported by patients in these various domains cannot be predicted by the amount of refractive error preoperatively. Similarly (Table XV), the correlations between change in satisfaction with vision or change in rating of vision and the RSVP and most of its subscales were significant, whereas there was no correlation at all between change in refractive error in either eye and change in satisfaction.

The responsiveness of the RSVP and its subscales was calculated using 2 statistical methods (effect size and Guyatt's responsive statistic [see Methods section]) and using 3 different external measures of improvement. These external measures included improved satisfaction with vision, having an uncorrected visual acuity of 20/20 or better in at least 1 eye, and not needing spectacle or contact lens correction postoperatively. Table XVI summarizes these calculations. According to Cohen,[88] it is reasonable to view an effect size of 0.2 as "small," 0.5 as "medium," and 0.8 as "large." The overall RSVP (*S*) demonstrated a large effect size in all the comparisons. As measured by these techniques, the responsiveness of the individual subscales varied substantially. *Driving* was consistently the least responsive, and *glare* and *optical problems* were modestly responsive. The subscales *concern* and *trouble with lenses* were consistently the most responsive. Finally, Table XVII illustrates the responsiveness of the RSVP and its subscales, stratified by preoperative refractive error. The responsiveness of the questionnaire subscales did not vary by preoperative refractive error with the exception of *physical functioning*, where there was a trend toward greater responsiveness for greater degrees of preoperative myopia.

A multivariate analysis was performed to try to identify factors associated with patient satisfaction with uncorrected vision postoperatively. As indicated in Section 1 of this thesis, previous research has indicated that the strongest predictors of dissatisfaction after refractive surgery are poor uncorrected distance acuity and ongoing need for spectacles and/or contact lenses. Since these variables are highly correlated, 3 separate analyses were done, each adjusting for age and sex (Table XVIII), where the first model included uncorrected visual acuity; the second, the use of corrective lenses for distance; and the third, the use of lenses for distance or near. In all 3 models, the worsening of 3 or more subscales of the RSVP was independently associated with dissatisfaction with vision following refractive surgery. In each model, worsening on 3 or more subscales was associated with approximately a sixfold excess risk of reporting dissatisfaction with vision postoperatively. Worsening on 3 or more RSVP subscales was found to be a stronger factor in predicting dissatisfaction than the traditional clinical assessments of uncorrected visual acuity and need for distance or reading lenses. Only the need for distance lenses was a stronger predictor.

To test the hypothesis that the RSVP or 1 or more of its components administered before surgery might be helpful in predicting postoperative outcomes, a final

TABLE XV: SPEARMAN CORRELATIONS BETWEEN CHANGES IN DIFFERENT OUTCOME MEASURES (N)

	CHANGE IN REFRACTIVE ERROR BETTER EYE	CHANGE IN REFRACTIVE ERROR WORSE EYE	CHANGE IN RSVP (S)	CHANGE IN CONCERN	CHANGE IN PHYSICAL FUNCTIONING
Change in satisfaction with vision	-0.10* (n=150)	-0.06† (n=150)	0.59‡ (n=174)	0.44‡ (n=173)	0.48‡ (n=167)
Change in rating of vision	0.28 (n=109)	0.21 (n=109)	0.58 (n=129)	0.31 (n=128)	0.50 (n=126)
	CHANGE IN DRIVING	**CHANGE IN SYMPTOMS**	**CHANGE IN OPTICAL PROBLEMS**	**CHANGE IN GLARE**	**CHANGE IN TROUBLE W/CORRECTIVE LENSES**
Change in satisfaction with vision	0.37‡ (n=164)	0.33‡ (n=164)	0.33‡ (n=164)	0.33‡ (n=164)	0.25† (n=169)
Change in rating of vision	0.52 (n=123)	0.44 (n=126)	0.52 (n=126)	0.31 (n=126)	-0.02 (n=126)

* *P* value = 0.237
† *P* value = 0.444
‡ *P* value ≤ 0.001

TABLE XVI: RESPONSIVENESS OF RSVP (S) AND ITS SUBSCALES S BY DIFFERENT DEFINITIONS OF IMPROVED OUTCOME

A. USING POSTOPERATIVE SATISFACTION WITH VISION AS MEASURE OF OUTCOME

RSVP SCALE	EFFECT SIZE*† IMPROVED SATISFACTION (N=91)	GUYATT'S RESPONSE STATISTIC*‡ IMPROVED SATISFACTION (N=91)
Concern	25.6/17.9=1.43	25.6/6.7=3.82
Physical functioning	13.5/13.9=0.97	13.5/7.2=1.88
Driving	7.4/21.7=0.34	7.4/8.3=0.89
Symptoms	14.0/18.0=0.78	14.0/5.8=2.41
Optical problems	6.5/15.6=0.42	6.5/4.4=1.48
Glare	9.4/18.7=0.50	9.4/7.2=1.31
Trouble with lenses	33.0/19.1=1.73	33.0/8.8=3.75
Total S	16.4/11.1=1.48	16.4/3.9=4.21

B. USING POSTOPERATIVE VISUAL ACUITY AS MEASURE OF OUTCOME

RSVP SCALE	EFFECT SIZE§‖ 1 EYE 20/20 OR BETTER (N=88)	GUYATT'S RESPONSE STATISTIC§‖ 1 EYE 20/20 OR BETTER (N=88)
Concern	19.2/18.4=1.04	19.2/6.7=2.87
Physical functioning	9.5/16.0=0.59	9.5/7.2=1.32
Driving	1.7/25.2=0.07	1.7/8.3=0.20
Symptoms	9.6/17.9=0.54	9.6/5.8=1.66
Optical problems	1.8/13.8=0.13	1.8/4.4=0.41
Glare	4.3/18.4=0.23	4.3/7.2=0.60
Trouble with lenses	29.8/17.4=1.71	29.8/8.8=3.39
Total S	11.9/11.8=1.01	11.9/3.9=3.05

C. USING POSTOPERATIVE NEED FOR CORRECTIVE LENSES AS MEASURE OF OUTCOME

RSVP SCALE	EFFECT SIZE*† NO DISTANCE LENSES (N=153)	GUYATT'S RESPONSE STATISTIC*† NO DISTANCE LENSES (N=153)
Concern	20.2/18.1=1.12	20.2/6.7=3.01
Physical functioning	8.8/13.8=0.64	8.8/7.2=1.22
Driving	-0.7/21.2=-0.03	-0.7/8.3=-0.08
Symptoms	8.9/16.4=0.54	8.9/5.8=1.53
Optical problems	1.8/13.7=0.13	1.8/4.4=0.41
Glare	4.1/17.0=0.24	4.1/7.2=0.57
Trouble with lenses	31.1/17.6=1.77	31.1/8.8=3.53
Total (S)	12.1/10.4=1.16	12.1/3.9=3.10

* Numerator is mean change in subscale score (or Total S) among those who reported any improvement in satisfaction with vision after surgery.
† Denominator is standard deviation of preoperative subscale score (or Total S) among those who reported any improvement in satisfaction with vision after surgery.
‡ Denominator is standard deviation of change in subscale score (or Total S) among stable group of myopes who did not undergo surgery.*
§ Numerator is mean change in subscale score (or totals) among those who had at least 1 eye with 20/20 vision after surgery.
‖ Denominator is standard deviation of preoperative subscale score (or Total S) among those who had at least 1 eye with 20/20 vision after surgery.

analysis was performed. In this analysis (Table XIX), the goal was to look for predictors of poor outcome as reported by patients. Poor outcome was defined as a postoperative report of being dissatisfied with vision or having a significant reduction in 3 or more RSVP subscales. Age, sex, and preoperative refractive error were not predictive, although age greater than 45 was consistently associated with an odds ratio of approximately 1.5 (ie, those over age 45 more likely to be dissatisfied). Three of the preoperative RSVP subscales (*expectations*, *physical functioning*, and *symptoms*) were associated with approximately a twofold likelihood of poor postoperative outcome. In these multivariate analyses, *physical functioning* reached borderline significance ($P=.06$) and *symptoms* was statistically significant ($P=.05$) as a predictor.

TABLE XVII: RESPONSIVENESS OF RSVP SUBSCALES AND TOTAL S BY PREOPERATIVE REFRACTIVE ERROR IN THE BETTER EYE

PREOPERATIVE REFRACTIVE ERROR IN THE BETTER EYE (DIOPTERS)	TOTAL S	CONCERN	PHYSICAL FUNCTIONING	DRIVING	SYMPTOMS	OPTICAL PROBLEMS	GLARE	TROUBLE W/LENSES
Hyperopic (N=7)	0.63	0.47	-0.30	-1.18	0.71	0.15	0.34	1.55
0.0 to -2.9 (N=26)	0.75	0.71	0.33	0.02	0.19	0.01	0.41	1.88
-3.0. to -5.9 (N=82)	1.15	1.20	0.59	-0.03	0.67	0.09	0.21	1.81
-6.0 to -9.9 (N=48	1.11	1.16	0.73	0.06	0.52	0.24	0.13	1.29
-10 or worse (N=13)	0.81	0.67	0.62	0.47	0.40	0.16	0.12	1.04

TABLE XVIII: PREDICTORS OF POSTOPERATIVE DISSATISFACTION WITH VISION

	MODEL 1		MODEL 2		MODEL 3	
	ODDS RATIO	95% CI	ODDS RATIO	95% CI	ODDS RATIO	95% CI
Age >45	1.75	(0.59, 5.16)	1.52	(0.53, 4.37)	0.93	(0.30, 2.92)
Female	2.20	(0.69, 6.98)	1.89	(0.61, 5.86)	2.06	(0.72, 5.94)
Preoperative refractive error*	1.02	(0.87, 1.19)	1.03	(0.87, 1.20)	1.00	(0.86, 1.16)
≥3 RSVP subscales w/significant worsening†	5.84	(1.88, 18.13)‡	6.96	(2.21, 21.87)‡	6.20	(2.10, 18.26)‡
Postoperative uncorrected acuity worse than 20/40 in either eye	3.54	(1.23, 10.19)§				
Wear distance lenses			11.68	(3.72, 36.73)‡		
Wear distance or reading glasses					4.86	(1.60, 14.80)‡

CI=confidence interval.
* Spherical equivalent, eye with less refractive error.
† Change greater than 2x standard error of measurement (see Methods).
‡ $P < .01$.
§ $0.01 < P < .05$.

CONCLUSIONS

As previously discussed, the standard indices for measuring patient outcomes following refractive surgery have largely been limited to assessing uncorrected acuity and refractive error. Patient-reported outcomes either have not been reported at all or have been typically limited to a report of satisfaction with vision. The RSVP and its subscales have been shown to exhibit a variety of properties that recommend it as an outcome measure which should be complementary to the traditional clinical assessments. First, the RSVP and its subscales have been shown to be highly responsive to the intervention of refractive surgery. Other measures, including more global health assessments, were not responsive. Second, the RSVP and its subscales have been shown to be correlated with change in satisfaction with vision postoperatively. Change in refractive error was not correlated at all with this outcome. Third, as illustrated in the Venn diagram (Fig 5), the use of uncorrected Snellen acuity, self-report of satisfaction with vision, and the RSVP as outcome measures do not identify the same group of patients as successes or failures of the surgical intervention. The RSVP clearly provides additional information about patient outcomes that is not captured by simply assessing patient satisfaction or uncorrected acuity. Moreover, as shown in the multivariate analyses, failure to improve on 3 or more RSVP subscales was independently predictive of dissatisfaction with vision. Fourth, the magnitude of improvement in the RSVP and its subscales did not vary significantly in relation to the magnitude of the initial preoperative refractive error. Although this might appear counterintuitive, it is analogous to the findings reported for cataract surgical patients when the VF-14 was evaluated as one of multiple outcome measures of cataract surgery.[9] For cataract surgery, it was found that the magnitude of perceived functional improvement was not greater for those with worse visual acuity preoperatively (eg, 20/200 versus 20/50). This indicated that the problems with visual function perceived by those who opted for cataract surgery were not reflected by Snellen acuity but by perceived functional

TABLE XIX: ASSOCIATION OF PREOPERATIVE RSVP SUBSCALES OR TOTAL S WITH POSTOPERATIVE DISSATISFACTION WITH VISION OR SIGNIFICANT WORSENING ON 3 OR MORE SUBSCALES

	ODDS RATIO	95% CI	ODDS RATIO	95% CI	ODDS RATIO	95% CI	ODDS RATIO	95% CI	ODDS RATIO	95% CI
Age 45 and over	1.42	(0.66, 3.06)	1.44	(0.66, 3.14)	1.56	(0.71, 3.41)	1.31	(0.60, 2.86)	1.40	(0.64, 3.03)
Female	1.07	(0.50, 2.30)	1.17	(0.54, 2.55)	1.03	(0.48, 2.24)	1.08	(0.49, 2.35)	1.22	(0.56, 2.70)
Better eye refractive error (spherical equivalent)	0.95	(0.85, 1.05)	0.95	(0.85, 1.07)	0.93	(0.83, 1.05)	0.97	(0.85, 1.09)	0.94	(0.83, 1.05)
Concern subscale*	0.79	(0.25, 2.53)								
Expectations subscale*			2.08	(0.84, 4.88)						
Physical functioning subscale*					2.35	(0.96, 5.76)†				
Driving subscale*							1.06	(0.44, 2.56)		
Symptoms subscale*									2.41	(1.00, 5.79)‡
Optical problems subscale*										
Glare subscale*										
Trouble with lenses subscale*										
Total S*										

	ODDS RATIO	95% CI	ODDS RATIO	95% CI	ODDS RATIO	95% CI	ODDS RATIO	95% CI
Age 45 and over	1.50	(0.69, 3.27)	1.40	(0.65, 3.02)	1.44	(0.66, 3.15)	1.42	(0.66, 3.07)
Female	1.14	(0.52, 2.48)	1.11	(0.51, 2.41)	1.23	(0.56, 2.71)	1.08	(0.50, 2.32)
Better eye refractive error (spherical equivalent)	0.94	(0.83, 1.06)	0.95	(0.84, 1.07	0.94	(0.84, 1.06)	0.95	(0.84, 1.07)
Concern subscale*								
Expectations subscale*								
Physical functioning subscale*								
Driving subscale*								
Symptoms subscale*								
Optical problems subscale*	1.41	(0.64, 3.10)						
Glare subscale*			1.17	(0.44, 3.09)				
Trouble with lenses subscale*					0.32	(0.07, 1.47)		
Total S*							1.02	(0.31, 3.37)

CI=confidence interval.

* Each subscale or Total S was dichotomized at the first decile with the lowest decile=1 and the remaining values=0.

† P=.06

‡ P=.05

need. One might infer, therefore, that the magnitude of refractive error is not adequate as a sole measure to characterize patients' functional status or perceived limitations (eg, symptoms, difficulties with glasses or contact lenses) related to their refractive error.

Although the RSVP produces an overall composite score, the use of this total score may not be optimal. For example, it is possible that the total score might show some improvement even if there were a significant (ie, important to the patient) decrement in one or more of the individual subscales. Therefore, it would be preferable to use and report the individual subscales in any characterization of patients undergoing refractive surgery. It would be potentially very informative to learn, for example, that an intervention may have a large benefit in patient-reported function but a worsening in *symptoms* or *glare*. Retention of the subscales allows this possibility. The RSVP and a number of its subscales were shown to be responsive to the intervention of refractive surgery as evidenced by the large effect sizes or Guyatt's responsiveness statistics found. In interpreting the data on effect size, the overall consistency of the data is more important than the individual effect sizes calculated. Also, the finding that a particular subscale has a small effect size does not necessarily imply that the subscale provides no useful information in the assessment of an intervention. For example, the *driving* subscale consistently was shown to have a small effect size. Yet, as shown in Table XII, an equal and large proportion of patients reported improvement and worsening of driving ability following refractive surgery. Clearly, one would not want to delete issues related to driving from an assessment of the outcomes of refractive surgery, even though this subscale was shown to have a low effect size.

From the perspective of surgeons using the standard clinical outcomes of uncorrected distance acuity and achieved refractive error, the outcomes of this cohort of refractive surgical patients was very good, especially given the significant number of individuals who had moderate to high myopia preoperatively. Yet, as demonstrated by the RSVP subscales, worsening was reported in the domains related to *driving*, *symptoms*, *optical problems*, and *glare* by 13% to 30% of patients. From the patient perspective, therefore, there remains significant room for improvement. The findings presented do not, of course, represent a final conclusion regarding patient outcomes of refractive surgery. The research described was performed to develop and evaluate the RSVP rather than to compare surgical outcomes by technique or other factors. The surgery performed on this cohort was done in 1997 in 5 centers. It is possible that one might find a greater benefit (eg, due to fewer patient-perceived limitations) to surgery performed in the year 2000 or in a different group of patients. Yet, it is likely that the incorporation of the patient's perspective on HRQoL associated with refractive error and its correction will provide a valuable new metric to assess and improve patient outcomes.

SECTION 4

FUTURE RESEARCH NEEDS AND PLANS

The RSVP and its subscales have been validated by accepted psychometric standards and have been shown to be responsive to the intervention of refractive surgery. The instrument provides useful information about patients and their outcomes that cannot be obtained from standard measures. However, there is additional work to be done to maximize its value as a research tool and modifications that should be considered to render it feasible and useful in clinical practice.

From a research perspective, it would first be valuable to administer the RSVP preoperatively and postoperatively to a larger cohort of patients with a wide range of refractive error where detailed clinical information is also collected. Although the items of the RSVP were generated through a process that included the concerns of patients with hyperopia and presbyopia, the instrument's validity and responsiveness were assessed in a population that was largely myopic. The development of a larger database of subjects with clinical and RSVP data would also allow one to refine the predictive models further. An important goal of this research is to define, on the basis of information collected *before* surgery, subgroups of patients who have a greater likelihood of worse outcomes after surgery. A fundamental assumption of this research program is that standard clinical information can be combined with insights from the RSVP (or similar questionnaires) to develop predictive models that are significantly more accurate than could be obtained using either the clinical information or the questionnaire data alone. The data collected on the cohort of patients presented in this thesis suggest that data derived preoperatively from the RSVP subscales *symptoms*, *physical functioning*, and perhaps *expectations* may be combined with age and sex to improve one's prediction of who will do poorly following refractive surgery. However, these analyses need to be repeated in larger cohorts of patients. This will allow not only an opportunity to confirm the findings presented here but also additional statistical power that would enable more detailed analyses of subgroups of patients.

A second aspect that I recommend for a research agenda on patient outcomes of refractive surgery is the incorporation of patient "utilities" into the assessment. A patient "utility" is simply the preference of a patient for one particular health state over another. There are a variety of different accepted methodologies for assessing patient prefer-

ences[64-66] that reflect different strategies to elicit patients to order their preferences for different states or outcomes on a scale. For example, a patient might be asked to rate having trouble with night driving on a scale, anchored at one end by "total blindness" and the other by "perfect vision." These techniques bear on the important issue of how important a given outcome is to an individual patient. Consider, then, 2 imaginary patients who have 20/20 uncorrected acuity following refractive surgery for the same degree of preoperative myopia. They also have identical RSVP and subscale scores that include significant (and identical) worsening on the *glare* and *driving* subscales. One patient, however, has rated limitations in night driving near the "total blindness" end of the preference scale, and the other considers such a limitation no more than a minor annoyance having rated it, as an isolated symptom, near the "perfect vision" end of the scale. Clearly, these 2 patients would feel that they had experienced very different outcomes of refractive surgery, and that difference may not have been captured by a HRQoL questionnaire such as the RSVP. In summary, therefore, it would be useful to incorporate a measure of patient preferences to help to interpret the results of the RSVP for individual patients.

Third, it would be valuable to learn whether the RSVP or at least certain of its subscales would be able to distinguish outcomes of competing refractive surgical techniques. Although the questionnaire has been shown to be very responsive to the intervention of refractive surgery, it does not necessarily follow that it would be sufficiently sensitive to distinguish between competing techniques, such as LASIK and PRK or other evolving techniques. Currently, at least for comparable degrees of myopia, the standard clinical assessments of refractive error and uncorrected Snellen acuity have not been able to distinguish the results of LASIK and PRK.[67] However, it is reasonable to consider that patient perspectives on the outcomes of these various approaches will be helpful, if not crucial, in their assessment.

Ideally, one would hope that a research tool such as the RSVP might inform and improve clinical practice. However, even given the assumption that the questionnaire provides insights that may be important to refractive surgeons and their patients, it will not be used routinely in a clinical setting unless a variety of criteria are met. The administration of the questionnaire (1) should not perturb the normal flow of patients in an efficient practice, (2) should expend little staff time, and (3) should result in the display of data in real time for the surgeon and patient to review. As it currently exists as a research tool, the RSVP would not meet these criteria. However, current efforts are now being devoted to programming the RSVP onto a personal computer platform in a manner that will allow patients to proceed rapidly through the questionnaire without supervision. The scoring algorithms will be embedded within this program so that the patient's total and subscale scores will be available immediately after the questionnaire has been completed. This questionnaire information could then be merged with the standard clinical markers (eg, age, sex, refractive error) on the same patient and compared with a large existing database of patients who had previously supplied outcomes data. This comparison would enable the surgeon and patient to use the predictive model in real time to inform their decisions regarding surgical intervention.

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APPENDIX

REFRACTIVE STATUS AND VISION PROFILE

1. Center: _____
2. Chart Number: _____
3. Patient Name (last, first) _____
4. Telephone numbers: _____-_____-_____(h) _____-_____-_____(w)
5. Date (*month/day/year*): _____/_____/_____

BACKGROUND INFORMATION

Patient Information

1. Age ___ ___ years

2. Sex (*check only one*)
   - Female (1)
   - Male (2)

Glasses and Contact Lens Use

3. In the past month, to see far away, I wore:
   - a. Only glasses (1)
   - b. Mostly glasses, sometimes contacts (2)
   - c. About equally, glasses and contacts (3)
   - d. Mostly contacts, sometimes glasses (4)
   - e. Only contacts (5)

4. In the past month, did you wear different glasses (or bifocals) to see close up?
   (No 1) (Yes 2)

5. If you wore contacts in the past month, were they:
   - a. Rigid gas permeable (hard) (1)
   - b. Soft lenses (2)
   - c. Disposable lenses (3)
   - d. Didn't wear in the past month (4)

6. If you wore contacts in the past month, did you ever wear them overnight

(Yes 1) (No 2)

We are interested in your vision during the past month.

For the following 3 questions, please answer by writing a number between 0 and 10, where 0 means completely blind and 10 means perfect vision:

8. Rate your vision, over the past month, with glasses: ___ ___

   Have not worn glasses at all in the past month ☐

9. Rate your vision over the past month with contact lenses: ___ ___

   Have not worn contact lenses at all in the past month ☐

10. Rate your vision, over the past month, with **no** glasses or contact lenses: ___ ___

11. During the past month, how satisfied have you been with your ability to do reading and near work (using the glasses or contact lenses you ordinarily use for reading, if you did (*check only 1*):

Very dissatisfied	(1)
Dissatisfied	(2)
Neither satisfied nor dissatisfied	(3)
Satisfied	(4)
Very satisfied	(5)
Not applicable	(6)

12. During the past month, how satisfied have you been with your current vision *with glasses* (*check only 1*):

Very dissatisfied	(1)
Dissatisfied	(2)
Neither satisfied nor dissatisfied	(3)
Satisfied	(4)
Very satisfied	(5)
Not applicable (did not wear glasses at all during the past month).	(6)

13. During the past month, how satisfied have you been with your current vision *with contact lenses* (*check only 1*):

Very dissatisfied	(1)
Dissatisfied	(2)
Neither satisfied nor dissatisfied	(3)
Satisfied	(4)
Very satisfied	(5)
Not applicable (did not wear contact lenses at all during the past month).	(6)

14. During the past month, how satisfied have you been with your current vision WITHOUT glasses or contact lenses (*check only 1*):

Very dissatisfied	(1)
Dissatisfied	(2)
Neither satisfied nor dissatisfied	(3)
Satisfied	(4)
Very satisfied	(5)

15. In general, during the past month, would you say your **health** has been (*check only 1*):

Excellent	(1)
Very good	(2)
Good	(3)
Fair	(4)
Poor	(5)

16. How concerned about your **health** have you been during the past 1 month (*check only 1*):

0 (not at all concerned)	(1)
1	(2)
2	(3)
3	(4)
4	(5)
5	(6)
6	(7)
7	(8)
8	(9)
9	(10)
10	(11)

Vision

Please respond to the questions as they apply to you over the past month

17. I worry about my vision (*check only 1*):

Never	(1)
Rarely	(2)
Sometimes	(3)
Often	(4)
Always	(5)

18. My vision is a concern in my life (*check only 1*):

Never	(1)
Rarely	(2)
Sometimes	(3)
Often	(4)
Always	(5)

19. My vision holds me back (*check only 1*):

Never	(1)
Rarely	(2)
Sometimes	(3)
Often	(4)
Always	(5)

20. I am frustrated with my vision (*check only 1*):

Never	(1)
Rarely	(2)
Sometimes	(3)
Often	(4)
Always	(5)

21. My vision makes me less self sufficient (*check only 1*):

Never	(1)
Rarely	(2)
Sometimes	(3)
Often	(4)
Always	(5)

22. Because of my vision, there are things I am afraid to do (*check only 1*):

Never	(1)
Rarely	(2)
Sometimes	(3)
Often	(4)
Always	(5)

23. I could accept less than perfect vision if I didn't need glasses or contact lenses any more (*check only 1*):

Strongly disagree	(1)
Disagree	(2)
Neither agree nor disagree	(3)
Agree	(4)
Strongly agree	(5)
Do not need to use glasses or contact lenses to get the best possible vision	(6)

24. As long as I could see well enough to drive without wearing glasses or contact lenses, I wouldn't mind having vision that was less than perfect (*check only 1*):

Strongly disagree	(1)
Disagree	(2)
Neither agree nor disagree	(3)
Agree	(4)
Strongly agree	(5)

We are interested in whether your vision caused you any difficulty with some common activities *during the past month*.

The following questions ask seperately about difficulty you may have had doing the activity with glasses, with contact lenses, and with no correction (neither glasses nor contact lenses).

Please give an answer for all 3 types of correction (there is a choice for "not applicable").

The choices for answers are:

0 Not applicable
1 No difficulty at all
2 A little difficulty
3 Moderate difficulty
4 Severe difficulty
5 So much difficulty that I did not do the activity with this type of correction
6 Never did the activity for other reasons (not related to vision)

During the past month, how much difficulty have you had with each activity, using these types of corrections?

Activity	**With Glasses** (circle a number)	**With Contacts** (circle a number)	**With No Correction** (circle a number)
21. Watching TV or movies	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
22. Playing or working outside	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
23. Taking care of or playing with children	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
24. Seeing your alarm clock	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
25. Seeing clearly when you wake up	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
26. Seeing a clock on the wall	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
27. Doing your job	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
28. Doing sports/recreation	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
29. Swimming	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
30. Your social life	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
31. Reading and near work	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
32. Driving at night	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
33. Driving when it is raining	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
34. Driving when there is a glare from oncoming headlights	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6

We are interested in whether you experienced certain problems with your eyes or vision *during the past month*.

The following questions ask seperately about each problem for glasses, contact lenses, and no correction (neither glasses nor contact lenses).

Please give an answer for all 3 types of correction (there is a choice for "not applicable").

The choices for answers are:

0 Not applicable
1 No trouble at all
2 A little trouble
3 Moderate trouble
4 Severe trouble
5 So much trouble that I did not do the activity with this type of correction

During the past month, how bothered have you been by each of the following things, using these types of corrections?

Problem	**With Glasses** (circle a number)	**With Contacts** (circle a number)	**With No Correction** (circle a number)
35. Your eyes feeling irritated	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
36. Drafts (from heating or air-conditioning) blowing in your eyes	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
37. Eyes being sensitive to light	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
38. Pain in your eyes	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
39. Changes in your vision during the day	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
40. Your vision being cloudy or foggy	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
41. Glare (reflections off shiny surfaces, snow)	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
42. Things looking different out of one eye versus the other	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
43. Seeing a halo around lights	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
44. Seeing in dim light	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
45. Your depth perception	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
46. Things appearing distorted	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6
47. Judging distance when going up or down steps (stairs, curbs)	0 1 2 3 4 5 6	0 1 2 3 4 5 6	0 1 2 3 4 5 6

The next set of questions ask about problems you may have experienced during the past month with glasses or contact lenses.

Please give an answer for each item (there is a choice for "not applicable").

The choices for answers are:

0 Not applicable (did not use this type of correction during this past month)
1 No trouble at all with this problem
2 A little trouble with this problem
3 Moderate trouble with this problem
4 Severe trouble with this problem
5 So much trouble with this problem I have not used this type of correction in the past month

During the past month, how bothered have you been with each of the following?

	(circle a number)
48. **Glasses** getting dirty or scratched	0 1 2 3 4 5
49. **Glasses** getting fogged up or wet	0 1 2 3 4 5
50. **Contacts** popping out/falling out of your eye	0 1 2 3 4 5
51. **Contacts** getting caught up under your eyelid, or moving around in your eye	0 1 2 3 4 5
52. The sensation of having **contacts** in your eye	0 1 2 3 4 5
53. Not being able to wear **contacts** as long as you need to	0 1 2 3 4 5
54. Losing a **contact lens**	

END OF QUESTIONNAIRE

Thank you for your time. Any comments or questions?