The Vision Correction Questionnaire (VCQ): An electronic patient reported outcome measure for refractive surgery

Purpose: To develop a psychometrically robust electronic patient outcome measure (ePROM) for refractive surgery

Setting: Moorfields Eye Hospital, London, United Kingdom.

Design: A questionnaire development study

Methods: Items were derived in 6 domains (spectacle dependence, visual quality, eye comfort, functional freedom, emotional wellbeing, and satisfaction with treatment) from existing Rasch adjusted instruments, patient and surgeon feedback, and refinement in semi-structured interviews before administration to a field test cohort (n=360) of patients undergoing routine refractive surgery. Spectacle dependence and satisfaction with treatment items were used to provide descriptive statistical information only. Contemporary criteria for item reduction and Rasch modelling were applied to the remaining domains. The finalised questionnaire was then administered to a second patient cohort (n=120) before and after surgery to assess sensitivity to change.

Results: A 5-item scale derived for emotional wellbeing was unidimensional and a good fit to the Rasch model with ordered category response profiles, adequate precision (person separation 2.22 logits, reliability coefficient 0.83), and no misfitting items. Mean logit scores were 0.91 higher after treatment (effect size 1.26) suggesting a positive impact on emotional wellbeing. Functional scales could not be derived for visual quality, eye comfort or functional freedom. Single item ratings for visual quality and eye comfort were retained in our final 11-item questionnaire.

Conclusons: This short ePROM should integrate well with routine clinical care and clinical trials in refractive surgery. The Rasch adjusted emotional wellbeing scale may help quantify the way patients feel about refractive surgery, with the remaining items providing useful descriptive information.

Synopsis

We used contemporary methodology to develop a short, self-administered, self-archiving electronic patient reported outcome measure for refractive surgery for integration into routine clinical care and clinical trials.

Introduction

Patient reported outcome measures (PROMs) are now considered integral to clinical trials design and the evaluation of new healthcare interventions as part of routine clinical care. [1-3] PROMs usually take the form of a questionnaire, or 'instrument'. These can be generic measures of health-related quality of life (QoL), such as the widely used EuroQoL Health Questionnaire (EQ5D), [4] designed to compare QoL gains across varied healthcare fields, or disease specific measures, designed for more sensitive comparisons within specific patient groups. [2]

A wide variety of disease specific PROMs are now available within ophthalmology, and quality frameworks have been developed to help investigators choose between them. [3 5 6] Questionnaires developed using Rasch modelling, [7, 8] a branch of item response theory, have advantages over older questionnaires developed using classical test theory alone such as the Refractive Status and Vision Profile (RSVP) and National Eye Institute Refractive Quality of Life (NEI-RQL). [5] These older questionnaires allocate an equal weight to response options regardless of item difficulty or the ability of the respondents. Rasch weighting takes account of both factors, and converts categorical data to a linear interval scale. [7 8] Other Rasch fit statistics can be used to remove redundant or poorly targeted items and under-used response categories, helping to minimise respondent burden. [9, 10] Principal component or factor analysis is then used to help ensure that each independently scored section (scale) of a questionnaire is unidimensional, containing only items relevant to the aspect of health-related quality of life ('domain' or 'latent trait') being measured. [6]

Kandel et al recently reviewed PROMs for refractive surgery. [11] They identified three refractive surgery PROMs developed using Rasch modelling: the Quality of Life Impact of Refractive Correction (QIRC) questionnaire, [9] the Quality of Vision (QoV) questionnaire, [12] and the Near Activity Visual Questionnaire (NAVQ). [13] The QIRC has the widest applicability and a publicly available scoring format. [14] But it was developed for a pre-presbyopic population [9] and has been found to be multidimensional.[15] The QIRC also includes items that may not be relevant to a post refractive surgery respondent. The QoV incorporates photographic illustrations of a set of visual symptoms to help respondent orientation, but suffers from poor targeting and differential item functioning. [11] The QoV also performs inconsistently against contemporary questionnaire quality criteria. [16] The NAVQ only covers near vision. It has poor targeting and item fit statistics, and has not been tested for dimensionality. [11]

Each of these questionnaires was developed for pen and paper completion, and would require further adaptation for use in digital healthcare. [3] The Patient-Reported Outcomes With LASIK (PROWL) questionnaire[17, 18] was developed recently for completion via a secure web portal, but was not developed using Rasch modelling for item reduction. It includes over 100 items and takes 20-35 minutes to complete. This is almost certainly too long for routine clinical use. [19] [6]

Brevity is a key requirement for any PROM designed to function well as part of routine clinical care. [2, 10] Other desirable attributes include relevance to the patient group being surveyed, free availability, clarity, an attractive layout, integration and compatibility with digital healthcare systems, automated data archiving, and clear presentation of results. [3, 20]

PROMs designed specifically with these attributes have been termed electronic PROMs (ePROMs). [21, 22]

We set out to develop a psychometrically robust ePROM for use in clinical trials and routine refractive surgery care.

Methods

The study was approved by the NHS Health Research Authority and conformed to the tenets of the Declaration of Helsinki. It was registered at clinicaltrails.gov (NCT03655743).

Conceptual framing and draft questionnaire development

Conceptual framing and draft development for the questionnaire[3] were based on a comprehensive literature review, patient and surgeon feedback during the Royal College of Ophthalmologists Refractive Surgery Standards[23] development consultation, and advice from expert collaborators.

The following aspects of vision related quality of life were identified as relevant to refractive surgery: dependence on spectacles or contact lenses (spectacle dependence), clear vision (visual quality), eye comfort, functional freedom, looking and feeling well (emotional wellbeing), and overall satisfaction with treatment.

The draft questionnaire was created for self-administration using Google Forms (Google LLC, Mountain View, CA), [24] with a 1-month recall period and 4 item response categories

throughout. Each section (domain) was prefaced with a short introductory statement to guide respondents.

Overall satisfaction and spectacle dependence questionnaire items were included to derive descriptive information only, listing percentages of patients in each response category. Overall satisfaction with treatment was omitted from the draft questionnaire administered to preoperative patients. For visual quality, eye comfort, functional freedom, and emotional wellbeing, an attempt was made to create unidimensional scales to fit the Rasch model starting with 10 items per scale. The draft questionnaire included photographic illustrations of visual symptoms similar to those used in previous refractive surgery questionnaires. [12, 17]

Each scale included a summary item. For example: “Overall, how would you grade any problems with your quality of vision” or “Overall, how would you grade any problems with your eye comfort”.

Where possible, items were derived from existing refractive surgery questionnaires developed using Rasch modelling. Item stems and/or response options were modified where necessary to fit a clear, consistent format. All changes in wording versus original versions were then tested and further modified in semi-structured interviews (cognitive interviews) on 40 pre and post refractive surgery respondents from a varied gender, age and educational background. Trained interviewers asked patients to describe in their own words what they thought each item meant, testing alternate wordings, and gathering suggestions for improvement. The draft eye comfort scale was reduced to 8 items after cognitive interviews.

The finalised draft questionnaire used in our subsequent field study (Supplemental Table 1) is summarised together with photographic illustrations for visual quality symptoms (Supplemental Figure 1) in supplemental material on-line (available at https://www.jcrsjournal.org).

Field testing and item calibration

360 respondents were recruited from patients undergoing routine refractive surgery. These were 120 preoperative cases, 120 cases post bilateral laser vision correction, and 120 cases post either bilateral phakic intraocular lens or multifocal intraocular lens implantation. Postoperative cases were sampled either early (120 cases) 2-4 weeks post-surgery or at discharge (120 cases) 2-6 months post-surgery. Patients with poor comprehension of written English were excluded. All respondents were over 18 years of age.

Consecutive patients in each category were approached by one of the investigators or practice staff at Moorfields Eye Hospital and asked if they would be prepared to complete a short research questionnaire. The questionnaire was self-administered on tablet computers (iPad, Apple Inc, Cupertino, CA) in the clinic waiting area. Patients were asked to read the brief introductory consent statement contained within the questionnaire before entering a study identification code at the prompt. The questionnaire was designed to be self-explanatory. No further instruction was given other than to hand the tablet back once the questionnaire was completed.

Google Forms automatically created a secure raw data archive on cloud servers, exportable as a CSV file for analysis. Personal data was not collected.

Rasch analysis

The raw response data was exported to WINSTEPS 4.01[25] for analysis using a polytomous partial credit model.

For each scale, iterative removal of misfitting items (infit/outfit mean square outside the range 0.70-1.30) and reanalysis was used for item reduction.[9] Aiming to minimize respondent burden, item reduction was continued in functional scales until a minimum of 5 items was reached[10] whilst maintaining adequate precision (person separation index >2.0; reliability coefficient >0.8). [5]

Scales were considered to be unidimensional if >60% of the variance was explained by the measure and the highest eigenvalue of the residual correlation matrix was <2.0 in principle component analysis. [5]

Scales were checked for ordered category response probability curves and for differential item functioning between the 2 postoperative respondent groups (laser vision correction and lens implantation) using standard criteria (<0.50 logits – insignificant; 0.50 to 1.00 logit – mild; >1.00 logit – significant). [5] Finally, targeting was measured with reference to the difference between item and person means on the logit scale.

From these analyses, a Rasch modified questionnaire was created, using either Rasch adjusted scales or, for scales that did not fit the Rasch model, replacement with a single overview item addressing the domain theme. Simple descriptive scoring, listing the percentage of respondents in each response category, was used for new single item scales as for overall satisfaction and spectacle dependence.

The Rasch modified questionnaire is summarized in Table 1.

Sensitivity to change (responsiveness)

The Rasch modified questionnaire was administered preoperatively and 2-6 months postoperatively to 120 refractive surgery patients: 80 cases undergoing bilateral laser vision correction, and 40 cases undergoing bilateral phakic intraocular lens or bilateral multifocal intraocular lens implantation.

For Rasch adjusted scales, effect size was measured by dividing the mean change in pre and postoperative logit scores by the pooled standard deviation. Effect size was evaluated against standard criteria (effect size >0.5 = moderate; effect size >0.8 = large). [26]

Response reliability

Finally, the Rasch modified questionnaire was administered to 32 stable pre or post refractive surgery cases, with repeat administration after an interval of 2 weeks. A 2-way mixed-effects Intraclass Correlation Coefficient was then calculated to assess test-retest reliability for Rasch scaled domains. [27] Questionnaire administration in this phase of the study was via an email link to the web form.

Construct validity

Construct validity was checked for Rasch adjusted scale scores and responses for single summary items by correlation with responses for overall satisfaction using the Spearman Rank Test.

Results

The age and sex distribution of respondents was similar in the field study (48.6±14.5 years; 50.9% female); the study of sensitivity to change (45.0±16.0 years; 54.5% female); and in the repeatability study (46.1±13.6 years; 55.0% female).

Rasch modelling

We were unable to obtain a good fit to the Rasch model for the visual quality, eye comfort, or functional freedom scales despite removal of misfitting items as detailed above. For each of these scales, precision was less than the minimum required level (person separation>2.0) [5] for all iterations of item exclusion. Only the emotional wellbeing scale functioned well overall (precision – person separation 2.22, reliability coefficient 0.83; item fit (5 items) – infit range 0.72-1.31, outfit range 0.76-1.22; ordered category response profiles, unidimensionality – variance explained by measures 60.9%, eigenvalue 1st contrast 1.78). There was evidence of mild/notable differential item functioning (DIF) (DIF contrast range (5 items) 0.25 – 1.01 logit units) in a comparison of data from patients treated with laser vision correction and lens implantation. The person mean was 2.11 logit units higher than the item

mean, with scores concentrated in positive response categories, especially at discharge after treatment.

Sensitivity to change

The Rasch adjusted emotional wellbeing scale was sensitive to change. The mean difference in logit scores between pre and postoperative completion of the Rasch adjusted emotional wellbeing scale was 0.91 logits. The pooled SD for the pre and postoperative logit scores was 0.72, giving an effect size of 1.26 (large).

Response reliability

The intraclass correlation coefficient for repeated administrations of the Rasch adjusted emotional wellbeing scale was 0.89 ($p<0.0001$), indicating good response reliability. [5]

Construct validity

Ratings for overall satisfaction with treatment were strongly correlated with overall visual quality (Spearman Rho = 0.56; $p<0.0001$), overall eye comfort (Spearman Rho = 0.36; $p<0.0001$), and Rasch adjusted scores on the emotional wellbeing scale (Spearman Rho = 0.37; $p<0.0001$).

Discussion

PROMs may simply derive descriptive information from questionnaire items about percentages of patients in each response category. For example, the percentage of patients

who would recommend an intervention they have had to a family member or close friend. They may also attempt to score a more abstract aspect of health-related quality of life ('domain', 'construct', or 'latent trait') such as quality of vision or functional freedom by combining scores from a number of questionnaire items addressing the same underlying theme. We were unable to do this successfully using contemporary methodology to examine 3 of 4 domains relevant to refractive surgery: visual quality, eye comfort, and functional freedom. Only the emotional wellbeing scale was a good fit to the Rasch model.

Poor targeting and ceiling effects were likely confounding factors. At discharge, over 98% of our patients were satisfied (16%) or very satisfied (82%) with their treatment, and over 95% responded in the top 2 categories for all items in the Rasch adjusted questionnaire after surgery. The difference between person and item means was greater than 2 logits for all scales. In terms of the Rasch model, this implies a highly significant mismatch between item difficulty and respondent ability [5] – most refractive surgery patients have very few problems. [28 29 30] Patients were more symptomatic in the early postoperative period; but, even then, 92% of respondents were either satisfied (38%) or very satisfied (54%) with the results of their treatment.

There was evidence that response patterns to the item "over the last month, how often have you felt secure" may differ between patients undergoing lens implantation and patients undergoing laser vision correction (DIF contrast 1.01). There was also possible mild differential item functioning for the items "over the last month, how often have you felt able to do the things you want to do" (DIF contrast 0.54) and "over the last month, how often have you felt free from health worries" (DIF contrast 0.54). Patients undergoing laser

vision correction were significantly younger than patients undergoing lens implantation (40±11 versus 58±14 years old; t test p<0.0001), and this may have been influential. There may also be real differences in emotional wellbeing after treatment with these different modalities.

Within the emotional wellbeing scale, responses may also have been influenced by external factors or secular trends. Completion of the study was delayed by the covid pandemic, and responses to any of the items in this scale could have been influenced by changes in employment status, lock-down restrictions, or covid infection itself during the recall period.

Despite these possible limitations, the emotional wellbeing scale was sensitive to change and a satisfactory fit to the Rasch model. Correlation with overall satisfaction was significant (Spearman Rho = 0.37; p<0.0001) but not so strong as to imply scale redundancy. [31] This suggests that the emotional wellbeing scale is a psychometrically robust measure, and should help to pick out the relatively small but very important group of patients that are unhappy following refractive surgery. [28] [29] [30] We have created a normalized scoring matrix for the emotional wellbeing scale of the Vision Correction Questionnaire to facilitate use by other investigators (Table 2).

We used items derived from other Rasch weighted instruments, including all of the items from the OCS questionnaire[32] and most of the items from the QoV questionnaire, [12] but our symptom data for visual quality and eye comfort did not fit the Rasch model. Other investigators re-analysing Rasch weighted refractive surgery PROMs have observed that Rasch fit varies depending on the patient sample studied and timing of questionnaire

administration. [15, 16] Continuous Rasch analysis has been advocated[15, 16] but may be impractical in routine clinical care. A simplified approach, using single transitional items or a cut-down item set and descriptive data may be more realistic, and would still yield valuable data. [2, 31] The single item Symptom Assessment iN Dry Eye (SANDE) eye comfort questionnaire, [33] for example, in which respondents rate the severity and frequency of any eye discomfort symptoms using a visual analogue scale, has been found to correlate closely with the widely used 12-item Ocular Surface Discomfort Index (OSDI), [34] deriving much the same information with a lower respondent burden. [35] As with the emotional wellbeing scale, our single items overall ratings for eye comfort and visual quality correlated well with overall satisfaction, indicating that scores for these single transitional items add useful information on symptoms underlying any dissatisfaction with treatment.

We did not include a separate single item measure of functional freedom in our final Rasch adjusted questionnaire because the emotional wellbeing scale included the question 'over the last month, how often have you felt able to do what you want to do?', which we felt was sufficient to embrace functional freedom as an aspect of emotional wellbeing.

Adaptive questionnaires, in which initial responses determine which of a bank of items is included, may help to enhance item targeting. [36] In an exploratory analysis of the field study data, we tried filtering out data from patients responding "no problem" to the summary 'overall' items for each of the scales. Using this variation of an adaptive approach, we were still unable to derive functional scales for eye comfort, quality of vision or functional freedom.

Positive aspects of the finalised questionnaire include many of the desirable attributes for an ePROM. With just 11 items, completion was quick and easy. The questionnaire was self-explanatory, and could easily be adapted from the Google Forms prototype to a self-scoring bolt-on application for electronic healthcare records or electronic data collection in clinical trials. Uptake was almost universal when patients were handed the questionnaire on a mobile device in the clinic waiting area for completion. An email prompt with a link to the questionnaire was less effective, with a non-response rate of 68% for an initial prompt in the repeatability phase of the study. Because the questionnaire is brief, it can easily be combined with generic PROMs to facilitate comparisons with other healthcare fields and health economic analyses.

We have developed a short, psychometrically robust ePROM for use in routine clinical care in refractive surgery as a compliment to objective outcome measures in digital healthcare research. At minimum, this instrument will derive useful descriptive statistics on spectacle dependence, satisfaction with surgery, eye comfort, and quality of vision. The Rasch adjusted emotional wellbeing scale should also help to provide a deeper insight into the way refractive surgery patients feel before and after surgery. Further work is required to develop the new ePROM as a freely available clinical and research tool, and to promote integration with data registries and electronic healthcare record systems.

Value Statement

What was known

- Patient reported outcomes are now considered integral to routine clinical care and clinical trials design.

- There is, to date, no widely-accepted refractive surgery questionnaire developed using contemporary methodology for self-administration on a touch screen.

What this paper adds

- The Vision Correction Questionnaire (VCQ) is both psychometrically robust and practical.
- It adds important information about the way patients feel before and after refractive surgery.

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Legends

Table 1 The Rasch adjusted questionnaire. We used this final iteration of the Vision Correction Questionnaire in the studies of sensitivity to change and response reliability.

Table 2 The Rasch adjusted scoring matrix for the emotional wellbeing scale of the Vision Correction Questionnaire. Positive values indicate greater wellbeing. Raw logit scores were normalized to create a more intuitive score out of 100 for the sum of 5 item responses.

Supplemental Table 1 Items included in the first iteration of the Vision Correction Questionnaire after refinement in semi-structured interviews. This version of the questionnaire was used in the field study.

Supplemental Figure 1 Symptom illustrations presented together with visual quality items in the first iteration of the Vision Correction Questionnaire: A = blur, B = glare, C = starbursts, D = halos, E = double vision or ghost images, F = shadows in peripheral vision, G = distortion in peripheral vision, H = smearing, I = poor contrast.

Table 1 The Rasch modified Vision Correction Questionnaire

Domain	Stem	Items	Response Options
Spectacle Dependence	Over the last month, how often have you needed glasses or contact lenses for…	... clear DISTANCE VISION? *(driving, television, sport, outdoor activity)* ... clear VISION at ARMS' LENGTH? *(computer screens, working with your hands)* ... clear VISION UP CLOSE? *(reading documents, phone screens, fine print, menus)*	Never Occasionally Some of the time Most of the time
Visual Quality	Over the last month, how would you grade any problems with…	… your quality of vision?	No problem Mild Moderate Severe
Eye Comfort	Over the last month, how would you grade any problems with...	… your eye comfort?	No problem Mild Moderate Severe
Emotional Wellbeing	Over the last month, how often have you felt...	... able to do the things you want to do? ... eager to try new things? ... excited about the future? ... free from health worries? ... secure?	Most of the time Some of the time Occasionally Never
Satisfaction ***(postoperative patients only)***	Considering your eyes and vision over the last month, are you...		Very satisfied Satisfied Dissatisfied Very dissatisfied

Table 2 Normalized scoring guide for the Vision Correction Questionnaire

	Most of the time	**Some of the time**	**Occasionally**	**Never**
…able to do the things you want to do	19.8	14.1	9.9	0
…eager to try new things	20.6	16	11.4	0.4
…excited about the future	20.7	15.1	10	0.4
…free from health worries	19.6	13.7	10.4	0.8
…secure	19.3	12.7	8.5	0.6