

Development and validation of the 40-item Glaucoma Visual Functioning Questionnaire

Haishun Huang, Junxiong Lin, Man Luo, Zhidong Li, Yingting Zhu, Jiaxu Han, Ling Jin, Yiaina Li, Yehona Zhuo 👴

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State Key Laboratory of Ophthalmology, Zhongshan Ophthalmic Center, Sun Yatsen University, Guangdong Provincial Key Laboratory of Ophthalmology and Visual Science, Guangdong Provincial Clinical Research Center for Ocular Diseases, Guangzhou, Guangdong, China

Correspondence to

Professor Yehong Zhuo and Professor Yiging Li, State Key Laboratory of Ophthalmology, Zhongshan Ophthalmic Center, Sun Yat-sen University, Guangdong Provincial Key Laboratory of Ophthalmology and Visual Science, Guangdong Provincial Clinical Research Center for Ocular Diseases, Guangzhou, Guangdong, China; zhuoyh@mail.sysu.edu.cn, liyiqing3@mail.sysu.edu.cn

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ABSTRACT

Aims To evaluate the psychometric properties of a newly designed questionnaire, the 40-item Glaucoma Visual Functioning Questionnaire (GVFQ-40), in a Chinese sample to capture the visual ability of patients with glaucomatous vision impairment in five domains. **Methods** Eighty-four glaucoma suspects (controls) and 270 glaucoma patients were recruited from the Glaucoma Clinic at Zhongshan Ophthalmic Centre in this cross-sectional, observational study. All subjects completed two questionnaires during routine clinical visits: the GVFO-40 and the validated National Eve Institute Visual Functioning Questionnaire-25 (NEI VFQ-25). The discriminant, criterion-related and construct validity of the GVFQ-40 were assessed. A subset of subjects completed the GVFQ-40 twice, with an interval of 7–21 days, to determine test–retest reliability. **Results** Domain-specific and total GVFO-40 scores were significantly higher (worse visual ability) in glaucoma patients than in controls (all p<0.001). All pairwise subgroup comparisons were statistically significant except for the 'mobility' domain comparison between the mild visual field loss and control groups (p=0.189). Significant differences between these two groups were observed in only 2 of the 12 dimensions on the NEI VFQ-25. The GVFQ-40 results demonstrated strong correlations with better-eye mean deviation and Visual Field Index (glaucoma severity measures). Exploratory factor analysis tended to confirm a threedomain structure. Test-retest intraclass correlation coefficients were higher than 0.927 for domain-specific and total GVFQ-40 scores.

Conclusions The GVFQ-40 possesses good validity and reliability. It can be used to evaluate the impact of glaucomatous damage on visual ability and has potential in the evaluation of intervention efficacy.

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INTRODUCTION

Glaucoma is ranked as the most common cause of irreversible blindness and the second leading cause of irreversible moderate and severe vision impairment (MSVI). In 2020, an estimated 3.61 million people worldwide were blind due to glaucoma, and an additional 4.14 million people had MSVI attributed to glaucoma.² These numbers continue to increase due to the growth and ageing of populations.³ As a large proportion of affected people live in China, China faces a substantial challenge in avoiding glaucoma-related vision impairment.² The development of better management strategies for extending clinical treatment and rehabilitation

Key messages

What is already known on this topic

⇒ A number of instruments have been developed to evaluate vision-related quality of life, restrictions in participation, symptoms of eye diseases, etc, but comparatively few questionnaires have been developed specifically to assess the visual ability in patients with glaucomatous vision impairment. With the expansion of glaucomatous rehabilitation services and the emergence of new rehabilitative interventions, there is an urgent need for an appropriate and standardised questionnaire to capture the effect of glaucoma on visual ability and to reflect the effectiveness of interventions.

What this study adds

⇒ A new glaucoma visual functioning questionnaire is presented, which shows good discriminant validity, criterion-related validity and construct validity, and has high test-retest concordance.

How this study might affect research, practice or policy

⇒ The newly designed 40-item Glaucoma Visual Functioning Questionnaire may be useful in research and clinical settings to elucidate the impact of glaucomatous damage on a patient's visual ability.

services is urgently needed. To deliver comprehensive and high-quality services, the effects of glaucomatous vision loss on daily activities and the effectiveness of interventions need to be evaluated, highlighting the importance of reliable and valid visual function assessment tools.

As objective measurements of vision, such as visual acuity (VA), may not adequately describe the total impact of diseases and treatments on a patient's visual world and because individuals with the same degree of vision loss may function completely differently, patient-reported outcomes of visual function are currently well accepted and applied.⁵ Although a number of vision-related instruments have been developed, most of them have been designed to estimate vision-related quality of life (VRQOL), restrictions in participation, symptoms of eye diseases, etc.^{6–10} VRQOL questionnaires, such as the National Eye Institute Visual Function



Questionnaire-25 (NEI VFQ-25), comprise multiple dimensions including visual ability as well as mental health, role difficulty, and social functioning. Since the number of items within visual functioning domains is insufficient to assess the range of activities that are difficult for the visually impaired and it contains many items that are nonresponsive to some degree, 11 these instruments may not be sensitive enough to assess the visual ability of patients with glaucomatous low vision and detect changes after using a visual aid or receiving training over a short trial duration. The Veterans Affairs Low-Vision Visual Functioning Questionnaire (VA LV VFQ-48) was designed to measure the difficulty in performing activities among low-vision patients, but it was developed in a high-income country setting and was initially designed for older persons. 12 There are comparatively few questionnaires specifically developed with the purpose of measuring visual performance in relation to daily activities for patients with glaucomatous vision impairment living in developing countries.

Although the 15-item Glaucoma Quality of Life (GQL-15) is disease-specific, ¹³ the number of items is not adequate to assess the range of affected activities, and some items, such as 'walking on steps/stairs', are not precise since the difficulties in walking up and down stairs are different. With the expansion of glaucomatous rehabilitation services in China and the emergence of new rehabilitative interventions, ^{14–16} an appropriate and standardised VFQ is urgently needed. The objective of this study was to develop and validate a questionnaire to capture visual abilities in patients with glaucomatous vision impairment living in China.

METHODS

This cross-sectional, observational study analysed the responses of enrolled participants on the newly designed 40-item Glaucoma Visual Functioning Questionnaire (GVFQ-40) to evaluate its validity and reliability.

Study subjects

Participants were recruited from the Glaucoma Clinic at ZOC, Guangzhou, China, between January 2021 and August 2021 during regular clinical visits. Eligible subjects were 18 years of age and older, were fluent in Chinese, had a confirmed diagnosis of primary glaucoma or glaucoma suspect in one or both eyes as determined by at least two glaucoma specialists and had undergone visual field (VF) testing with normative optical correction in both eyes within 3 months using the 30–2 Swedish interactive threshold algorithm (HFA2; Carl Zeiss Meditec, Dublin, California, USA) with reliable results (fixation losses less than 20% and false-positive rates less than 15%). To Glaucoma suspects were required to (1) present with at least one of the following: elevated intraocular pressure, an enlarged cup-to-disc ratio or a family history of glaucoma, (2) have a glaucoma hemifield test result of 'within normal limits' or 'borderline' and (3) have a presenting VA (PVA) of 20/40 or better (Early Treatment Diabetic Retinopathy Study chart) in both eyes. 18 19 Glaucoma patients were categorised into three groups by better-eye mean deviation (MD, \geq -6 dB, -12 to -6 dB and <-12 dB corresponding to mild, moderate and severe VF loss, respectively).

The exclusion criteria were (1) any diseases or conditions preventing them from participating in the study or providing informed consent (eg, cognitive or hearing impairment), (2) surgical intervention (incisional or laser) within 2 weeks of the date of questionnaire completion (before or after), (3) other ocular pathologies affecting retinal or optic nerve function (eg, diabetic retinopathy) and (4) conditions external to the

eye that may interfere with the scale scores (eg, physical motor dysfunction).

Questionnaires

Two questionnaires were completed in random order by the subjects after they received oral instructions: the GVFQ-40 and NEI VFQ-25. Then, their responses were checked by a research assistant to ensure that each question was answered. If they needed help, they were assisted by the assistant and not by family members. All questionnaires were completed on the same day during a routine clinical visit. A subset of subjects completed the GVFQ-40 twice at an interval of 7–21 days to evaluate test-retest reliability.

The development of the GVFQ-40 mainly comprised three stages. Initially, a literature review and focus groups were conducted to establish a bank of 91 items. The published literature on vision-related instruments was reviewed to collect all important activities that were commonly reported to be difficult by visually impaired patients. Focus groups to identify patient-perceived difficulties in daily life and determine their needs or expectations for intervention were conducted with 42 representative patients with different stages of glaucoma. Subsequently, 64 items that reflected the issues confirmed in focus groups were extracted from existing questionnaires and translated into Chinese following the process of translation, backtranslation and cross-cultural adaptation.²⁰ 21 Another 27 items were drafted based on the content identified in focus groups but not covered in existing instruments. All items were summarised into five domains: mobility, visual motor skills, reading, recognition and night vision. The second phase was to determine the use of a Likert-type scale and five difficulty rating categories. In the third stage, all 91 items were assessed by a multidisciplinary team consisting of glaucoma specialists, vision rehabilitation specialists, ophthalmologists, optometrists and research staff. The Delphi method was used to achieve consensus. After eliminating irrelevant or highly similar questions and iterative revisions of items, an initial 50-item version was administered to 26 glaucoma patients and seven medical staff in the glaucoma department. Based on their feedback, the final 40-item version was derived via further modification.

The GVFQ-40 contains five domains, and each domain contains eight items. For the first 32 items, participants are asked how difficult it is to perform certain tasks in daylight. For the last eight items, the answers correspond to the difficulty of performing tasks in dim light or under nighttime conditions. Responses to all items are rated on the following scale: not difficult at all (1) slightly difficult (2) moderately difficult (3) extremely difficult (4) to impossible (5). An additional available response was that the activity was not performed for nonvisual reasons (missing data). Scores for each domain and the total scores were analysed using average scores in this study. The participants self-administered the questionnaire based on the instructions. An interviewer-administered format was used only when the subjects' vision was insufficient to read the printed questionnaires.

The NEI VFQ-25, validated as a short version of the NEI VFQ and featuring 25 items across 12 domains, is a VRQOL instrument for persons with chronic eye diseases or low vision. The measurement scale ranges from 0 to 100, and higher scores represent better VRQOL. The instrument is frequently used in QOL studies for various eye diseases. We used this questionnaire as a reference for assessing the discriminant validity of the GVFQ-40.

Clinical science

Demographic and clinical variables

Demographic questions regarding sex, age, employment status, etc. were answered by participants at the time of questionnaire completion. Clinical variables, including MD, Visual Field Index (VFI), pattern SD (PSD), PVA in logarithm of the minimum angle of resolution units, ophthalmic medical history, comorbidities and so on, were collected from electronic health records and clinical files.

Statistical analysis

All data were double entered into EpiData V.3.1 (EpiData Association, Odense, Denmark), and analyses were performed using SPSS V.25 (IBM) and GraphPad Prism V.6 (GraphPad Software, La Jolla, California, USA). Group differences were analysed using independent t-tests for normally distributed continuous variables, rank-sum tests for nonnormally distributed continuous variables and χ^2 tests for categorical variables. Spearman rank correlation was used to evaluate the relationships of GVFQ-40 scores and measures of glaucoma severity. The internal construct of the GVFQ-40 was examined using exploratory factor analysis (EFA), and varimax rotation was used to conduct principal component extraction. A Kaiser-Meyer-Olkin value >0.5 and a p<0.05 for the Bartlett test of sphericity were considered to satisfy the conditions. An item with a loading less than 0.45 was indicated to be unrelated to the factor. Internal consistency was assessed by Cronbach's α coefficient, and test-retest reliability was evaluated by the intraclass correlation coefficient (ICC) and Bland-Altman analysis. 25-27 Statistical significance was set at p < 0.05 (two tailed).

RESULTS

Participant characteristics

A total of 354 subjects participated in this study. The mean age was 41.21±13.28 years (range 18–83 years), and 174 subjects

(49%) were female. There were 270 patients in the glaucoma group (mild, moderate and severe VF-loss groups corresponding to 91, 84 and 95 patients, respectively) and 84 subjects in the control group. Table 1 summarises the demographic and clinical characteristics of the included subjects. Of the 270 glaucoma patients, 194 (71.9%) had a better-eye PVA of 20/40 or better, 39 (14.4%) had a PVA worse than 20/40 but equal to or better than 20/60, and 1 (0.4%) had a PVA less than 20/200.

Validity

The content and scoring characteristics of the GVFQ-40 are summarised in online supplemental table 1. All items of the GVFQ-40 were considered in the analysis given that every item was answered by at least 93% of subjects.

Median scores were significantly higher in glaucoma subjects than in controls for domain-specific and total GVFQ-40 scores (all p<0.001; table 2). Glaucoma patients with a better-eye PVA of 20/40 or better also showed significant differences in GVFQ-40 results compared with controls (all p<0.001; online supplemental table 2).

Figure 1 presents the results of subgroup analyses according to better-eye MD. Significant differences among the four groups were found in the GVFQ-40 results (online supplemental table 3). All pairwise comparisons were statistically significant except for the 'mobility' domain comparison between the mild VF-loss and control groups (p=0.189 after Bonferroni correction). In the subgroup analysis for the NEI VFQ-25 (online supplemental figure 1), significant differences between these two groups were observed in only 2 of the 12 dimensions, and some other group comparisons showed no differences (online supplemental table 4). All these results demonstrated that the GVFQ-40 is equipped to differentiate subjects with varying degrees of vision loss and confirmed the discrimination validity of the GVFQ-40.

Characteristic	Glaucoma group (n=270)	Control group (n=84)	P value
Age (years), mean (SD)	41.93 (12.81)	38.89 (14.54)	0.067*
Female, no (%)	125 (46)	49 (58)	0.054†
Education level (≥high school), no (%)	178 (66)	75 (89)	<0.001†
Employed, no (%)	130 (48)	55 (65)	0.005†
Urban, no (%)	178 (66)	68 (81)	0.009†
LogMAR PVA in the better eye			
Mean (SD)	0.27 (0.25)	0.10 (0.12)	<0.001*
Median (IQR)	0.20 (0.10-0.40)	0.10 (0.00-0.20)	
MD in the better eye (dB)			
Mean (SD)	-11.30 (9.51)	-1.71 (1.30)	
Median (IQR)	-7.93 (-16.84 to -3.47)	-1.53 (-2.43 to -0.98)	<0.001‡
PSD in the better eye (dB)			
Mean (SD)	5.70 (3.77)	1.49 (0.68)	
Median (IQR)	4.83 (2.26–8.56)	1.50 (1.29–1.75)	<0.001‡
VFI in the better eye			
Mean (SD)	0.71 (0.30)	0.99 (0.01)	
Median (IQR)	0.84 (0.54–0.97)	0.99 (0.99–1.00)	<0.001‡
Diagnosed for more than 2 years, no (%)	163 (60)	NA	
History of glaucoma surgery, no (%)	146 (54)	NA	

[&]quot;Iwo-sample t test.

 $^{1\}chi^2$ test.

[‡]Wilcoxon rank sum test.

LogMAR, logarithm of the minimum angle of resolution; MD, mean deviation; NA, not available; PSD, pattern SD; PVA, presenting visual acuity; VFI, Visual Field Index.

Table 2 Comparison on the 40-item Glaucoma Visual Functioning Questionnaire (GVFQ-40) scores between the glaucoma group and control group

GVFQ-40 (Score 1–5)	Glaucoma group (n=270)*	Control group (n=84)*	P valuet
Mobility	1.25 (1.00–2.13)	1.00 (1.00–1.00)	<0.001
Visual motor skills	1.38 (1.13–2.50)	1.00 (1.00-1.00)	< 0.001
Reading	1.50 (1.13–2.50)	1.00 (1.00-1.13)	< 0.001
Recognition	1.38 (1.13–2.25)	1.00 (1.00-1.25)	< 0.001
Night vision	1.88 (1.25–3.00)	1.00 (1.00-1.31)	< 0.001
Total score	1.55 (1.18–2.33)	1.04 (1.00–1.15)	< 0.001

^{*}Data are presented as medians (IQR). A higher score means worse visual ability. †Wilcoxon rank sum test.

Domain-specific and total GVFQ-40 scores showed markedly higher correlations with the better-eye MD and VFI (r=-0.600 to -0.718, all p<0.001; table 3) than PVA (r=0.485 to 0.594, all p<0.001). The association between the total GVFQ-40 score and the better-eye MD also persisted after adjustment for imbalanced covariates in table 1 (p<0.001; online supplemental table 5). These data supported the criterion-related validity of the GVFQ-40.

Based on EFA, all items were found to be correlated to one latent theme in the initial component solution. Three factors with eigenvalues greater than 1 were identified, which explained 33.88%, 28.29% and 24.19% of the variance in rotation sums of squared loadings, respectively. Table 4 shows the item loadings for the GVFQ-40.

Reliability

The Cronbach's α values were greater than 0.95 for domain-specific and total GVFQ-40 scores. Item-total correlations were higher than 0.60 for all 40 items. Interitem correlations were stronger within domains than between domains. These results illustrated the high internal consistency of the GVFQ-40, which focuses on five different aspects of the same property.

To examine whether the GVFQ-40 results were consistent over time, 30 participants with various levels of VF loss were readministered the questionnaire 7–21 days after initial completion. The test–retest ICC was 0.979 (95% CI 0.956 to 0.990) for the total score and greater than 0.927 for each domain score, indicating high test–retest concordance. For each domain score,

Table 3 Associations of the 40-item Glaucoma Visual Functioning Questionnaire (GVFQ-40) scores with clinical measures of visual function (VF)

		VF, better-eye		
GVFQ-40	PVA, better-eye	MD	VFI	PSD
Mobility	0.485*	-0.651*	-0.677*	0.447*
Visual motor skills	0.538*	-0.701*	-0.718*	0.501*
Reading	0.531*	-0.600*	-0.617*	0.448*
Recognition	0.594*	-0.617*	-0.607*	0.412*
Night vision	0.515*	-0.651*	-0.669*	0.453*
Total score	0.566*	-0.691*	-0.707*	0.506*

^{*}Significant at 0.001 level, Spearman rank correlation.

MD, mean deviation; PSD, pattern SD; PVA, presenting visual acuity; VFI, Visual Field Index.

the mean difference between the first and repeated tests was not more than 0.088. For the total scores, the mean difference was -0.029 (95% CI -0.108 to 0.051), and the 95% limits of agreement were -0.447 to 0.389 (figure 2).

DISCUSSION

In this study, we present the development process and psychometric validation results of the GVFQ-40, which showed good discriminant and criterion-related validity. A three-domain structure tended to be confirmed by EFA. It also had high test–retest concordance, which supports its potential in the assessment of intervention effectiveness.

The levels of missing data (<7%) for all items were low, indicating that items contained in the GVFQ-40 cover problems relevant to most individuals. We observed that three items related to ball games and leisure activities (items 12, 13 and 14) had larger proportions of missing data, which can be explained by these activities involving personal interests. This finding is similar to that of a previous study of the IVI by Weih *et al*, but the percentage of missing responses was higher in their study. One explanation is that the enrolled subjects in that study were comparatively older (72±14 years).

It is worth noting that all pairwise comparisons except for the comparison of the 'mobility' domain between the mild VF-loss group and controls were statistically significant after Bonferroni correction. The lack of a significant difference may be explained by mobility difficulties being reported by mostly moderate and

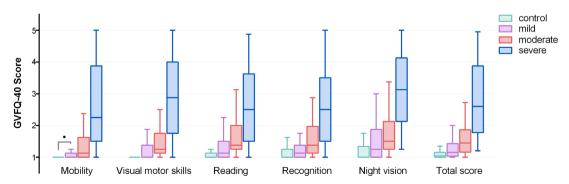


Figure 1 Comparison of domain-specific and total 40-item glaucoma Visual Functioning Questionnaire (GVFQ-40) scores between subgroups. Glaucoma patients were stratified by the better-eye mean deviation (MD, ≥ $-6\,dB$, $-12\,to$ $-6\,dB$ and $<-12\,dB$ correspond to mild, moderate, and severe visual field (VF) loss, respectively). The sample sizes from the control group to the severe VF-loss group were 84, 91, 84 and 95. Higher scores indicate worse visual ability. All pairwise comparisons, except for the comparison on the 'mobility' domain between the mild VF-loss group and controls, were statistically significant at p<0.05 (see online supplemental table 3) for p values). The dot indicates a statistically nonsignificant between-subgroup difference. The median, IQR, minimum and maximum (whiskers) values are presented.

Table 4 Exploratory factor analysis of the 40-item Glaucoma Visual Functioning Questionnaire*

Domain	Item	Varimax rotation		
		Factor 1	Factor 2	Factor 3
Mobility	1	0.765	0.482	0.327
	2	0.686	0.573	0.316
	3	0.677	0.559	0.348
	4	0.819	0.395	0.305
	5	0.762	0.471	0.343
	6	0.622	0.594	0.380
	7	0.705	0.490	0.411
	8	0.790	0.404	0.380
Visual motor skills	9	0.574	0.601	0.413
	10	0.634	0.483	0.454
	11	0.775	0.383	0.403
	12	0.633	0.495	0.480
	13	0.428	0.738	0.350
	14	0.517	0.674	0.390
	15	0.654	0.548	0.326
	16	0.737	0.415	0.401
Reading	17	0.460	0.385	0.678
	18	0.539	0.254	0.681
	19	0.255	0.539	0.722
	20	0.219	0.488	0.766
	21	0.346	0.461	0.754
	22	0.554	0.356	0.626
	23	0.600	0.286	0.672
	24	0.636	0.354	0.554
Recognition	25	0.446	0.513	0.576
	26	0.375	0.627	0.516
	27	0.570	0.440	0.502
	28	0.551	0.536	0.509
	29	0.494	0.537	0.563
	30	0.781	0.258	0.458
	31	0.552	0.295	0.665
	32	0.523	0.444	0.592
Night vision	33	0.655	0.553	0.357
	34	0.520	0.685	0.375
	35	0.427	0.776	0.365
	36	0.425	0.731	0.411
	37	0.441	0.716	0.420
	38	0.533	0.628	0.371
	39	0.542	0.600	0.394
	40	0.291	0.779	0.391

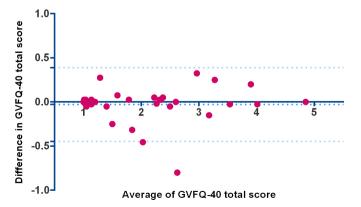


Figure 2 Bland-Altman plot presenting test—retest concordance for overall scores on the 40-item Glaucoma Visual Functioning Questionnaire (GVFQ-40). The dotted lines correspond to the mean difference in the two tests and the 95% limits of agreement.

severe glaucoma patients. ²⁸ ²⁹ However, in the subgroup analysis of the NEI VFQ-25, we found significant differences between subjects with mild VF loss and controls in only 2 of the 12 dimensions (general vision and role difficulties), and comparisons between mild and moderate VF-loss groups showed differences in only three domains (near activities, distance activities and social function). Additionally, a previous study by Gothwal *et al*³⁰ found that there was no difference in GAL-10 (derived from the GQL-15) scores between the mild and moderate VF-loss groups (p=0.07). These results provide support that the GVFQ-40 has good discriminant validity that may be better than those of some existing questionnaires.

As a questionnaire evaluating the visual ability of glaucoma patients, GVFQ-40 scores were expected to correlate with measures of glaucoma severity. Responses on the GVFQ-40 showed markedly high correlations with the better-eye MD, whereas the correlation coefficient between the GAL-10 score and better-eye MD reported by Gothwal et al^{30} was -0.40. The associations between GVFQ-40 scores and VA were moderate but still stronger than those between the scores of some validated questionnaires and VA (rho <0.40 generally). 9 30 31 The lowest correlation was found between the GVFQ-40 score and better-eye PSD because the PSD initially increased and then gradually decreased with an increasing degree of VF loss. 32 33 It is worth emphasising that the level of self-reported difficulty in the GVFQ-40 items was more strongly correlated with VF damage than VA loss, which concurs with the actual clinical situation of glaucoma and further confirms the criterion validity of the GVFQ-40.

The results of the EFA suggest a three-domain structure. Activities involving mobility or visual motor skills tended to load on factor 1. Items related to night vision highly loaded on factor 2. Factor 3 was mainly composed of reading and recognition tasks. Items 22, 23, 24, 33, 34, 38 and 39 also loaded on factor 1, which was expected since these items are closely correlated with mobility or visual motor skills. Items 27, 30, 31 and 32 loaded on factor 1 and factor 3, which can be explained by the fact that these tasks involve eye movement and recognition. We noted that item 28 and 29 loaded on three factors, indicating that the wording of the question was misleading and that the distance needed to be limited. Considering that the responsiveness of items to therapeutic or rehabilitative interventions is also an important reference for modification, further removal or rewriting of items will be reported in future studies.

The test–retest ICC of the GVFQ-40 was higher than those of some existing questionnaires⁶ 9 13 34 and can be compared with results of Richman *et al* 35 for the Spaeth/Richman contrast sensitivity test (0.97) and PR chart (0.98), suggesting that the GVFQ-40 possesses good reproducibility.

There are several limitations in our study. First, individuals with a lower education level or living in remote areas may have been less likely to participate. Second, control subjects had higher levels of education and employment and were more likely to live in cities than glaucoma patients. However, the relationship between the total GVFQ-40 score and VF severity remained significant after adjustment for these imbalanced covariates. Moreover, standardised β coefficients indicated that total GVFQ-40 scores were mainly affected by visual damage. Third, we did not choose healthy controls but glaucoma suspects, which may have biased our results towards a lower impact of glaucoma on daily tasks. However, the included controls were people with relatively normal visual function who did not have sufficient clinical evidence to be diagnosed with glaucoma. Additionally, glaucoma suspects who attended the same clinic may

be more similar to glaucoma patients considering unmeasured factors than healthy controls.

In conclusion, the GVFQ-40 possesses good validity and reliability, supporting its use in evaluation of the visual ability of Chinese patients with glaucomatous vision impairment. It could be useful in elucidating the impact of glaucomatous damage on a patient's visual function, even when VA remains good. Future work is needed to test the responsiveness of the instrument to therapeutic or rehabilitative interventions for visual impairment.

Contributors HH, JL, ML, YL and YZ designed the study; HH, ZL and JH collected the data; HH, JL and LJ analysed and interpreted the data; HH drafted the manuscript; HH, ML, YZ, YL and YZ revised the manuscript. YZ is responsible for the overall content.

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Competing interests None declared.

Patient consent for publication Not applicable.

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ORCID iD

Yehong Zhuo http://orcid.org/0000-0003-3247-7199

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