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Title

An Italian translation and validation of the Near Activity Visual Questionnaire (NAVQ).

Short Title

Validation of NAVQ in Italian

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Abstract

Purpose: To validate the Near Activity Vision Questionnaire (NAVQ) in Italian to allow the assessment of presbyopia corrections in Italian speaking patients.

Method: An Italian version of the NAVQ was arranged through several steps: an initial forward translation (from English to Italian), a backward translation (from Italian to English) and finally a consensual version to check against the original NAVQ. This prospective study enrolled native Italian speaking presbyopes, with corrected distance visual acuity of 0.20 logMAR or better in each eye and free of ocular anomalies. Six different groups of patients were asked to complete the questionnaire: emerging presbyopes, reading spectacle users, multifocal spectacle users, multifocal contact lens (CL) wearers, monovision CL wearers and monofocal intraocular lenses patients. Subjects were asked to answer to the questionnaire again after 2 weeks the first completion.

Results: Two hundred and seven subjects completed the questionnaire. Data analysis showed very good internal consistency (Cronbach $\alpha = 0.93$) and factorial validity with only one factor explaining 62.0% of the variance. Test–retest reliability resulted extremely good (ICC = 0.92) as well as discriminatory power of the questionnaire able to discriminate between subjects without different forms of presbyopic correction.

Conclusions: The Italian version of the NAVQ matches the properties of the original English version. It is a valid instrument to evaluate near activity visual quality of presbyopic Italian speakers.

Introduction

The ‘Holy Grail’ for presbyopes is a spectacle free correction achieving clear vision at all focal distances. Contact lenses (CLs) can attempt to correct presbyopia through monovision or simultaneous image designs, with translating designs achievable with rigid gas permeable lenses (RGPs) in some patients (1). There have been surgical attempts at monovision with intraocular lenses (IOLs) or laser surgery (2) along with other techniques to induce corneal multifocality (3-7). Other approaches such as corneal inlays, (8-9) pseudo-accommodating and multifocal IOLs (10-12) and scleral expansion techniques (13) are amongst the surgical options available to patients but each modality has its own advantages and disadvantages (14). To judge the success of any treatment option both objective visual function measures and subjective perception should be assessed. Subjectively, patient perception can be measured by a patient-reported outcome (PRO) that typically is a validated questionnaire (15). PRO instruments are extremely useful in medical product development and in clinical trials (16). One PRO instrument, the Near Activity Visual Questionnaire (NAVQ), is designed specifically to assess the benefits of presbyopia correction and was introduced and standardised for English speakers by Gupta et al[17] and developed further by Buckhurst et al (18). This is a 10-item questionnaire, plus an item rating overall satisfaction with near vision, that showed good reliability with Cronbach **α** coefficient of 0.95 and an ICC for test–retest reliability of 0.72. It has been used to compare outcomes after refractive surgery or contact lenses for presbyopia (19-21).

The availability in other languages of this questionnaire could be useful, but the process of translation and validity in other languages has to follow a certain procedure to maintain the validity of the original instrument (22). A translated

questionnaire needs to be framed in a new cultural and linguistic context (23-24) and it has to be revalidated in order to guarantee the equivalence to the original (25).

In the field of Vision Sciences only few questionnaires have been translated and validated into Italian; the National Eye Institute Visual Function Questionnaire or NEI VFQ-25; (26) the Glaucoma Symptom Scale; (27) and the Amblyopia and Strabismus questionnaire (28).

The aim of this research was to produce a validated Italian translation of the NAVQ to allow the assessment of the relative subjective benefits of presbyopia corrections in Italian speaking patients.

Methods

Procedure

An Italian version of NAVQ was arranged according to recommendations and guidelines for a comprehensive multistep methodological process for translating, adapting and validating psychometric instruments in health care research (22, 24). The processes involved 3 steps.

1. Forward translation - two different native Italian speakers, familiar to questionnaires and vision sciences, translated the NAVQ from English to Italian. The translators were required to emphasise conceptual rather than literal equivalence with the original version of the NAVQ. A consensus preliminary initial translated version was obtained by the two translators.

2. Backward translation - the forward translation was given to a bilingual British-Italian vision sciences researcher who translated the Italian NAVQ back into English.

3. Consensual version development - the backward translation was reviewed by two native English speaking vision sciences researchers of the Ophthalmic Research

Group in Aston University, who checked the translation for conceptual equivalence with the original NAVQ version. As the questionnaire was to be conducted across spectacle as well as non-spectacle visual corrections, question 10 was amended to "Conducting near work?"

Patients

Patients were recruited in Italy according the following inclusion criteria:

-People cognitively able to respond to a questionnaire;

-Native Italian speakers who were presbyopic;

-Corrected distance visual acuity of 0.20 logMAR or better in each eye;

-Absence of any ocular pathology or binocular vision anomalies.

Six different groups of patients were tested:

1) Emerging presbyopes: People over 45 years old, who were not constantly using any form of reading correction as yet.

2) Reading spectacle users: Presbyopic subjects using single vision reading spectacle for near visual activities.

3) Multifocal spectacle users: Presbyopic subjects habitually using spectacles with progressive additional lenses.

4) Multifocal CL wearers: Presbyopic subjects who had been habitually using multifocal CLs for at least 6 months at the time of the study.

5) Monovision CL wearers Presbyopic subjects who had been habitually using monovision CLs for at least 6 months at the time of the study.

6) Monofocal IOL patients: Presbyopic subjects who had bilateral implantation of monofocal (single vision) IOLs focussed for distance vision, with the second eye surgery performed at least 6 months before being enrolled in the study and at this time were not using reading spectacles for near vision as they had not yet been

prescribed for them. This group were not corrected for near vision and they would act as a control group to see if the questionnaire was sensitive enough to pick up deficiencies in near vision performance, if so then this group would show the worst results.

All patients were asked to complete the questionnaires based on their vision with their habitual correction

To calculate test–retest reliability further questionnaire responses were requested 2 weeks after the first completion of the NAVQ. Two weeks was considered long enough to minimise memory effects from the first completion and short enough that any significant fluctuations in vision were unlikely. In the case of a subject failing to return the second questionnaire they were called and /or emailed.

For each participant data was collected relating to refraction, near addition needed and optical device used.

The 6-item distance vision sub scale of the Italian version of the questionnaire NEI-VFQ 25 (26) was used to investigate the subjective perception of distance vision of the subjects, which in some optical methods of correction may be compromised (such as multifocal CLs or monovision CLs).

The study was approved by the local ethical committee and performed in agreement with the tenets of the Declaration of Helsinki. All patients provided informed consent after receiving an explanation of the nature of the study and local ethical approval was in place.

Data analyses

Internal consistency of the Italian translation of the NAVQ was determined using the Cronbach **α** coefficient. It was calculated directly on the raw responses of the 10-

items of the first NAVQ completed by all participants irrespective of the group. An exploratory factor analysis (Principal Component Analysis) was carried out to confirm factorial validity of the Italian translation of NAVQ questionnaire. Factor analysis was conducted on the raw responses at the 10-item NAVQ for the first NAVQ filled by all participants irrespective of the group.

Repeatability of NAVQ outcomes was evaluated with the intra-class correlation coefficient (ICC) obtained by all participants irrespective of their habitual refractive correction for both; the Rasch scores were determined from the sum of the scores of the 10 items of the NAVQ (missing values and responses that were marked as 'not applicable (n/a)' were scored according to the median overall score;[18] and the score of the item rating overall satisfaction with near vision.

Discriminatory power (concurrent validity) of the Italian version of NAVQ questionnaire was explored by the comparison between different groups investigated. A non-parametric one-way ANOVA between the groups (independent-samples Kruskal-Wallis Test) was applied as the distribution of Rasch scores was not normal in the emerging spectacle and spectacle wearing cohorts (group 1, 2 and 3; Kolmogorov-Smirnov $p<0.05$). Paired comparisons among groups were performed by Mann Whitney test.

The same statistical tests were used to evaluate differences between groups for NEI-VFQ 25 sub-scale for distance since the scores distribution in all presbyopia correction modality groups were significantly different from normality (Kolmogorov-Smirnov, in all groups $p<0.05$).

Results

Data was obtained from 207 subjects. Table 1 shows the demographic data of the subjects and refractive condition as a function of the 6 different presbyopia correction modality groups. Age was statistically different amongst groups (One way ANOVA, $F_{5,201}$=53.8, p<0.001), post-hoc comparisons showed a significant difference between group 1 (Emerging Presbyopes*)* and all the other groups and between group 6 (Monofocal IOLs) and all the others. Groups 2, 3, 4 and 5 did not show differences with age.

Internal consistency of NAVQ measured on the overall sample, by Cronbach α coefficient for the 10-Item, was good with a value of 0.93.

To explore factor validity of the Italian translation of the NAVQ a Spearman correlation calculation between all the items was performed. The correlation matrix (Table 2) revealed that the 10 items were strictly correlated to each other. Principal component analysis was run for factor extraction. Only one component was extracted with analysis and it was not possible rotate the solution (Table 3). Factor 1 alone explained 62.0% of the variance.

Of the overall number of 207 interviewees, 182 (87.9%) returned their second questionnaire. The mean Rasch score of these 182 patients was (mean ± SD) 27.9 ± 18.4 (range 0.00/90.6) for the first response and 27.6 ± 18.3 (range 0.00/90.6) for the retest. The ICC was calculated to be 0.92 (two-way mixed effects model for test–retest reliability) and 0.90 for the item rating overall satisfaction with near vision. A comparison between the 6 different groups of presbyopes was run to evaluate the discriminatory power of the Italian version of the NAVQ (Table 4). The NAVQ Rasch scores demonstrated significant differences in the quality of near visual satisfaction between habitual presbyopic refractive modalities (Kruskal-Wallis Test, p<0.001; Table 5), with all presbopyic corrections outperforming monofocal IOLs as expected,

spectacles outperforming successfully worn contact lens presbyopic modalities, whereas emerging presbyops had a result similar to contact lenses.

The NEI-VFQ distance subscale scores differed between habitual presbyopic correction modality groups (Kruskal-Wallis Test, p=0.001; Table 6), being reduced in contact lens presbyopic modalities (multifocal p<0.001 and monovision p=0.012) and monofocal IOLs (p=0.027) compared to emerging presbyopes (Mann-Whitney test).

Discussion

The availability of a standardised questionnaire to achieve a self-assessment of near visual ability and satisfaction in presbyopic patients is crucial in a period of time in which many new optical devices and surgical options are been developed to correct presbyopia.

The aim of this study was to produce and validated an Italian translation of the NAVQ in order to allow clinicians and researcher to get a patient-reported outcome (PRO) from Italian spoken presbyopic people.

The Italian version of NAVQ showed good reliability, very close to the original English version (18). Internal consistency of Italian NAVQ, measured by Cronbach α coefficient (=0.95), demonstrated that all items are strongly related to each other, demonstrating the unidimensionality of the questionnaire. For the original NAVQ (18) Cronbach α was 0.93. These levels are similar to other validated questionnaires that assess near visual functionality with specific sub scales, such as the National Eye Institute Visual Functioning Questionnaire (NEI VFQ) (29) or the National Eye Institute–Refractive Error Quality of Life (NEI-RQL) (30) with a Cronbach α of 0.94 and 0.85 respectively. However, Pesudovs at al (31) have that Cronbach’s alpha values higher than 0.90 can indicate a certain redundancy in the instrument.

The Italian version of NAVQ showed better test-retest reliability (ICC = 0.92) compared to the original English version (ICC = 0.72) (18). In the subscale cited above, relative to near visual functionality of the National Eye Institute Visual Functioning Questionnaire (NEI VFQ) (29) and the National Eye Institute–Refractive Error Quality of Life (NEI-RQL) (30) the ICC resulted 0.91 and 0.74 respectively. Generally, the discriminatory power (concurrent validity) of a PRO can be evaluated looking at the result of comparison between people that the specific PRO should theoretically be able to discriminate (31). The Italian version of NAVQ was clearly able to discriminate between subjects without presbyopia correction (implanted with monofocal IOLs) compared with those with presbyopia corrections. Like previously shown (18), those using multifocal spectacles outperformed other forms of presbyopia correction despite the inconveniences (fogging, contact with the skin etc.) and optical compromises (magnification, frame inducted scotomas, vergence distortion, the need to rotate the head and eyes to maintain clear vision and peripheral image distortions) compared to CL simultaneous image or monovision options.

A further confirmation of the good discriminatory power of Italian NAVQ derives from the analysis of the “cut off” total Rasch score from Buckhurst and colleagues (18) that was able to detect near vision difficulties (44.25 out of the 0 to 100 range). From table 4 it is evident that the only group with a Rasch score higher than this cut off is the monofocal IOL implanted patient, not corrected for near. In the remaining groups, who were successfully coping with their presbyopic refractive correction or emerging presbyopes who were managing sufficiently without a near correction, the vision achieved was rated as below the cut off value, as expected.

In conclusion, the Italian version of the NAVQ matches the properties of the original

English version in being able to rapidly determine near activity visual quality of life as a single concept, with high discriminatory ability between different forms of vision correction.

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Group	Number	Age (years) Mean ± SD (Range)	Gender (Male/Female)	RE MSE (D) Mean ± SD (Range)	LE MSE (D) Mean ± SD (Range)	RE Add for near (D) Mean ± SD (Range)	LE Add for near (D) Mean ± SD (Range)
1-Emerging Presbyopes	44	46.3 ± 2.6 (42.0/51.5)	21/23	-0.35 ± 1.32 (2.00/-5.50)	-0.32 ± 1.33 (3.00/-5.00)	1.33 ± 0.48 (0.00/1.75)	1.23 ± 0.58 (0.00/1.75)
2-Reading Spectacles	46	56.5 ± 7.1 (45.6/80.4)	26/20	-0.43 ± 1.94 (3.13./-9.00)	-0.49 ± 2.14 (3.38./-9.50)	2.03 ± 0.62 (1.00/3.50)	2.03 ± 0.62 (1.00/3.50)
3-Multifocal Spectacles	47	56.0 ± 7.4 (44.2/75.6)	21/26	0.22± 2.02 (4.00./-6.13)	0.30 ± 2.18 (4.00./-7.38)	1.99 ± 0.61 (0.75/3.50)	1.99 ± 0.61 (0.75/3.50)
4-Multifocal CLs	32	57.9 ± 7.7 (46.4/77.0)	10/22	0.74± 3.72 (7.00./6.00)	0.68 ± 3.90 (7.13./-6.00)	2.29 ± 0.54 (1.50/3.00)	2.29 ± 0.54 (1.50/3.00)
5-Monovision CLs	18	58.6 ± 6.5 (49.0/71.6)	3/15	-1.67 ± 4.53 (3.63./-9.25)	-1.13 ± 3.98 (3.00/-10.25)	2.00 ± 0.47 (1.00/2.50)	2.00 ± 0.47 (1.00/2.50)
6-Monofocal IOLs	20	74.2 ± 5.6 (66.5/87.1)	11/9	-0.23 ± 0.64 (1.00./-1.13)	-0.25 ± 0.53 (0.50/-1.38)	3.25 ± 0.47 (2.00/4.00)	3.26 ± 0.51 (2.00/4.00)
Significance		One way ANOVA **p<0.001**	χ^2=11.7 **p=0.04**	One way ANOVA p=0.10	One way ANOVA p=0.00	One way ANOVA **p<0.001**	One way ANOVA **p<0.001**
Total	207	56.3 ± 9.7 (42.0/87.1)	92/115	-0.40 ± 3.19 (7.00./-9.25)	-0.38 ± 2.76 (7.13/-10.25)	2.12 ± 0.79 (0.75/4.00)	2.11 ± 0.80 (0.75/4.00)

Table 1: Characteristics of the patients recruited in the 6 groups to validate the Italian version of NAVQ. All data of ‘MSE’ and ‘Add’ refer to spectacle prescription.

	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10
Item 1										
Item 2	**0.783****									
	N=205									
Item 3	**0.714****	**0.675****								
	N=205	N=206								
Item 4	**0.603****	**0.584****	**0.782****							
	N=205	N=205	N=205							
Item 5	**0.470****	**0.423****	**0.596****	**0.560****						
	N=203	N=203	N=203	N=203						
Item 6	**0.496****	**0.552****	**0.656****	**0.615****	**0.629****					
	N=203	N=202	N=203	N=204	N=201					
Item 7	**0.542****	**0.474****	**0.659****	**0.709****	**0.648****	**0.627****				
	N=197	N=198	N=198	N=198	N=196	N=196				
Item 8	**0.481****	**0.518****	**0.479****	**0.467****	**0.431****	**0.511****	**0.498****			
	N=202	N=202	N=202	N=203	N=201	N=201	N=197			
Item 9	**0.589****	**0.602****	**0.559****	**0.584****	**0.488****	**0.522****	**0.449****	**0.546****		
	N=202	N=202	N=202	N=202	N=200	N=200	N=195	N=199		
Item 10	**0.652****	**0.617****	**0.619****	**0.563****	**0.421****	**0.518****	**0.526****	**0.527****	**0.517****	
	N=203	N=203	N=203	N=202	N=201	N=201	N=196	N=200	N=200	

** Correlation is significant at the 0.01 level

Table 2: Spearman correlation matrix among items in the overall sample of subjects.

	Component
	1
Item 1	0.81
Item 2	0.77
Item 3	0.88
Item 4	0.85
Item 5	0.76
Item 6	0.83
Item 7	0.82
Item 8	0.67
Item 9	0.75
!tem 10	0.70

Table 3: Component matrix and loadings.

	Median	Mean	SD	Asymmetry	Kurtosis	Min	Max	IQ range
1-Emerging Presbyopes	33.3	35.7	17.1	0.43	-0.16	0.00	77.7	28.6
2-Reading Spectacles	23.1	21.3	16.2	0.22	-0.83	0.00	54.8	25.3
3-Multifocal Spectacles	18.1	20.7	20.5	1.36	2.29	0.00	90.6	27.0
4-Multifocal CLs	38.7	36.4	14.0	-0.96	1.18	0.00	56.9	15.9
5-Monovision CLs	30.3	31.5	11.5	0.69	-0.27	18.1	54.8	17.5
6-Monofocal IOLs	64.7	63.8	14.8	0.44	0.74	36.1	100.0	17.9

Table 4: descriptive statistics for the NAVQ Rasch score for each single group.

	1-Emerging Presbyopes	2-Reading Spectacles	3-Multifocal Spectacles	4-Multifocal CLs	5-Monovision CLs	6-Monofocal IOLs
1-Emerging Presbyopes						
2-Reading Spectacles	**P<0.001**					
3-Multifocal Spectacles	**P<0.001**	P=0.46				
4-Multifocal CLs	P=0.38	**P<0.001**	**P<0.001**			
5-Monovision CLs	P=0.37	**P=0.02**	**P=0.005**	P=0.08		
6-Monofocal IOLs	**P<0.001**	**P<0.001**	**P<0.001**	**P<0.001**	**P<0.001**	

Table 5: Significance for each paired comparison between groups (Mann Whitney).

Comparisons have been calculated on the NAVQ Rasch score.

	Median	Mean	SD	Asymmetry	Kurtosis	Min	Max	IQ range
1-Emerging Presbyopes	100	98.2	4.3	-2.72	7.02	83.3	100	16.7
3-Multifocal Spectacles	100	97.2	4.7	-1.53	1.26	87.5	100	6.3
4-Multifocal CLs	95.0	92.9	6.2	-0.52	-0.53	79.2	100	12.5
5-Monovision CLs	95.8	95.1	6.4	-1.96	4.89	75.0	100	8.3
6-Monofocal IOLs	100	92.7	11.0	-1.52	1.36	66.7	100	12.5

Table 6: descriptive statistics for the NEI-VFQ 25 distance subscale scores for each single group. Note this questionnaire has not been requested for reading glasses patients (group 2).

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