

Development of a New Subjective Questionnaire: The Freedom from Glasses Value Scale (FGVS)

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ABSTRACT

PURPOSE: To develop a patient self-administered questionnaire assessing the added value of complete independence from spectacles (hereafter referred to as glasses) after multifocal intraocular lens (IOL) surgery.

METHODS: Exploratory interviews with five cataract patients and six presbyopic patients with AcrySof ReSTOR IOLs (Alcon Laboratories Inc) implanted in both eyes for at least 6 months were conducted. The questionnaire's conceptual framework was developed after interview analysis. Based on the identified concepts, items were generated simultaneously in French and Spanish using patients' own words, and comprehension tested with six French patients; the Spanish questionnaire underwent clinician review and was further tested with four Spanish patients. French and Spanish versions were accordingly refined. The questionnaire was linguistically validated in UK English and Danish.

RESULTS: Interview analysis resulted in the identification of 9 global concepts: global vision, practical constraints related to wearing glasses, impact of eye surgery on the patient's life, improvement of practical issues without glasses, improvement of psychological constraints without glasses, physical appearance/aesthetic aspect, self-image and in the eyes of others, eyesight problems left behind after surgery, and recommendation of surgery to others. The initial version of the test questionnaire contained 23 items; 2 items were deleted and changes were made after clinician review and patient testing. The final questionnaire named Freedom from Glasses Value Scale (FGVS) contained 21 items and four general additional questions.

CONCLUSIONS: Beyond functional aspects, this qualitative study identified additional benefits in cataract and presbyopic patients living free of glasses after receiving multifocal IOLs. The FGVS now needs to be psychometrically validated (eg, construct validity and reliability). [*J Refract Surg.* 2010;26(6):438-446.] doi:10.3928/1081597X-20090728-03

Cataract and presbyopia are both conditions characterized by visual impairment. Cataracts are due to opacities of the crystalline lens, leading to functional visual impairment and visual loss. They account for 40% of blindness worldwide, and remain one of the leading causes of blindness in developing countries.^{1,2} Presbyopia is characterized by a loss of elasticity of the crystalline lens. With the population of baby boomers now in their fifties and a higher life expectancy, the number of patients with presbyopia is likely to increase in the coming years³; similarly, with the population aging, the number of persons affected by cataract is expected to rise.^{2,4}

Surgery is the only treatment currently available for cataracts, and cataract surgery is the most common surgical procedure in developed countries. Traditional intraocular lenses (IOLs) are monofocal. They offer vision at one distance

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only (near, intermediate, or far) and require the patient to wear spectacles (hereafter referred to as glasses) or contact lenses after surgery. The new multifocal accommodating IOLs are an alternative that has shown efficiency in correcting both near and distant vision, eventually resulting in freedom from glasses.⁵⁻⁸ Multifocal IOLs use different technologies—some are apodized diffractive, others are zonal refractive or full-aperture diffractive—but all are designed to decrease glasses dependency. Although near and distance vision is improved with multifocal IOLs, perfect intermediate vision remains more difficult to achieve, with differences noted among IOLs, although visual function improvement is well established.^{9,10} Accommodating IOLs, designed to correct near, intermediate, and distance vision after lens removal surgery, could provide better intermediate vision. Vision-specific patient reported outcome questionnaires, such as the newly developed Freedom from Glasses Value Scale (FGVS), should help identify the perceived vision benefit of forthcoming new IOL technologies.

Patient-reported outcomes are acknowledged as sound, valid, and reliable endpoints, provided they are properly developed, validated, assessed, and analyzed.^{11,12} The critical importance of qualitative work and the need to adequately document and report the early steps in patient-reported outcome instrument development have been highlighted.¹³

Reading and work at intermediate and near distance and driving are essential aspects in industrialized societies, therefore explaining, at least partially, the significant clinical and social impact of cataracts and presbyopia. With good visual acuity now being achieved by most patients receiving IOL implantation, attention is increasingly directed towards a full evaluation of the impact of visual impairment and disabilities on patients' daily lives. Several studies assessing the impact of cataract or presbyopia surgery correction from a patient's perspective revealed positive outcomes, mostly due to decreasing visual symptoms (eg, halos and glare) and by reducing dependency on glasses.^{5,10,14-17} A majority of patient-reported outcome instruments used in these studies were designed for measuring the difficulties patients encounter with tasks and symptoms, such as the Visual Disability Assessment (VDA) questionnaire, the Activities of Daily Vision Scale (ADVS), and the Visual Function (VF-14) index^{16,18-20}; some items of the cataract Type specification questionnaire allow the assessment of visual disability with and without glasses.²¹⁻²⁴ Beyond functioning assessment, some instruments such as the National Eye Institute Visual Function Questionnaire (NEI-VFQ and NEI VFQ-25) were designed in an attempt

to capture the influence of vision correction on multiple health-related quality of life dimensions.^{24,25}

Several questionnaires specifically address issues related to refractive correction and spectacle or contact lens independence on a patient's life; these instruments include the National Eye Institute Refractive Quality of Life (NEI-RQL), the Refractive Status and Vision Profile (RSVP), the Contact Lens Impact on Quality of Life Questionnaire (CLIQ), and the Quality of Life Impact of Refractive Surgery questionnaire (QIRC).²⁶⁻²⁹ The majority of these questionnaires have been tested with patients with cataracts or the presbyopic population, but very few are suitable for presbyopic patients alone. The NEI-RQL questionnaire^{8,30} and the questionnaire developed by Gupta et al³¹ are appropriate for the latter population.

These various instruments cover many domains of a patient's life that are likely to be impacted by vision correction, including surgery. Despite being a major expectation after cataract surgery, no data or specific questionnaires regarding patients' perception of freedom from glasses and benefits beyond the functional aspects of multifocal IOLs following surgery are available.

The FGVS was developed to assess the added value of complete independence from glasses after multifocal IOL surgery. We present the early steps of the development of the questionnaire, including the description of patient interviews and the conceptual framework development and item generation, in keeping with regulatory authorities' requirements for market authorization of drugs and medical devices. The questionnaire was simultaneously developed in French and Spanish; the linguistic validation of the English (UK) and Danish versions is also presented.

PATIENTS AND METHODS

CONCEPTUAL FRAMEWORK DEVELOPMENT

The first step of the patient interview process was carried out in France. Voluntary male and female patients diagnosed with cataracts or presbyopia and who had undergone surgery with implantation of a multifocal IOL (AcrySof ReSTOR; Alcon Laboratories Inc, Ft Worth, Tex) in both eyes for at least 6 months were recruited by two ophthalmologists (P.L. and Simon Coulon, MD). Patient criteria were age <75 years, no longer wearing glasses, and no ocular comorbidities or other major pathologies.

A semi-directive approach was used to interview the patients. The aim of this approach was to offer speaking time to interviewees by means of open questions so patients could express their awareness and perception of the advantages of not having to wear glasses due to

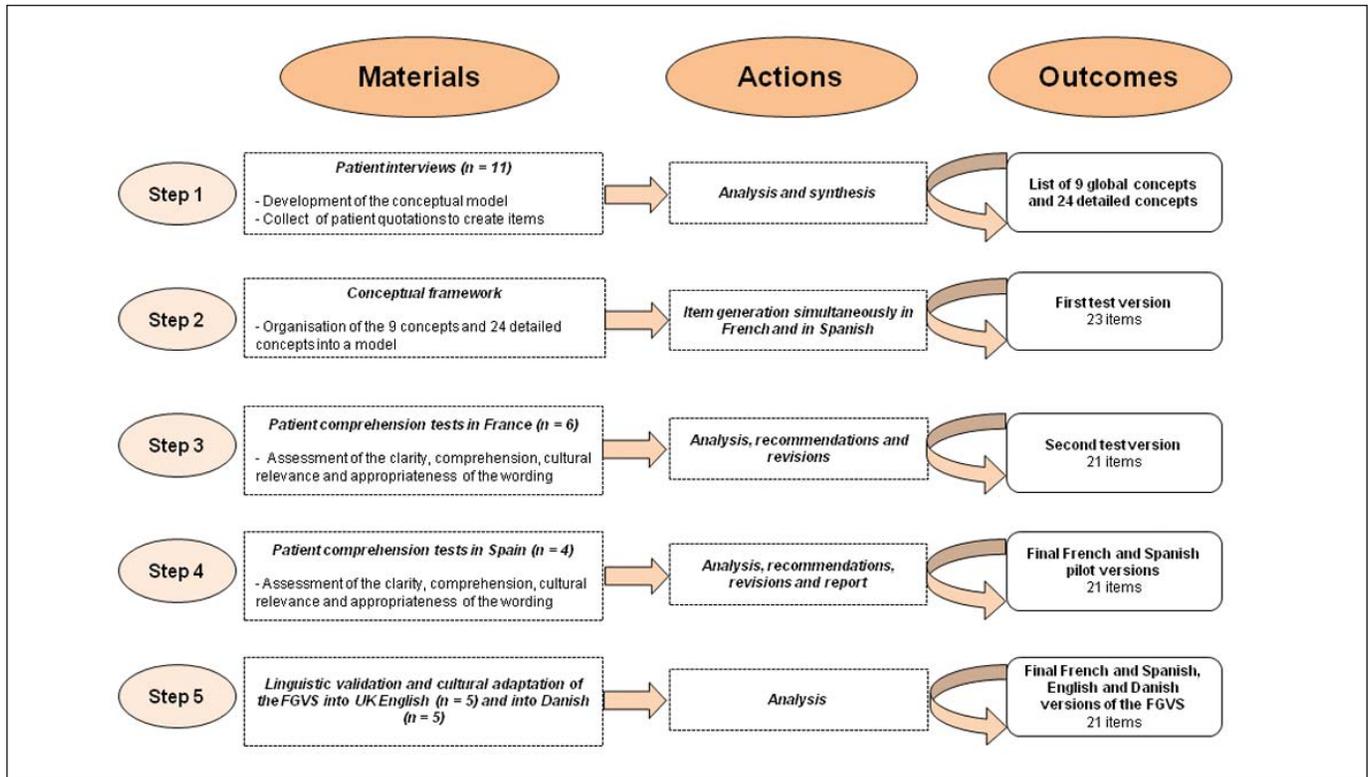


Figure. Overview of the development of the Freedom from Glasses Value Scale (FGVS).

the implants.³² The face-to-face exploratory patient interviews were conducted by two health psychologists (Marc Vigneux, MSc and Claire Colussi, MSc) to 1) identify the attributes and descriptive agents of the perceived benefit of not wearing glasses after successful IOL implantation in both eyes; and 2) to collect patients' actual comments related to this topic. Interviews were analyzed using the Interpretative Phenomenological Analysis approach³²⁻³⁴ and allowed the identification of global and detailed concepts that were relevant to patients regarding freedom from glasses. A conceptual framework was developed and agreed upon during a meeting in which experts in patient-reported outcomes and a physician working in the field of ophthalmology participated. A response scale and the name of the questionnaire were chosen at this step.

ITEM GENERATION AND PRODUCTION OF QUESTIONNAIRE TEST VERSION

Based on identified concepts related to the specific topic to be assessed during the interviews described above and using patients' verbatim responses, the items were simultaneously generated in French and in Spanish by three French and three Spanish native speakers. This process ensured that each item in the subsequent questionnaire was relevant to both French

and Spanish patients. Following discussions on the relevant domains and the overall structure, a consensus was reached on a test version of the questionnaire in both languages.

FRENCH AND SPANISH COMPREHENSION TESTS

The questionnaire content validity of the French version was tested during six face-to-face interviews with patients representative of the target population. Patients were native French speakers, were diagnosed with either cataracts (n=2) or presbyopia (n=4), and had multifocal IOL implants in both eyes for at least 6 months. During interviews, the questionnaire was submitted to a comprehension test to assess the clarity, appropriateness of wording, and acceptability of the questionnaire structure and content to patients. Following reformulation of the French version, the Spanish test version was modified accordingly. The Spanish test questionnaire was backward translated into French, reviewed by a clinician, and then comprehension tested with four patients with cataract and/or presbyopia. Patients were recruited on the same inclusion criteria as for the first interviews. During in-depth, face-to-face interviews with trained interviewers, patients were asked to comment on their understanding of each item and to suggest alternative

formulations in the case of problematic wording. An additional open question was asked at the beginning of the interviews to obtain qualitative feedback data on the overall perception of patients regarding not having to wear glasses any longer. The question was worded as follows: “I would like to speak about your intraocular lenses. Could you describe what it feels like not wearing glasses any longer?”

The master French version was used to carry out a linguistic validation in UK English and Danish.

LINGUISTIC VALIDATION OF THE QUESTIONNAIRE INTO ENGLISH (UK) AND DANISH

The French version questionnaire was adapted into English (UK) and Danish using a standard linguistic translation methodology.³⁵ The questionnaire was first forward-translated into English (UK), from which the Danish version was subsequently elaborated. A backward translation of the version was then produced by a professional translator who was a native speaker of the source language and fluent in the target language. The questionnaire was then reviewed by a clinician in each country. Finally, a comprehension test was performed with five individuals from the target country to assess the clarity, appropriateness of wording, and acceptability of the translated questionnaire. After proofreading steps, the translated questionnaires were linguistically validated.

FRENCH AND SPANISH PILOT VERSIONS OF THE QUESTIONNAIRE

After analysis of the comprehension tests performed with Spanish patients, a pilot version of the questionnaire was issued in French and in Spanish.

RESULTS

The steps outlining the development of the study are illustrated in the Figure.

PATIENT CHARACTERISTICS

Sociodemographic and clinical characteristics of the patients are presented in Table 1. Of the 11 patients recruited, 6 had cataracts and 5 were presbyopic. Mean age was 64 years (range: 57 to 73 years); men and women were equivalently represented with all living as a couple or having a family. The majority of patients had basic-level education or held an undergraduate degree.

CONCEPTUAL FRAMEWORK DEVELOPMENT

Nine global concepts and 24 detailed concepts were identified from the exploratory interview analysis. The corresponding conceptual framework is presented in Table 2. Global concepts covered global vision,

TABLE 1

Patient Sociodemographic and Clinical Characteristics From the Exploratory Interviews For the Freedom from Glasses Value Scale (FGVS)

Characteristic	Value (N=11)
Ocular disease (n)	
Presbyopia/cataract	6/5
Gender (n)	
Female/male	5/6
Mean age (range) (y)	63.7 (57 to 73)
Living situation (n)	
Single/couple or family	0/11
Level of education (n)	
Basic/graduate/postgraduate	6/4/1
Working status (n*)	
Full-time/retired	2/8

**One patient failed to choose an option in this category.*

impact of eye surgery on patient life, practical constraints related to wearing glasses, improvement of the practical issues without glasses, improvement of the psychological constraints without glasses, physical appearance/aesthetic aspect (self-image), physical appearance/aesthetic aspect (in the eyes of others), eyesight problems left behind after surgery, and recommendation of surgery to others. As the aim of the questionnaire was to assess the added value of complete independence from glasses after multifocal IOL surgery, safety and financial aspects were not retained. According to the concepts that were described, the questionnaire was named “Freedom from Glasses Value Scale (FGVS).”

ITEM GENERATION AND PRODUCTION OF THE FGVS TEST VERSION

Based on patients’ verbatim responses, 23 items assessing the 9 concepts described above were simultaneously developed in French and in Spanish, and constituted the test questionnaires. The distribution of the items into each of the global concepts is summarized in Table 3, along with the item content.

Three general descriptive questions on sociodemographic criteria (age and gender) and whether the patient had to wear glasses since his/her surgery were added for further surveys.

TABLE 2

Conceptual Framework of the Freedom from Glasses Value Scale (FGVS)

Global Concept	Detailed Concept	Selected Patients' Own Words	Number of Items
Global vision	Assessment of the patients' global vision following surgery (without glasses)	"I can read medicine labels perfectly, whereas before it was impossible."	1
Impact of eye surgery on patient life	Changes in patients' lives following eye surgery	"I am very happy."	1
Practical constraints related to wearing glasses	Assessment of the constraints linked to wearing glasses	"But wearing glasses is a constraint. It's always the same, it bothers me." "Because with glasses, it's a lot more bothersome, less easy, you are always bothered by something."	1
Improvement of the practical issues without glasses	Improvement of bother and constraints linked to: frames (visual field), lenses (thickness, weight); steaming up; glasses sliding down nose; cleaning glasses; breaking glasses; scratching glasses; losing glasses	"When I sweat for example, when I do DIY (do-it-yourself), I sweat and my glasses steamed up, stuff like that." "And my problem was that I always saw the frames of my glasses and it bothered me, it bothered my field of vision, when I was in the woods I had to pay attention because I was being hurt by the branches because I couldn't see them to avoid them." "I had the marks here on my nose, there were really very heavy, they were heavy glasses. Looking for them because they are never where they should be! No, it is really a big, big constraint."	8

COMPREHENSION TESTS OF THE FRENCH FGVS TEST VERSION

The majority of patients found the FGVS easy to understand, easy to answer, and well-formatted. None of the patients had difficulty understanding instructions. Analysis of items led to the deletion of two because they were not well understood by patients. Six items were slightly modified to make them clearer. The Spanish FGVS test version was modified accordingly.

LINGUISTIC VALIDATION OF THE SPANISH QUESTIONNAIRE VERSION

Some inconsistencies were detected during the backward translation process. The Spanish version was therefore amended. These changes were related to linguistic or idiomatic issues. Only minor additional changes were made after clinician review that corresponded to the addition of choices of responses for one

of the general descriptive questions. Further, patient feedback from the comprehension tests necessitated changes to be made to several items (n=5) of the Spanish version; one extra question regarding wearing sunglasses was added to the three descriptive questions. The French FGVS pilot version of the questionnaire was amended accordingly.

FRENCH AND SPANISH FGVS PILOT VERSIONS

Pilot self-administered questionnaires thus included 21 items and a module of 4 descriptive questions for use in surveys. Items had a 5-point Likert response scale.

DISCUSSION

The reduction in glasses dependency that results from multifocal IOL implants contributes significantly to patient satisfaction and improved quality of life,

TABLE 2 (CONT'D)

Conceptual Framework of the Freedom from Glasses Value Scale (FGVS)

Global Concept	Detailed Concept	Selected Patients' Own Words	Number of Items
Improvement of the psychological constraints without glasses	Improvement perceived regarding comfort; freedom, well-being/happiness; looking younger; feeling of having "new eyes"	<p>"The feeling of being more free, of no longer having this constraint of glasses (put them on, taking them off, cleaning them, putting them back on)."</p> <p>"And you told Dr XXX that the operation had made me a lot younger, and it's true, I still believe it."</p> <p>"I feel like, I mean, that I've gone back in time in my life and that my eyes are brand new."</p>	5
Physical appearance/aesthetic aspect (self-image)	Physical appearance/aesthetics improvement of self-image	"When I compare myself in a mirror, I prefer myself without glasses to with them."	1
Physical appearance/aesthetic aspect (in the eyes of others)	Physical appearance/aesthetics improvement perceived through the eyes of others	<p>"Other people always said 'oh my God, I can't believe it, you've changed, what have you done? You've got younger'. It's nice to hear that I've got younger."</p> <p>"I prefer the way other people look at me when I'm not wearing glasses, to the way they do when I am."</p>	1
Eyesight problems left behind	Feeling of having forgotten the surgery	"And now I don't even think about the fact that I have implants."	1
Recommendation of surgery	To oneself: if I had to do it again... To others: recommendation of surgery to others	<p>"I would do it again tomorrow, no problem."</p> <p>"To all the people who want to have it done, I tell them, go on, it's very good."</p>	2

which is extensively reported.^{10,15,17,36} Even symptoms that may occur after implantation do not affect the satisfaction level of patients, which remains high as long as they do not have to wear glasses again.¹⁰ In contrast, practical, aesthetic, and psychological concerns of having to depend on glasses are poorly documented despite the fact that dependence on an assistive device may be a source of dissatisfaction and limits the benefits of such a device in terms of functional impact, ultimately resulting in its abandon.^{30,37} Yet, no instruments are available that encompass the benefits of freedom from glasses perceived by patients after surgery. Regarding presbyopia, very few instruments are specifically designed for this condition.^{8,31}

The FGVS questionnaire was therefore created for the purpose of providing and describing perceived outcomes regarding the effect of freedom from glasses, directly from patients suffering from cataract or presbyopia. A rigorous and standardized methodology was followed, with the development of a questionnaire conceptual framework from semi-structured patient interviews. One limitation that should be noted is the absence of a formal saturation process. However, the well-delineated purpose of these interviews, together with good knowledge of the condition in the literature and the homogeneity of the sample population interviewed, are reassuring as the comprehensiveness and the consistency of the conceptual model was reached after the 11 interviews.³⁸

TABLE 3

Structure and Item Content of the Freedom from Glasses Value Scale (FGVS)

FGVS Concepts (No. Items)	Item Content
Global vision (1)	Evaluation of eyesight since operation
Impact of eye surgery on patient life (1)	Change in life since operation
Practical constraints related to wearing glasses (1)	Bother of wearing glasses
Improvement of practical issues without glasses (8)	Lenses steaming up Sliding down nose Cleaning glasses Frames restrictive Breaking glasses Scratching glasses Losing glasses Pressing on nose
Improvement of psychological constraints without glasses (5)	Comfort Freedom Well-being Youth Feeling of having new eyes
Physical appearance/aesthetic aspect (self-image) (1)	Self-image
Physical appearance/aesthetic aspect (in the eyes of others) (1)	Other people's image of you
Eyesight problems left behind (1)	Eyesight problems in past
Recommendation of surgery to oneself (1)	Willingness to undergo surgery again
Recommendation of surgery to others (1)	Willingness to recommend to others

Analysis of the patients' own words obtained in this study highlighted the fact that the assessment of functioning vision and quality of life in cataract and presbyopic patients, as they are commonly measured, does not fully cover what patients perceive after multifocal IOL implantation. Especially, questionnaires that are currently used such as the VF-14, ADVS, VDA, NEI-VFQ, or the Cataract TyPE specification do not assess patients' feelings regarding freedom from glasses, and evaluation of their perception is lacking.^{18-20,22,25,39} Instruments that measure quality of life related to refractive correction (impact of spectacles, contact lenses, and refractive surgery) simultaneously capture several major concepts of the impact of correction on patients' lives.²⁴⁻²⁸ However, no questionnaires assess patient perception of life without glasses after surgery compared to when wearing glasses.

Instruments available to assess patient perception in ophthalmic conditions have mostly been developed with an a priori conceptual framework defined by cli-

nicians prior to questionnaire development.^{16,23} The majority of these instruments tend to focus on the measure of cataract surgery outcomes with respect to visual disability and symptoms.^{16,18,19,21,40} One may assume that patients' own perspectives are far more complex and more detailed than what they generally show and say to their doctors. Exploring patient beliefs, values, attitudes, and perceptions with no a priori is essential to really capture how they live with a medical condition. This has been previously done for other ophthalmic diseases (eg, glaucoma) through individual interviews⁴¹ and other questionnaires such as the NEI-VFQ, NEI-RQL, or QIRC for example, which were developed based on patient focus groups.²⁵⁻²⁷

As can be observed from responses to the FGVS, patients' perceptions of multifocal IOL benefits goes beyond functional improvement. Besides the impact of eye surgery on patients' lives and practical constraints related to the necessity of having to wear glasses, patients describe an improvement of these

practical issues (eg, glasses sliding when sweating, having to constantly find their glasses, having to clean glasses regularly) and of psychological constraints (eg, comfort, freedom, feeling of being younger) without glasses. Patients' physical appearance and aesthetic concerns, in terms of self-image as well as through others' eyes, are also positively affected by the surgery. Patients do not have the feeling they had surgery, leaving their eyesight problems behind them. Lastly, the implantation has an impact on patients' attitude towards surgery in that they would recommend it to others and would undergo it again. Overall, patients gave positive feedback on their current global vision after surgery. Some concepts or items revealed during these interviews are common to content areas already captured by the questionnaires measuring quality of life related to refractive correction, whether developed for cataract or presbyopic patients and using different approaches (ie, Rasch analyses or content related to qualitative work). For example, overall quality of vision is captured by the NEI-RLQ and NEI VFQ-25^{24,26}; appearance through the eyes of others or oneself is also found in the QIRC and NEI-RQL^{26,27}; aspects of psychological impacts including comfort, well-being, or sensations of freedom are covered by the QIRC, NEI-RQL, NEI VFQ-25, and RSVP^{24,27,28}; and items in the RSVP capture practical issues due to corrective lenses.²⁸ Other instruments, such as the Psychosocial Impact of Assistive Devices Scale, that aim at defining the impact of assistive devices on patient quality of life, also include items similar to those covered by the psychological concept of the FGVS.^{37,42}

A limitation of our study is that the focus was only on the benefits of patients being able to live without wearing glasses. The functional aspects and side effects following multifocal IOL implants are not covered by the FGVS; these are, however, fully covered by other questionnaires such as the Cataract Type specification questionnaire.²¹ The small sample of patients used for the development of the FGVS is also a limitation.

French and Spanish versions of the FGVS were developed simultaneously. In addition, the questionnaire underwent linguistic validation in UK English and Danish, which will facilitate its use in international studies. However, to be fully useable, the validity, reliability, and sensitivity of the FGVS need to be assessed. The psychometric analyses are currently being performed based on data from an international observational study conducted with a large sample of patients (approximately 300). These analyses will enable the definition of the FGVS scoring, and its validation and

psychometric properties to be determined. The results are planned to be communicated in a future publication.

The FGVS is a new, short, simple instrument that may be useful for the assessment of the benefits that patients perceive from being free of glasses after IOL implantation. It is also suitable for cataract and presbyopic patients. Once psychometrically validated, this questionnaire can complement the evaluation of the functional impact on patients' quality of vision and quality of life, which are already measured with other instruments.

AUTHOR CONTRIBUTIONS

Study concept and design (G.B., B.A.); data collection (P.L., D.E.); analysis and interpretation of data (O.D., I.G., K.B., G.B., B.A.); drafting of the manuscript (K.B., G.B.); critical revision of the manuscript (P.L., D.E., O.D., I.G., G.B., B.A.); obtained funding (G.B.); administrative, technical, or material support (G.B.); other (development of the Spanish version [I.G.]

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