Author’s response to reviews

Title: Measuring benefits and patients’ satisfaction when glasses are not needed after cataract and presbyopia surgery: scoring and psychometric validation of the Freedom from Glasses Value Scale (FGVS(c))

Authors:

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Author’s response to reviews: see over
Dear Editor,

Thank you and the reviewers for your feedback on our manuscript, “Measuring benefits and patients’ satisfaction when glasses are not needed after cataract and presbyopia surgery: scoring and psychometric validation of the Freedom from Glasses Value Scale (FGVS(c))”, Gilles Berdeaux, Juliette Meunier, Benoit Arnould and Muriel Viala-Danten.

Below we provide our point-by-point responses to these comments.

**Reviewer:** Mark Atkinson

**Reviewer’s report:**

This manuscript is quite well written and reports on the psychometrics of a newly developed measure (FGVS) for cross-sectional evaluation of patients’ satisfaction with surgical outcomes. There are a number of places in the manuscript that would help the reader understand the performance of the measure; as well as some factors researchers may want to consider when examining scale performance as it relates to sample composition(s). Also the use of certain terms and statistical methods should be reworked or justified.

We took into consideration each comment detailed below and revised the manuscript accordingly when we believed it was necessary to reinforce the comprehension and strength of the paper. We hope the revisions made in the manuscript will help readers to fully understand our choices in terms of methods and results presented.

**The title is long, can it be shortened?**

We agree that the title is quite long but we believe that shortening it would reduce the information on the content of the paper, which may decrease the interest of the readers in reading our manuscript. As the
name alone of a patient-reported outcome questionnaire is often not eloquent enough, it is important to complete the title with information on the content of the questionnaire, i.e. on what it measures and for which type of population it has been designed. This is the reason why the first part of the title (“Measuring benefits and patients’ satisfaction when glasses are not needed after cataract and presbyopia surgery”) is useful. The second part of the title (“scoring and psychometric validation of the Freedom from Glasses Value Scale (FGVS®)”) is also of major importance as it contains the complete name of the questionnaire and as the terms “scoring and psychometric validation” are useful to avoid confusion with the paper presenting the development of the questionnaire.

Pp 2: Background, last sentence: “which measures the benefits in cataracts…” perhaps the benefits of… among cataracts…” would be clearer.

The sentence has been modified as follows: “which measures benefits of freedom from glasses perceived by cataract and presbyopic patients after multifocal intraocular lens (IOL) surgery”.

Pp 3: Para 1, Sentence 3: Is the use of the term crystalline lens correct, don’t you mean natural lens?

“Crystalline lens” has been replaced by “natural lens” in our revised manuscript.

Pp 4: Para 2, The FGVS: Please define the response options for the 5 point rating scales.

The 5-point response scales ranged from “much better” to “much worse”, “very positive” to “very negative”, “no, not at all” to “yes, absolutely”, “totally agree” to “totally disagree” or “definitely better without glasses” to “definitely better with glasses”. As suggested, this has been added in the revised manuscript.

Pp 4: Para 3, Patients and study design: It would be informative to list the general criteria used to identify surgical candidates (e.g., the severity criteria for presbyopia or cataracts in terms of visual acuity assessment).

Information on the study design and inclusion and exclusion criteria have been completed in the revised manuscript as follows:

“An observational, cross-sectional, non-comparative, multicentre study was conducted in France and Spain between June 2007 and January 2008 involving patients who had a ReSTOR® lens implanted in both eyes, with the last eye operated at least 1 year before the inclusion date. Centres were selected from each country in which surgeons were experienced ReSTOR users and had implanted numerous lenses in the preceding 18 months. Patients included were all over 49 years old, with age-related cataract or
bilateral presbyopia. They had cataract or presbyopia surgery using phaco-emulsification with IOL implantation in the posterior chamber resulting in post-operative emmetropia. None had refractive surgery before the Restor lens implantation (i.e. LASIK and PRK) or a ReSTOR lens implanted as part of a clinical trial. None had intra-operative difficulties that required them to later wear glasses, post-operative complications necessitating a refractive correction, or concomitant ocular diseases at the time of surgery deteriorating the visual acuity prognosis. Patients meeting the inclusion criteria were selected from an exhaustive list of cases. The target was to include 150 patients per country.

The main objective of this survey, described in another paper, was to describe the clinical outcomes of ReSTOR® implantation according to daily practice. Therefore visual acuity before cataract surgery was documented but not used as an inclusion criterion.

Pp 5, Last Para: The authors operationalize the terms convergent and discriminant validity of items in unusual ways. Typically demonstration of construct convergence and discrimination employ the use of other (previously validated) measures. Please provide references to support the use of these types of validity analyses applied to item-item and item-scale construct analyses. (http://www.socialresearchmethods.net/kb/convdisc.php)

Indeed, convergent and discriminant validity can relate to the concurrent validity, which aims to analyse correlation levels between the scales of a newly developed instrument and the scales of a well-established instrument. Thus we understand that a confusion can be done when referring to the terms convergent and discriminant validity. The item convergent and discriminant validity corresponds to the same approach as it aims at checking the convergence of similar constructs and the divergence of dissimilar constructs. The difference is that the measure of interest is the item instead of the scales of the instrument.

One of the main reference papers for item convergent and discriminant validity is the paper written by Hays et al in 1990 entitled “Beyond internal consistency reliability: rationale and user’s guide for multitrait analysis program on the microcomputer” (1990). In this paper, the authors used multitrait analysis to evaluate the convergent and discriminant validity. This approach focuses on the items of an instrument and thus the fundamental elements of multitrait scaling are the item-scale correlations within a particular instrument. Each item in an hypothesised scale must be substantially, linearly related to the underlying concept being measured and more related to its hypothesised scale than to the other scales. We used this approach as the basis for item convergent and discriminant validity in our study, and this reference has thus been added in our revised manuscript.

Pp 6, Para 3: Why were non-parametric statistics used if the rating scale were likert-type? These sorts of analysis is a bit weaker than parametric methods. Moreover, the use of PCA is a
parametric method. Consistency is important here and, if selecting non-parametric analytic approaches MDS or Cluster analysis might have been more appropriate?

Our study involved only patients who had no complications during surgery that required them to wear glasses and no post-surgery infectious complications. Therefore, responses to FGVS items, measuring the benefit of freedom from glasses following surgery, were expected to be highly skewed. This has been verified with the analysis of the distribution of the FGVS item scores, and explains the use of non-parametric analyses rather than parametric analyses in our study.

We agree that PCA may not be the most appropriate method to reduce the number of items and create the scoring method of the FGVS in our study, even though it is the traditional method used to identify the structure of a questionnaire. Our first strategy was to conduct a Multiple Correspondence Analysis (MCA) as this method uses the items as categorical variables, and analyses the pattern of relationships between the items. However, no clear structure could be identified using the MCA. We thus decided to conduct a PCA to achieve our objective of creating the scoring methods of the FGVS, which would have probably been not feasible using methods such as Multidimensional Scaling (MDS) and cluster analysis. In addition, PCA is rather appropriate as it is not based on strong probabilistic hypotheses, and is thus likely to be less sensitive to deviation from the normal distribution than other methods.

Pp 6, Last Para: Would it be possible to report the visual acuity ranges for hyperopia, astigmatism and myopia prior to surgery?

As suggested, we added the description of the best corrected visual acuity before surgery in table 1.

The reported percentage of hyperopia is surprisingly high. Did this group also contain persons with presbyopia? Also, the study was reported to include persons with cataracts and presbyopia, but there is no description of the percentages of participants with presbyopia.

About 16% of the patients had ReSTOR implanted for presbyopia. Subjective refraction parameters before surgery were not collected and the high hyperopia incidence rate is likely to include a majority of mild hyperopia. These points have been added in our revised manuscript.

Pp 7, Para 3: It would be interesting to know the ceiling effects associated with the with vs. without glasses groups, I suspect that most of the observed effects would be among those who did not use glasses following surgery.

Indeed, the highest percentages of patients answering positively to FGVS items were observed for patients who did not have to wear glasses after surgery. Moreover, this finding is clearly demonstrated through the statistically significant difference observed for all dimension and sub-dimension FGVS scores.
between patients wearing or not wearing glasses after surgery, as reported in table 6 of our revised manuscript. As results at the dimension and sub-dimension score level are already presented in our paper regarding this point, we believe that adding results at the item level would not add substantial information.

**Pp 8, Para 1 & Table 3:** Please report the item factor loadings, Eigen values, and R squared statistics for the two scales.

The results of the PCA, including factor loadings, eigenvalues and proportion of the variance explained by each factor, have been reported in an additional table (table 3 in the revised manuscript) and the following sentence has been added in the results section:

“The PCA conducted on the 21 FGVS items resulted in four factors with an eigenvalue greater than 1, explaining 66% of the total variance.”

**Pp 9, Last Paragraph:** Please clarify why means were reported when non-parametric analyses were performed, wouldn’t medians be more appropriate?

Indeed, as non-parametric tests used in our study are based on ranks, we added medians in table 5 (table 6 of the revised manuscript).

**Table 5:** The potential impact of co-morbidities on scale performance is interesting. Please indicate what co-morbidities contributed to FGVS variation, as this could be important to other using the measure.

The other ocular diseases since surgery were reported in patients who had to answer yes or no to the question “Have you developed a new eye disease since your eye surgery?” and then to specify which eye disease, with no pre-defined choices, if they had answered yes to the first part of the question. All 21 patients who answered having developed a new eye disease since surgery specified a different eye disease, which included for example conjunctivitis, problems with tears, sty or retinal detachment. This information has been added as a footnote of table 5 (table 6 in the revised manuscript).

**Table 1:** Since the percentages do not add up to 100%, this table should have a note indicating the co-occurring conditions of myopia, hyperopia and astigmatism (and presbyopia) in the sample.

As suggested, a note has been added to explain the total percentages for patients’ vision greater than 100% for each country as follows: “Myopia, hyperopia and astigmatism may occur simultaneously for some patients, explaining a total percentage by country higher than 100% for patients’ vision”.

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Table 4: A Cronbach’s alpha was computed for a theoretical scale with two items (i.e., Evaluation of the Results), how was this statistic estimated?

The Cronbach’s alpha was calculated for the scale Evaluation of the results that includes two items using the following formula:

\[
\alpha = \frac{n}{n-1} \left(1 - \frac{\sum_{i=1}^{n} \sigma^2_{Y_i}}{\sigma^2_X}\right)
\]

with \(n\) the number of items, \(\sigma^2_{Y_i}\) the variance of item \(i\), and \(\sigma^2_X\) the variance of the score (the score is calculated as the sum of the \(n\) item scores).

Because of the \(\frac{n}{n-1}\), the formula cannot be applied for a single-item scale but can be applied for scales including at least two items.

Table 6: Could be enhanced by reporting statistics and tests for various types of post-surgical co-morbidities.

All 21 patients who answered having developed a new eye disease since surgery specified a different eye disease, which included for example conjunctivitis, problems with tears, sty or retinal detachment. Because of the variety of eye diseases reported by patients and because of the small sample size (21), it was not appropriate to conduct further analyses on this parameter.

**Reviewer:** Annegret Dahlmann-Noor

**Reviewer’s report:**

In this paper, the authors describe the development and validation of a new tool to measure client satisfaction with surgical lens extraction and multifocal lens implantation, focussing on one outcome measure, namely satisfaction with Freedom from Glasses. The aim of the study is well defined.

**Major compulsory revisions**
1. The methods section describes in detail the statistical tests employed to reduce the number of items and to analyse data. However, several major points are missing from the methods. The most important is patient selection – the only information the authors give is that patients had surgery at least one year prior to questionnaire administration, and that they had not suffered per- or postoperative complications. The paper should include whether patients were a consecutive series, how many surgeons operated on these patients, and what the indication for surgery was.

Information on the study design and inclusion and exclusion criteria have been completed in the revised manuscript as follows:

"An observational, cross-sectional, non-comparative, multicentre study was conducted in France and Spain between June 2007 and January 2008 involving patients who had a ReSTOR® lens implanted in both eyes, with the last eye operated at least 1 year before the inclusion date. Centres were selected from each country in which surgeons were experienced ReSTOR users and had implanted numerous lenses in the preceding 18 months. Patients included were all over 49 years old, with age-related cataract or bilateral presbyopia. They had cataract or presbyopia surgery using phaco-emulsification with IOL implantation in the posterior chamber resulting in post-operative emmetropia. None had refractive surgery before the Restor lens implantation (i.e. LASIK and PRK) or a ReSTOR lens implanted as part of a clinical trial. None had intra-operative difficulties that required them to later wear glasses, post-operative complications necessitating a refractive correction, or concomitant ocular diseases at the time of surgery deteriorating the visual acuity prognosis. Patients meeting the inclusion criteria were selected from an exhaustive list of cases. The target was to include 150 patients per country."

About 16% of the patients had ReSTOR implanted for presbyopia. This information has been added in our revised manuscript.

It appears that the patient cohort was a mixed group of individuals suffering from cataracts (reduced vision for distance and near, plus specific other symptoms) and other undergoing surgery for presbyopia (reduced vision for near, reading glasses required). These two groups would have very different expectations from surgery, and are also likely to report outcomes very differently.

Although patients with presbyopia might have different expectations than patients with cataract, the number of patients with presbyopia included in our survey was not great enough to allow any inferences. Moreover, the question of the relation between factors such as the age, gender or medical history, and expectations is still not resolved. Additional research with specific experimental designs should be conducted to confirm these findings.

This text has been added in the discussion.
Selection bias could also derive from patients declining to take part in the study. The paper should mention how many patients were originally approached, and how many took part.

In France, 152 patients were finally included in the study out of the 172 patients contacted. In Spain, 152 patients were finally included in the study out of the 174 patients contacted. This information has been added in the revised manuscript.

2. As for the questionnaire itself, the methods section does mention that it was generated based on patient interviews. Again, more details would be helpful – who conducted these? How many patients were interviewed?

The FGVS was developed using first exploratory interviews conducted by health psychologists with five cataract patients and six presbyopic patients with AcrySof ReSTOR® IOL implanted in both eyes since at least 6 months previously. Based on the concepts identified during these interviews, 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.

The complete development of the FGVS has been reported in a paper recently accepted for publication in the Journal of Refractive Surgery (available at http://www.journalofrefractivesurgery.com/preprint.asp). This reference has been added in our revised manuscript.

For this study, the tool was administered by phone. By whom? How many observers were involved? How did patients select their response on the 5-point-Likert scale (numbers, or were the answers read out to them for each question)? How long did questionnaire administration take on average?

For the present study, the phone interviews were conducted by a company (ProClinica) specialised in this type of study. Eight persons from the call center were specifically trained to conduct the phone interviews. The questionnaire was presented to patients by reading out each item and each corresponding possible answer. The questionnaire administration took about 15-20 minutes.

Minor essential revisions

1. The results section in itself is sound. However, it is difficult to judge the significance of the findings without knowing details about patient selection. The authors mention that 87% of patients
did not require glasses after surgery, and that these individuals had higher scores. This leads back to the question about expectations from surgery. Presbyopia-only individuals would undergo surgery solely to get out of their glasses, and would be more disappointed if this target was not reached. More details are needed about the 13% who did have to wear glasses postoperatively – if the aim of surgery was full refractive correction, why did these patients require glasses postoperatively, and how might these reasons affect the satisfaction score?

This paper was dedicated to report the FGVS psychometric validation. Predictive factors of being free of glasses are described in another paper.

Other comments

The manuscript does adhere to the relevant standards for reporting and data deposition. The discussion and conclusions are fairly well balanced and adequately supported by the data, but omit discussing the points raised above. Some limitations of the work are clearly stated, such as the lack of prospective data collection and evaluation of basic aspects of any test, such as test-retest reliability, inter- and intra-observer variability etc.

We took into consideration each point raised above and revised the manuscript accordingly when we believed it was necessary, to reinforce the comprehension and strength of the paper. We hope the revisions made in the manuscript will help readers to fully understand our study, with its strengths as well as its limitations.

We hope that the revisions and answers to your questions and comments meet your expectations, and that you will consider our revised manuscript for publication.

Yours sincerely,

Juliette Meunier, on behalf of the co-authors