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))

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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.

Editorial request:

You have mentioned that the study was carried out in compliance with the Declaration of Helsinki, but we need you to clarify if you have received ethical approval for this study: Ethics - Experimental research that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Helsinki Declaration (http://www.wma.net/e/policy/b3.htm), and any experimental research on animals must follow internationally recognized guidelines. A statement to this effect must appear in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate.

We took into account your request by adding a statement in the methods section of the manuscript as follows: “This study received approval of the CNIL (the French data protection permanent committee, authorization N° 907054), the CCTIRS (the French advisory committee dealing with data processing on health research) and the CNOM (the French council of the college of physicians) for France. This study also received approval of the AEMPS (the Spanish agency of drugs and health products) and Comité Ético de Investigación Clínica Regional del Principado de Asturias (the ethical committee of clinical research of the Principality of Asturias) for Spain.”
Reviewer: Mark Atkinson

Reviewer’s report:

This manuscript is much improved and the authors have satisfactorily addressed most of my earlier comments/concerns. A few points remain:

Pp 3: Para 3: Since my earlier review, I researched the strong statement made that ‘no scale exists that measures the perceived benefits of patients’ freedom from glasses’. Other related measures do seem to exist and could be considered for review in terms of missing content coverage etc. Alternately, the original statement should be qualified.

*(QIRC) Quality of Life Impact of Refractive Correction

(CLIQ) Contact Lens Impact on Quality of Life Questionnaire

(PIADS) The Psychosocial Impact of Assistive Devices Scale <a general scale>

As suggested, these measures have been added as references in our manuscript, with a short explanation of the missing content for our study. Also, the statement “No scale exists that measures the perceived benefits of patients’ freedom from glasses” has been modified as follows: “To our knowledge, no scale exists that measures the perceived benefits of patients’ freedom from glasses.”

Pp 5: Para 1, Sentence 2: “The target was to include...” would better read “The target sample included...”

This sentence has been modified in the manuscript as follows: “The target sample included about 150 patients per country”.

Pp 7, Para 1, Sentence 2: Seems to be a sentence fragment.
Sentence 2 was not clear as it appeared before the results regarding the mean age and percentage of females in the study. This sentence has been moved after the sentence regarding the ocular problems of the subjects.

Last sentence: A statement was made regarding post-surgical complications following surgery, the timeframe for post-surgical assessment is unclear.
The timeframe for post-surgical assessment is one year after surgery. In order to clarify this statement, the sentence has been modified as follows: “A large majority of patients did not develop new eye disease and did not present posterior capsular opacification 1 year after surgery (93% and 85% respectively).”
Pp 6, Last Para: The reported percentage of hyperopia seem high, raising a question as to mean differences between surgery groups (wearing vs. not-wearing glasses) and countries might reflect differential selection (re: Pp 5, Par 1, sentence 1). This should be addressed a limitation, which can only be definitively addressed in a RCT.

This has been added to the discussion as follows: “This high rate of hyperopia might influence the spectacle independence rate. This possible selection bias can only be definitely addressed using a randomized clinical trial.”

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