Author's response to reviews

Title: Development and Validation of the Patient-Rated Ulnar Nerve Evaluation

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Author's response to reviews: see over
Thank you to the reviewers for their efforts which we have incorporated to improve the manuscript.

Individual responses cited below.

Reviewer's report:

Major Compulsory Revisions

1) At page 8 the “patient recruitment” is poorly described.

We have added additional details about the patient sample. Not all information requested was available. For example, occupation and presumed causes.

a) The authors should provide details on type and duration of the symptoms, objective neurological findings, occupation of patients, presumed causes of UNE, electrophysiological methods and results.

b) The authors excluded all patients unable to complete self-report forms. How many were these patients?

Patients who were incapable of completing self-report questionnaires are excluded from the study because it isn't possible for them to complete questionnaires. For example, people with dementia were excluded. This was a small number of people but we did not specifically count the number.

c) What do “comorbid health or life conditions” mean?

Health problems that occur simultaneously with their presenting problem of ulnar neuropathy.

d) Were patients with associated carpal tunnel syndrome (and other diseases of peripheral nervous system) excluded or included?

Yes, based on electrophysiological findings.

2) I think that pain items referred to “hand/arm” is not sufficiently specific, because, for example, work-related UNE is associated to pain due to other musculoskeletal disorders than UNE.

It can be difficult to tell patients where to localize on a questionnaire. We agree that patients may have concurrent hand conditions that would cause pain in the hand or arm that would be difficult for them to differentiate. This is a limitation of questionnaires. However, the questionnaire demonstrated strong measurement properties and it is not possible to change the wording at this point. Other questionnaires that have been used with this disorder such as the DASH would refer to the entire upper extremity so tried to include questions that had greater specificity recognizing the inability to isolate questions to ulnar neuropathy alone.

3) Test-retest reliability of the questionnaire was tested but the authors did not provide details i.e. did the authors administer the same questionnaire to a sample of the same patients to verify if the patients give the same response to separate occasions (for example after 2-3 days)? If so, clarify the methods. I do not well understand the columns “test 1” and “test 2” of table 4. If these columns refer to
test-retest reliability, the authors must report these methods in the method section of “reliability” at page 10.

Patients did that complete a questionnaire on the second occasion- 2-5 days later. This is now specified. Test one test two are the scores from these two separate occasions.

4) The ulnar nerve gives off no branches in the upper arm, it supplies the flexor carpi ulnaris and flexor digitorum profundis and many intrinsic hand muscles. The ulnar nerve provides especially to fine hand movements. So what’s the item “lift a heavy object”? The muscles of the ulnar nerve are not involved in lifting heavy objects. Moreover in table 3, in third column “Meaning of ICF language”, the authors explain what “lift a heavy object” means, but "lift a glass from a table" even from a lower to a higher level is not a heavy movement. The authors must clarify this point.

Lifting heavy objects typically requires gripping and maintaining a strong wrist. Ulnar innervated muscles would contribute to the ability to lift a heavy object. This item was highly ranked by people with UNE and so it was validated by patients.

To clarify the linking procedure. Items are linked to the most appropriate ICF Code. The linked code is for lifting without specifying and the only objects. The item on the PRUNE adds the additional detail of a heavy object. The description in ICF language is a quote of what that code refers to and uses lifting a glass as one example of a lifting task. Lifting a heavy object would be included as a lifting task in ICF- in this case we provided the additional qualifier of heavy lifting since this was relevant patients.

5) The authors should provide a convincing explanation of the utility of the first item of pain “when it is at its worst” in the view of the following five items that specify “when”.

Pain at its worst is commonly used clinically to indicate the most severe level of people experience.

6) The authors refer to Kleinman-Bishop score when they report type of work, severity of residual symptoms, hand strength (tested with pinch and grip), results of surgery in table 6, leisure activity, work status. These important findings are insufficiently described. How did the authors define “heavy or light, repetitive or intermittent” the type of the work? How “severe, moderate and mild-occasional” symptoms were evaluated? How pinch and grip were measured? How the authors define “worse”, “unchanged” and “better” the “change following surgery”? Only sensitivity is clearly described (two-point discrimination). It is insufficient and too vague the reference to Kleiman-Bishop score.

The scale was verbally administered as indicated by the developer. The developer does not provide any guidance as to how to interpret these items.. We cannot provide any additional detail on the criterion is scoring since it was not provided by the developer. Thus, it is up to the clinician and patient to make this
decision. We used these criteria to indicate subgroups of patients. Despite the limitations and the scale these items were very effective in distinguishing subgroups of patients within our sample.

Minor Essential Revisions -
Introduction thank you for all of these editing suggestions which have helped improve our manuscript we have made the suggested changes as indicated below.
At page 3, the sentences of lines 6-15 (“The prevalence of UNE... were not [7]”) and at page 5 lines 13-17 (“The first author... measures”) are useless in the view of the aim of the paper.

Edits were made

Methods
1- By whom, how and when (how many days before surgery, after electrophysiological confirmation of clinical diagnosis or...) was the questionnaire administered?
This was variable. The baseline questionnaire was administered prior to surgery but we did not record how many days until there surgery.

2- At page 6 in “Scale development process” the items were grouped in 3 constructs: pain, sensory symptoms and motor symptoms. In the following PRUNE paragraph the items were separated in four subscales (pain, sensorimotor, specific activity and usual activity). This can cause of confusion in the reader. Also in “scale development process” the items should be separated in the same four constructs.

Edited
3- The acronym ICF appears in the manuscript for the first time at page 6 in the penultimate line of “Scale development process” without full explanation. The explanation of ICF was provided only at page 9. Correct this editing mistake.

Edited
4- At page 7 the parentheses of the sentence “(by dividing the grand total by 2)” should be eliminated.

Edited
5- At page 7 what does “the final stage of beta testing” mean?
Since process is iterative, it means in the final stage of scale refinement

6- At page 10 what does “(2,1)” mean after reliability intraclass correlation coefficients?
That is the ICC model that was used as described by shrout and fleiss (referenced)

7- At page 12 -Responsiveness- what does “change score” mean?
The change from baseline to follow-up
8-A brief description of the type of surgery or a reference can be reported.

Results
1- At page 13 the central section is heavy to read, some concepts are difficult to understand
2- At page 14, antepenultimate line the figure reporting “carrying a heavy object..” is not 2b but 2c.
3- Was there relation between the total score and age and level of education of patients?
   
   This was not tested
4- The authors did not report the results after 3 months, especially the effect size after 3 months should be provided.
   
   3 months is early for clinical change; and we had too much data to present everything so we elected to pick the key follow-up times

Discussion
Most of page 17 is cumbersome and difficult to understand, it could be shortened and made more intelligible

edited

In table 1, Items “affected side”: the choice “left and right“ is useless, change in dominant and not dominant side.
Changed to surgical side

Figures
I think that Figure 3 corresponds to figure 2b, if so the authors could report “figure 2b”.
What do the open circles mean in figures 2d (=fig5) and one open circle with four little rectangles in fig.3?
they are outliers and represent a single point

RESPONSE TO SECOND REVIEWER

Major Compulsory Revisions
Material & Methods
1. The authors assessed patients with the PRUNE and compared it to the SF-36 which assesses health status. Did the authors consider also using an upper extremity questionnaire such as the DASH? It appears that many of the items in the PRUNE are also included in the DASH. It would be interesting and perhaps more relevant to assess how this new questionnaire compares to an upper extremity disability questionnaire.
2. Page 11-12. For the groups described in the construct validity analysis, was there a separate questionnaire given to the patients at each assessment? If not, how were these categories derived (such as global rating of change at 2 years as improved, versus no change, or worse; asymptomatic versus those who had mild-occasional, moderate, or severe symptoms; leisure was unlimited versus those who were limited)?

These items are on the clinician based scale administered by an independent evaluator—this is now clearer.

Results
3. In the text (perhaps at the beginning of the Results section), it would be useful to present the number of patients assessed. Were there any patients that declined to participate?

4. In the Results section or in the tables, it would be helpful to report the means and standard deviations for the PRUNE (with the sample size) at each assessment time.

Added; where it varied it was noted

5. Were there patients that were lost to follow-up? In Table 5 (24 month follow-up), there are different sample sizes for each set of data. Similarly in Table the numbers vary since some people did not address an item or missed a follow-up visit—thus we gave the actual number in the analysis

6. I assume that the sample size is in the second row. Why are there over 75 subjects reported in these results and a decline in the results reported in the other tables? Were missing data deleted from that analysis on a pair-wise basis or was some other method used? The method used to handle missing data should be stated in the Methods.

Missing data meant that some analysis did have fewer cases

6. Table 5. How did the authors determine the “ability to do activities” categories of “limited” and “not limited”? Also there are only 52 patients represented in these data. Were the remainder not assessed at 24 months?

Yes fewer cases in long-term follow-up. This item was from the Bishop scale and administered as described above.
7. Page 13. If the PRUNE questionnaire asks patients about their “average experience over the past week”, then I believe that all of the items fall into one classification (rational). If all of the items are in one classification, then is this a 2-level classification as indicated on Page 10.

Thanks for that point; agree and have added that.

8. On page 16, Tables 6 and 7 are cited as information regarding the factor analysis. I do see this information in these tables. The table numbers should be verified. Also the details regarding the factor analysis should be reported in the Results. It is stated in the Discussion on page 19 but not in the Results.

Changes made

Discussion

9. Page 18. The authors report a minimal detectable change of 6.2 for the PRUNE. Is this reported in the Results? Perhaps I missed it, but this should be reported in the Results section.

In table 4 and text

10. Page 18. The authors state “lower reliability (although still excellent) on the usual activity subscale may be partially explained by the fact that it is only 4 items”. The section with “other symptoms” also has 4 items. I would suggest deleting this explanation based on the number of items and would suggest that it may be more related to the broad categories.

Agree and done

Minor Essential Revisions

Abstract

11. There is no clear study purpose stated in the abstract; other than the reason for the need for this questionnaire. I would suggest that a statement similar to the one in the introduction should be included in the abstract.

done

Introduction

12. In the first paragraph, the statement regarding the prevalence requires a reference. I think that it would be more representative to also include a reference from North America.

There is limited work on this topic reference added

13. At the end of the Introduction, the authors have stated “ulnar nerve injury”. I would suggest changing this to “ulnar nerve compression” unless the intent of this measure is to assess both. However in this study only patients with ulnar nerve compression were included in the sample.

Agree and done

Tables & Figures
14. Figure 3 is not cited in the text. Also why did the authors choose to report the data at 3 months? Why not include 24 month assessment?

The early data had more items and later we reduced; we have rechecked figure labelling/citation of figures

15. Table 6. The asterisk should be defined in the table legend.

yes

16. Table 7. Why are some values highlighted?

Explained in footnote- is to help direction people to where items loaded given the large number of numbers

17. Table 8. There are no values for the PRUNE total score. Should the mean change be a negative value indicating improvement from pre-op to 24 month follow-up? Also what was the sample size for this analysis?

The change is positive since baseline score– FUP,