Author’s response to reviews

Title: Factors related to subjective satisfaction following microendoscopic foraminotomy for cervical radiculopathy

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Responses to the Reviewer’s Comments

Responses to Karolina Wartolowska’s, M.D., D.Phil., (Reviewer 1) Comments:

Thank you very much for your valuable suggestions. We have provided responses to each of your comments below.

Comment 1: Firstly, authors have chosen five outcome measures (NDI, three pain scores and EQ-5D, tested at baseline and at follow-up, but did not correct the results for multiple comparisons. Accounting for multiple testing makes most of the results not significant.

Response: The unsatisfied group and the unwillingness group included 8 and 6 cases, respectively. One guideline has suggested that the accurate estimation of discriminant function
parameters requires a sample size of at least 20 cases for each independent variable in the logistic regression [Hair JF, Anderson RE, Tatham RL, Black WC. Multivariate Data Analysis with Readings. 5th edition. Englewood Cliffs, NJ: Prentice-Hall; 1998.]. Therefore, we could not perform multivariate analysis due to the small sample size. We were only able to perform univariate analysis.

Comment 2: Secondly, the authors collected measures of satisfaction and willingness to undergo this procedure again on a 7-point ordinal scale. There is no mention of analysis of ordinal data in the "Statistical analysis" section and the ordinal data are not presented. Instead, the satisfaction and willingness to undergo the procedure are recoded into binary data arbitrarily classifying "0" as a negative score. This is not correct, the scores on the 7-point scale should be presented and analysed using ordinal regression.

Response: In order to clarify our analysis, we created a new table presenting the details of the 7-point scale data (Table 4). Furthermore, in the “Statistical methods” section, we clarified how we converted the 7-level rating scale results into a 2-level rating scale (page 8, lines 6-10).

Comment 3: The reported number of patients included in the study changes throughout the manuscript: 42 in the Abstract, 43 in the Results section and again 42 in the tables.

Response: We have corrected this to reflect 42 patients in the Results section.

Comment 4: The first paragraph of Discussion would fit better in the Background section

Response: We have moved the paragraph to the Background section as you have recommended (page 5, lines 14-19 and page 6, line 2).

Comment 5: Differences in the scores mentioned in the second paragraph of Discussion should be in Table 3 and all the scores in this table should have standard deviations (if these are mean values)

Response: We added the differences in the scores and the standard deviations of all scores to Table 3.

Response to Lucio Marinelli’s (Reviewer 2) Comments:

Thank you very much for your valuable recommendations. We have provided responses to each of your comments below.
Comment 1: Page 7 (Methods): authors state that in a 2-years time span 44 patients underwent foraminotomy after unsuccessful 4-months conservative treatment. It would be interesting to report the total number of treated patients and therefore the number of those responding to conservative treatment in this case series.

Response: We collected the data from the operation database of our hospital. We have added this point under “Subjects” in the Methods section (page 6, lines 13-15). Given the form of data collection, we were not able to obtain information about the number of those who responded to conservative treatment for cervical radiculopathy in our hospital. We added this limitation, related to selection bias, to the Discussion section (page 13, lines 9-10).

Comment 2: Page 7-8: Numeric Rating Scale (NRS) was used to rate both pain and disability in neck, back and arm districts? This looks very coarse; which is the contribution of pain and which of disability? Why separated NRS were not used? What question was asked to patients? Furthermore, what is meant by "back"? Dorsal segment, lumbosacral? Both? Why other districts apart from neck and arm have been investigated?

Response: We used the NRS to evaluate the degree of pain, not disability. We regarded the NDI as the proper tool for evaluating disability. We corrected the sentence about the NDI and NRS in the Methods section (page 7, lines 5-7). We had used the term “back” to refer to the “upper back.” To clarify, we have replaced the word “back” with “upper back” throughout the manuscript and tables. The area was shown diagrammatically on the questionnaire. We added this point to the Methods section as well (page 7, lines 7-8). The reason we used three areas of the NRS was that cervical radiculopathy could cause pain in the neck, upper back, and arm.

Comment 3: Page 8, line 1 "EuroQOL-5D (EQ-5D) score was also used": it should be specified if EQ-5D-3L or EQ-5D-5L was used and also that the EQ-5D index values (0-1) derived from the original score were calculated and used for statistical analysis.

Response: We used the EQ-5D-3L, and calculated the score according to the previous report. We added sentences about this to the Methods section (page 7, lines 9-10).

Comment 4: Page 8, lines 6-7 "We regarded the former question as a direct evaluation of satisfaction and the latter question as an indirect evaluation of satisfaction": it is difficult to understand which questions the authors refer to. The following sentence can be clarified to help the reader, for example: "We regarded the former question (subjective satisfaction) as a direct evaluation of satisfaction and the latter question (willingness to undergo the same operation if needed) as an indirect evaluation of satisfaction".

Response: We have adjusted the sentence as you have recommended (page 7, lines 14-17).
Comment 5: Statistics: who administered the rating scales? Which was the blinding status of the examiner/s?

Response: We have clarified in the Methods section that we obtained the following outcome scores by self-written questionnaire (page 7, lines 4-5).

Comment 6: Page 9, line 2 (Results) "A total of 43 patients were included in this study.": in the methods it was stated that 42 patients have been included, which is correct?

Response: We have corrected the number of included patients to 42 in the Results section.

Comment 7: Results: no informations are provided about the symptomatic side; it would be interesting to know how many reported symptoms on right, left or both sides. It would be also interesting to understand possible correlations with subjects’ handedness (eg. right handed subjects report more frequently radiculopathy on the right side?) and job.

Response: We have added information about the symptomatic side to Table 2. We have also added the relationship between the symptomatic side and the satisfaction evaluations to Table 5 and Table 6. The operated side for the two-level foraminotomies was the same side in all 13 two-level cases (page 8, line 18 to page 9, line 1). We were not able to obtain information about subjects’ handedness and job.

Comment 8: Page 9, line 9 "venus plexus craniad to the nerve root": mispelled "cranial"?

Response: The term of “cranial” is certainly a correct word and is in the dictionary according to the English proofreading company.

Comment 9: Page 9, lines 18-19 "The response to the direct satisfaction survey and willingness to undergo the same operation were significantly related (p = 0.0079).": which statistical test was performed? No correlation analysis was declared in the methods.

Response: We have added text to the “statistical methods” in the Methods section explaining that we performed a correlation analysis between the responses to the subjective satisfaction survey and the willingness to undergo the same operation (page 8, lines 2-3).

Comment 10: Page 10 from line 17 (Discussion) "Parker et al. have reported the minimal clinically important difference...": the authors compare the mean minimal clinically important difference obtained in the current study for NDI, NRS for the neck, NRS for the arm, and EQ-5D with those reported by Parker et al in a study involving anterior cervical discectomy and fusion. In the present study the differences are comparable or more relevant for NDI and NRS for the neck but less relevant for NRS for the arm and EQ-5D; based on such observation the authors
state that "we can regard microendoscopic foraminotomy for CR as an effective treatment method." (page 11, lines 3-4). This statement seems unsupported by data.

Response: We have corrected the sentences as follows in the Discussion section: “The differences for the NDI and NRS for the neck are equivalent to the previous study; therefore, we can infer that microendoscopic foraminotomy for CR reduced disability and neck pain in a manner similar to ACDF for CR (page 10, lines 12-14).

Comment 11: Page 12, lines 11-12 "low accuracy of the area under the receiver operating characteristic curves, which were 0.65 and 0.53, respectively.": the meaning of this sentence is not clear to me.

Response: We have deleted the sentence.

Comment 12: Table 3: measures of variability are missing

Response: We have added the standard deviations of all scores to Table 3.

Comment 13: Table 5 - NDI: the decimal point for significance is missing. Also NRS for the arm is here reported as "upper extremity"; please correct for consistency.

Response: We have corrected the decimal point, and replaced the term “upper extremity” with “arm.”