Author’s response to reviews

Title: An immediate effect of PNF specific mobilization on the angle of trunk rotation and the Trunk-Pelvis-Hip Angle range of motion in adolescent girls with double idiopathic scoliosis – a pilot study

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Author’s response to reviews:

Dear Reviewers,

We would like to thank you very much for your review. We really appreciate all your remarks and suggestions included in the reviews as well as time you devoted to the analysis of our manuscript

Reviewer 1:

This is a paper about PNF to increase trunk rotation in AIS. No previous study as presented data about this topic, and we don't really know which affect to expect in AIS patients. There are a many points to address
Main

Introduction

The study question is not clear. Please follow the PICOT and improve it. Moreover, it seems the study question is stated twice, at lines 69-72 and 81-85, and the whole paragraph from line 69 to 85 could be better written, avoiding repetitions and moving some parts describing the technique (78-80) to the methods.

The study question was corrected. The part of the text from the line 69 to 85 has been changed. The fragment concerning the technique has been moved to the methods section. We tried to follow the PICOT. We supplemented information concerning population (participants), intervention applied in the study, outcome and time of recruitment. Unfortunately, we didn’t have a control group in this study. There is a limitation of our study, we pointed this in the limitations section.

Methods

Sample: Please describe only the inclusion criteria and the sampling procedure here, while the characteristics of the included patients should be reported in the results.

It was corrected, the characteristic of the included patients is reported in Results section now.

How were the patients selected? Where they consecutive? Which was the accessible population? There is a table including data from 133 patients, is it the accessible population?

While submitting the attachments to the manuscript I made a mistake and uploaded an improper table. There were two files with similar names on my computer. I would like to apologize for misleading you, as it was incidental. Now I’ve attached a proper table with the data of 83 girls
who participated in the study. The accessible population included 87 girls with idiopathic scoliosis. These girls were consecutively qualified for the study in three independent medical centers in the period of six months. Four girls did not come to the meeting with a physiotherapist. Finally 83 girls participated in the study.

> Which were the inclusion and exclusion criteria?

The criteria for inclusion were: female, double idiopathic scoliosis with a right-sided thoracic curve and a left-sided lumbar/thoracolumbar curve with a Cobb angle of minimum 100, absence of systemic diseases, age 10-17 years, participation consent.

The exclusion criteria were: other types of scoliosis, a spinal curvature with a Cobb angle of less than 100, pain or a history of traumatic injury.

> Which is the main outcome? This is totally unclear.

It was proved in the study that the use of unilateral PNF mobilization significant decreased the angle of trunk rotation, increased the Trunk-Pelvis-Hip Angle range of motion and improved motion symmetry in the transverse plane.

We agree with the argument that the presentation of the main outcome was not clear. We hope that this version of text is more understandable.

> Which is the repeatability of the TPHA measure? This is info in crucial for this study.

The assessment of the TPHA measure reliability showed excellent agreement of measurements - the interobserver reliability for three investigators was 0.970 (THPAleft) and 0.976 (TPHARight), the intraobserver reliability was 0.872 (TPHARight) and 0.810 (TPHARight). This information is in the text line 111-114.
Who assessed the TPHA? Was he/she expert in this? How was trained? Who assessed the outcome and who applied the PNF technique? Was the same operator? In case it is, it's a limitation that must be addressed in the discussion.

ATR and TPHA measurements and mobilization mPNF were performed by the same person – one of three physiotherapists with long experience in treating scoliosis. They were trained in execution of TPHA measurement before the study.

We realize this is limitation, we have included this information in limitation section at the end of discussion.

> Results

> You have uploaded a file with all the data of the patients, including their names. This is not ethical. Please provide only the main data.

I would like to apologize for my mistake once again. I know the rules of ethics and follow them.

> Were the changes clinically relevant? According to your raw data, only about 30% of subjects had changes larger than 2° in the ATR (the minimal clinically relevant change), with some outliers who changed more than 10°. This should be reported and discussed, since at least for this parameter the clinical effect is doubtful.

Indeed in many participants reduction of ATR value in one of curves did not exceed 2°. On the other hand simultaneous analysis of both curve angles showed that in most of the subjects one of the ATR values (ATRT or ATRL) changed by at least 3 degrees. It may be important fact in the analysis of clinical effect of intervention. We reported this results and discussed.
Discussion

The change in the ATR at short time must be interpreted in cautious way because we don't know it's meaning. Usually an increase in the spinal mobility is associated with a worsening of the ATR, while when the spine becomes more stiff the ATR reduces. So your results are quite unexpected. Please discuss this point. Moreover, a increase in the spinal mobility is considered dangerous for scoliosis, so it's not a goal for the treatment. Studies about rhythmic gym showed this clearly. Please discuss this point.

This point was included in the manuscript. We agree with the opinion that the change in ATR is immediate and it is difficult to interpret it, even if it is statistically significant. This point requires further studies. We realize that the most important to assess the effectiveness of therapy is radiological assessment of the spine. Unfortunately we suppose that any ethics commission does not agree on an x-ray after a short period of the use of intervention.

We know the research on hypermobility in scoliosis subjects and studies about rhythmic gym. In our opinion it is important to define what does it mean “increased spinal mobility”. Spine motion is complex. We do not know all the mechanisms of spine movements in subjects with scoliosis. We have also little knowledge about the compensations occurred in three planes during motion. As ballet dancers as rhythmic trainers need a lot of mobility in the sagittal plane, especially extension. This reduces thoracic kyphosis, as in scoliosis. But it doesn't mean that in these girls hypermobility occurs in other planes. Sometimes hypermobility in one plane causes limitations in other planes. Beighton scale contains a bending forward test in the sagittal plane and does not take into consideration motion in the transverse plane. In the background/ discussion section an issue regarding mobility/hypermobility in scoliotic patients was addressed in lines 61-62/ 266-276.

Our goal was to increase ROM of the spine in the transverse plane, because results of the previous studied showed limitation of rotation. This limitation was confirmed also in this study. It was simultaneously an attempt of correction of the spine in the transverse plane. Stabilization of the corrected posture should be the next step. We obtained a significant improvement but we highlighted in our research that improvement in ROM in patients with scoliosis should be every time carefully analyzed.
> Many part of the discussion are not relevant. For example lines 231-239.

Lines 231-239 were removed.

> Line 295: "this study is the first which demonstrates the effectiveness of selected PNF in treatment of AIS". This is not supported by your data since you have only immediate effect on ATR and no radiography or other measures.

We discussed this above. It is difficult to prove the efficiency of immediate or short time intervention by X-ray. It has been emphasized in the conclusion that the effects of our study should be treated only as immediate and further studies are required to determine the long-term effect of mPNF on the spinal alignment.

Minor:

> Reference 3 is out of date, there is a new version of the guidelines from 2011.

A new version of the guidelines was used.

> About PNF, can you please cite scientific articles instead of books?

More information regarding the PNF method was included in the discussion section and additional references were added to the list of references.

Thank you very much for your review. We really appreciate all your remarks and suggestions included in the reviews as well as time you devoted to the analysis of our manuscript

Kind regards
Reviewer 2

> I want to congratulate with the authors for their effort to increase the current knowledge in conservative of AIS. I hope that this rejection will not discourage them in pursuing this attempt. The present research is a preliminary one, which is not yet able to add nothing new to the currently available knowledge.

Indeed, the research is a preliminary one. It was emphasized in the title and the text of the article. It doubtlessly the study has limitations but may be considered valuable since it addresses the issue rarely mentioned in the literature. The study was an attempt at analyzing biomechanical mechanisms connected with scoliosis and the authors suggested an intervention suitable for functional disorders found in individuals with double scoliosis in the previous study. Human body moves are very complicated and not fully recognized. Biomechanics of the spine in scoliotic patients still arises numerous doubts. Therefore, in our opinion, the analysis of certain phenomena connected with musculoskeletal system movements is really desirable.

> In fact, the generalizability of the results and the clinical usefulness appear to me too limited to allow the publication.

In this version of the manuscript we completed more detailed information relating the participants, applied intervention, statistics, results, neurophysiological ground of observed changes. We discussed issues related to hypermobility and doubts about the not relevant clinically changes in ATR.

> According to what I understood after reading the article, the authors tested the immediate effect of a mobilization technique (in the method section you should describe the technique in details including timing, how many repetitions and duration of each session for example).

The mobilization technique mPNF was describe in details in Table 1. We have included the information in the text – line 135-139.
In the present research the immediate effect was tested, and the authors state that PNF is effective for scoliosis treatment. This statement is not acceptable. First of all because the results you showed do not agree with this statement: you found a statistically significant difference in the ATR, but it is not clinically significant as it remains within the measurement error. In addition, it is strongly recommended in the SOSORT and SRS guidelines for research in the field of conservative treatment to test the efficacy of Physiotherapy in the long term if possible, or in the short term at least by meaning several weeks of treatment and not the immediate effects after one treatment session, as there is a higher risk to fall into the type I error.

Certainly, an issue whether the obtained results are clinically relevant is debatable, although they are statistically significant. Confirming this relevance is not possible without further long-term research and radiography. However, in the majority of the subjects changes in ATR values are one-directional. We added a graphic interpretation to illustrate it (Figure 2, Figure 3).

Long-term observation of scoliotic patients who are treated with PNF mobilization has already been commenced.

Therefore, I encourage the authors to continue their study, by improving the methodology, according to the following suggestions:

* Define clearly the protocol, including duration of each session and duration of the entire treatment

The mobilization technique mPNF, including duration of one session, was describe in details in Table 1 in the first version of the manuscript. We have included the information in the text – line 135-139.

We will consider the long term observation.

* Include Risser score into your inclusion criteria, age is not sufficient to define the risks. If possible consider the long term observation.
We completed information about Risser score in this version of article. Some of GLM models showed that Risser test is the factor influenced changes in ATR values. We decided however that these analysis are too detailed to be undertaken in this article.

> * Pay attention to the mobilization effects, which can enhance scoliosis progression, as stated in the Guidelines for scoliosis conservative treatment, This can have also ethical implications.

Mobilization mPNF was planned based on the results of previous studies that have evaluated the mobility of the spine in the transverse plane. One sided limitation of rotation was found in subjects with double scoliosis. Guidelines for scoliosis conservative treatment included recommendation for correction 3D. Sometimes it is difficult to correct the spine in three dimensions if movement in one of the planes is limited. Often the use of techniques to increase mobility in the direction of limitation causes changes in the joint position and causes correction. We know the studies on hypermobility in scoliosis subjects, but the rotation was not evaluated in these studies. In our opinion generalized joint hypermobility doesn’t mean that the spine is hypermobile in three planes.

You mentioned about ethical implications. It was not proved in the long time that mPNF is effective, but it was not also proved that this technique enhance scoliosis progression. We don’t know all mechanisms of compensations and progression. Maybe limited ROM in the transverse plane is one of factors conducive to the development and progression of scoliosis? The aim of this study was to assess the immediate impact of mPNF on ATR and TPHA values. An immediate effect was evaluated especially for ethical reasons. This is a first step - to know the phenomenon. Results gave us some information that can be used in subsequent studies. The study was approved by the Ethics Commission. It was important for us to know “the direction” of changes. A tendency to decrease ATR values was found in the majority of participants. mPNF is not the typical manual mobilization of the joints, it is a soft muscle technique. Mobilization carried out in collaboration with the patient without pain, so it becomes safer.

> * Consider the effect size and the Minimally Clinical Significant difference for the outcome measures you consider, search the literature, and calculate the sample size during research planning.
Power and sample size analysis revealed that with the number of subjects N=83, the test power for all the examined parameters was higher than 90%. We enclose more information in the additional file. The size of the group allows for multiple statistical analyzes within the group.

> * Remember that to state that a treatment is effective for scoliosis treatment you should refer to Cobb angle.

We know that only the evaluation of X-ray is used to evaluate the effectiveness of treatment. Appropriate changes were made in the manuscript. Unfortunately, we do not possess such documentation and we suppose that Ethics Commission would not accept such practice for immediate or short effects.

> * Follow the CONSORT guidelines when writing the manuscript.

We try to follow these guidelines.

Thank you for your all advices and knowledge.

Kind regards

Reviewer 3,

> The phrase "a pilot study" should be added to the title of the article.

Thank you for this comment, the title has been changed.

> - It is a major defect for the study that it lacks a "control group" (where a different stretching approach could be applied).
Indeed, the lack of control group is limitation of the study and such information was included in the final part of the discussion section – line 350-351.

> - It should be explained in details why only one intervention approach was applied throughout the study.

Mobilization mPNF was planned based on the results of previous studies that have evaluated the mobility of the spine in the transverse plane. One sided limitation of rotation was found in subjects with double scoliosis. A position of the body during mobilization and movement pattern were suitable for the vertebra orientation in the horizontal plane in double scoliosis and limitations of TPHA motion noted in previous studies. With the application of a larger number of patterns, analysis of the impact of mPNF would be difficult. Proper corrections have been made in lines 318-324.

> - The "Background" part in "Abstract" section needs to be shortened. The last two sentences (line 29-32) must be moved to "Methods".

Thank you, it has been changed.

> - In line 46 (Conclusion), it is said that "there is a correlation between...". However, there is no correlation analysis in your study.

We fully agree with your remark that the first sentence in the conclusion section was unclear and it did not comply with the aim of the research. In the present version the results are compliant with the research objectives and statistical analysis.

> - In "Methods" it is said that "&x2026; MANOVA were used &x2026;". However, no results of MANOVA are mentioned in the "Results" Section. This needs to be corrected in the "Discussion" part, too.
Due to a serious health problem of one of the authors responsible for statistics, we were forced to collaborate with another statistician and apply a different method. In the statistical analysis the SAS rel. 13.2 software with multivariate GLM models was used. Such information is included in the manuscript. A multivariate analysis confirmed the a considerable influence of PNF mobilization on the significant changes of ATR, TPHA and BD. Information was added as in the results as in discussion sections.

> - Statistical analysis section must be revised .It is mentioned in line 148-149 that non-parametric tests were used. It should be explained which non-parametric were used for Paired Sample t test and MANOVA.

Statistical analysis section was revised, as mentioned above. New information concerning statistical analysis is included in the manuscript in lines 143-147, 218-225, 280-284.

> - It would be very appropriate to include the following 2 in the "Methods":

> 1. The reason why the sample size was 83.

The research lasted 6 months and was conducted in three independent centers. In this period scoliotic girls were consecutively qualified for the study. 87 girls were qualified for participation in the study. Four girls didn’t come for testing. Ultimately, the study was performed on 83 girls with double scoliosis.

> 2. Power analysis of the study.

Power and sample size analysis revealed that with the number of subjects N=83, the test power for all the examined parameters was higher than 90%. We enclose more information in the additional file.
> - Body mass index of the participants should be given.

Information concerning BMI was added to the manuscript.

> - Test-Retest or inter/intratester reliability of the measurement of the Trunk-Pelvis-Hip Angle Test should be given. If not, a reference regarding this reliability should be provided in the "Methods" section.

The assessment of the TPHA measure reliability showed excellent agreement of measurements - the interobserver reliability for three investigators was 0.970 (THPAl)eft and 0.976 (TPHAr)ight, the intraobserver reliability was 0.872 (THPAl)eft and 0.810 (TPHAr)ight. This information is in the text line 111-114.

> - It would be very appropriate to add a table containing a comparison between ART and TPHA left vs. right.

We supplemented Table 3 and have included new charts for the parameters of ATR and TPHA. We hope this is enough to present results.

> - In line 140-141, it should be mentioned how many times the application was administered.

We supplemented and have included the information in the text – line 135-139 and in Table 1 in the corrected version of manuscript.

> - Line 155-156 needs to be restated in a more clear and understandable way.
This sentence has been changed

> - In line 187, the abbreviation TMB needs to be explained.

I should be TPHA, it was corrected.

> - In line 196, TMHA needs to be corrected.

Thank you it has been changed.

> - Lines 188 to 193 should be removed. Discussion needs to start with the primary finding of the study.

The discussion begins with the primary findings of the study.

> - The information provided in line 260 is not available in Results.

Statistical analysis has been changed. Information are available in method, results and discussion sections.

> - Limitations of the study should all be gathered under one heading.

Limitations of the study are placed under one heading.

> - Throughout the article, there is no finding in relation with the information provided in line 312-313 (Conclusion). This should be corrected.
Conclusions have been changed. Thank you for this right comment.

> - Figure 2a and b can be converted into tables.

We converted Figures 2a and 2b into one table (Table 4).

> - Figure 3a and b should be combined.

Figures 3a and 3b were combined in one figure. It was very good suggestion. Thank you

> - An overall revision regarding the English used in the text would be highly appreciated.

The text has been corrected by a native speaker.

Thank you once again

Kind regards

Reviewer 4

> Title: The short-time effect of PNF specific mobilization on the angle of trunk rotation and spinal mobility in adolescent girls with idiopathic scoliosis
> Reviewers' comments:

> 1. In abstract, the authors are stated that the purpose of this study was to decrease the difference of range of motion in the transverse plane between the right and left sides in the trunk-pelvis-hip complex, expressed as Trunk-Pelvis-Hip Angle, in girls with adolescent idiopathic scoliosis. How would you know at the start of the study that all your scoliosis subjects had range of motion limitation in the transverse plane? Is that your inclusion criteria? Otherwise, there is a need for a healthy control group to make a decision on that. Please clarify the purpose of this study considering results.

Thank you for your question. After reading all the reviews we realized that the text was not clear and we didn’t emphasized important facts. The aim of the study was not clear pointed. We expected limitation in the transverse plane in the group of girls with double scoliosis, because the previous studies showed rotational asymmetry in subjects with this type of deformity. These asymmetry was expressed also in the latest study as significant differences between Trunk-Pelvis- Hip Angle on the left and right sides of the body. We found also a more limited range of motion in the transverse plane in scoliotic girls compared to their non-scoliotic peers. Our article, after review, has been accepted for print and we added this article to references.

Our hypothesis behind this study was that in adolescent girls with idiopathic double scoliosis the opposing directions of vertebral rotation in each of the curves unilaterally limit motion assessed by the measurements of TPHA.

Mobilization mPNF was planned based on the results of previous studies, but also in this study one sided limitation of rotation was confirmed in girls with double scoliosis. Mobilization mPNF was performed in the direction of limitation found in the girls with double curve scoliosis.

> 2. The article requires some grammatical attention. For example in abstract, the statement "mean +SD:13.71.9" needs to be 13.7±1.9. There is a need to report scoliotic curve angles in degrees (°).
It has been changed

> 3. In background, there is some disunity between the paragraphs. In background, in the second paragraph, authors reported that measurement of the angle of trunk rotation (ATR) is an important part of examination in scoliosis. However, a standard physical examination does not include assessment of the spine rotation range. But why do you prefer to investigate spine rotation range? What is its importance? Please explain the relationship between ATR and spinal rotation range with literature, in this paragraph.

Our main goal was to assess the immediate impact of mPNF, based on the movement in the transverse plane, on ATR and TPHA values. We were interested if this muscle mobilization would reduce ATR values and change the range of motion. A standard physical examination has not included assessment of the spine rotation range, maybe due to the fact that scoliotic individuals demonstrate significantly more frequent generalized joint hypermobility. But generalized joint hypermobility doesn’t mean that the spine is hypermobile in three planes. Mechanics of the scoliotic spine is not well understood and requires further research.

It is difficult to explain the relationship between ATR and spinal rotation range with literature, because there are not many reports on the subject. It was noted that the limitation in the range of rotation increases with the Cobb angle, so it is just indirect relationship.

> 4. In background, 3rd paragraph, lines 62-63, the statement "In the present authors' opinion there is a relationship between the ATR and the mobility of the spine and pelvis in the transverse plane." refers that one purpose of this study is to investigate this relationship. In lines 69-72, the purpose of this study was reported to develop a method to reduce the differences between the values of the Trunk-Pelvis-Hip Angle (TPHA) on the left and right side of the body in girls with idiopathic scoliosis during motion of the trunk-pelvis-hip complex in the transverse plane. Is this purpose, another purpose of the study?

The purpose of this study was to assess the immediate effect of specific mobilization PNF (mPNF) on the angle of trunk rotation and TPHA range of motion in adolescent girls with double scoliosis. We clarified this aim in the corrected version of manuscript. We noticed a tendency to decrease ATR in majority of participants together with an increase in TPHA values. But it doesn’t mean that there is any statistical correlation between these parameters. Terms such as “correlation” or “relationship” were used in the wrong sense and have been removed in this
> In addition, selected patterns of Proprioceptive Neuromuscular Facilitation (PNF) were used to increase the limited range of motion (ROM). What was the reason for choosing especially PNF method? What does the literature tells about effects of PNF method on improving ROM? In what problems, PNF was previously used? Furthermore, what are other techniques to improve ROM in patients with scoliosis? Why did the authors especially choose the PNF method?

PNF gives many possibilities in the planning of individual physiotherapy. Precisely described movement patterns allow the therapist to act selectively on particular parts of the musculoskeletal system, including the spine. Several authors have demonstrated the effectiveness of PNF muscle relaxation techniques. These muscle relaxation techniques are considered to be very effective for increasing the range of motion, especially in short term. More explanation regarding the PNF method was included in the background and discussion section and additional references were added to the list of references.

> In methods section, what was the reason for including 83 subjects to the study? Did the authors make any power analyses for determining sample size? Please consider and report in statistical analyses section.

The adequate explanation is provided in statistical analyses section. Power and sample size analysis revealed that with the number of subjects N=83, the test power for all the examined parameters was higher than 90%. We enclose more information in the additional file.

> In page 5, lines 104-110, What do you mean with short-term effect? How long did you give the PNF training? Was it one session? If it was one session, how long did it take? And how did you determine this?

We have changed the term “short-time effect” to “immediate effect”, because it was one session.
The mobilization technique mPNF was describe in details in Table 1. Now we supplemented and included the information in the text – line 135-139 and in Table 1 in the corrected version of manuscript.

> In methods section, Did the patients receive previously any other treatment? or was patients receiving any other treatment during PNF training period? Reporting should include these information.

Yes, most study patients underwent some kind of physiotherapy before participation in the study, but it was very diverse.

> 8. The measurement techniques, such as ATR and TPHA, require citations in methods section. Citation have been supplemented.

> 9. In results section, what was the number of subjects, who was eligible for this study? Did you have any drop out? Please provide information. In addition, a flow chart may be added.

The research lasted 6 months and was conducted in three independent centers. In this period scoliotic girls were consecutively qualified for the study. 87 girls were qualified for participation in the study. Four girls didn’t come for testing. Ultimately, the study was performed on 83 girls with double scoliosis.

> 10. In the first paragraph of results section, it seems that this study includes mild and moderate curves, both. Were patients wearing a spinal brace during the study? If they were wearing, this data should be provided.

Information regarding size of scoliosis, Risser test and brace were included in results in lines 158-164. These factors were taken into account in the multivariate GLM model.
11. In discussion, what did your study demonstrate? Please state first. What was your main outcome and what was its importance in the literature?

Discussion section has been changed. The discussion begins with the primary findings of the study.

> Discussion section needs some revisions and grammatical considerations. First of all, positive effects of PNF in this study are short-term effects. This should be emphasized. In addition please discuss in which ways PNF provided these positive effects on ROM and ATR?

Your remarks were taken into consideration while revising the manuscript and proper corrections have been made. Explanation is included in lines 288-324.

> In page 12, lines 267-268, how would PNF alter spatial orientation of the spine with short time application? Please reconsider and clarify.

Explanation as above – lines 288-324.

> 14. In page 13, lines 289-292, Authors stated "A reduction in the angle of trunk rotation contributes to improved appearance while increased ROM in the TPHA test may influence the respiratory function as reduced mobility of the vertebral column and thorax is a factor responsible for respiratory dysfunction." These effects might occur as a result of the long-term application of the PNF method. The short-term effect of PNF may not address these changes. Please reconsider this statement.

You are right. Immediate effects of PNF dont influence these changes. This fragment was removed.
15. In page 14, lines 307-308, What is the relation of this statement "The differences between the ranges of TPHA left and TPHA right observed in our study may be related to gait asymmetry." with your hypothesis?

We agree that it is too generalized thinking. We removed all fragments related to gait.

16. What are the limitations of this study?

Limitations of the study are placed under one heading at the end of article. Line 345-357.

17. In conclusion section, the effects should be emphasized as short-term effects.

Effects are emphasized as immediate in discussion and conclusion sections.

18. The title is "The short-time effect of PNF specific mobilization on the angle of trunk rotation and spinal mobility in adolescent girls with idiopathic scoliosis" But the authors investigated the short-time effect of PNF specific mobilization on the angle of trunk rotation and TPHA ROM. The spinal mobility is a general term and includes many aspects. Please reconsider to change the title.

The title was changed according to the suggestion.

Thank you for all advices

Kind regards