1. Please take this opportunity to thoroughly proofread the manuscript to ensure that there are no spelling or grammar issues.

The manuscript has been reviewed by an English editor.

1. Please upload each Table individually to your Editorial Manager account as an .xls or .xlsx file.

Done

3. Please revise the title to be more concise.

The title has been shortened.

4. Please provide an email address for each author.

Email addresses are now provided on page 1.

5. Please rephrase the Short Abstract to clearly describe the protocol and its applications in complete sentences between 10-50 words: “Here, we present a protocol to …”

Done

6. Please rephrase the Introduction to include a clear statement of the overall goal of this method.

The overall goal of the paper is now stated on page 3, second paragraph.

7. Please revise the protocol text to avoid the use of any personal pronouns (e.g., "we", "you", "our" etc.).

Revised.

8. Please revise the protocol to contain only action items that direct the reader to do something (e.g., “Do this,” “Ensure that,” etc.). The actions should be described in the imperative tense in complete sentences wherever possible. Avoid usage of phrases such as “could be,” “should be,” and “would be” throughout the Protocol. Any text that cannot be written in the imperative tense may be added as a “Note.” Please include all safety procedures and use of hoods, etc. However, notes should be used sparingly and actions should be described in the imperative tense wherever possible.

The protocol section has been entirely revised.

9. In the JoVE Protocol format, “Notes” should be concise and used sparingly. They should only be used to provide extraneous details, optional steps, or recommendations that are not critical to a step. Any text that provides details about how to perform a particular step should either be included in the step itself or added as a sub-step. Please consider moving some of the notes about the protocol to the discussion section.

Done

10. The Protocol should be made up almost entirely of discrete steps without large paragraphs of text between sections. Please move the introduction/discussion about the protocol to the Introduction or Discussion sections. Some examples:  
1.1: Please move the introduction of the LATCH assessment tool to Introduction.

We have tried our best to meet this requirement and focus on steps in the “Protocol” section.

11. Please simplify the Protocol so that individual steps contain only 2-3 actions per step and a maximum of 4 sentences per step. Use sub-steps as necessary.

Revised.

12. Please include single-line spaces between all paragraphs, headings, steps, etc.

Done

13. After you have made all the recommended changes to your protocol (listed above), please highlight 2.75 pages or less of the Protocol (including headings and spacing) that identifies the essential steps of the protocol for the video, i.e., the steps that should be visualized to tell the most cohesive story of the Protocol.

Done

14. Please highlight complete sentences (not parts of sentences). Please ensure that the highlighted part of the step includes at least one action that is written in imperative tense.

Done

15. Please include all relevant details that are required to perform the step in the highlighting. For example: If step 2.5 is highlighted for filming and the details of how to perform the step are given in steps 2.5.1 and 2.5.2, then the sub-steps where the details are provided must be highlighted.

Done

16. As we are a methods journal, please revise the Discussion to explicitly cover the following in detail in 3-6 paragraphs with citations:  
a) Critical steps within the protocol-

We have revised the discussion section with respect to this comment.

17. For in-text references, the corresponding reference numbers should appear as superscripts after the appropriate statement(s) in the text (before punctuation but after closed parenthesis). The references should be numbered in order of appearance.  
18. Please ensure that the references appear as the following: [Lastname, F.I., LastName, F.I., LastName, F.I. Article Title. Source. Volume (Issue), FirstPage – LastPage (YEAR).] For more than 6 authors, list only the first author then et al.

All references have been revised according to this format.

19. References: Please do not abbreviate journal titles.

Done

Reviewers' comments:  
  
Reviewer #1:  
Manuscript Summary:  
I think this is a very important topic for further study due to relevance of breastfeeding to the infant's and maternal health. I felt there were a number of problems with the abstract:  
  
Paragraph 1: Is it appropriate to characterize the feelings of LC's as powerless? Can you really know this? It was not part of the study.

We thank the reviewer for this comment. We agree that this was not part of the study and have therefore removed this statement (page 1, 1st paragraph of the abstract)  
  
Paragraph 2: Can you be certain that your protocol "ensures infant's cooperation.?" I have never seen any protocol that can predict how a newborn will act.

Thank you for pointing this out. The protocol duration should indeed be adjusted according to infants’ needs. We have therefore removed the confusing statement.  
  
Paragraph 3: first sentence makes no sense and needs revision: Structures in lesions are inadequacy (in adequacy) of anatomical zones involved in {latching on}; the term used should be attachment.

This sentence has been revised.  
  
Second sentence: "This study is to document an osteopathic profile of infants…"Did that mean that is the goal or purpose of this study?

Objectives of the paper have been clarified, on page 3, 2nd paragraph.  
  
The statements about documented biases and blinding of parents do not belong in the abstract as these give recommendations for further studies.

This has been revised.  
  
The abstract should be only the direct protocol (or findings) of the study. Recommendations should be part of the discussion, usually as part of limitations.

This has been addressed.   
  
Major Concerns:  
How the infants were actually recruited puts the entire study in jeopardy. You seem to have professionals who have no background in musculoskeletal or biomechanical assessment determining who enters the study. This should be tightened or explained in more detail.

As described in the first section of the protocol (Section 1), recruiters were trained lactation consultants, midwives, or perinatal nurses with strong knowledge of the biomechanics of suckling. In addition, we trained all of them at the beginning of the study regarding the specifics of the trial. Re-assessment of the infants’ eligibility was also performed prior to randomization by the study LCs. Of note, none of the 97 babies recruited had 10 over 10 at the first Latch Assessment Tool score, therefore indicating some disabilities.  
  
The precision of goniometric measurement of the infant's active cervical range of motion seems very unlikely to be accurate. Further explanation of how this accuracy was assured needs to be addressed.

Following Gajdosik et al. 1987, Cheng (1999) and Ohman (2013) we adopted a standardized method of testing using a small soft goniometer by only one osteopath, with babies lying on a couch. Gajdosik (1987) claimed that standardization of testing procedures improved reliability. The starting fixed point was the top of the infant's skull. The axis of rotation was the baby's nose. The goniometer measured the amplitude of rotation before the shoulder elevation, if any. Some studies expressed the intratester and intertester reliability of a soft goniometer. The Pearson correlation coefficient for intra-tester reliability ranged from 0.83 to 0.98 for the head rotation assessment (Farooq, 2016)

It is unethical to collect data that you do not plan to use in the findings. This appears to have been the case with the maternal pain assessment.

This paper is not the only one disseminating study results. This paper focuses on methods. Please refer to Herzhaft-Le Roy et al., 2017 to see how maternal pain assessment was used in this study.   
  
There is lack of critical reflection throughout the article.

Keeping in mind the nature and purpose of the publication, we would be happy to revise any parts of the manuscript should the reviewer be more specific with respect to this comment.

Minor Concerns:  
Introduction: Line73. Restrictions of skull sutures impacting on latch requires a reference.

A reference has been added.

Line 76-81: The Fraval study should be critically reviewed: small study; more details about the relevance of milk fat content, significance, etc. should be discussed.

The literature review has been revised to focus only on studies that have tested osteopathic manipulation to treat biomechanical impairments to suckling.

Line 84 onward: The same is the case for the Cerritelli study, which appears to have very important findings; however, it is poorly worded and one cannot be sure which group showed lower hospital costs.

We have removed this trial from the introduction. See comment above.

Protocol: There is insufficient evidence that the LATCH tool is the best tool for suck assessment. I suggest there are better more up-to-date assessment instruments. At a minimum, there should be a complete discussion of why this tool was chosen and was the best for the use in this study.

We have addressed this concern on page 3, 4th paragraph.

Line 167: there is no evidence that shows how you validated the reliability of the osteopathic palpation. This needs to be dealt with in detail. How many osteopaths participated? How was the protocol determined? How was it tested? How was it validated? How was reliability measured? Did each test measure what it was intended to measure? Were the findings reliable, both between intra-examiner and inter-examiner. This is a main weakness in the protocol.

This is described in detail in Herzhaft-Le Roy et al., 2017.

Line 180: "recruit mother-infant dyads with biomechanical suckling dysfunctions through referral from nurses in perinatal care, LCs and midwives." How did they determine that the babies had biomechanical suckling dysfunction? What were the signs and symptoms at the basis of recruitment? Since these professionals are not necessarily trained musculoskeletal dysfunctions of the sucking mechanism, how did they determine there was a problem or problems? This is a significant weakness in the study. Without knowing how this was done, there is no evidence that these babies actually fitted the criterion? You did make a list of criterion, but it needs to be noted how these were determined, calibrated, measured and if one feature was sufficient for referral, or did the babies have most or all of them? Wouldn't that make a great difference into who was eligible to enter the trial. More detail is needed on this.  
As described above, an information and training session was conducted before implementing the study, based on Genna’s description of the biomechanics of the sucking sequence. All infants were recruited by a health care professional in the perinatal field (perinatal nurse, midwife or lactation consultant) during a lactation consultation. If they could not resolve the difficulty with lactation support and the infant met the eligibility criteria, the mother-infant dyad could be refered to the study.

Line 193: What was the size of the blocks in the randomization process?

Details about the randomization have been removed from the manuscript to focus on the methods. This information can be found in the results paper (Herzarft-Le Roy et al., 2017)

Line 228: How was the infant incited to reveal his/her full cervical range of motion? This is very difficult to do with any accuracy. By using the goniometer rather than eyeball assessment, it presumes that the measurements were exact and accurate. How did you assure that the baby was trying their best? This assessment seems to imply an accuracy that is doubtful in any real clinical situation.

It was a passive head rotation respecting the baby’s limits (stopping when baby expressed discomfort).

Line 244: the grid should be added as a figure.

The grid is now presented as Figure 1.

Lines 247-254: 30 minutes is a long period of time for a sham manipulation Was this really necessary?

We wanted to ensure treatment allocation blinding by allowing the same amount of time in both groups.

Line 274: "quasi always used technique'" I do not understand what this means.

This has been revised.

Line 294: what does the word "liquids" mean in the context of fascia, muscles and bones?

This has been replaced by “fluid”.

Line 321: "maternal perceptions of potential improvement" should read change, if any. This presumes that there would be an improvement which biases the study.

This has been revised.

Line 336: Were the data parametric or non-parametric?

We appreciate the reviewer’s concern with respect to the statistical tests used. We invite the reviewer to consult our results paper for more details. The current paper focusses on the methods (this is the mission of JOVE), and thus, only lesion results are provided.

Line 344: How were clinical differences defined and categorized? Were the statistical differences significant and at what level?

We believe the statistical results provided in this manuscript (see comment above) are clearly reported and chose not to address this comment.

I was asked only to assess the protocol, not the results, so I will not comment further. However, the protocol does need to be thorough in how results will be assessed and found meaningful. Further, it is unethical to collect data that you do not intend to use and this appears to be the case with the mother's pain data.   
  
  
Reviewer #2:  
Manuscript Summary:  
The presented protocol is a randomized controlled trial that assesses the efficacy of osteopathic approach to infant with biomechanical suckling difficulties. The protocol is supplemented with results, suggesting the efficacy of the protocol.  
  
  
Major Concerns:  
However, major concerns are raised: Osteopathic intervention is not properly described. Choice of osteopathic approaches, techniques are not detailed enough to ensure reproducibility of the protocol. Authors should better describe these section and ideally reference their choice of techniques and therapeutic approaches.

We have revised the protocol section extensively to address this concern.

Minor Concerns:  
Minor edits needs to be done prior to acceptance of the manuscript:  
  
Line 39: 'Structure in lesions are inadequacy' Sentence needs to be rephrased; not proper English and contradiction to a similar sentence found in the Discussion, line 361

Revised

Line 42: 'controlled for in subsequent…' not proper Englsih

Revised  
  
Protocol: Authors should use the proper LATCH acronym terms to facilitate the reader's understanding. (Line 111-117)

This is been added on page 3, 4th paragraph.

Line 131: describe what a goniometer is and what will be used for in the presented study

Description of a goniometer has been added.

Line 134: for all the infants, should be rephrase to: every infant involve in the study.

Done

Line 149: LCs to use the tools: Details should be added to explain which tools LCs will be train on using.

Done  
  
Line 199: Section 4.3: sham manipulations should be quickly describe here or the reader should be informed that it will be describe later.

This has been addressed (step 7.3)

Line 232: The line describing the uterine contraction impact on the infant is superfluous.

This has been removed

Line 258: Section on Osteopathic intervention, the osteopathic treatment should be better describe with proper technique terminology and ideally referenced on the choice of technique selection to ensure the protocol is reproducible.

This has been addressed throughout the protocol section.  
  
Line 360: Please rephrase the sentence: Structure exhibiting lesions are in adequacy of anatomical zones… It is not clear what the authors are trying to mention.

Done  
  
Discussion, it is not clear to the reviewer why authors are explaining the results as not statistically significant when in the previous results section, authors mention that results of the goniometer was statistically significant. Therefore, authors should be more precise and descriptive on which result they are discussing about.

The discussion has been revised to focus on the methods, and results presented in this paper only.  
  
Line 372: Which Spinal nerves are the Authors referring to?

We now specify the spinal nerves we refer to.  
  
Line 374: Authors should be more precise in their anatomical description: 'Hypoglossal transits the foramen of the occiput'. Please better describe the hypoglossal canal.

Done  
  
Line 376: process of labor and birth instead of birthing process.

Done  
  
Line 400: Authors should have previously mentioned in the Results the results they collected from the VAS tools about Nipple pain.

As discussed above, the discussion has been revised to focus on the methods, and results presented in this paper only.

General comment: Authors should not use the second person throughout the manuscript, e.g. Assess the infant head… should be: The osteopath will assess the infant's head. The third person would be more appropriate.

We have revised the paper to respect the format recommended by JOVE.  
  
This would also ensure the manuscript is gender neutral. In the present manuscript osteopaths are female and infant are male.

This has been revised throughout the manuscript.  
  
The proper anatomical term for Occiput is Occipital bone. The authors should change throughout the manuscript.

Done  
  
Authors should describe what 'release' means when describing the osteopathic intervention. This could not be clear to the reader.

We have added a description on page 7, 1st paragraph.  
  
Table titles should be consistent with table legend

This has been revised.  
  
Table 3 Items in table 3 are precise location of lesions and not Osteopathic lesions.  
Authors should be describing better the lesion or the title should be changed to 'Precise location of osteopathic lesions areas'

Revised.  
  
Socket: should be replace by orbit  
Collarbone: by clavicle  
Endothoracic: can the author describe how the osteopath can precisely identify the Endothoracic fascia from the parietal pleura. This should be better describe or Authors should only be mentioning a general tissue area; precision of palpation can be argued by other reviewers/readers.

Clarifications have been made. We have used the International Federation of Associations of Anatomists (IFAA) terminology to revise the manuscript as well as this Table. We thank the reviewer for this thoughtful comment.  
  
Table 4: Numbers do not fit the legend. Would have been interested to take multiple measurement to ensure consistency and report Standard deviation. Legend mention number in bracket are endpoints. There is no number in brackets in the table.

This has been revised. We now report on mean degrees and standard deviation.