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## Protocol to assess the efficacy of an osteopathic treatment coupled with lactation consultation in infants with biomechanical impairments to suckling --Manuscript Draft--

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**TITLE:**

Assessment of the Efficacy of An Osteopathic Treatment in Infants with Biomechanical Impairments to Suckling

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**KEYWORDS:**

Randomized controlled trial, osteopathy, lactation consultation, breastfeeding, dysfunctional suckling, osteopathic lesions

**SUMMARY:**

Osteopathy is an emerging field of clinical research. Here we present a protocol to assess the efficacy of an osteopathic intervention coupled with lactation consultation, in infants with biomechanical issues impeding breastfeeding.

**ABSTRACT:**

Breastfeeding can be challenging for mother-infant dyads experiencing biomechanical suckling difficulties. Although lactation consultants (LCs) all over the world have increased their skills in this field and can provide support to help position the infant at the breast, the impact of their intervention might be limited in the presence of stiff structures in the infants. Here we present a protocol for a randomized controlled trial to assess the efficacy of osteopathic treatment, coupled with lactation consultation, for infants' biomechanical suckling difficulties. It proposes a set-up and a sequence of actions to ensure an optimal context for treatment, as well as a blinding of parents and LCs to the intervention. Data such as the infant's latch ability measured with the LATCH Assessment Tool, the mother's nipple pain with a visual analog scale (VAS), and the mother's perceptions are collected by LCs four times over a 10-day period. Osteopathic lesions are documented by the osteopath, using a standardized assessment grid. Structures of interest are coherent with the anatomical zones involved in latching onto the breast. This protocol also proposes a strategy to document systematically an osteopathic profile of infants with biomechanical suckling difficulties in their first weeks of life. The implementation of this protocol confirms its feasibility for osteopathic assessment and treatment and paves the way for future trials to further explore the efficacy of osteopathic techniques for infants with biomechanical

suckling difficulties.

## **INTRODUCTION:**

Over the last thirty years, international recommendations from the World Health Organization<sup>1</sup>, followed by national recommendations in many countries<sup>2-4</sup>, have advocated for breastfeeding. Its health benefits are now well-known<sup>5,6</sup> and breastfeeding exclusively for the first six months of the infant's life and maintaining it for two years or longer is described as the norm<sup>1</sup>.

As highlighted by Homdrum and Miller<sup>7</sup>, more than half of the mothers who stop breastfeeding within the first month reported biomechanical difficulties. Suckling biomechanical issues typically include suboptimal head extension and rotation, restricted mouth opening or jaw stiffness, biting the nipple, restricted tongue mobility, and inefficient mouth vacuum to stimulate the release of milk from the mother's breast<sup>8</sup>. Any neurological impairment also affects the optimal function of the normal primitive reflexes, crucial to an optimal latch.

The emergence of LCs worldwide has provided a great source of breastfeeding support for mother-infant dyads and has contributed to increasing the scientific knowledge in this specific field. For example, LCs have studied extensively the biomechanics of suckling from birth to weaning. In parallel, they have created tools to assess the function of breastfeeding and to efficiently detect dyads with special needs<sup>9,10</sup>.

Osteopathy is a manual practice meant to restore normal functions of the human body, based on the body's capacity for self-regulation<sup>11</sup> and structure-function relationship<sup>1</sup>. During an osteopathic consultation, various palpation techniques are used, based on thorough knowledge of human anatomy and physiology<sup>12</sup>. Some scholars have linked physical restrictions with suckling dysfunction<sup>13-17</sup>. Restrictions of skull sutures or motility of skull bones have also been described to impact an infant's ability to latch<sup>13-18</sup>. However, research on the efficacy of osteopathy techniques on biomechanical suckling difficulties is scarce<sup>19,20</sup>.

Aside from a few case reports describing an osteopathic intervention to improve an infant's ability to latch<sup>21,22</sup>, only one pilot study<sup>23</sup> documented the impact of such interventions. Six infants between three to six weeks of age were recruited and assessed by an LC. Mothers were given breastfeeding advice and then met the osteopath. Four treatments (once a week for four weeks) were performed. Treated infants were compared with six control infants whose mothers received only LC support. The authors found improvement in the milk fat content, which has been shown to be a marker for effective feeding<sup>24</sup>. Due to its small sample, these pilot study results are not generalizable but established the feasibility of a randomized controlled trial coupling the expertise of LCs and osteopaths.

These studies have paved the way for a single-blind randomized controlled trial to assess the efficacy of an osteopathic treatment coupled with lactation consultations on infants' ability to latch. The protocol for this trial is presented herein. The trial took place in a mother-to-mother support group, where LCs provided lactation consultations three days a week, free of charge for parents<sup>25</sup>.

Assessment tools for the trial included 1) the LATCH Assessment Tool to measure the main aspects of the biomechanics of suckling<sup>26</sup>; 2) a VAS to assess the mother's nipple pain; 3) a goniometer, a soft plastic instrument to measure the rotation of the infant's head's angles; and 4) *de novo* questionnaires to assess the mother's perception of her infant's ability to latch, as well as sociodemographic data and potential intervention side-effects.

The LATCH Assessment Tool was chosen amongst several others for its specific assessment of the biomechanics of the suckling structures and the global ability of the mother-infant dyad to position themselves comfortably<sup>27</sup>. While breastfeeding assessment tools are currently discussed in the international lactation community<sup>28,29</sup>, the tool is easy to use in the clinic, reliable, and widely implemented among this community to detect early breastfeeding difficulties<sup>30</sup>. The choice of the tool also enables comparisons with other studies on breastfeeding. Each letter in "LATCH" corresponds to an item to assess an element of the biomechanics of suckling. "L" is for the ability of the infant's tongue, jaws, and lips to sustain the actions and vacuum, and to activate the milk let-down reflex efficiently (Latch). "A" is for Audible swallowing as it is evidence of suckling effectiveness, "T" is for the Type of the nipple at the end of the feed (inverted, flat, or everted), "C" is for the Comfort of the breast and nipple, and "H" is for the assessment of the ease with which the infant is Held in a comfortable and effective position at the breast. The result is a five-item score out of 10 (normal is 10 out of 10) with an interrater reliability of 0.94<sup>31,32</sup>.

The VAS is a 10 cm line to estimate the severity of pain felt by mothers, from 0 (no pain) to 10 (maximum pain). For this trial, the VAS was completed at the beginning of the feed, once the infant was latching on, and once the milk let-down had started.

A soft plastic goniometer was used to assess the passive rotation of the infant's head, as described by Cheng<sup>33</sup>. Assessments were completed immediately before and following the osteopathic assessment for the control group, and before the assessment and following the osteopathic treatment in the treatment group. Intrarater reliability has been reported to range from 0.83 to 0.98 for the head rotation assessment<sup>34</sup>.

Finally, a standardized assessment grid was completed by the osteopath for every infant involved in the study, documenting all of the areas exhibiting osteopathic lesions. Osteopathic lesions are areas with lack of mobility or motility, with excess rigidity, or with a lack of tone in the structure. Lesions are classified in three levels of severity, ranging from a structure with limited mobility to a stiff structure with no mobility. In the osteopathic treatment group, all structures addressed during the treatment were documented (**Table 1**).

Data were analyzed with an intention-to-treat analysis using descriptive statistics. Chi-square tests were used to explore potential correlations between all identified lesion sites and a one-point or more improvement on the LATCH Assessment Tool.

#### **PROTOCOL:**

This randomized controlled trial protocol was approved by the Comité d'éthique et de la

recherche en santé de L'humain at the Centre hospitalier Universitaire de Sherbrooke and the Comité d'éthique et de la recherche at the Centre intégré de santé et services sociaux de la Capitale Nationale in Québec City, Canada.

## **1. Identification of Collaborators and the Preparation of Recruitment**

1.1. Network with LCs and/or a local mother-to-mother support groups where frequent lactation consultations are provided in order to identify where the study will take place.

1.2. Organize a training session (roughly 2 h) for potential recruiters (LCs from the group identified at step 1.1, external LCs, midwives, and perinatal nurses) on biomechanical suckling difficulties based on Genna's description of the innate sequence of suckling behavior<sup>8</sup>, and the eligibility criteria for this study. Include a brief description of potential osteopathic techniques used in this context.

1.3. Ensure that the LCs identified at step 1.1 are familiar with the tools used in the study and, if necessary, are trained to use the LATCH Assessment Tool, the VAS, and the questionnaires.

1.3.1. Test-run the protocol procedures, such as welcoming the mother-infant dyads, explaining and facilitating the signing of the consent form, and completing the assessment using the tools.

1.4. Validate the reliability of the osteopathic palpation with other osteopaths experienced in pediatric osteopathy. Train the study osteopath to be able to evaluate and perform the osteopathic treatment needed within 30 min maximum, in order to minimize inconsistencies arising from the infants' behavior, such as sleep stages and suckling skills and stamina.

## **2. Selection of Implementation Sites**

2.1. Select a site with at least two hospitable rooms with conveniences for families to host the study. Consider providing drinking water, a comfortable place to breastfeed, and diaper changing facilities. Also, provide pillows or cushions to support the mothers' arms, a footboard for better positioning, and chairs for family members accompanying the mother-infant dyad and the LC (when performing the evaluation).

NOTE: The rooms must be easy to access with a stroller and for mothers with limitations following a C-section delivery. A sofa is optimal, but a rocking chair for the mother plus a small bench for the osteopath is another option.

## **3. Recruitment and Enrollment of Mother-infant Dyads**

3.1. Identify eligible infants with biomechanical suckling dysfunctions through referrals from LCs, nurses in perinatal care, and midwives, after their first lactation consultation. Refer them to the study.

3.1.1. Select infants less than six weeks of age, with biomechanical suckling dysfunctions (suboptimal head extension, restricted head rotation, restricted mouth opening, jaw stiffness, habit of biting the nipple, restricted tongue mobility).

3.1.2. Exclude infants with a cleft palate, cleft lip, surgical tongue-tie, or other medical conditions; twins; and infants with prior treatment using any type of manual therapy.

3.2. On the first appointment following the referral, welcome mother and infant and explain the full study process. Obtain informed consent.

3.3. Once screened, clearly establish how parents will contact the clinic, to ensure a rapid turn-around for the intervention and to schedule an appointment.

NOTE: The LC provides an initial lactation consultation prior to the preintervention assessment and, then, determines the LATCH scores and the VAS pre- and postosteopathic intervention.

#### **4. Assessment of Baseline Study Outcomes**

4.1. Ask the mother to give one breast. Observe the infant's suckling rhythm.

4.2. Assess the infant's baseline ability to latch, using the LATCH Assessment Tool, right at the beginning of the feed. Be aware that, sometimes, infants are in a deep sleep and it may take a long time to awaken them. Be prepared to complete the administrative process quickly if the infant is hungry and upset prior to the feed.

4.3. Request the mother to complete a VAS at the beginning of the feed.

4.4. Administer a baseline questionnaire for sociodemographic data, breastfeeding data (*e.g.*, number of feeds per day, number of bottle feeds *versus* breastfeeds, number of diapers changed in the last 24 h), and maternal perceptions of biomechanical difficulties (*e.g.*, infant bites the nipple during the feed, opens his mouth widely to latch, or slips on the nipple while feeding).

4.5. Ask the mother to remove the infant from the breast when the suckling movement is slowing.

NOTE: When the assessment is completed, the LC leaves the room.

#### **5. Performance of an Osteopathic Assessment**

5.1. Open the sealed and opaque envelope with the corresponding study number for the mother-infant dyad, which will assign the dyad to the control or treatment group.

5.2. Ask the mother to sit on a couch with a cushion on her knees and the infant lying back on it. Sit by her side. Connect with the infant by making eye contact. Talk to the infant before putting

hands on its body.

5.3. Begin with a general observation of the infant's posture, tone, and any asymmetries.

5.4. Assess the infant's head passive rotation left and right with the goniometer. Respect any discomfort manifestation or limitation (for example, ipsilateral shoulder elevation).

5.5. Observe the infant's body attitude and assess any osteopathic lesions for each part of the body regardless of the allocation group, using the standardized grid described in **Table 1**.

5.6. Begin the treatment with the pelvic area since it is an important sphere of compression during the birth process<sup>16,35</sup>. Assess the tissue texture and tone in the lower limbs' fascia, sacroiliac joints, sacrum, and hips, as well as the range of motion of the pelvic sphere *versus* the lumbar spine.

5.7. Move hands from the infant's pelvis to its skull and similarly assess tissue texture and tone and, as appropriate, the range of motion of the abdominal cavity, spine, diaphragm, thorax, and cervical spine. Pay careful attention to the first cervical vertebrae, and assess the anterior structures of the neck, the hyoid bone, and sublingual muscles.

5.8. Be very precise and gentle as to the placement of fingers at the skull base, as structures are tiny and delicate.

5.9. Move forward from the base of the skull to the occipital bone, temporal bones, parietal bones, sphenoid bone, frontal bone, and features of the face, including the jaw. Infants yawn frequently; observe the jaw movements and the symmetry of the face.

5.10. For each structure, record observations of the texture, tone, quality and range of motion, and straining on the standardized grid (**Table 1**).

## 6. Performance of Osteopathic/Sham Intervention

NOTE: The osteopathic techniques described in this protocol are key osteopathic approaches available for infants with biomechanical suckling difficulties. They focus on improving the infant's ability to latch, improving pelvic mobility, improving head rotation and extension, improving mouth opening, and freeing the XII cranial nerve, which is responsible for the tongue motion.

6.1. Lie the infant down on his/her back on a pillow on his/her mother's knees. Sit alongside the mother on the couch, at the infant's head.

6.2. Perform the osteopathic treatment.

6.2.1. Start the osteopathic treatment by addressing areas previously identified as dysfunctional.

6.2.2. Begin by treating the pelvic area. Place the hands on each side of the infant's pelvis, covering the iliac bones. Ensure that thumbs are on the anterior part of the iliac bones and fingertips are at the sacroiliac joint on each side. Using indirect technique, place the restricted structure in a comfortable position. Use continuous feedback until the complete loosening of the structure is achieved (known as a release)<sup>17,36</sup>.

6.2.3. Place fingers of both hands around the occipital bone, tips of the ring fingers contacting the condyles area, index fingers contacting the mastoid area and middle fingers between the occipital bone and the first cervical vertebra, as described for the condylar decompression technique<sup>37</sup>. Gently separate the fingers in the various spatial plans until the tissues soften and the condyles move freely.

NOTE: At the upper cervical spine, spots are very close together and fragile.

6.2.4. Place one hand under the occipital bone and the other on the frontal and sphenoidal bones, avoiding eyes, in a fronto-occipital hold<sup>17</sup>. Place the occiput and sphenoid in their position of least resistance. Monitor the decrease in resistance and readjust the positioning of the structures until the release occurs.

6.2.5. Place one hand cupping under the occipital bone and the first three cervical vertebrae and the index finger and thumb of the other hand on each side of the hyoid bone. Wait until a release of the hyoid bone is felt through the structures in the other hand. Monitor and reassess, as done in a myofascial release technique<sup>36</sup>.

6.2.6. End the osteopathic treatment by a global body harmonization. Put one hand on the pelvic area and the other on the skull. Gently balance the body volumes, addressing fascia, muscles, bones, and fluid, at least until a coherent and global release is perceived.

6.3. Perform a sham intervention.

6.3.1. Place hands on areas far from those with detected dysfunctions, without any intention of treatment.

6.3.2. Answer questions from the parents about osteopathy and the infant's psychomotor development.

6.4. Postpone the infant feed until the end of the intervention. Use a pacifier or the mother's finger if necessary to soothe the infant.

6.5. Assess the infant's left and right passive head rotation with the goniometer.

6.6. Make sure the evaluation and sham manipulation or the evaluation and osteopathic treatment have the same 30 min duration in order to keep the parents and the LCs blind as to treatment allocation.

6.7. Leave the room. Fill in the standardized assessment grid (**Table 1**). Record details of the treatment performed.

## **7. Reassessment of the Mother-infant Dyad**

NOTE: The LC re-enters the treatment room.

7.1. Take time to set up the mother and the infant comfortably, to ensure the best conditions to take the breast again. Reassess the infant's ability to latch with the LATCH Assessment Tool.

7.2. Ask the mother to complete a second VAS.

7.3. Perform a usual lactation consultation.

7.4. Schedule a second appointment 48 h later. Inform the mother that there will be another breastfeeding evaluation, meaning that she will have to manage to feed her infant during this meeting.

## **8. Final Face-to-face Assessment**

NOTE: For this assessment, parents will only meet an LC.

8.1. Set up the mother and infant comfortably to create the best conditions to breastfeed. When the infant is ready (it may take some time), assess the ability to latch with the LATCH Assessment Tool.

8.2. Ask the mother to complete a second VAS at the beginning of the feeding.

8.3. Administer a second questionnaire for breastfeeding follow-up, maternal perceptions of the infant's ability to latch, and perception of their allocated group.

8.4. Perform a second lactation consultation.

8.5. Offer osteopathic treatment for infants in the control group.

8.6. Make a phone appointment one week following this second visit.

## **9. Assessment of the mother-infant dyad 10 days post enrolment**

9.1. Call the mother to complete the 10-day questionnaire, including breastfeeding follow-up and potential side effects. Remind the mother to complete the postal questionnaire, which includes a VAS and satisfaction component regarding their participation in the protocol.

9.2. Wait to receive the postal questionnaire. Call back 1x if necessary.

## **REPRESENTATIVE RESULTS:**

Ninety-seven mother-infant dyads were recruited and randomly assigned to one of the two study groups. The participants' characteristics and delivery mode are summarized in **Table 1**. Only 1/3 had a natural birth, meaning that the other 2/3 experienced epidural and vacuum (15.9%), forceps-assisted (2.9%), or C-section (18.8%) births. In this study, all infants had skull lesions (**Table 3**). The posterior quarter represented by the occipital and the temporal bones was the main area identified; in particular, the right side of this quarter. The pelvis was the second most common lesion site, followed by the face. Lesion sites are described in detail in **Table 4**; the majority of lesions being situated at the level of the occipital bones, temporal bones, and skull sutures, followed by the sacrum.

The infants' head rotation, as assessed with the goniometer prior to and following the osteopathic intervention (sham manipulation or osteopathic treatment), was improved (statistically significant change) by the osteopathic treatment, for both right and left head rotation (**Table 5**).

## **FIGURE AND TABLE LEGENDS:**

**Table 1: Standardized assessment grid for osteopathic lesions.**

**Table 2: Participants' main characteristics.** The control and treatment groups are similar in terms of participant characteristics.

**Table 3: Area of osteopathic lesions.** All infants involved in this study had skull lesions, with a majority in the posterior quarter.

**Table 4: Osteopathic lesions.** Osteopathic lesions were identified in all infants (both control and intervention groups).

**Table 5: Head rotation of the infants.** Mean degrees of the infants' head rotation before and after the osteopathic or sham intervention.

## **DISCUSSION:**

This study is one of the first randomized controlled trials to assess the efficacy of an osteopathic treatment for infants with biomechanical suckling difficulties. When performed promptly, this intervention might reduce the risk of stopping breastfeeding earlier than originally intended.

With no prior models, this trial was designed pragmatically, including the need to act quickly to address breastfeeding difficulties and nipple pain that may be experienced with a newborn. The protocol also minimizes the difficulties of dyads having to commute several times in the early days postpartum.

Structures identified with osteopathic lesions correspond to the anatomical zones involved in suckling. The results provide a first osteopathic profile of lesions found in infants younger than six weeks of age with biomechanical suckling issues. This study expands critical thinking about structures involved in the function of suckling. The standardized assessment grid developed for this project has been found helpful and valuable to communicate with other health professionals about the lesions that have been treated.

A central practical detail is the willingness of the infant to latch during the first visit. The LC must assess a latch pre- and postintervention. This was best achieved by feeding the infant at the first breast, assessing the first latch with the LATCH Assessment Tool, disengaging the infant from the breast, performing the osteopathic intervention (sham or osteopathic manipulation) and assessing the latch again at the second breast. Often, particularly in the control group, infants cried and tried to crawl onto their mother's chest, which can make sham intervention challenging. In the treatment group, infants were found to be more relaxed and, at times, even fell asleep.

A possible protocol modification would be to replace the soft goniometer with an arthrodiagonal protractor, keeping the osteopath's hands free when assessing the rotation of the infant's head.

The 97 dyads were referred by perinatal nurses or LCs from the health service network and from mother-to-mother support groups, over a 12-month period. This suggests that the first step of the protocol, namely networking and the LCs' training, is efficacious. Many authors<sup>32,38</sup> support the idea that dyads are assessed and referred better when this is done during the first 24 h of the infant's life by well-trained lactation support personnel. This remains to be further investigated.

Finally, the study population included infants of an average of two weeks of age, with all younger than six weeks. It would be interesting to assess, in a further trial, the best timing for osteopathic intervention, as well as signs and symptoms that may be used by parents or LCs to detect cases most likely to benefit from an osteopathic intervention.

This first randomized controlled trial published in the field of breastfeeding and osteopathy paves the way for future research with a standardized collection of osteopathic data from infants with biomechanical suckling difficulties, by coupling osteopathic treatment with lactation consultation.

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#### **DISCLOSURES:**

The authors have nothing to disclose.

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Standardized assessment grid for osteopathic lesions					
Assessment date:		Study number:			
Treatment group					
Skull			*+	*++	*+++
Respiratory rate					
SBS	No lesion				
	compression/ compaction				
	SBR				
	Physiologic lateral strain				
	Non physiologic lat strain				
	Vertical strain	sup	inf		
occipital bone	No lesion				
	Right condyle				
	Left condyle				
	Condyles: post/ ant bilat				
	Lambda				
	Foramen magnum				
	Occipitomastoid suture				
	Squamous part				
Temporal bone	No lesion				
	Petrous part	R	L		
	Squamous part	R	L		
	Auditory canal	R	L		
	Carotid canal	R	L		
	Temporomandibular joint	R	L		
	Internal rotation				
Sphénoïd bone	No lesion				
	Greater wing/Lesser wing				
Parietal bone	No lesion				
	Parietal eminence	R	L		
	External rotation	R	L		
	Internal rotation	R	L		
	suctioned				
	compressed				
Cerebral Dura Mater	No lesion				
	Tentorium cerebelli				
	Falx cerebelli				
	Spinal Dura Mater				
Sutures	No lesion				
	With parietal bones				
	With temporal bones				
	Asterion				
	Coronal suture				
	Metopic suture				
	Sagittal suture				
Brain	no lesion				
	Brain hemisphere				
	Posterior fossa				
	Cerebral trunk				
	veinous sinus				
	Spinal fluid				
Face:	No lesion				
	Orbital symetry				
	Zygomatic bone				
	Maxilla				
	Frontal bone				
	Nasal bone				
	Ethmoid				
	Vomer/				

	Mandible	
Neck	no lesion Hyoid bone Digastric muscle Sub-mandibular muscle Cervical fascia Neck visceral sheath Scalenes muscle	
Cervical Vertebrae	no lesion Sternocleidomastoid Atlas/ Axis Other cervical vertebrae	
Thorax	No lesion Clavicle First-second ribs Anterior myofascial structures Posterior myofascial structures Oesophagus Stomach mediastinum diaphragm	R            L R            L
Spine	No lesion Thoracic vertebrae Lumbar vertebrae	
Sacrum	No lesion compaction Dura mater traction Intra osseous lesion restriction	
Hip bone	No lesion anterior/posterior position Intra osseous lesion restriction	ant            post
Other		

**Memo:**

<b>Assessment</b>	Respiratory rate	listen/ feel motion	Flex/Ext Exp./Retr.
	Palpation	structures range of motion	
	Fluids	Spinal fluid Venous sinus	Fluid lesion
	5 spheres: alignment (DD)		
<b>Osteopathic treatment</b>	Motility non physiological no axis non physiological with axis Physiological lesion		

**Mechanisms**

No lesion  
Musculoskeletal  
Core-link  
fascias  
Fluids  
Pressure  
Visceral  
Cranial field

Goniometer before

Right

Left

Goniometer after

Right

Left

## Standardized assessment grid for o

Assessment date:

Treatment group

Skull		
Respiratory rate		
SBS	No lesion compression/ compaction SBR Physiologic lateral strain Non physiologic lat strain Vertical strain	sup
occipital bone	No lesion Right condyle Left condyle Condyles: post/ ant bilat Lambda Foramen magnum Occipitomastoid suture Squamous part	
Temporal bone	No lesion Petrus part Squamous part Auditory canal Carotid canal Temporomandibular joint Internal rotation	R R R R R
Sphénoïd bone	No lesion Greater wing/Lesser wing	
Parietal bone	No lesion Parietal eminence External rotation Internal rotation suctioned compressed	R R R
Cerebral Dura Mater	No lesion Tentorium cerebelli Falx cerebelli Spinal Dura Mater	
Sutures	No lesion	

<p>Brain</p> <p>Face:</p>	<p>With parietal bones</p> <p>With temporal bones</p> <p>Asterion</p> <p>Coronal suture</p> <p>Metopic suture</p> <p>Sagittal suture</p> <p>no lesion</p> <p>Brain hemisphere</p> <p>Posterior fossa</p> <p>Cerebral trunk</p> <p>veinous sinus</p> <p>Spinal fluid</p> <p>No lesion</p> <p>Orbital symetry</p> <p>Zygomatic bone</p> <p>Maxilla</p> <p>Frontal bone</p> <p>Nasal bone</p> <p>Ethmoid</p> <p>Vomer/</p> <p>Mandible</p>	
<p>Neck</p> <p>Cervical Vertebrae</p>	<p>no lesion</p> <p>Hyoid bone</p> <p>Digastric muscle</p> <p>Sub-mandibular muscle</p> <p>Cervial fascia</p> <p>Neck visceral sheath</p> <p>Scalenes muscle</p> <p>no lesion</p> <p>Sternocleidomastoid</p> <p>Atlas/ Axis</p> <p>Other cervical vertebrae</p>	
<p>Thorax</p>	<p>No lesion</p> <p>Clavicle</p> <p>First- second ribs</p> <p>Anterior myofascial structures</p> <p>Posterior myofascial structures</p> <p>Oesophagus</p> <p>Stomach</p> <p>mediastinum</p> <p>diaphragm</p>	<p>R</p> <p>R</p>

<b>Spine</b>	No lesion Thoracic vertebrae Lumbar vertebrae	
<b>Sacrum</b>	No lesion compaction Dura mater traction Intra osseous lesion restriction	
<b>Hip bone</b>	No lesion anterior/posterior position Intra osseous lesion restriction	ant
<b>Other</b>		

**Memo:**

<b>Assessment</b>	Respiratory rate	listen/ feel motion
	Palpation	structures range of motion
	Fluids	Spinal fluid Veinous sinus
	5 spheres: alignment (DD)	
<b>Osteopathic treatment</b>	Motility non physiological no axis non physiological with axis Physiological lesion	

Mechanisms

No lesion  
Musculoskeletal  
Core-link

fascias  
Fluids  
Pressure  
Visceral  
Cranial field

Goniometer before

Right

Goniometer after

Right

osteopathic lesions

Study number:

	*+	*++	*+++
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post

Flex/Ext

Exp./Retr.

Fluid lesion

Left

Left

Participants Main Characteristics	
	Control group n=48
First baby, n (%)	34 (70.8)
Natural birth, n (%)	18 (37.5)
Epidural, n (%)	35 (72.9)
Vertex presentation, n (%)	26 (54.2)
Infant mean age in days at T0 (IQR)	15 (7.5, 18)

Treatment group
n=49
35 (71.4)
19 (38.8)
36 (73.5)
27 (55.1)
15 (7.5, 22.4)

Areas	n (%; 95% CI)
<b>Skull</b>	97 (100,0 ; 0,95, 1)
Anterior quarter	22 (22,7 ; 0,16, 0,32)
Posterior quarter	82 (84,5 ; 0,76, 0,90)
<i>Right posterior</i>	54 (55,7 ; 0,46, 0,65)
<i>Left posterior</i>	28 (28,9; 0,21 , 0,38)
<b>Face</b>	72 (74,2; 0,65 , 0,82)
<b>Neck</b>	50 (51,5; 0,42 , 0,61)
<b>Thorax</b>	52 (53,6; 0,44 , 0,63)
<b>Cervical spine</b>	41 (42,3; 0,33 , 0,52)
<b>Spine (except cervical)</b>	18 (18,6; 0,12 , 0,27)
<b>Pelvic</b>	80 (82,5; 0,74 , 0,89)

Structures	n (%; IC 95%)
<b>Skull</b>	
Occipital bone	95 (97.9; 0.92, 1)
Temporal bones	71 (73.2; 0.64, 0.81)
Sphenoid	52 (53.6; 0.44, 0.63)
Parietal bones	32 (33.0; 0.24, 0.43)
Sutures	76 (78.4; 0.69, 0.85)
<b>Face</b>	
Frontal bone	60 (61.9; 0.52, 0.71)
Ethmoid	14 (14.4; 0.09, 0.23)
Maxilla	3 (3.1; 0.01, 0.09)
Mandible	31 (32.0; 0.24, 0.42)
Orbit asymmetry	15 (15.5; 0.10, 0.24)
<b>Neck</b>	
Hyoid bone	38 (39.2; 0.30, 0.49)
Digastric muscle	3 (3.1; 0.01, 0.09)
Supramandibular muscle	31 (32.0; 0.24, 0.42)
Sternocleidomastoid muscle	6 (6.2; 0.03, 0.14)
<b>Thorax</b>	
Left clavicle	14 (14.4; 0.09, 0.23)
Right clavicle	10 (10.3; 0.05, 0.19)
First ribs	3 (3.1; 0.01, 0.9)

soft thoracic tissues	26 (26.8; 0.19, 0.37)
Diaphragm	44 (45.4; 0.36, 0.55)
<b>Spine</b>	
Atlas/Axis	41 (42.3; 0.33, 0.52)
Other cervical vertebrae	11 (11.3; 0.06, 0.19)
Thoracic vertebrae	17 (17.5; 0.11, 0.27)
Lumbar vertebrae	3 (3.0; 0.01, 0.09)
<b>Pelvic</b>	
Sacrum	80 (82.5; 0.74, 0.89)
Sacrum compaction	37 (44.6; 0.29, 0.49)
Dura mater traction	26 (31.3; 0.19, 0.37)
Hip bones	4 (4.1; 0.02, 0.10)

	<b>Control group, mean (25th, 75th percentiles)</b>
Degrees	
Right head rotation T0	81.15 (70, 90)
Right head rotation T1	83.02 (76, 90)
Left head rotation T0	81.56 (70, 90)
Left head rotation T1	83.68 (76, 90)

Treatment group, mean (25th, 75th percentiles)	p value
80.82 (70, 90) 90.21 (90, 90)	p=0.001
80.61 (70, 90) 90.71 (90, 90)	p=0.001

Name of Material/ Equipment	Company	Catalog Number	Comments/Description
sofa or armchair			comfortable enough for a new mother with potential ceasarean section scar to stay half an hour with the infant in her arms and comfortable enough for the osteopath to perform the intervention
cushion			to put the infant on it and helpful if required, to breastfeed the infant
Goniometer	Dufort et Lavigne or similar	ALM 324000	in smooth plastic, not too long to be handle with one hand



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Protocol for a randomized controlled trial to assess the efficacy of an osteopathic treatment coupled with lactation consultation in infants with biomechanical impairments to suckling

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Author(s):

Juliette Herzaft-Le Roy; Marianne Xhignesse, Isabelle Gaboury

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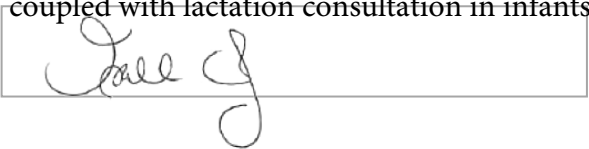
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[The title has been shortened.](#)

4. Please provide an email address for each author.

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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, 1<sup>st</sup> 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, 2<sup>nd</sup> 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, 4<sup>th</sup> 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 referred 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 (Herzhaft-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 English

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, 4<sup>th</sup> 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, 1<sup>st</sup> 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.