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Efficacy of an Osteopathic Treatment Coupled With Lactation Consultations for Infants' Biomechanical Sucking Difficulties: A Randomized Controlled Trial

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Abstract

Background: Despite well-known recommendations from national and international bodies including the World Health Organization, few mothers achieve the goal of breastfeeding exclusively for 6 months. Half of mothers stop breastfeeding due to biomechanical issues in the first month, despite increasing support from lactation consultants. Osteopaths worldwide work with these babies, but there is little empirical evidence for this type of treatment.

Research aim: This study aimed to determine the efficacy of an osteopathic treatment coupled with usual lactation consultations on infants' ability to latch. Secondary objectives included assessment of nipple pain and mothers' perceptions of the effect of treatment.

Methods: We conducted a single blind, randomized controlled trial at a mother-to-mother support group between January and December 2015. Data were collected at four different times over a 10-day period (T0-T10) from 97 mother–infant dyads using the LATCH assessment tool, a visual analog scale (VAS) to document mothers' nipple pain, and a de novo questionnaire for breastfeeding management and potential treatment side effects.

Results: There were consistent statistical and clinical differences in the mean LATCH scores between the treatment and the control groups ($p < .001$). However, no significant differences in the VAS scores were reported over time ($p = .713$). Mothers reported no serious or unexpected side effects during the follow-up period.

Conclusion: This study is one of the first to bring together lactation consultants and osteopaths to address infants with biomechanical sucking difficulties. Findings support the hypothesis that the addition of osteopathy to regular lactation consultations is beneficial and safe.

Keywords

breastfeeding, dysfunctional suck, lactation consultant, LATCH assessment tool, mother–infant dyad, sucking difficulties, osteopathic treatment

Background

The World Health Organization and Health Canada recommend breastfeeding exclusively for the first 6 months, and they support maintaining it for 2 years or longer with appropriate complementary feeding (Infant Feeding Joint Working Group, 2015). Few mother–infant dyads achieve these recommendations (Li, Fein, Chen, & Grummer-Strawn, 2008). According to Statistics Canada (Gionet, 2013), it is within their first month of life that babies are most at risk of being weaned. Half of mothers who stop breastfeeding in the first month report biomechanical issues (Homdrum & Miller, 2015).

Lactation consultants around the world have extensively studied the biomechanics of sucking, from birth to weaning. International Board Certified Lactation Consultants (IBCLCs) are trained to assess difficulties, correct positioning, provide emotional support to the mothers, and help babies express their behavioral sequence leading to

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breastfeeding from birth. However, these professionals often feel helpless when biomechanical sucking difficulties persist in infants despite their advice (Genna, 2013; Hazelbaker, 2010; Smith & Kroeger, 2010). Osteopathy has been used and documented by some and the approach appears promising (Lee, 2011; Wescott, 2004).

Few studies, however, have explored the effect of an osteopathic treatment on infants' breastfeeding biomechanical difficulties. Some authors have described cranial dysfunctions and restrictions of skull sutures being linked to breastfeeding difficulties. Frymann (2000), in an exploratory study on the effect of birthing on 1,255 newborns, found that more than 88% of infants had cranial restrictions. Lalauze-Pol (2009), based on a cohort of more than 1,000 babies, identified different restrictions in skull sutures and their potential effect on cranial nerves involved in the sucking process (Magoun, 1994; Still, 2007; Sutherland, 1962).

Fraval (1998) conducted a pilot study involving six infants ages 3 to 6 weeks. Based on Woodward, Rees, and Boon (1989), he measured prefeed and postfeed percentage of fat in human milk (creamatocrit), as it has been shown that fat concentration in human milk could be a marker for effective feeding. Mothers and infants were first assessed by an IBCLC, given advice, and referred to an osteopath for 4 weeks of treatment (once a week). There was a significant change in creamatocrit before and after the month of treatment. Prefeed and postfeed fat in human milk with six infants feeding normally were then compared. Creamatocrit after four treatments was improved, suggesting that osteopathic treatments are more effective than lactation consultations alone.

Nonetheless, it appears that scientific literature on the subject of biomechanical sucking dysfunctions and osteopathy is sparse. In addition, no study to our knowledge has been conducted to assess the effect of an osteopathic treatment coupled with lactation consultation on these difficulties.

In this article, we report the results of a study primarily designed to evaluate the effect of an osteopathic treatment coupled with lactation consultations on the ability of infants with a biomechanical sucking dysfunction to properly latch and suck. Our secondary objectives were to evaluate changes in the mothers' level of nipple pain and mothers' perception of breastfeeding improvement and to identify any potential side effects in the treatment group. This study took place in a mother-to-mother support group where phone support is usually provided and completed by in-person lactation consultations if needed. We hypothesized that an osteopathic intervention coupled with lactation consultations is better than usual care (lactation consultations alone) within this delivery mode of support.

Key messages

- Perinatal healthcare providers are often confronted with biomechanical sucking difficulties. Osteopaths offer treatment for these difficulties with little empirical evidence.
- A statistically significant improvement in sucking skills (measured by the LATCH score) was found in treated newborns compared with usual care.
- The combination of lactation and osteopathic consultations seems to be promising.

Methods

Design

A single blind randomized controlled trial was implemented. An initial pilot version of the trial was conducted on 16 infants to confirm methodological choices and procedural organization and to familiarize the IBCLCs with the tools to be used. This study was approved by the Comité d'éthique de la recherche en santé de l'humain at the Centre hospitalier Universitaire de Sherbrooke (14-116) and the Comité d'éthique et de la recherche at the Centre intégré de santé et de services sociaux de la Capitale Nationale (2015-842) in Québec City, Canada.

Setting

This study took place in Quebec City, Canada, at a mother-to-mother support group from December 19, 2014, to December 31, 2015. This primary care support group had three IBCLCs providing lactation consultations 3 days per week, free of charge for parents.

Sample

Eligibility criteria included breastfeeding mothers with infants younger than 6 weeks, who had biomechanical sucking dysfunctions as defined by Genna (2013), who were assessed by health care providers with breastfeeding training (e.g., community nurses or IBCLCs from maternity wards or one of the five mother-to-mother support groups in the area), and who were born in Quebec City (where the support group had its office). Twins as well as babies with cleft palate, cleft lip, surgical tongue-tie, or other medical conditions were excluded. Babies with prior exposure to any type of manual therapy (e.g., physiotherapy treatment, chiropractic care, or osteopathic care) were also excluded.

Measurement

Three assessment tools were used. First, the LATCH assessment tool, which was originally developed by Jensen (1994) to better target babies with sucking difficulties for referral to community nurses before they leave the maternity ward, was used. Each letter corresponds to an item that assesses a part of the biomechanics of sucking. "L" is for latch (ability of

the tongue to move in all planes of motion, lips, jaws), "A" for audible swallowing (sucking effectiveness), "T" for the type of the nipple at the end of the feed "C" for comfort (breast or nipple comfort), and "H" to assess how the mother is able to hold her infant to the breast (proper positioning). This results in a 5-item score out of 10, with an interrater reliability of 0.94 (Riordan, Bibb, Miller, & Rawlins, 2001; Riordan & Koehn, 1997).

A visual analog scale (VAS) was used to determine the mothers' nipple pain (McClellan et al., 2012). Mothers were instructed to mark a 10-cm line corresponding to the pain severity they felt, from 0 (*no pain*) to 10 (*maximum pain*).

Finally, de novo questionnaires were created to capture maternal perceptions (improvement, worsening infant's latch), potential side effects, breastfeeding management (number of feeds per day, number of bottle feeds per day, use of accessories such as a nipple shield), and sociodemographic data.

Data Collection

One of the three IBCLCs from a mother-to-mother support group explained the study and initiated the consent process among eligible dyads who were either self-referred or referred by community health care professionals. During the consent process (prior to baseline/Time 0), potential participants were told that they would be randomly assigned to one of two groups: two lactation consultations and a 30-minute session of osteopathic assessment and sham manipulations (control) or two lactation consultations coupled with a single 30-minute session of osteopathic assessment and osteopathic treatment (treatment). Using the LATCH assessment tool, the IBCLC assessed the infant's baseline ability to latch. Mothers were then asked to complete the VAS, the questionnaire for breastfeeding follow-up, maternal perceptions, and sociodemographic data. Once the assessment was completed, the IBCLC left the room. The osteopath (primary author) then entered the room and opened a sealed and opaque envelope containing the computerized, block-randomized (2 or 4) treatment allocation group. She assessed and performed sham manipulations for the control group participants or assessed and conducted an osteopathic treatment for the treatment group participants.

Mothers were seated on a couch with the baby lying on his or her back on a cushion placed on the mother's knees. In the treatment group, after assessing somatic dysfunctions and cranial strains based on tissue texture, tone, asymmetry, and quality of motion, active treatment was carried out, most commonly using techniques such as balanced membranous tension, cranial sutures, and myofascial release. In the control group, after assessing for the same dysfunctions, sham manipulations were performed, consisting of light touch far from the osteopathic dysfunctional areas found.

The osteopath gathered data using a standardized treatment framework for each infant, regardless of the assignment group, to identify dysfunctions found in this sample of babies with biomechanical sucking difficulties. The duration of the osteopath's presence with the family was approximately 30 minutes, regardless of the allocation group, to ensure blinding of the IBCLC and the parents.

After the intervention or sham procedure, the osteopath left the room. The IBCLC returned and assessed the infant a second time (Time 1) using the LATCH assessment tool and asked the mother to once again rate her nipple pain on the VAS. She then provided a lactation consultation. Mothers and infants had to return 2 days later (Time 3). The infant's ability to latch and the mother's level of nipple pain, maternal perceptions, and breastfeeding follow-up were repeatedly assessed with the same tools, and a second lactation consultation was offered. Lactation consultations lasted for at least 1 hour each, focusing on emotional support and better positioning of mothers and babies. The IBCLC phoned the family 1 week later (Time 10) to collect data regarding breastfeeding follow-up and to inquire regarding any potential side effects. Finally, mothers completed a postal questionnaire (Time 10), reporting nipple pain using the same VAS and their satisfaction with participation in this research.

Data Analysis

The sample size was determined based on preliminary results from the pilot version of the trial. To detect a 1-point difference on the LATCH assessment tool, assuming a standard deviation of 1.67 in both groups, using an alpha value of 0.05, power of 80%, and a provision of 7 dyads potentially lost to follow-up, recruitment of 97 mother–infant dyads was deemed to be necessary.

All analyses were conducted on an intent-to-treat basis. Descriptive statistics were computed for infants and delivery characteristics. Chi-square tests were used for categorical variables such as maternal perceptions. Longitudinal regression models (using generalized estimating equation techniques) were performed to test intergroup differences in the primary outcome (LATCH scores) as well as mothers' nipple pain. Data were analyzed using SPSS 23 (IBM Corporation, Armonk, New York).

Results

Participant Characteristics

Ninety-seven mother–infant dyads were recruited between December 2014 and December 2015 and used for analysis (see Figure 1). Participant characteristics are shown in Table 1, whereas birth outcomes are summarized in Table 2. Infants were most often a first child, from a normal pregnancy, within the range of normal birth weight. Only one-third had a natural, unassisted birth. Using the standardized assessment framework, we noticed that all infants had cranial dysfunctions, with 97.9% of infants presenting with an occipital dysfunction.

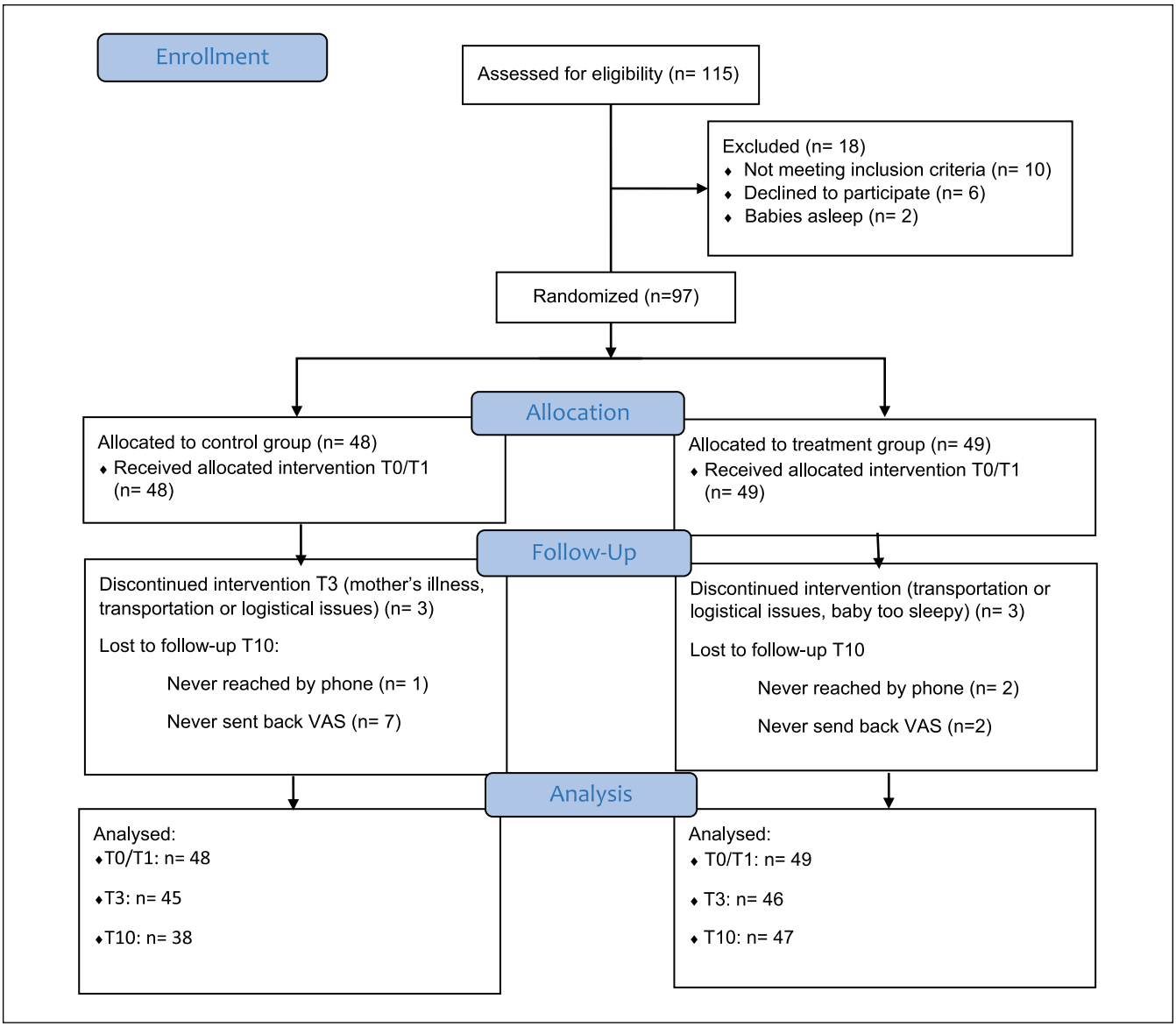

Figure 1. Participant flow chart.

This was most often represented by compression (i.e., one occipital condyle on the first cervical vertebra blocking the lateral flexion of the head, or compression of the squamous part restricting the posterior fossa or the lateral part and the jugular fossa).

Primary Outcome: Infant's Ability To Latch

Infants exhibited moderate latching skills at baseline (overall LATCH mean score = 7.64, standard deviation [*SD*] = 1.39). The LATCH score improved more in the treatment group (T3 mean score = 9.22, *SD* = 0.92) than in the control group (T3 mean score = 8.18, *SD* = 1.60; $p = .001$) (see Figure 2).

To further explore these results, the LATCH score was analyzed by item. Items L and H in particular diverged between the two groups at T3, with latch (L) improving to 2 out of 2 in 45.8% of infants in the control group as opposed to 65.8% in the treatment group ($p = .037$). Similarly, holding (H) of the infant was 2 out of 2 in 87.8% of the treatment group and 72.9% of the control group infants ($p = .032$). A (swallowing), T (nipple shape following feeding), and C (breast or nipple comfort) differences between groups did not reach statistical significance ($p = .078$, .076, and .234, respectively).

Secondary Outcomes

There was no statistical difference between the control and treatment groups regarding nipple pain VAS mean scores over time ($p = .713$). Most of the mothers recruited presented a baseline VAS score ≤ 3 at T0, despite 27.9% reporting

Table 1. Demographic Characteristics of the Participants.

	Control group (n = 48)	Treatment group (n = 49)
Maternal age (years)		
18-25	4 (8.7)	2 (4.7)
26-30	16 (34.8)	19 (44.2)
31-35	16 (34.8)	15 (34.9)
36 +	10 (21.7)	7 (21.7)
Infant gender		
Male	22 (45.8)	22 (44.9)
Female	26 (54.2)	27 (55.1)
First baby	34 (70.8)	35 (71.4)
Normal pregnancy	42 (87.5)	45 (91.8)
Natural, uncomplicated birth	18 (37.5)	19 (38.8)
Vertex presentation	26 (54.2)	27 (55.1)
Induced labor	14 (29.2)	7 (14.3)
Assisted birth	7 (14.6)	11 (22.5)
Cesarean section	9 (18.8)	12 (24.5)
Epidural	35 (72.9)	36 (73.5)
Jaundice	12 (25.0)	17 (34.7)
Insufficient milk production	7 (14.6)	9 (18.4)
Use of bottle	30 (62.5)	29 (59.2)

Note. Data are given as n (%). No differences were found between groups.

Table 2. Descriptive Data for Labor Outcomes and Baby's Age at the Beginning of the Study.

	Control group (n = 48)	Treatment group (n = 49)
Birth weight (g)	3354 (412.9)	3416 (339.9)
Length of labor (hours)[a]	12 (10.53)	10 (8.07)
Time of pushing (min)[a]	49 (55.24)	49 (61.58)
Baby's age at Time 0 (days)	15 (10.38)	15 (10.44)

Note. Data are given as M (SD).
[a] Missing values: length of labor = 1; time of pushing = 6.

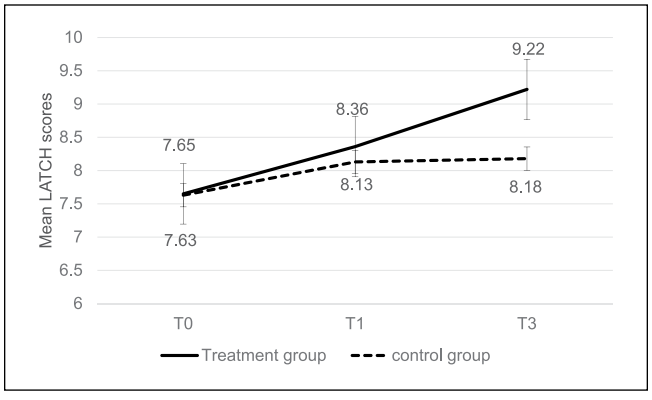

Figure 2. Comparison of mean LATCH scores at the three measurement times.

Table 3. Mothers' Perceptions at Time 3.

	n (%)			
	Control group (n = 48)	Treatment group (n = 49)	χ^2	p
Biting the nipple[a]			9.90	< .042
Similarly	22 (47.8)	12 (25.0)		
Less	5 (10.9)	13 (27.1)		
No longer	1 (2.2)	3 (6.3)		
Opening the mouth[a]			12.18	< .016
Similarly	30 (62.5)	14 (28.6)		
Better	10 (20.8)	17 (34.7)		
No more trouble	4 (8.3)	11 (22.5)		
Slipping on the nipple[a]			17.21	< .002
Similarly	31 (64.6)	14 (28.6)		
Less	5 (10.4)	20 (40.8)		
No longer	2 (4.2)	2 (4.1)		

Note. From the mothers' perspective at Time 3 (3 days), biting the nipple, opening the mouth, and slipping on the nipple were improved in the treatment group compared with the control group (p = .042, p = .016, p = .002, respectively).
[a] Missing values: biting the nipple = 3; opening the mouth = 2; slipping on the nipple = 2.

vasospasm and 60.9% cracked nipples in both groups combined (data not shown). However, pairwise comparisons revealed a significant decrease in pain on the VAS between T1 and T3 in the intervention group (mean change = −1.37, SD = 2.57; p = .001). This was found to be different from the control group (p = .029), but it did not persist to T10 (mean change = 0.37, SD = 2.58; p = .850).

Using the self-administered questionnaire data (mothers' perspectives), there were statistically significant differences between the two groups regarding their infant's ability to open their mouth widely, nipple biting, and the tendency for the infant's mouth to slip on the nipple (see Table 3).

No serious or unexpected side effects were reported by mothers at T10. Some infants (16.5%) exhibited behavioral modifications during the days following the treatment. Mothers of babies receiving the osteopathic treatment reported that their infants slept better, appeared soothed, or better enjoyed lying on their back, whereas they had been perceived as uncomfortable before the osteopathic treatment.

Of note, mothers could not accurately guess to which group their infant was allocated. Sixty percent of mothers from the control group thought they had been allocated to the treatment group, whereas 71% of mothers in the treatment group thought they had been allocated to the treatment group (p = .303).

Discussion

This study highlights that a single osteopathic treatment coupled with usual care (lactation consultations) for infants with biomechanical sucking difficulties is more effective to improve latch and sucking than usual care alone. Mothers also perceived an improvement in breastfeeding their infants in terms of comfort and infant's ability.

In most industrialized countries, rates of initiation and duration of exclusive breastfeeding are suboptimal compared with World Health Organization recommendations. Mothers experiencing breastfeeding difficulties due to biomechanical sucking dysfunctions in their infants might seek help, as the public health message that breastfeeding is best for infants is well known. International Board Certified Lactation Consultants are concerned about these dyads, as their numbers have grown along with the enhancement of breastfeeding rates. The biomechanics of sucking is better known and understood (Colson, Meek, & Hawdon, 2008; Elad et al., 2014; Geddes et al., 2012; Genna, 2015; Genna & Barack, 2010; McClellan et al., 2008; Sakalidis et al., 2013), and it is suggested that manual therapies could be helpful in cases where babies have biomechanical difficulties latching properly (Lee, 2011; Wescott, 2004). Our study contributes to the emerging field of research around the potential benefit of osteopathy for mechanical breastfeeding difficulties using a randomized controlled trial.

Osteopathy is based on the concept that the body is a unit and that a structural dysfunction will affect physiological function (World Health Organization, 2010). Pizzolorusso et al. (2013) published a retrospective study of data describing the cranial dysfunctions found in a population of preterm and term babies admitted to a neonatal intensive care unit in Italy. They found that 36.8% of infants had compression and strain of the sphenobasilar synchondrosis. Frymann (1966) evaluated 1,250 infants at 5 days of age, without exclusion criteria, and found compression of the occipital bone in 68.6% of cases. These studies were conducted on a general population of babies. The rather high proportion of cranial dysfunction observed in this trial points toward a correlation between such dysfunctions and sucking difficulties, as observed by Lalauze-Pol (2009). To our knowledge, this assumption has never been tested.

Because most infants in this trial presented with occipital dysfunctions, we assume that rebalancing the occipital bone or tissues related to it (e.g., suboccipital muscles, occipito-temporal suture) can enhance the range of motion of the head (e.g., extension, rotation) and free the hypoglossal nerve, which is essential for tongue movements. This could explain the improvement of the L and H items on the LATCH score, which particularly focus on movement of the head and facial structures. This is consistent with Lalauze-Pol (2009), who proposed assessment of upper cervical vertebra and skull sutures where cranial nerves emerge. Carreiro (2006) and Sergueef (2007) both argued that compression during pregnancy or the birth process can affect the hyoid bone, which is involved in sucking coordination and tongue stability. Finally, Landouzy and colleagues (2009) discussed the imbalance between the tongue and the upper jaws in newborns.

The LATCH assessment tool was found to be user friendly and is widely used in clinical practice and scientific research due to its sensitivity and ability to identify dyads who might benefit from specialized support. In this study, the improvement in the average LATCH score in the treatment group indicated a statistically and clinically significant effect after a single osteopathic treatment. Moreover, the comparisons of individual LATCH items indicated that the intervention enhanced the infant's ability to open the mouth, extend the tongue, seal the lips around the areola, move the jaws rhythmically, and extend and rotate the head to grasp the breast. The three other items (A, T, and C) are related to the infant's efficacy but can also be time dependent. For example, if the baby was not efficient, the mother's milk production could be affected and, thus, swallowing could still be diminished at the time of assessment. Mothers' perceptions from questionnaires at T3 were congruent with these findings.

Regarding the mothers' nipple pain, a statistically significant improvement was observed in the treatment group between T1 and T3, but this did not last over time. Some points could be raised to better understand this. Mean baseline nipple pain ranged from 3 to 4 out of 10 at T0, which is a relatively low level of pain. Although this will help to generalize the results to a broader population of dyads experiencing biomechanical sucking difficulties, having screened mothers for a higher level of pain, such as 7 out of 10 (which is commonly considered as severe pain), could perhaps have resulted in significant differences. On the other hand, cracked nipples take some time to resolve despite lactation support.

We designed a pragmatic intervention (single treatment) to maximize participation and to limit the number of required in-person encounters. Although we found a statistically significant improvement in terms of latching (using the LATCH assessment tool and mothers' perceptions), results were suboptimal with regard to reduction of pain levels. An initial osteopathic treatment at a younger age, a second osteopathic treatment within a few days, or another lactation consultation within a shorter time frame all merit consideration. Indeed, we can imagine that treatment at a younger age would prevent infants from having poor sucking habits for a relatively extended period of time. Our cohort of infants was on average 15 days old. An osteopathic treatment at an earlier time after birth may have had a sustainable effect on infants, but this remains to be explored.

According to Tornese et al. (2012), any infants scoring below 10 on the LATCH tool should be provided with lactation support. As IBCLCs are recognized as an effective support for mothers experiencing breastfeeding difficulties (Patel & Patel, 2015), an additional visit between T3 and T10 may have further enhanced mothers' and infants' abilities in

terms of proper latch and positioning. A second osteopathic treatment may also be beneficial following 1 week, to support rebalancing structures involved in sucking. The combination of lactation and osteopathic consultations seems to be promising and the potential complementary roles of these two professions should be further explored.

Some pathologies may also need more time to resolve (e.g., cracked nipples) or would benefit more from a treatment targeted to the mother (vasospasm can be caused by the infant's improper latch and/or the mother's condition). The potential benefit of osteopathy for these conditions remains to be adequately studied.

Finally, no serious or unexpected side effects were reported in this study when the IBCLC phoned the parents at T10. This is consistent with the limited findings existing worldwide in osteopathic pediatric practice (Barry & Falissard, 2012; Cerritelli et al., 2013; Fawkes, Leach, Mathias, & Moore, 2010).

The involvement of a single osteopath could have been a potential information bias despite the conducting of a pilot study including calibration tests to attempt to minimize this bias. This, however, had the advantage of optimizing the consistency of our osteopathic results.

A strong pre-existing collaborative network and the involvement of community nurses and community IBCLCs were effective to target and refer infants with biomechanical sucking difficulties (Lamontagne, St-Pierre, & Hamelin, 2008). The mean age of infants in our cohort was 15 days. An earlier intervention may well have further improved infant sucking skills (LATCH score of 10) and nipple pain and could be the focus of a future study.

Conclusion

These results provide a first step to better understand how osteopaths can support mother–infant dyads experiencing biomechanical sucking difficulties. It opens the way to exploring the efficacy of collaborative work involving IBCLCs. International Board Certified Lactation Consultants routinely collaborate with many stakeholders in the perinatal field. Although local practices may differ, integrating osteopaths in the IBCLCs' network could be helpful when babies experience biomechanical sucking difficulties. These findings suggest that a single osteopathic treatment coupled with lactation consultation is effective to reduce biomechanical sucking difficulties in infants younger than 6 weeks. Positive results observed in sucking efficacy need to be confirmed by subsequent studies.

Future research in the area of biomechanical sucking dysfunctions should focus on identifying mother–infant dyads who would most benefit from an osteopathic treatment. Birth conditions and immediate sucking behavior as well as easily detected babies' bodies' attitudes such as torticollis or asymmetric jaws could be assessed. Where osteopaths and lactation consultants are available, an in-hospital screening tool could be created and research conducted with infants younger than 2 weeks.

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Declaration of Conflicting Interests

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