The Effect of Tongue-Tie Revisions on Breastfeeding Outcomes

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Abstract

A short and thickened lingual frenulum characterizes tongue-ties. Infants with this condition are likely to have issues with their latch, weight gain, and the ability to breastfeed exclusively. Mothers typically struggle with nipple pain and trauma. Tongue-tie procedures have become increasingly more popular as families turn to this intervention when struggling with breastfeeding. The purpose of this quality improvement project is to collect data on tongue-tie revision procedures to explore the benefits, risks, and patient satisfaction with the clinical process. Questionnaires were created to collect information on tongue-tie revisions. Participants were asked to identify symptoms related both to the mother and infant. The type of feeding was assessed before and after to identify if the tongue-tie revisions increased exclusive breastfeeding. Likert-type scales were used to address maternal nipple pain, overall improvements in breastfeeding, and patient experience. A total of 36 participants completed the pre-op questionnaire, and 22 completed the post-op questionnaires over four months. The results found that this was a low-risk procedure that helped improve breastfeeding or maternal and infant symptoms. There should be continued efforts to find ways to continue to collect this data, as it will increase the awareness of tongue-tie's effect on breastfeeding.

Keywords: breastfeeding, tongue-tie, frenotomy, lactation

Tongue-Tie Revision Effect on Breastfeeding

Research has shown that breastfeeding is the best nutritional option for infants (Martin et al., 2016). Unfortunately, breastfeeding can be challenging, with many factors that play a role in breastfeeding success. Ankyloglossia or tongue-tie is a congenital abnormality characterized by a short and thickened lingual frenulum that results in limitation of tongue mobility (Wakhanrittee et al., 2016). The topic of tongue-ties has become increasingly popular as families turn to this intervention when looking for help in their breastfeeding journey. With resistance from some healthcare providers, who may not understand the procedure and its benefits for breastfeeding, it is essential to understand the data supporting it. This paper will review the research of tongue-tie revisions to explore the benefits, risks, and ability to help women breastfeed longer.

Problem Statement

The American Academy of Pediatrics recommends that infants be exclusively breastfed for the first six months with the continuation of breastfeeding alongside the introduction of complementary foods for at least one year (CDC, 2018). Approximately 84% of mothers initiate breastfeeding in the US. However, less than 50% of infants are exclusively breastfed at three months, and about 25% are exclusively breastfed at six months, according to the 2018 CDC Breastfeeding Report Card. Healthy People 2020 objectives were created to improve these numbers through high-quality breastfeeding services and support (CDC, 2018).

Ankyloglossia prevents the tongue from extending beyond the lip; this often results in ineffective latching, sucking, and swallowing (Jin et al., 2018). Infants with this condition are likely to have increased breastfeeding difficulty, including issues with their latch, weight gain, and the ability to breastfeed exclusively. Mothers will struggle with nipple pain and trauma due to a poor latch (Ghaheri et al., 2017). The incidence of infants with tongue-ties ranges from 1 to

11% of infants, with 25% of those having difficulty breastfeeding (Illing et al., 2019; Wakhanrittee et al., 2016). According to CADTH (2016), the rate of frenotomy increased by 89% from 2004 to 2013, rising from 2.8 to 5.3 per 1000 live births. Frenotomy is the procedure to correct tongue-ties and help decrease breastfeeding issues. Currently, there is limited education and training provided to health care providers in assessment, treatment, and referral of tongue-ties. Jin et al., (2018) found that nurses and allied health professionals were more likely than doctors and dentists to agree that feeding difficulties are caused by tongue-tie. They also found that resistance is due to lack of training, the belief that breastfeeding education and support are more important, and the belief that the frenotomy procedure has no impact on lactation (Jin et al., 2018). With the increasing rates of tongue-tie revisions, data collection is necessary to ensure infants receive the most up-to-date, evidence-based breastfeeding support and interventions.

There are a limited number of standardized diagnostic tools for health care providers to use, but they are not routinely used during primary care visits. According to Rowan-Legg (2015), a survey of otolaryngologists, pediatricians, dentists, speech pathologists, and lactations consultants reported significant disparities within and among these groups concerning their approach to tongue-ties and their beliefs regarding its association with feeding, speech, and social problems. Because there is a lack of strong evidence between tongue-tie and resolution of breastfeeding problems, there are wide variations in rates of frenotomy (Brandão et al., 2018). Without the support of evidence-based data, infants with tongue-ties and breastfeeding difficulties will continue to struggle with breastfeeding.

Purpose and Rationale

Breastfeeding has been shown to have many health benefits for children and mothers. It reduces childhood illnesses such as acute otitis media, asthma, atopic dermatitis, and

gastrointestinal infections. Positive maternal outcomes include reduced risk of breast and ovarian cancer and type 2 diabetes (Bibbins-Domingo et al., 2016). This paper will look at the use of frenotomy to investigate if it can help increase rates of exclusive breastfeeding in Arizona. Furthermore, the collection of post-procedural data will help support this intervention, help educate other healthcare providers, and ensure that the current process provides the best outcomes for patients and breastfeeding longevity.

Background and Significance

With the increase in tongue-tie procedures, it is important to understand the research on risk and benefits. Increased awareness and education on this topic can help identify infants early to prevent early cessation of breastfeeding and other health-related problems, like poor weight gain, failure to thrive, and reflux. A literature review was completed to identify research studies, position papers, and health initiatives that address the topic of tongue-tie revisions and breastfeeding.

Mother-Infant Dyads

The American Academy of Pediatric Dentistry (AAPD) released a policy statement regarding the increased frequency of frenotomy and its support for additional research on this topic. There are many symptoms reported when women seek breastfeeding support. They found the most common symptoms to be poor or shallow latch, slow or poor weight gain, reflux, irritability from swallowing too much air, prolonged feeding times, poor seal leading to leaking milk, clicking or smacking noises during feedings, and painful nursing (AAPD, 2019). Other symptoms reported in the literature review included mastitis, early weaning of breastfeeding, difficulty to maintain breastfeeding, restlessness when feeding, difficulty maintain latch, frequent

feedings, persistent sore and cracked nipples, and concerns regarding later speech problems (Sharma & Jayaraj, 2015; Billington et al., 2018; Muldoon et al., 2017).

Collection of Post Frenotomy Data

The evaluation of studies in this review included studies within the past five years. These studies focused on identifying if symptoms would improve after frenotomy, identifying if the intervention increased the time women exclusively breastfeed, and identifying any complications after the procedure. In these studies, data was collected preprocedural and post-procedural with follow-ups ranged from 24 hours to 6 months. Braccio et al., (2016) reported a decrease in symptoms, including nipple pain, prolonged feedings, fussiness at the breast, and shallow latch. Ghaheri et al., (2017) found in their study that moms reported an increase in the milk transfer rate, along with a reduction in nipple pain and reflux symptoms. In studies where nipple pain was assessed using a standardized 0-10 pain scale, nipple pain decreased by 3-4 points (Wakhanrittee et al., 2016; Illing et al., 2019; Muldoon et al., 2017). Illing et al., (2019) also found that feeding times reduced on average from 39 minutes a feeding to 20 minutes after the procedure.

Post frenotomy data collection showed that 80-85% of mothers had immediate improvement in breastfeeding at two weeks and complete resolution of feeding symptoms at three months (Billington et al., 2018; Benoiton et al., 2016; Muldoon et al., 2017). An increase of exclusive breastfeeding was found at three months to be between 49-68% and 56% at six months which are higher than the state and national average for exclusive breastfeeding rates (Dollberg et al., 2014; Braccio et al., 2016; Billington et al., 2018). The studies demonstrated that tongue-tie revisions are a safe, quick procedure that can be carried out in an outpatient setting with immediate benefit to breastfeeding (Sharma & Jayaraj, 2015; Benoiton et al., 2016). Finally, the studies reported no cases of post-procedure bleeding, infection, or ulceration and no incidence of

life-threatening or persistent complications (Braccio et al., 2016; Illing et al., 2019; Billington et al., 2018).

Future Practice

Findings suggest frenotomy should be offered to infants with confirmed tongue-ties with breastfeeding difficulties (Billington et al., 2018; Braccio et al., 2016). The AAPD (2019) supports the use of laser technology as it has demonstrated a shorter operative time, better ability to control bleeding, decreased intra- and post-operative pain and discomfort, fewer complications, no need for suture removal, and an increase in patient acceptance.

An improvement project can help prevent problems before they arise by deeply understanding the process of care and allows clinics to search for better ways to improve patients' and families' lives (Frankel et al., 2017). Feedback from patients helps provide data that can be input in various reporting systems to share information, generate insight, and prompt action and learning (Frankel et al., 2017). The studies in this review collected data with in-person appointments or phone calls. One study used pre-stamped envelopes, and two used web-based questionnaires to collect data. Implementation of data collection using one of these methods can help collect information on patient satisfaction, outcomes, and adverse reactions.

Internal Evidence

In a breastfeeding clinic in the southwestern US, a family nurse practitioner owns and operates the clinic with several International Board-Certified Lactation Consultants (IBCLC). The electronic medical record does not track the total number of procedures performed; however, frequency data can be pulled from billing spreadsheets. On average, this clinic completes 125 tongue/lip tie procedures per month. The families are scheduled for at least one follow-up 1-week post-procedure appointment and any additional appointments as needed for lactation

support. Close to 90% of infants return at one week. The office also allows for patients to stop in at any time for a wound check. Preoperative questionnaires are collected on every patient and are stored in binders. No data is currently being collected from those questionnaires. Currently, no long-term follow-ups are completed to support frenotomy in improving breastfeeding issues and address rates of exclusive breastfeeding at three months post-procedure. A process will need to be constructed that allows for an easy response from patients, a process that will not cause an increase in work for staff, and a process that allows for easy access and evaluation of data; to reach the goal of implementing long-term data collection for this clinic. Using the following PICOT question will drive the project that will achieve these goals.

PICOT Question

In mother-infant dyads (P) how do tongue-tie revision (I) compared to no revision (C) affect breastfeeding symptoms, length of exclusive breastfeeding, and satisfaction of patient outcomes (O) in a 12 weeks (T) quality improvement project?

Search Strategy

This literature review included an exhaustive search in the electronic databases PubMed, Cumulative Index of Nursing and Allied Health Literature (CINAHL), and the Cochrane Library. These databases were chosen for their relevance to healthcare topics and availability to provide current evidence to answer the PICOT question.

Inclusion criteria focused the search on English language studies that were dated from 2014 to present. Exclusion criteria included articles greater than five years, opinion articles, and case studies. Inclusion criteria allowed studies in English and studies from multiple countries that were primary research studies. Inclusion and exclusion criteria were consistent for all database searches.

Keywords included infants, tongue-tie, ankyloglossia, breastfeeding, frenotomy, patient outcomes, treatment outcomes, pain relief, symptom reduction, and alternative words for each of these key terms. Key terms for the type of tool used for frenotomy and the term exclusively breastfeeding were excluded as it reduced results significantly. These search tactics provided a focused selection of literature to assess by reading the title and abstracts.

A search of PubMed using keywords newborns, breastfeeding, tongue-tie, and frenotomy generated 109 results. Additional terms including patient outcomes, treatment effectiveness, and symptom reduction narrowed results to 61. Date restriction narrowed results to 37. A search of CINAHL using keywords newborns, breastfeeding, tongue-tie, and frenotomy generated 55 results. Date restrictions lower results to 42. The Cochrane Library search using keywords newborns, breastfeeding, tongue-tie, and frenotomy resulted in 14 results. A total of 93 studies were reviewed and narrowed down to 26 full-text copies of relevant studies. The reference list of each study was scanned to identify any relevant studies on this topic. Rapid appraisals were completed, outlined inclusion and exclusion criteria evaluated to produce the ten most relevant and highest quality studies to answer the PICOT question.

Critical Appraisal and Synthesis

The final ten studies included three control trials, and the remaining seven studies were lower levels of evidence, including prospective cross-sectional studies, prospective cohort studies, and retrospective cohort studies. Control trials are infrequent on this topic, as it can be considered unethical to withhold an intervention that could be beneficial to the infant. Furthermore, most infants in the control trials received the intervention shortly after the experimental group, preventing any long-term follow-up on breastfeeding outcomes. Melnyk and

Fineout-Overholt (2019), a rapid appraisal was used to evaluate the studies and find the most appropriate research that supported the PICOT question.

These final studies were organized into an evaluation table to identify similarities and differences between the supporting evidence (see Appendix A, Table A1). Three studies identified funding from a hospital or clinic and one from the National Institute for Health Research. No bias was reported. All studies except one were conducted internationally, emphasizing the need for increased research on this topic locally. Five studies were outpatient, four were inpatient, and one included both (see Appendix A, Table A2). The authors identified no theoretical or conceptual models in these studies. The studies' limitations included subjective maternal responses, bias in the interview process, and a small sample size in the control trials.

Multiple types of measurement tools were used in these studies to measure breastfeeding problems and improvement. Five used validated measurement tools, four used questionnaires created by the researchers, and one used both (see Appendix A, Table A2). Due to the lack of tongue-tie-specific tools, some research studies created a questionnaire to measure post-procedure outcomes. The infants included in all studies examined in this review showed homogeneity as all had been diagnosed with tongue-ties and had breastfeeding difficulties. The age limits were all under six months, except for one study that looks at infants over 12 months (see Appendix A, Table A2). The intervention variable was the frenotomy procedure in all ten studies. Dependent variables were highly focused on maternal nipple pain and an overall improvement in breastfeeding. Three studies looked at an increase in exclusive breastfeeding and the length of exclusive breastfeeding. Other variables included reflux, feeding method, feeding type, and milk intake (see Appendix A, Table A2).

Conclusion of Critical Review

Overall, results supported the use of frenotomy as an intervention to help the reduction of nipple pain and improve breastfeeding. Minimal to no adverse events were reported, and no reports of significant complications occurred from the procedure. Evidence supports that this procedure is safe and should be recommended to any infant diagnosed with a tongue-tie and having breastfeeding difficulties. Increased training on assessment and diagnosis will increase recognition of this problem and help more women breastfeed longer.

Theoretical Model and Implementation Framework

The theory of unpleasant symptoms by Elizabeth R. Lenz is a middle-range theory that will help guide the intervention (see Appendix B, figure B1). This theory has three major components: the symptoms that the individual is experiencing, the influencing factors that give rise to or affect the nature of the symptom experience, and the consequences of the symptom experience (Lenz et al., 1997). This model allows for more than one symptom to be experienced simultaneously, which are affected by physiologic, psychologic, and situational factors and, in turn, affect the performance and success of breastfeeding. There are many symptoms experienced as women struggle with breastfeeding, as identified above. These symptoms often indicate that pathology exists, including breast abnormalities, hormone imbalance, the anatomy of the breast and oral cavity, fatigue, stress, pressure from society, and lack of family support. The relationship between symptoms is not necessarily straightforward or simple (Lenz et al., 1997). These factors can exacerbate symptoms and lead to low milk supply and the cessation of breastfeeding. With tongue-tie revision and breastfeeding support, this clinic aims to alleviate the factors that are causing the symptoms that lead to negative performance outcomes.

The model chosen for this project is the Donabedian Model (see Appendix B, figure B2), a quality improvement model created by Avedis Donabedian, MD. The three aspects of this

model include structure, process, and outcomes to examine health services and evaluate health care quality (Ibn El Haj, Lamrini, & Rais, 2013). The structure identifies the personnel and the setting where the care takes place. The process looks at the activities taking place during the delivery of care. It identifies the application of current medical science and technology to maximize the balance between benefit and risk. These activities include accuracy of diagnosis, appropriateness of therapy, complications of treatment, and care coordination between different disciplines involved. Outcomes assess the outcome measures, which seek to capture whether the goal of care was achieved (Ibn El Haj et al., 2013).

The Donabedian model of structure, process, and outcome will be applied to the process of collecting post-procedural data to ensure positive outcomes. Each component of this model is influenced by the previous, making the components interdependent (Gardner, Gardner, & O'Connell, 2014). The model will evaluate (1) the clinical site and personal involved (structure), (2) the current process of tongue-tie revision (process), and (3) identify if the outcomes reflect the quality of care based on data collection (outcomes). Outcomes are measured through health status, length of exclusive breastfeeding, patient satisfaction, and decreased breastfeeding symptoms (Gardener et al., 2014).

Implication for Practice

Evidence supports the use of tongue-tie revisions in infants having breastfeeding difficulties. In many pediatric primary care offices, breastfeeding concerns are not commonly addressed, and infants are not assessed for barriers to breastfeeding. The theory of unpleasant symptoms supports the identification of interventions, not just alleviate the unpleasant symptom but also provide feedback that will alter factors that are causing the symptoms and increase the success rate of breastfeeding. The creation of a post-procedural questionnaire that identifies how

symptoms have improved, rates of exclusive breastfeeding, any adverse reactions, and satisfaction with the process will help identify any improvements needed in the clinics' process. An online survey would be ideal for convenience for patients and ease of data collection. Survey engines such as SurveyMonkey can be used due to the convenience of being online and the capability to send reminders for moms to complete the survey. Working closely with the clinic staff is necessary to identify the best options to implement that can be continued in the future.

Potential Outcomes

Outcomes of this project will help the clinic identify areas of improvement needed in the clinical process, additional support needed by parents, the intervention's effectiveness, and the success in the length of exclusive breastfeeding compared to the state average. These improvements will be based on patient experience and satisfaction with care. Utilizing this model for quality improvement looks at the entire clinic from the structure, staff, and process. The information collected in this project can be shared in the future with other providers to help support tongue-tie revisions as a beneficial breastfeeding intervention. It can increase awareness of the incidence of tongue ties and the need for primary care providers to assess infants for this as a barrier to breastfeeding. Lastly, the information gathered regarding the use of tongue-tie revisions can be used to spread awareness of tongue-tie revisions to mothers in the community, including more families with different racial or socio-economic backgrounds.

Methods

This quality improvement project will be surveying mothers regarding their infants' tongue-tie revision outcomes and experience. The intervention of a tongue-tie revision is an established part of the clinic; there will be no change to the current process. The care of these infants will not be affected by this project. Its purpose is to implement a way that the clinic can

start collecting post-tongue-tie revision data and evaluate the patients' satisfaction with the process. The population will include breastfeeding mother-infant dyads who are having difficulty with breastfeeding, and the infant diagnosed with a tongue-tie.

Implementation and Data Collection

Four questionnaires will be developed to address the project's evaluation questions. After a review of similar studies on the topic of tongue-tie revisions, along with input from the clinic, a questionnaire was created that allows the clinic to gather information on tongue-tie revisions, information on improving processes, and patient satisfaction. For four weeks, the first questionnaire was collected during the tongue-tie revision procedure appointment. This first questionnaire collected demographic information and pre-procedure data, including maternal and infant symptoms, if the infant is on any medications and feeding methods. A second questionnaire was collected at the 1-week follow-up appointment or through a 1-week REDCap questionnaire. This questionnaire repeats questions to address current feeding methods, if the infant is currently on medications, current maternal and infant symptoms, and if the infant had any complications related to the procedure. A questionnaire was sent through REDCap at one month, that repeated questions to address current feeding methods, if the infant is currently on medications, current maternal and infant symptoms, and if the infant had any complications related to the procedure. Furthermore, this questionnaire addressed the overall experience with the procedure and the clinic. It asks for short answers to questions about changes they would like to see with the clinic and satisfaction with the procedure. It addressed how the families felt about the information and support they received from the staff. Lastly, a fourth questionnaire was sent through REDCap 3-months after the procedure; it repeated questions to address current feeding methods, if the infant is currently on medications, current maternal and infant symptoms, and if

the infant had any complications related to the procedure. It also asked questions about an overall improvement in breastfeeding, complications, rating of their overall experience and answer questions about improvements or changes they would like to see in the future. Furthermore, it addressed how the families felt about the information and support they received from the staff.

Creating a questionnaire that reflects the information already collected by the clinic allows for a complete understanding of outcomes related directly to this clinic. No standardized questionnaire is available that would address the many aspects of this project. Additionally, it was decided that having pre-procedure and post-procedure questionnaires to compare answers to see if patients had positive outcomes with the procedure will increase the validity of the results. Open-ended questions about patient experience and satisfaction will provide valuable feedback for the clinic. This clinic's overall goal is to implement a process of continued data collection to allow for continuous evaluation of patient outcomes and patient satisfaction.

IRB

There is minimal risk for mothers to participate in this project, as it will only involve patient follow-up to determine procedural outcomes. Also, there are no foreseeable risks, discomforts, or inconveniences related to participation in this project. Participation in this study is voluntary, so participants can choose not to participate or to withdraw from the study at any time. Responses will be confidential, and personal identification information will be secured and not shared with anyone outside the clinic. This quality improvement project received IRB expedited approval to collect tongue tie revision data and quality improvement information.

Budget

Direct cost includes printing professional-colored copies of the questionnaires completed in person and the project introduction documents that inform families about the project, and a

release of information form. These will need to be printed at approximately 40¢ per page. The follow-up questionnaires will be online and will not have a cost associated with them. Indirect costs include staff training on introducing the project to patients. Data collection will be completed through REDCap, which does not have a fee for its use. Time to review and analyze data by the FNP, requesting this information be collected (see Appendix C).

No funding was received for this project. The student will cover any direct costs, and the clinic will cover indirect costs. An increase in supportive data collection on the benefits of tongue-tie revisions will increase community support for the procedure. With increased community support, there could be an increase in the number of patients requesting this procedure in the future and increase revenue for the clinic. Most insurance companies cover the tongue-tie procedures, or it is around $300 out of pocket.

Results

Participants

Thirty-six participants enrolled to participate in this quality improvement project. Eighteen responded to the 1-week questionnaire, nineteen responded to the 1-month questionnaire, and eighteen responded to the 3-month questionnaire. The average maternal age was 32 years old with a range of 23 to 42 years old. The infants who had the procedure done were on average 40 days with a range of 2 to 103 days old. Of the 36 infants enrolled, it was reported that 18 were girls and 17 were boys, and one gender was missing. Gestational age at birth included three preterm, born before 37 weeks, and 33 full-term births. 42% (n=17) mothers reported never breastfeeding before, and 50% (n=18) had breastfed at least one infant before, one mother did not report. 69% (n=25) were Caucasian, 19% (n=7) were Hispanic/Latino. The remaining 11% (n=4) reported as Asian, Black/African, or other (see Appendix D, Table D1).

Mothers' Complaints

The participants were asked to rate their nipple pain on a scale of 0-10, 0 meaning no pain, and 10 meaning severe pain. Pre-procedure 33% (n=12) reported pain of 5 and above; at 1-week post-procedure, only 13% (n=2) reported pain 5 and above. 0% reported pain of 5 and above at one month and three months post-procedure. Pre-procedure 20% (n=7) reported 0 pain and at 3 months 67% (n=12) reported 0 pain ($\chi 2$=4.437, p=0.015).

A Repeated Measures ANOVA was conducted to determine whether there were significant differences among the pain scales pre-procedure, 1-week, 1-month, and 3-months. The results were examined based on an alpha of 0.05. Pre-procedure pain scale was significantly greater than 1-month pain scale ($t(11) = 3.33$, $p = .029$), pre-procedure pain scale was significantly greater than 3-month pain scale ($t(11) = 3.78$, $p = .014$), 1-week pain scale was significantly greater than 1-month pain scale ($t(11) = 3.17$, $p = .038$), and 1-week pain scale was significantly greater than 3-month pain scale ($t(11) = 4.02$, $p = .009$). Table 5 presents the marginal means contrasts for the Repeated Measures ANOVA (see Appendix D, Table D2).

The participants were asked to report if they experienced nipple trauma. Pre-procedure 54% (n=19) has reported nipple trauma, at 3-months fewer participants 11% (n=2) reported nipple trauma ($\chi 2$=3.265, p=0.017). There was a reported incidence of 17% (n=6) of participants who reported mastitis pre-procedure and only 6% (n=1) who reported mastitis at 3 months post procedure ($\chi 2$=3.95, p=0.047). Bobbing on and off breast was reported 72% (n=26) pre-procedure and 50% (n=9) at 3-months ($\chi 2$=5.844, p=0.016) (see Appendix D, Table D3). Poor or incomplete breast drainage was reported 44% (n=23) pre-procedure and 28% (n=5) at 3 months ($\chi 2$=5.294, p=0.021). Signs of reflux: chronic spitting up, gassiness, or vomiting was reported in

61% (n=22) pre-procedure and 33% (n=6) at 3 months (χ2-4.00, p=0.046) (see Appendix D, Table D4).

The 1-month questionnaire showed a decrease in participants reporting symptoms from pre-procedure to 1-month post-procedure. 55% fewer participants reported fussiness at the breast, 52% fewer reported poor latch, 50% fewer reported poor & incomplete breast drainage, 48% fewer reported chronic burping & flatulence, 100% fewer reported distended or bloated belly, 43% fewer reported signs of discomfort, 56% fewer reported bobbing on and off the breast, and 46% fewer reported shallow latch. For maternal symptoms, 69% fewer reported nipple trauma, 58% fewer reported breast swelling or clogged ducts, and 71% fewer reported mastitis (see Appendix D, Table D5).

Participants were asked has there been an improvement in symptoms since the release of the tongue-tie. At 3-months 50% (n=9) reported significant improvement compared to 22% (n=4) at 1-week post-procedure (χ2=4.205, p=0.009). At 1-week 66% (n=12) and at 3-months 89% (n=16) reported moderate to significant improvement in symptoms. No participants reported no improvement or worse symptoms.

Participants were asked to describe any complications after the procedure. The responses included partial reattachment, scar tissue that had to be massaged out, one infant refused to latch for 48 hours, Arnica (a homeopathic remedy for pain) gave one infant green mucus bowel movement and an upset stomach. One participant reported colitis and GERD as a complication.

Satisfaction

The participants were asked if they would choose to have the procedure again; all 19 said yes. The reasoning for choosing again included participants reporting breastfeeding as better, easier, helping tremendously, and improved. One said, “it saved breastfeeding for us”, another

stated, “because the pain was unbearable, and I did nothing with my firstborn and suffered for months”. Three participants reported hope for benefits in the future, long-term outcomes, and prevention of negative consequences related to having a tongue tie into adulthood.

Participants were asked what they would change about the appointment. A majority said they would change nothing. One reported they would have liked “more guidance about different ways to improve latch” and more time and education from the provider who did the procedure. They were also asked what information they wished they knew before the procedure. Most participants said that they needed no additional information. Others wished they understood the healing process and the extra attention needed to prevent reattachment; how unpleasant the post-procedure stretches are; that they would be next to the procedure room and hear all the infants crying; that the baby would be uncomfortable for 3-4 days; how much pressure to use for the exercises. One other wished she knew the infant had a tongue-tie sooner.

The participants were asked if they would recommend this procedure to another mother with an infant with a tongue tie. 32% (n=5) responded they would likely refer, and 63% (n=12) responded highly likely; only one responded they were neutral, and none responded they were unlikely to respond. They were also asked what advice they would give to another mom whose infant had a tongue-tie. Many participants responded supporting the release, stating it was worth it, get it done early, or as young as possible, to be patient with the healing process, do the exercises, research pros and cons and trust your provider. One participant reported, “breastfeeding will be so much better afterward; just patiently wait for the baby to learn how to latch and suck properly”. Other advice included “it will not be an instant fix and not feel guilty if reattachment happens and to keep trying, despite the challenges”. The majority of the advice recommended the tongue-tie release.

Participants were asked how many follow-up appointments they had after the procedure. The follow-up appointments ranged from 0-4 appointments, with 95% (n=18) had at least one follow-up. When asked if this was enough support, 89% (n=17) felt they had enough support.

Discussion

The data collection results showed the majority of patients were satisfied with the procedure and the clinic supports. Areas identified for improvement include increased education related to the post-procedure exercises. When a tongue-tie procedure is completed, still providing education on breastfeeding techniques the moms can work on at home. Furthermore, providing a better understanding of how the infant will handle the procedure during the initial days.

The findings of this data collection revealed positive outcomes and benefits from the tongue-tie procedure. The clinic can treat this as a pilot study on how to implement this on a larger scale. The clinic would need to collect data over more time to allow for more participants to enroll. Ideally, entirely online would allow for easy organization and interpretation of the data. Simplifying the data collection to preprocedural and 1-month post-procedure may increase participation and provide the best data since, at one week, the family is still adjusting to the released tongue. At three months, many factors are playing into the results.

The results found mothers reported higher pain rates before the procedure as indicated on the numerical rating pain scale. It was also shown that more women had no pain (score of 0) after the procedure was completed. With the infant able to create a proper latch, the maternal nipples will heal from the trauma and experience less pain. Maternal symptoms of nipple trauma and mastitis had decreased by 3 months. Maturation of the infant can influence the finding at 3 months, with infant growth and development breastfeeding can become easier and more natural.

Furthermore, mothers reported a decrease in infant symptoms after the procedure, including signs of a poor latch, with bobbing on and off the breast. Mothers reported an increase in breast drainage after the procedure. Once the infant has learned to use the full range of the tongue, they can more effectively remove milk from the breast. They also reported a decrease in reflux signs, including chronic spitting up, gassiness, or vomiting, which represent many complaints primary care providers see in the clinic.

Participants reported satisfaction with the procedure with minimal adverse events. They supported the procedure and would likely refer another mother who has a tongue-tied infant. Almost all participants had at least one follow-up appointment and felt they had enough support after the procedure. Due to a lack of return responses, there was not enough information to determine if there was a change in types of feeding or increases in the length of exclusive breastfeeding.

Overall, the collection of this data can be used to support this procedure and help educate other health care providers. When an infant shows signs of reflux or if the mom complains of pain, providers in the community should consider tongue-tie in their differential diagnosis. Increased awareness can lead to increased education, their ability to assess and treat or refer an infant with a tongue-tie.

Limitations, Barriers, and Strengths

There are some limitations to this project. There was no control group of infants who had a tongue-tie and did not receive the procedure, missing data, a small number of participants. Time restriction for recruitment and collection of data was limited to 4 months. The questionnaires used were not standardized, and participants were not randomized. Barriers to this project included issues with staff follow-through and limitations due to the pandemic. Lastly, the

data collected was entirely maternal self-reported, strengthening the findings as women experience firsthand challenges with breastfeeding and are in the best place to notice any changes.

Conclusion

Similar to the findings in the literature review. The tongue-tie procedure is a quick, low-risk procedure that helped improve breastfeeding, along with maternal and infant symptoms. There should be continued efforts to find ways to continue to collect this data, as it will increase the awareness of the tongue-tie effect on breastfeeding. Since breastfeeding is the gold standard of infant nutrition, helping women be successful is the goal. This project showed that a tongue-tie revision may help improve maternal and infant symptoms. Furthermore, there was positive feedback about the clinical process and support provided to the participants. Lastly, the participant feedback was supplied to the clinic for review and assessment toward the clinic goals.

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Appendix A

Evaluation and Synthesis Tables

Table A1

Evaluation Table of Quantitative studies

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement/ Instrumentation	Data Analysis	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Wakhanrittee et at., (2016) The outcomes of a frenulotomy on breastfeeding infants followed up for 3 months at Thammasat University Hospital **Funding:** Thammasat University Hosp. **Bias:** None recognized. **Country:** Thailand	Not stated	**Design**: Prospective cross-sectional study **Purpose:** Assess effects of fren. on NP, latch and EBF	**N: 328** **Sample Demographics:** Maternal: Age m (29.61 y.o.), Number of children in family 1-4 Infant: Sex, age at fren. M (50 hrs.), birth weight m (3.102 g), present weight m (3.102 g), severity of TT. **Inclusion Criteria:** Born at hosp., < 1 mo., presence of TT dx by pediatric surgeons, presence of BF problem BF problems: Maternal NP, nipple	**IV:** Fren. **DV1:** NP **DV2:** Latch **DV3:** EBF rates	LATCH score 5-item ($\alpha = 0.70$) Numeric rating scale	Paired sample t-test, Wilcoxon sign-rank test, Fisher's exact test, Student's t-test or Mann-Whitney U test, risk ratio Data analyzed using STATA11.0	**DV1:** Pain score decreased (MD = 3 and 4, P <0.001 **DV2:** LATCH score was sig. inc. (MD = 1.92 and 2.13, $p < 0.001$ **DV3:** EBF at 3 mo. was 66.67%	**LOE: IV** **Strength:** Use of standardized measurement tools **Limitations:** EBF rates could be influenced by the 3 mo. maternity leave in Thai. No control group **Harm:** Not stated **Conclusion:** Fren. could sig. reduce NP, inc. LATCH score and positively associated with

avg. – average; **BF** – breastfeeding; **CI** – confidence intervals; **CG** – control group; **DV** – dependent variable; **dx** – diagnosed; **EBF** – exclusive breast feeding; **EG** – experimental group; **Fren.** – Frenotomy; **g** – grams; **hosp.** – hospital; **hrs.** – hours; **improv** – improvement; **inc.** – increase; **IQR** – interquartile range; **IV** – independent variable; **LOE** – level of evidence; **LT**- Lip tie; **M** – Median; **m –** mean; **MD** – mean difference; **min.** – minute; **mo.** – month; **N** – number of participants; **n** – number in each group; **NP** – nipple pain; **RCT** – random control trial; **Sig.** – significantly; **TT** – tongue-tie; **VAS** – Visual analog scale; **wk.** – week; **Wks.** – Weeks; **y.o.** – years old

			trauma, infant unable to suck, unable to form seal and sucked air, tongue could not reach areola. **Exclusion Criteria:** Mothers who had contraindications for bf, who had an emergency condition, or severe critical illness.					the success of EBF.
Ghaheri et al., (2017) Breastfeeding improvement following tongue-tie and lip-tie release: A prospective cohort study **Funding:** None **Bias:** None stated **Country:** United States	Self-Efficacy Theory - inferred	**Design**: Prospective cohort study **Purpose:** Determine the impact of surgical TT release on BF impairment	**N:** 237 **Sample Demographics:** Infant age m (4.4 wks.), (86% white/Caucasian, (56%) were male, (75%) had hosp. births, (84%) delivered vaginally **Inclusion Criteria:** Currently BF, infant ≤12 wks. of age and ≥37 wks. gestational age, infant went surgical correction of upper lip tie to TT. **Exclusion Criteria:** Infants with life-threatening	**IV:** Lingual fren. and/or maxillary labial fren. **DV1:** GERQ-R **DV2:** VAS pain scale **DV3:** Breastmilk intake	Self-Efficacy Scale-Short Form (α = 0.95) VAS for pain Revised Infant Gastroesophageal Reflux Questionnaire (α = 0.86-0.87)	Two-tailed test, Paired sample t-test or Wilcoxon F test Statistical comparison using SPSS	**DV1:** GERQ-R (F (2) = 85.3; P < .001) **DV2:** VAS pain scale (F (2) = 259.8; P < .001) **DV3:** Breastmilk intake improv 155% from 3.0 to 4.9 ml/min (P < .001)	**LOE: IV** **Strength:** Use of standardized measurement tools **Limitations:** No control group The study does not account for complementary treatments infants may receive. **Harm:** Not stated **Conclusion:** Surgical release resulted in sig. improv at 1 wk. and 1 mo. post-op

avg. – average; **BF** – breastfeeding; **CI** – confidence intervals; **CG** – control group; **DV** – dependent variable; **dx** – diagnosed; **EBF** – exclusive breast feeding; **EG** – experimental group; **Fren.** – Frenotomy; **g** – grams; **hosp.** – hospital; **hrs.** – hours; **improv** – improvement; **inc.** – increase; **IQR** – interquartile range; **IV** – independent variable; **LOE** – level of evidence; **LT**- Lip tie; **M** – Median; **m –** mean; **MD** – mean difference; **min.** – minute; **mo.** – month; **N** – number of participants; **n** – number in each group; **NP** – nipple pain; **RCT** – random control trial; **Sig.** – significantly; **TT** – tongue-tie; **VAS** – Visual analog scale; **wk.** – week; **Wks.** – Weeks; **y.o.** – years old

			comorbid conditions, previous treatment for TT or LT by another provider, multiple births, and mothers with previous breast surgery or insufficient glandular tissue					
Muldoon at al., (2017) Effect of frenotomy on breastfeeding variables in infants with ankyloglossia (tongue-tie): A prospective before and after cohort study **Funding:** None **Bias:** None recognized. **Country:** Ireland	Not stated	**Design**: Prospective before and after cohort study **Purpose:** Determine associated effects of fren. on BF variables in infants with TT.	**N:** 98 **Sample Demographics:** Postpartum women over 18 y.o. Infant age m (7 wks. 3 days) **Inclusion Criteria:** Infants undergoing fren. at 7 healthcare clinics **Exclusion Criteria:** Participant did not return survey	**IV:** Fren. **DV1:** Pain **DV2:** LATCH scale **DV3:** Improv in BF	Modified version of LATCH scale Questionnaire developed by researcher	Descriptive statistics Z-test	**DV1:** Pain VAS scale: (pre-fren. m 5.6 (SD 3.3) verses post-fren. m 2.7 (SD 2.6); MD -2.90, 95% CI -3.75 to -2.05) **DV2:** LATCH scale: (MD 0.50; 95% CI 0.33 to .067) **DV3:** Improv in BF: 91% reported overall improv	**LOE: IV** **Strength:** Maternal self-reporting **Limitations:** Unable to calculate sample size. Use of non-standardized measurement tools Self-report involves a level of recall which leads to bias. Use of non-standardized measurement tools. **Harm:** Not stated **Conclusion:** Fren. has positive effects on BF

avg. – average; **BF** – breastfeeding; **CI** – confidence intervals; **CG** – control group; **DV** – dependent variable; **dx** – diagnosed; **EBF** – exclusive breast feeding; **EG** – experimental group; **Fren.** – Frenotomy; **g** – grams; **hosp.** – hospital; **hrs.** – hours; **improv** – improvement; **inc.** – increase; **IQR** – interquartile range; **IV** – independent variable; **LOE** – level of evidence; **LT**- Lip tie; **M** – Median; **m –** mean; **MD** – mean difference; **min.** – minute; **mo.** – month; **N** – number of participants; **n** – number in each group; **NP** – nipple pain; **RCT** – random control trial; **Sig.** – significantly; **TT** – tongue-tie; **VAS** – Visual analog scale; **wk.** – week; **Wks.** – Weeks; **y.o.** – years old

								variables in infants with TT.
Braccio et al., (2016) Tongue-tie division. Is it worth it? A retrospective cohort study **Funding:** No funding received **Bias:** None stated **Country:** United Kingdom	Not stated	**Design**: Retrospective cohort survey **Purpose:** Assess value of fren. On impact of BF related problems	**N: 272** **Sample Demographics:** Infants age 2 wks. to 5 mo. **Inclusion Criteria:** Suspected tongue tie with BF problem **Exclusion Criteria:** No TT, TT with no BF problems	**IV:** Fren. **DV1:** Feeding method **DV2:** Pain **DV3:** Frequent/prolonged feeds	Standard questionnaire	Not stated	**DV1:** Feeding method EBF at 48h (P<0.0001, OR = 4.857, 95% CI 2.120-12.983) Formula use at 48h (P= 0.2812, OR = 0.632, 95% CI 0.280-1.370) **DV2:** Pain at 48h (P<0.0001, OR = 0.013, 95% CI 0.000-0.074) **DV3:** Frequent/prolonged feeds (P<0.0001, OR 0.027, 95% CI 0.003-0.101)	**LOE: IV** **Strength:** Not stated **Limitations:** Single center study Questionnaire was non-standardized and subjective **Harm:** No cases of major bleeding, infection, or ulceration **Conclusion:** Frenotomy is a safe surgical procedure with low complication rate
Illing et al, (2019) The value of frenotomy for ankyloglossia from a parental perspective **Funding:** Hokowhitu Medical Centre	Self-Efficacy Theory - inferred	**Design**: Prospective survey **Purpose:** Effects of fren. and impact on BF	**N: 176** **Sample Demographics:** Infants age m (44 days), maternal age m (30 yrs.,) Male (109), Female (67), and infant ethnicity **Inclusion Criteria:** Infant with confirmed TT	**IV:** Fren. **DV1:** Inc. in fully BF infants **DV2:** Feeding time **DV3:** NP	Pre-procedure questionnaire Follow-up phone call.	Data processed with EXCEL Analysis used a general inductive analysis approach Quantitative analysis using Stata and paired T-test	**DV1:** Inc. in fully BF infants, (statistics not reported) **DV2:** Feeding time from 39 min. to 20 min. (p value <0.0001) **DV3:** NP avg. improvement of 3.3 points, (statistics not reported)	**LOE: IV** **Strength:** Significant sized population High follow-up rate (89%) **Limitations:** No control population, Measures reported

avg. – average; **BF** – breastfeeding; **CI** – confidence intervals; **CG** – control group; **DV** – dependent variable; **dx** – diagnosed; **EBF** – exclusive breast feeding; **EG** – experimental group; **Fren.** – Frenotomy; **g** – grams; **hosp.** – hospital; **hrs.** – hours; **improv** – improvement; **inc.** – increase; **IQR** – interquartile range; **IV** – independent variable; **LOE** – level of evidence; **LT**- Lip tie; **M** – Median; **m –** mean; **MD** – mean difference; **min.** – minute; **mo.** – month; **N** – number of participants; **n** – number in each group; **NP** – nipple pain; **RCT** – random control trial; **Sig.** – significantly; **TT** – tongue-tie; **VAS** – Visual analog scale; **wk.** – week; **Wks.** – Weeks; **y.o.** – years old

Bias: No known bias **Country:** New Zealand			receiving fren, for feeding issues **Exclusion Criteria:** Prior fren. that reattached					were parental experience **Harm:** No ongoing significant adverse events **Conclusion:** Fren. For infants with TT and BF issues appears to be a safe and effective practice
Sharma et al. (2015) Tongue-tie division to treat breastfeeding difficulties: Our experience **Funding:** No funding received **Bias:** None stated **Country:** United Kingdom	Self-Efficacy Theory - inferred	**Design**: Control trial **Purpose:** Determine benefits of fren. and determine the influence of age	**N:** 42 **n:** 36 (EG) **n:** 6 (CG) **Sample Demographics:** Age M (38 days), gender 23 males 19 females, BF history, and status of fren. procedure **Inclusion Criteria:** infant diagnosed with TT **Exclusion Criteria:** No TT	**IV:** fren. **DV1:** Improvement in BF DV2: Infant BF assessment tool score	Infant BF assessment tool (Inter-rater reliability of 91%)	Fisher's exact test and paired student's t-test Significance was set at $p<0.05$ using GraphPad Software	**DV1:** Improvement in BF (EG) 81% reported improv BF (CG) 17% reported improv BF ($P = 0.0074$) **DV2:** (EG) Pre-fren. score was 3.33 ± 1.51 vs. 9.19 ± 2.44 post-fren. ($p = 0.0001$) (CG) Pre-fren. score 4.17 ± 0.75 vs. 6.00 ± 1.73 post-fren. ($p = 0.16$)	**LOE: III** **Strength:** Has control group Used a validated assessment tool, findings similar to previous studies **Limitations:** Small number of patients, nature of telephone survey introduces selections bias, no blinding **Harm:** No surgical complications **Conclusion:** Fren. is a safe, short procedure

avg. – average; **BF** – breastfeeding; **CI** – confidence intervals; **CG** – control group; **DV** – dependent variable; **dx** – diagnosed; **EBF** – exclusive breast feeding; **EG** – experimental group; **Fren.** – Frenotomy; **g** – grams; **hosp.** – hospital; **hrs.** – hours; **improv** – improvement; **inc.** – increase; **IQR** – interquartile range; **IV** – independent variable; **LOE** – level of evidence; **LT**- Lip tie; **M** – Median; **m –** mean; **MD** – mean difference; **min.** – minute; **mo.** – month; **N** – number of participants; **n** – number in each group; **NP** – nipple pain; **RCT** – random control trial; **Sig.** – significantly; **TT** – tongue-tie; **VAS** – Visual analog scale; **wk.** – week; **Wks.** – Weeks; **y.o.** – years old

								with low morbidity that improves BF outcomes
Billington et al., (2017) Long-term efficacy of a tongue tie service in improving breast feeding rates: A prospective study **Funding:** Evelina Children's Hospital **Bias:** None stated **Country:** United Kingdom	Not Stated	**Design**: Prospective study **Purpose:** Determine the 3-mo. BF rates in infants after attending TT clinic	**N: 87** **Sample Demographics:** Infant age 2-88 days, **Inclusion Criteria:** Infants with confirmed TT and difficulty establishing BF **Exclusion Criteria:** infant did not require fren, and infant requiring second fren.	**IV:** Fren. **DV1:** Improvement in BF **DV2:** Type of feeding	Phone interviews	Not stated	**DV1:** Improvement in BF Complete resolution 80% Moderate resolution 15% Minimal resolution 5% **DV2:** Type of feeding EBF- 49% BF with formula supplement 41% Formula feeding 10%	**LOE: IV** Strength: Findings similar to previous study **Limitations:** Questionnaire was non standardized **Harm:** Not stated **Conclusion:** Fren should be offered to infants with confirmed TT with BF difficulties
Dollberg et al., (2014) Lingual frenotomy for breastfeeding difficulties: A prospective follow-up study	Not stated	**Design**: Prospective study **Purpose:** Evaluate BF for 6 months after fren.	**N:** 264 **Sample Demographics:** Gender 143 male 101 females, birth order, all Jewish parentage, age (1-135 days) **Inclusion Criteria:**	**IV:** fren. **DV1:** Length of BF	Phone interview	Mann-Whitney test Fisher's Exact test Chi-square test Statistical analyses was performed using SAS for Windows 9.2 software	**DV1:** Length of BF 2 wks. 75% 3 mos. 68% 6 mos. 56%	**LOE: IV** **Strength:** large sample size **Limitations:** Subjective maternal data, interview may introduce bias, selection not random

avg. – average; **BF** – breastfeeding; **CI** – confidence intervals; **CG** – control group; **DV** – dependent variable; **dx** – diagnosed; **EBF** – exclusive breast feeding; **EG** – experimental group; **Fren.** – Frenotomy; **g** – grams; **hosp.** – hospital; **hrs.** – hours; **improv** – improvement; **inc.** – increase; **IQR** – interquartile range; **IV** – independent variable; **LOE** – level of evidence; **LT**- Lip tie; **M** – Median; **m –** mean; **MD** – mean difference; **min.** – minute; **mo.** – month; **N** – number of participants; **n** – number in each group; **NP** – nipple pain; **RCT** – random control trial; **Sig.** – significantly; **TT** – tongue-tie; **VAS** – Visual analog scale; **wk.** – week; **Wks.** – Weeks; **y.o.** – years old

Funding: No funding received **Bias:** None stated **Country:** Israel			No congenital abnormalities **Exclusion Criteria:** No other exclusion criteria					**Harm:** Minimal bleeding/pain No noticeable complications **Conclusion:** There is favorable long-term effects of fren. upon the prevalence and length of BF
Berry et al., (2012) A Double-blind, randomized, control trial of tongue-tie division and its immediate effect on breastfeeding **Funding:** None stated **Bias:** None exist **Country:** United Kingdom	Not stated	**Design**: Double blind randomized control trial **Purpose:** To investigate if a maternally reported, immediate improv in BF following fren. due to a placebo effect	**N:** 60 **n:** 27 (EG) **n:** 30 (CG) **Sample Demographics:** Age m (32 days), gender 23 males 19 females, BF history, and status of fren. procedure **Inclusion Criteria:** <4 mos. old, symptoms of BF problem, TT present **Exclusion Criteria:** No TT	**IV:** Fren. **DV1:** Improved feeding **DV2:** Maternal pain	LATCH score 5-item ($\alpha = 0.70$) Infant BF assessment tool (Inter-rater reliability of 91%) Pain Numeric Score	Two tailed Mann-Whitney U Test Two group x^2 test with a 0.05 two-sided significance level will have 80% power to detect the difference between success Statistical analysis: SPSS for Windows version 11 and Analyse-it. CI calculated using CI Analysis (CIA) Software.	**DV1:** Improved feeding – (EG) 78% (CG) 47% (P < 0.02, 95% CI, 6-51%) **DV2:** Maternal pain – (EG) avg. pain score decreased from 4.1 to 1.6, change of -2.5 (SD±1.9) (CG) avg. pain score decrease from 4.2 to 2.9, change of -1.3 (SD±1.5) (Not sig. at p = 0.13 95% CI, -.03 to 2.4)	**LOE: III** **Strength:** Has control group Used a validated assessment tool **Limitations:** None stated **Harm:** Complications reported in 5%, none sig. **Conclusion:** RCT found that the maternally reported, immediate improv in BF after fren. is real and not a placebo effect.

avg. – average; **BF** – breastfeeding; **CI** – confidence intervals; **CG** – control group; **DV** – dependent variable; **dx** – diagnosed; **EBF** – exclusive breast feeding; **EG** – experimental group; **Fren.** – Frenotomy; **g** – grams; **hosp.** – hospital; **hrs.** – hours; **improv** – improvement; **inc.** – increase; **IQR** – interquartile range; **IV** – independent variable; **LOE** – level of evidence; **LT**- Lip tie; **M** – Median; **m –** mean; **MD** – mean difference; **min.** – minute; **mo.** – month; **N** – number of participants; **n** – number in each group; **NP** – nipple pain; **RCT** – random control trial; **Sig.** – significantly; **TT** – tongue-tie; **VAS** – Visual analog scale; **wk.** – week; **Wks.** – Weeks; **y.o.** – years old

Edmond et al., (2014) Randomized controlled trial of early frenotomy in breastfeeding infants with mild-moderate tongue tie **Funding:** National Institute for Health Research (NIHR) **Bias:** None exist **Country:** United Kingdom	Not stated	**Design**: randomized, parallel group, pragmatic trial **Purpose:** To determine if immediate fren. was better than standard BF support.	**N:** 107 **n:** 55 (EG) **n:** 52 (CG) **Sample Demographics:** Term infants <2 wks. old **Inclusion Criteria:** Infant with mild to moderate degree TT, difficulty BF HATFF score of 6-12 LATCH score <8 **Exclusion Criteria:** Infant > 2wks, prematurity) <37 wks.), congenital orofacial malformations, and infant weight loss (>10% birth weight)	**IV:** Fren. **DV1:** HATLFF **DV2:** LATCH score **DV3:** IBFAT score **DV4:** BSES **DV5:** Pain VAS score	Hazelbaker Assessment tool for Lingual frenulum Function-(HATLFF-short form) ($\alpha = 0.86$) LATCH scale – 4 item ($\alpha = 0.74$) Infant BF assessment tool (IBFAT) (Inter-rater reliability of 91%) BF self-efficacy score- short form ($\alpha = 0.95$) Pain VAS score	Mann-Whitney test x^2 test or Fisher's Exact test	DV1: HATLFF 0-5 days (EG) 4.5(IQR 3.3-6) (CG) 0 (IQR 0-2.3) (p= < 0.0001) DV2: LATCH score 0-5 days (EG) 1 (IQR 0-2) (CG) 1 (IQR 0-2) (p= 0.52) DV3: IBFAT score 0-5 days (EG) 0 (IQR -1.8 to 1.0) (CG) 0 (IQR 0-1) (p= 0.36) DV4: BSES 0-5 days (EG) 9 (IQR 1.8-12.9) (CG) 1 (IQR -4 to +7.5) (p= 0.002) 5 days- 8 wks. (EG) 3 (IQR 0-13) (CG) 10 (IQR 2-18) (p= 0.082) DV5: Pain VAS score 0-5 days (EG) -2 (IQR -3 to 0.4) (CG) -1 (IQR 13.5-1) (p= 0.09) 5 days-8 wks. (EG) -2 (IQR -3 to -1) (CG) -2 (IQR -3.5 to -0.6) (p= 0.83)	**LOE: III** **Strength:** Has control group Used a validated assessment tool **Limitations:** Measures used to assess BF were insensitive in picking up difficulties in attachment **Harm:** No adverse events **Conclusion:** Early fren. did not result in an objective improv in BF but was associated with improved self-efficacy.

avg. – average; **BF** – breastfeeding; **CI** – confidence intervals; **CG** – control group; **DV** – dependent variable; **dx** – diagnosed; **EBF** – exclusive breast feeding; **EG** – experimental group; **Fren.** – Frenotomy; **g** – grams; **hosp.** – hospital; **hrs.** – hours; **improv** – improvement; **inc.** – increase; **IQR** – interquartile range; **IV** – independent variable; **LOE** – level of evidence; **LT**- Lip tie; **M** – Median; **m –** mean; **MD** – mean difference; **min.** – minute; **mo.** – month; **N** – number of participants; **n** – number in each group; **NP** – nipple pain; **RCT** – random control trial; **Sig.** – significantly; **TT** – tongue-tie; **VAS** – Visual analog scale; **wk.** – week; **Wks.** – Weeks; **y.o.** – years old

Table A2

Synthesis table

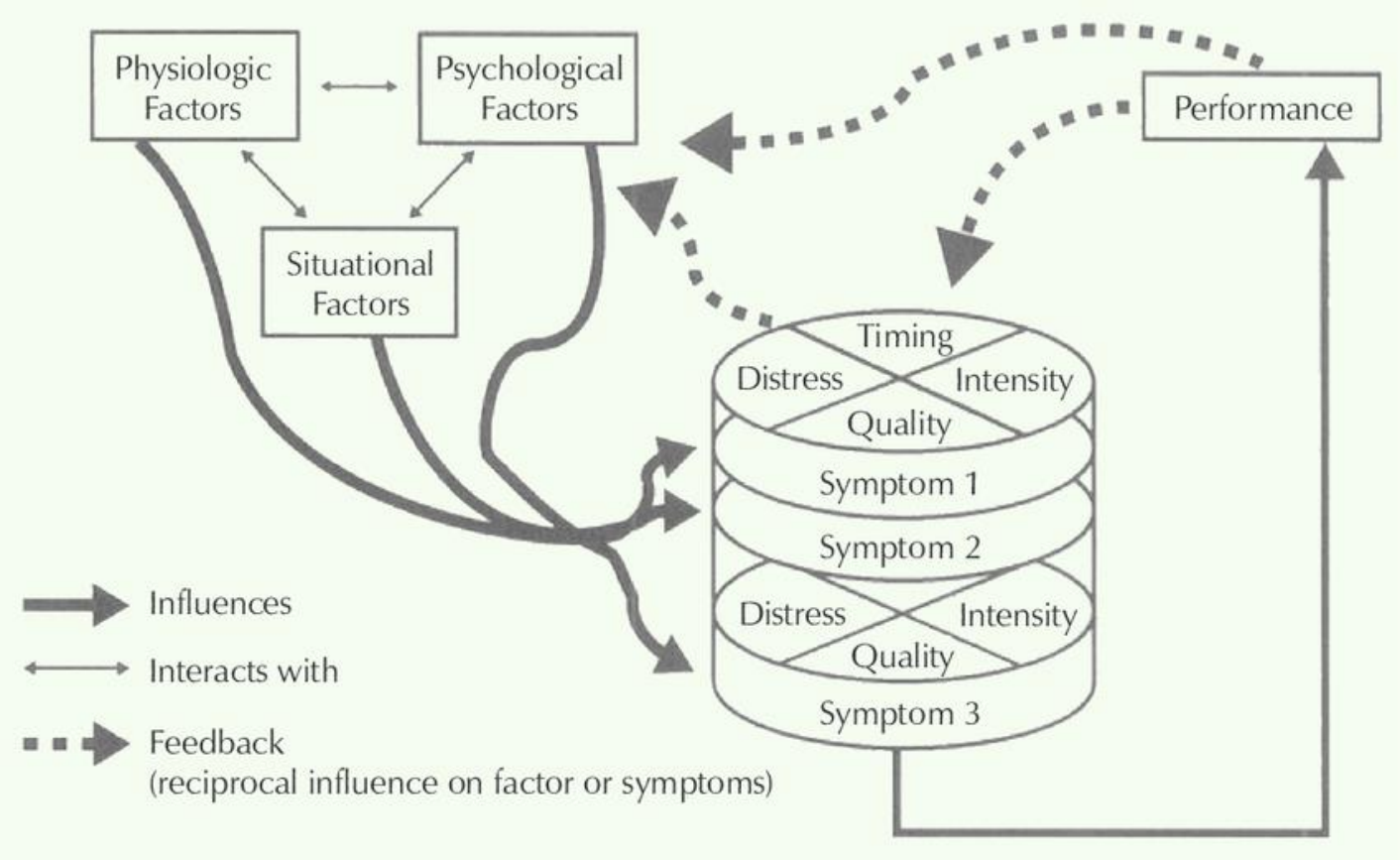
	Wakhanritt ee (2016)	**Ghaheri (2017)**	**Muldoon (2017)**	**Braccio (2016)**	**Illing (2019)**	**Sharma (2015)**	**Billington (2017)**	**Dollberg (2014)**	**Berry (2012)_**	**Edmond (2014)**
LOE	**IV**	**IV**	**IV**	**IV**	**IV**	**III**	**IV**	**IV**	**III**	**III**
Study Design	PCSS	PCS	PCS	RCS	PS	CT	PS	PS	RCT	RPT
Sample Size	**N:** 328	**N:** 237	**N:** 98	**N:** 272	**N:** 176	**N:** 42 **n:** 36 (EG) **n:** 6 (CG)	**N:** 87	**N:** 264	**N:** 60 **n:** 27 (EG) **n:** 30 (CG)	**N:** 107 **n:** 55 (EG) **n:** 52 (CG)
Length	3 mo.	1 mo.	1 mo.	1 mo.	23 days	1 mo.	3 mo.	6 mo.	3 mo.	5 days
Outpatient	X	X	X		X		X	X		
Inpatient	X			X		X			X	X
International	X		X	X	X	X	X	X	X	X
Local		X								
Intervention										
Frenotomy	X	X	X	X	X	X	X	X	X	X
Age Range	< 1 mo.	<6 mo.	0-6 mo.	1 day - 5 mo.	< 6 mo.	>12 mo.	2-88 days	1-135 days	5-115 days	8-16 days
Outcomes										
Nipple pain	↓	↓	↓	↓	↓				↓	↓
EBF rates	↑							↑		
Reflux		↓								
Feeding method				↑			↑			
Feeding time				↓	↓					
Increased in EBF					↑					
Overall BF improvement			↑			↑	↑		↑	
Milk intake		↑								
Measurement tools										
LATCH scale	X	X	X						X	X
IBFAT						X			X	X
BSES		X								X
Pain VAS score		X	X							X
Pain Numeric Score	X								X	
GERQ-R		X								
Personalized questionnaire			X	X	X		X	X		

BF – breastfeeding, **BSES** – breastfeeding self-efficacy scale, **CG** – control group, **CT** – control trial, **EBF** – exclusive breastfeeding, **EG** – experimental group, **GERQ-R** – gastroesophageal reflux questionnaire – revised, **IBFAT** – infant breastfeeding assessment tool, **LOE** – level of evidence, **N** – number of participants, **PCS** – prospective cohort study, **PCSS** – prospective cross-sectional study, **PS** – prospective study, **RCT** – randomized control trial, **RPT** – randomized pragmatic trial, **VAS -** visual analog scale

Appendix B
Models and Frameworks

Figure B1

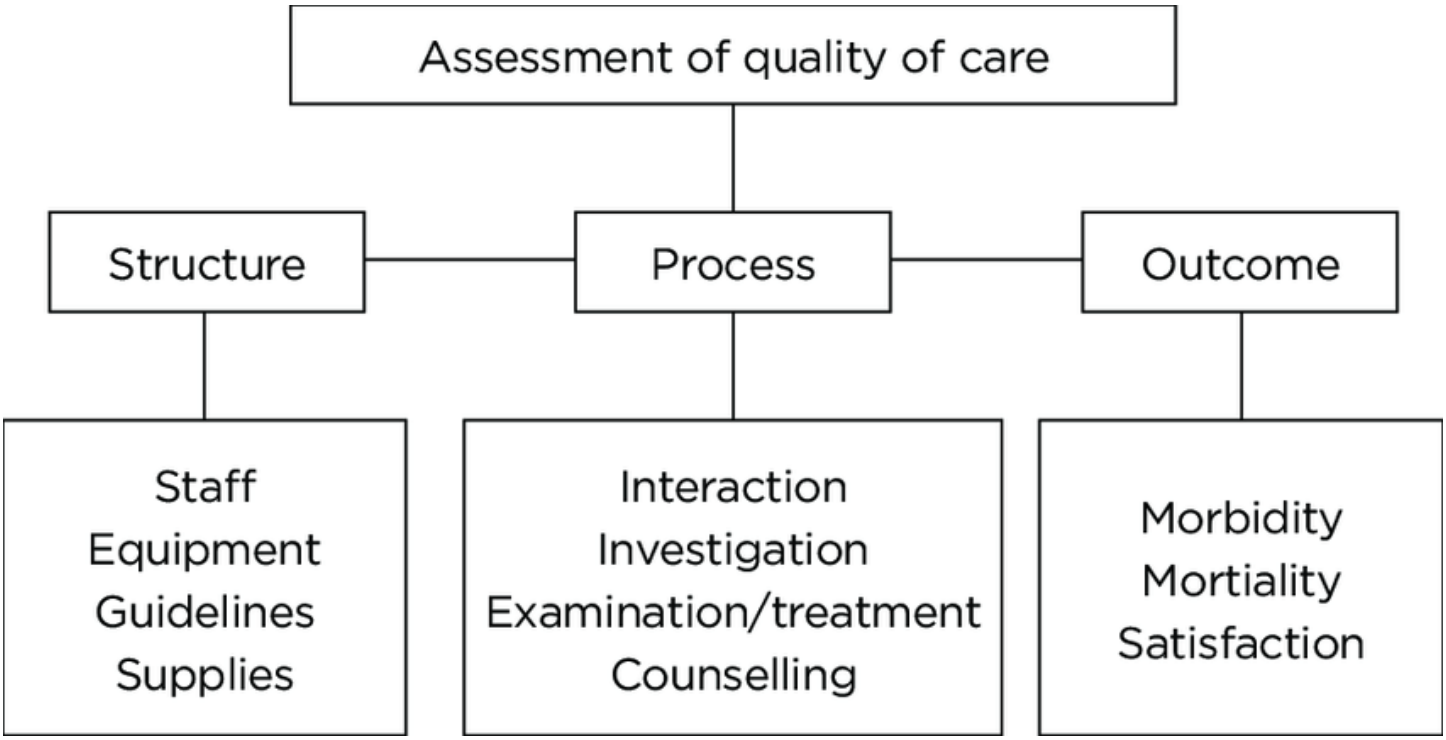
Theory of Unpleasant Symptoms



Lenz et al., (1997).

Figure B2

The Donabedian Model for Assessment of Quality of Care



Kidanto, H. L (2019).

Appendix C
Budget

Phase	Activities	Cost	subtotal
Preparation	Printed copies of first questionnaire, project information form and release of information form. 300 copies at OfficeMax. *Direct Cost	.40 per copy x 300 copies	**$120.00**
	Time for staff meetings IBCLC $30/hr. FNP $50/hr. Support staff $20/hr. *Indirect Cost	$100/hr. x 3 hours	**$300.00**
Delivery	REDCAP *Direct Cost	Free through university	**$0**
Evaluation	Electronic reminders or questionnaire *Direct Cost	Free through REDCAP	**$0**
	Review and analysis of results *Indirect Cost	FNP $50 x 4 hours	**$400.00**
TOTAL			**Direct $120** **Indirect $$700** **$820.00**

Appendix D
Tables

Table D1

Frequency Table for Nominal Variables

Variable	*n*	*%*
Number_previously_breastfed_Q1		
0	17	47.22
1	10	27.78
2	6	16.67
3	2	5.56
Missing	1	2.78
infant_gender_Q1		
Girl	18	50.00
Boy	17	47.22
Missing	1	2.78
gestational_age_Q1		
Preterm	3	8.33
Full term	33	91.67
ethnicity_Q1		
Asian	1	2.78
Black/African	1	2.78
Caucasian	25	69.44
Hispanic/Latino	7	19.44
Other	2	5.56

Table D2

The Marginal Means Contrasts for each Combination of Within-Subject Variables for the Repeated Measures ANOVA

Contrast	Difference	SE	Df	T	p
Pre-procedure pain scale - 1-month pain scale	3.42	1.03	11	3.33	.029
Pre-procedure pain scale - 3-month pain scale	3.33	0.88	11	3.78	.014
1-week pain scale - 1-month pain scale	1.75	0.55	11	3.17	.038
1-week pain scale - 3-month pain scale	1.67	0.41	11	4.02	.009

Note. Tukey Comparisons were used to test the differences in estimated marginal means.

Table D3

Maternal Symptoms	Pre-procedure	3-months	$\chi 2$	P
Nipple trauma	54%	11%	3.265	0.017
Mastitis	17%	6%	3.95	0.047

Table D4

Infant symptoms	Pre-procedure	3-months	$\chi 2$	P
Poor/incomplete breast drainage	44%	28%	5.294	0.021
Bobs on and off breast	72%	50%	5.844	0.016
Signs of reflux	61%	33%	4.00	0.046

Table D5

Maternal Symptoms	*Pre-procedure*	*1-month*	*% of decreased reporting*
nipple trauma	54%	17%	69%
breast swelling or clogged ducts	33%	5%	85%
mastitis	17%	5%	71%

Infant Symptoms	*Pre-procedure*	*1-month*	*% of decreased reporting*
fussiness at the breast	58%	26%	55%
poor latch	78%	37%	53%
gumming/chewing nipple	64%	32%	50%
chronic burping & flatulence	67%	37%	45%
distended or bloated belly	25%	0%	100%
signs of discomfort	56%	32%	43%
reported bobbing on and off the breast	72%	32%	56%
shallow latch	78%	42%	46%