Effective Health Care Program

Comparative Effectiveness Review
Number 149

Treatments for Ankyloglossia and Ankyloglossia With Concomitant Lip-Tie

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None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input.

We welcome comments on this systematic review. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Key Informants

In designing the study questions, the EPC consulted several Key Informants who represent the end-users of research. The EPC sought the Key Informant input on the priority areas for research and synthesis. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest.

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Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicting opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

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Peer Reviewers

Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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Treatments for Ankyloglossia and Ankyloglossia With Concomitant Lip-Tie

Structured Abstract

Objectives. We systematically reviewed the literature on surgical and nonsurgical treatments for infants and children with ankyloglossia and ankyloglossia with concomitant lip-tie.

Data sources. We searched MEDLINE® (PubMed®), PsycINFO®, Cumulative Index of Nursing and Allied Health Literature (CINAHL®) and Embase (Excerpta Medica Database), as well as the reference lists of included studies and recent systematic reviews. We conducted the searches between September 2013 and August 2014.

Review methods. We included studies of interventions for ankyloglossia published in English. Two investigators independently screened studies against predetermined inclusion criteria and independently rated the quality of included studies. We extracted data into evidence tables and summarized them qualitatively.

Results. We included 58 unique studies comprising 6 randomized controlled trials (RCTs) (3 good, 1 fair, 2 poor quality), 3 cohort studies (all poor quality), 33 case series, 15 case reports, and 1 unpublished thesis. Most studies assessed the effects of frenotomy (a procedure in which the lingual frenulum is divided) on breastfeeding-related outcomes. Four RCTs reported improvements in breastfeeding efficacy using either maternally reported or observer ratings, while two RCTs using observer ratings found no improvement. Mothers consistently reported improved breastfeeding effectiveness after frenotomy, but outcome measures were heterogeneous and short term. Future studies could provide additional data to confirm or change the measure of effectiveness; thus, we consider the strength of evidence (SOE; confidence in the estimate of effect) to be low at this time. Furthermore, this literature is characterized by (1) a lack of details about the surgical procedure, (2) cointerventions allowed variably in control groups, and (3) diversity of provider settings. Pain outcomes improved for mothers of frenotomized infants compared with control in one study of 6-day old infants but not in studies of infants a few weeks older. Given these inconsistencies and the small number of comparative studies and participants, the SOE is low for an immediate reduction in nipple pain. Three studies with significant limitations reported improvements in other feeding outcomes with frenotomy, and four poor-quality studies reported some improvements in speech articulation but mixed results related to overall speech sound production. Three poor-quality comparative studies noted some improvements in social concerns and gains in tongue mobility in treated participants. SOE for all of these outcomes is insufficient. SOE is moderate for minor and short-term bleeding following surgery and insufficient for other harms (reoperation, pain).

Conclusions. A small body of evidence suggests that frenotomy may be associated with improvements in breastfeeding as reported by mothers, and potentially in nipple pain, but with small short-term studies, inconsistently conducted, SOE is generally low to insufficient. Comparative studies reported improvements in some measures of speech, but assessment of outcomes was inconsistent. Few studies addressed tongue mobility and self-esteem issues.

Research is lacking on nonsurgical interventions, as well as on outcomes other than breastfeeding.

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Executive Summary

Introduction

Ankyloglossia is a congenital condition characterized by an abnormally short, thickened, or tight lingual frenulum, or an anterior attachment of the lingual frenulum, that restricts mobility of the tongue.[1] It variably causes reduced anterior tongue mobility and has been associated with functional limitations in breastfeeding; swallowing; articulation; orthodontic problems, including malocclusion, open bite, and separation of lower incisors; mechanical problems related to oral clearance; and psychological stress. One review including studies of infants, children, and adults reported rates of ankyloglossia ranging from 0.1 to 10.7 percent,[2] but definitive incidence and prevalence statistics are elusive due to an absence of a criterion standard or clinically practical diagnostic criteria.

Recognition of potential benefits of breastfeeding in recent years has resulted in a renewed interest in the functional sequelae of ankyloglossia. In infants with anterior or posterior ankyloglossia, there is a reported 25- to 80-percent incidence of breastfeeding difficulties, including failure to thrive, maternal nipple damage, maternal breast pain, poor milk supply, maternal breast engorgement, and refusing the breast.[2] Ineffective latch is hypothesized to underlie these problems. Mechanistically, infants with restrictive ankyloglossia cannot extend their tongues over the lower gumline to form a proper seal and therefore use their jaws to keep the breast in the mouth for breastfeeding. Adequate tongue mobility is required for breastfeeding, and infants with ankyloglossia often cannot overcome their deficiency with conservative measures such as positioning and latching techniques, thereby requiring surgical correction.[2]

Nonetheless, consensus on ankyloglossia's role in breastfeeding difficulties is lacking. A minority of surveyed pediatricians (10%) and otolaryngologists (30%) believe it commonly affects feeding, while 69 percent of lactation consultants feel that it frequently causes breastfeeding problems.[3] Therefore, depending on the audience, enthusiasm for its treatment varies. Currently, the U.K. National Health Service and the Canadian Paediatric Society recommend treatment only if it interferes with breastfeeding.[4,5] A standard definition of "interference" with breastfeeding is not provided, leaving room for interpretation and variation in treatment thresholds. The absence of data on the natural history of untreated ankyloglossia further promulgates uncertainty. Some propose that a short frenulum elongates spontaneously due to progressive stretching and thinning of the frenulum with age and use.[1] However, there are no prospective longitudinal data on the congenitally short lingual frenulum. Without this information it is difficult to inform parents fully about the long-term implications of ankyloglossia, thereby complicating the decision-making process.

Although most ankyloglossia research is focused on the infant and breastfeeding issues, concerns beyond infancy include speech-related issues, such as difficulty with articulation, and social concerns related to limited tongue mobility. Individuals with untreated ankyloglossia may experience difficulty with oral mechanism, particularly in relation to licking ice cream, kissing, drooling, playing wind instruments, and licking the lips. Self-esteem or psychological issues may also be a concern for affected older patients.

Treatment Strategies

Ankyloglossia may be treated with surgical or nonsurgical approaches. Surgical modalities include frenotomy, frenulectomy, and frenuloplasty. These interventions involve clipping or

cutting of the lingual frenulum, generally without sedation. Laser frenotomy or frenulotomy has also been described, and proponents argue that its use is more exact and provides better hemostasis than standard frenotomy or frenulotomy. Frenuloplasty, more technically involved than frenotomy or frenulotomy, generally refers to rearranging tissue or adding grafts after making incisions and closing the resultant wound in a specific pattern to lengthen the anterior tongue. Frenuloplasty is most commonly performed under a general anesthetic and used in older infants and children or in more complex frenulum repairs.

Nonsurgical approaches include speech therapy, lactation interventions, and observation to determine if intervention is warranted.

Scope and Key Questions

Scope of the Review

This systematic review provides a review of potential benefits of treatments (surgical and nonsurgical) as well as harms associated with those therapies in individuals with ankyloglossia and tight labial frenulum (lip-tie) concomitant with ankyloglossia. We sought information on outcomes related to breast- and bottle-feeding and related to tongue-tie in later life (e.g., orthodontic and dental issues, speech, self-esteem).

Key Questions

We synthesized evidence in the published literature to address the following Key Questions (KQs):

KQ 1. What are the benefits of various treatments in breastfeeding newborns and infants with ankyloglossia intended to improve breastfeeding outcomes? Surgical treatments include frenotomy (anterior and/or posterior), frenuloplasty (transverse to vertical frenuloplasty), laser frenulectomy/frenulotomy, and Z-plasty repair. Nonsurgical treatments include complementary and alternative medicine therapies (e.g., craniosacral therapy), lactation intervention, physical/occupational therapy, oral motor therapy, and stretching exercises/therapy.

KQ 2a. What are the benefits of various treatments in newborns, infants, and children with ankyloglossia intended to prevent, mitigate, or remedy attributable medium- and long-term *feeding* sequelae, including trouble bottle-feeding, spilling and dribbling, difficulty moving food boluses in the mouth, and deglutition?

KQ 2b. What are the benefits of various treatments in infants and children with ankyloglossia intended to prevent, mitigate, or remedy attributable *other* medium- and long-term sequelae, including articulation disorders, poor oral hygiene, oral and oropharyngeal dysphagia, sleep disordered breathing, orthodontic issues including malocclusion, open bite due to reverse swallowing, lingual tipping of the lower central incisors, separation of upper central incisors, crowding, narrow palatal arch, and dental caries?

KQ 3. What are the benefits of various treatments for ankyloglossia in children through 18 years of age intended to prevent or address social concerns related to tongue mobility (i.e., speech, oral hygiene, excessive salivation, kissing, spitting while talking, and self-esteem)?

KQ 4. What are the benefits of simultaneously treating ankyloglossia and concomitant tight labial frenulum (lip-tie) in infants and children through age 18 intended to improve or remedy breastfeeding, articulation, orthodontic and dental, and other feeding outcomes? What are the relative benefits of treating only ankyloglossia when tight labial frenulum (lip-tie) is also diagnosed?

KQ 5. What are the harms of treatments for ankyloglossia or ankyloglossia with concomitant lip-tie in neonates, infants, and children through age 18?

Analytic Framework

Figure A depicts KQs 1, 4, and 5 within the context of the PICOTS (population, intervention, comparator, outcomes, timing, setting). The figure examines surgical and nonsurgical treatments in neonates and infants to improve breastfeeding outcomes. Intermediate outcomes include maternal nipple pain, ability to latch and maintain latch, tongue mobility, and aerophagia. Final outcomes include duration of breastfeeding, failure to thrive, infant weight gain, and oral and oropharyngeal dysphagia. Harms (KQ 5) may occur at any point after the intervention is received.

Figure A. Analytic framework for ankyloglossia in neonates and infants

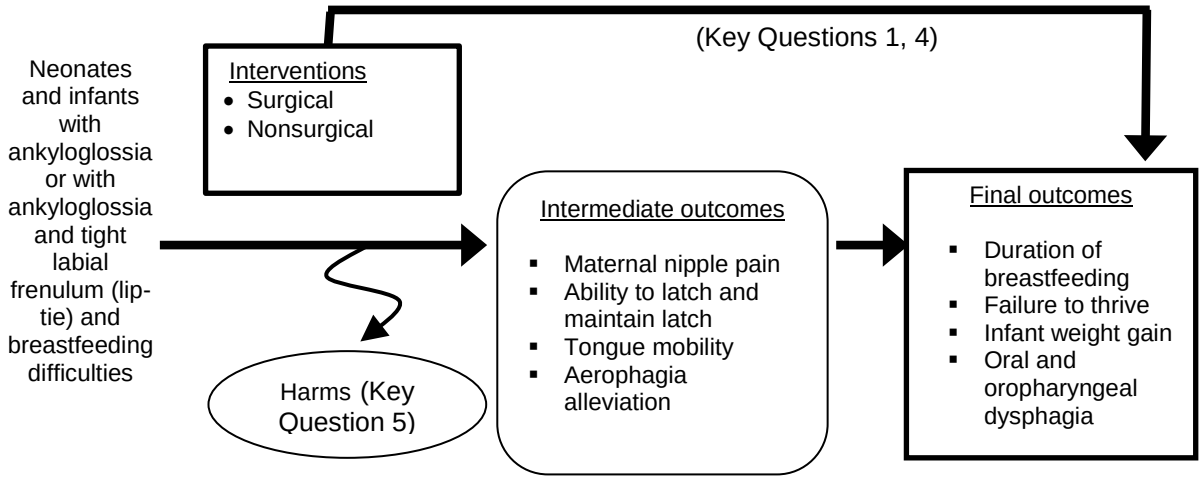
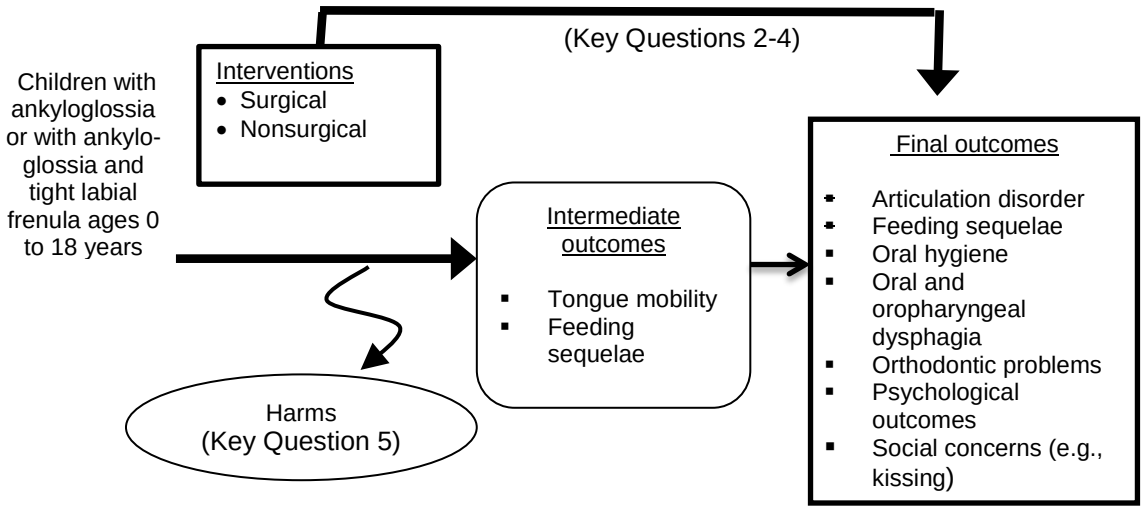


Figure B depicts KQs 2, 3, 4, and 5 within the context of the PICOTS. The figure examines surgical and nonsurgical treatments in infants and children with ankyloglossia (KQ 2, KQ 3) or ankyloglossia with concomitant lip-tie (KQ 4). The intermediate outcomes include maternal nipple pain and tongue mobility, and final health outcomes are articulation disorder, oral hygiene, oral and oropharyngeal dysphagia, orthodontic problems, psychological outcomes, and social concerns, including kissing. Harms (KQ 5) may occur at any point after the intervention is received.

Figure B. Analytic framework for ankyloglossia in infants and children through18 years of age



Methods

Literature Search Strategy

A librarian employed search strategies provided in Appendix A of the full report to retrieve research on interventions for children with ankyloglossia. We searched MEDLINE® via the PubMed® interface, PsycINFO® (psychology and psychiatry literature), the Cumulative Index of Nursing and Allied Health Literature (CINAHL®) and Embase (Excerpta Medica Database). We limited searches to the English language and imposed no publication date restrictions. Our last search was conducted in August 2014. We manually searched reference lists of included studies and of recent narrative and systematic reviews and meta-analyses.

Inclusion and Exclusion Criteria

We developed criteria for inclusion and exclusion in consultation with a Technical Expert Panel (Table A).

Table A. Inclusion criteria

Category	Criteria
Study population	Children ages 0–18 with ankyloglossia or ankyloglossia with concomitant tight labial frenulum (lip-tie); studies with participants with Van der Woude syndrome, Pierre Robin syndrome or sequence, Down syndrome, or craniofacial abnormalities were excluded ,as were studies of premature babies (<37 weeks of gestation[5])
Publication languages	English only
Admissible evidence (study design and other criteria)	Admissible designs Randomized controlled trials, prospective and retrospective cohort studies, nonrandomized controlled trials, prospective and retrospective case series, and crossover studies Case reports to assess harms Other criteria Original research studies providing sufficient detail regarding methods and results to enable use and aggregation of the data and results Studies must address one or more of the following: • Surgical interventions (simple anterior frenotomy, frenulotomy, or frenectomy; laser frenotomy, , or frenulectomy; posterior frenulectomy; Z-plasty repair) • Nonsurgical treatments, including complementary and alternative medicine therapies (e.g., craniosacral therapy, myofascial release, and other chiropractic therapies), lactation intervention, speech therapy, physical therapy, oral motor therapy, and stretching exercises/therapy • Baseline and outcome data (including harms) related to interventions for ankyloglossia Relevant outcomes must be able to be extracted from data in the papers Data must be presented in the aggregate (vs. individual-participant data)

Study Selection

Two reviewers independently assessed each abstract. If one reviewer concluded that the article could be eligible based on the abstract, we retained it for full-text assessment. Two reviewers independently assessed the full text of each included study. Disagreements were resolved by a senior reviewer.

Data Extraction and Synthesis

We extracted data from included studies into an evidence table that reports study design, descriptions of the study populations (for applicability), description of the intervention, and baseline and outcome data on constructs of interest. Data were initially extracted by one team member and reviewed for accuracy by a second. The final evidence table is presented in Appendix D of the full report.

We extracted outcomes for all included studies, and data are presented in summary tables and analyzed qualitatively in the text.

Quality (Risk-of-Bias) Assessment of Individual Studies

We used four tools to assess the quality of individual studies: the Cochrane Risk of Bias Tool for Randomized Controlled Trials;[6] a cohort study assessment instrument based on questions and a tool for case series, both adapted from RTI Item Bank questions;[7] and a four-item harms

assessment instrument for cohort studies derived from the McMaster Quality Assessment Scale of Harms (McHarm) for Harms Outcomes[8] and the RTI Item Bank.[7] The tools are presented in Appendix E of the full report.

Quality assessment of each study was conducted by two team members independently. Discrepancies were adjudicated through discussion between the assessors to reach consensus or via a senior reviewer. The results of these tools were then translated to the Agency for Healthcare Research and Quality standard of "good," "fair," and "poor" quality designations, as described in the full report. Quality ratings for each study are in Appendix F of the full report.

Strength of the Body of Evidence

Two senior investigators graded the entire body of evidence using methods based on the "Methods Guide for Effectiveness and Comparative Effectiveness Reviews."[9] The team reviewed the final strength-of-evidence designation. Strength of evidence is assessed for a limited set of critical outcomes, typically those related to effectiveness of an intervention, and reported in comparative studies.

The possible grades were—

- High: High confidence that the evidence reflects the true effect. Further research is unlikely to change estimates.
- Moderate: Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- Low: Low confidence that the evidence reflects the true effect. Further research is likely to change confidence in the estimate of effect and is also likely to change the estimate.
- Insufficient: Evidence is either unavailable or does not permit a conclusion.

Applicability

Applicability describes issues related to how applicable (generalizable) the included studies are likely to be in practice. We assessed applicability by identifying potential population, intervention, comparator, outcome, and setting (PICOS) factors likely to affect the generalizability of results (i.e., applicability to the general population of children with ankyloglossia). For this particular review, the most likely factors that could affect applicability are the severity/degree of ankyloglossia, age range of participants, setting of intervention (e.g., newborn nursery, outpatient office), and provider (e.g., otolaryngologist, lactation consultant, dentist, pediatrician).

Results

Article Selection

We identified 1,626 nonduplicative titles or abstracts with potential relevance, with 244 proceeding to full-text review (Figure 3 of the full report). We excluded 187 studies at full-text review, which yielded 57 published studies included in the review. We also included one unpublished thesis in our results; thus, the report summarizes data from 58 unique publications.

KQ 1. Benefits of Interventions To Improve Breastfeeding Outcomes

Twenty-nine studies addressed the benefits of surgical treatments intended to improve breastfeeding outcomes; there were no studies of nonsurgical treatments. These studies included five randomized controlled trials (RCTs) conducted in the United Kingdom (n = 3),[10-12] United States (n = 1),[13] or Israel (n = 1)[14] and one poor-quality retrospective cohort study conducted in the United States.[15] We rated the RCTs as good,[10,11,13] fair,[12] and poor[14] quality for outcomes related to breastfeeding effectiveness and maternal pain related to breastfeeding. One poor-quality retrospective cohort study and 23 case series also addressed outcomes of surgical treatment. We focused on RCTs of higher quality in this summary but noted that the lower quality studies typically reported improvements in breastfeeding effectiveness.

Two RCTs compared frenotomy to sham surgery,[11, 13] one to usual care,[10] and one to intensive lactation consultation,[12] and one used a crossover design to compare frenotomy followed by sham surgery to sham surgery followed by frenotomy, with assessment of breastfeeding after each order of intervention (i.e., frenotomy and sham).[14] Similarly, the retrospective cohort study compared frenotomy to usual care.[15] For all studies, sham comparison involved taking infants to an intervention room for the same amount of time as the infants receiving the procedure and then returning them to the mothers.

The earliest reported RCT used nonblinded maternally assessed breastfeeding effectiveness and reported that 96 percent of frenotomized infants had improved feeding within 48 hours, compared with 3 percent in the control group, but this study had significant limitations.[12] In a later RCT, mothers again self-reported improved breastfeeding among infants immediately after frenotomy (78% in the treated group vs. 47% in the comparison group; $p < 0.02$).[11]

Three RCTs used an observer to assess breastfeeding effectiveness. In all three, the observer was blinded to the treatment. Among these,[10,11,13] one reported improvement in breastfeeding effectiveness based on the Infant Breastfeeding Assessment Tool (IBFAT; score range, 0 [poor feeding] to 12 [vigorous and effective feeding]) score immediately postfrenotomy compared with sham treatment (mean, 11.6 ± 0.81 vs. 8.07 ± 0.86; $p = 0.026$).[13] In contrast, in two of the three RCTs, the independent blinded observers did not detect a difference in breastfeeding improvement. Outcomes that failed to show a difference in these two RCTs included percent improvement (50% vs. 40%) immediately after intervention[11] and Latch, Audible swallowing, Type of nipple, Comfort, Hold (LATCH) and IBFAT change 5 days postintervention: LATCH change score median 1 (interquartile range [IQR], 0 to 2) versus median 1 (IQR, 0 to 2); $p = 0.52$ and IBFAT change score 0 (IQR, -1.8 to 1.0) versus 0 (IQR 0 to 1); $p = 0.36$.[10]

One RCT reported significant and immediate improvement in maternally reported nipple pain among frenotomized infants compared with sham treatment.[13] Both remaining RCTs found nonsignificant reductions in maternally reported nipple pain between the frenotomy and sham groups at immediate[11] and 5-day[10] postprocedure assessments. However, in the one study that assessed pain at 5 days (the longest followup), a large number of infants in the control group had crossed over to receive frenotomy before outcomes were assessed.[10]

Harms were rare and nonsignificant, and are discussed in more detail in KQ 5.

KQ 2a. Benefits of Treatments To Mitigate Feeding Sequelae

Three studies examined medium- and long-term benefits related to feeding outcomes and sequelae of various interventions for infants and children with ankyloglossia.[12,16,17] One was an

RCT[12] (fair quality for feeding outcomes) and one was a poor-quality retrospective cohort study;[16] the remaining study was a case series, so it provided no data for comparison.[17]

In one RCT that included bottle-fed infants, 76 percent had major problems with dribbling and 71 percent had "excess wind" (gas). Mothers reported significant improvement in bottle-feeding in all eight infants who received the frenotomy and in none of the nine who did not. The interval to ascertainment of the outcomes was not specifically reported, but outcomes were obtained within the first 4 weeks of life.[12]

The retrospective cohort study compared parent-reported (typically maternal) outcomes at age 3 years for three groups of children born in 2010: children who received frenotomy for tongue-tie (n = 71; frenotomy group); those whose parents were offered frenotomy for tongue-tie for their children but declined it (n = 15; no-frenotomy group); and children without ankyloglossia (n = 18; control group).[16] The frenotomy group performed better than the no-frenotomy group at age 3 years on cleaning the teeth with the tongue, licking the outside of the lips, and eating ice cream, and did not differ significantly from the comparison group without ankyloglossia.

KQ 2b. Benefits of Treatments To Prevent Other Sequelae

Two cohort studies attempted to assess the effectiveness of frenotomy for preventing other sequelae,[16,18] and one RCT compared two surgical approaches to frenotomy.[19] A speech-language pathologist measured speech outcomes in two studies,[18,19] with the third study using parental assessment.[16] No studies included data related to sleep disordered breathing, occlusal issues, and dysphagia in nonbreastfeeding children.

Two poor-quality cohort studies[16,18] reported an improvement in articulation and intelligibility with ankyloglossia treatment, but benefits in word and sentence accuracy and intelligibility and fluent speech were unclear. The one poor-quality RCT comparing surgical methods reported improved articulation in patients treated with four-flap Z-frenuloplasty compared with horizontal-to-vertical frenuloplasty.[19] Numerous noncomparative studies[20-26] reported a speech benefit after treating ankyloglossia; however, these studies primarily discussed modalities, with safety, feasibility, or utility as the main outcome rather than speech itself, and they provided no comparative data.

KQ 3. Benefits of Treatments To Prevent Social Concerns Related to Tongue Mobility

Only one poor-quality retrospective cohort study assessed outcomes related to social concerns other than speech in 3-year-old children who had received frenotomy as infants.[16] The group that had received frenotomy had better parent-reported ability to clean teeth with tongue, lick outside of lips, and eat ice cream compared with untreated participants.

KQ 4. Benefits of Simultaneously Treating Ankyloglossia and Lip-Tie

We did not identify any studies addressing this question.

KQ 5. Harms of Treatments for Ankyloglossia or Ankyloglossia With Concomitant Lip-Tie in Neonates, Infants, and Children Through Age 18

In order to identify all possible harms, we sought harms from all comparative studies and case series that we identified as potentially providing effectiveness data, and we sought case reports of harms. With this approach, we examined harms information from 46 studies that reported that they had looked for harms, either reporting actual harms or specifically indicating that they found none. These included 6 RCTs, 1 cohort study, 25 case series, and 15 case reports. Most studies that reported harms information explicitly noted that no significant harms were observed (n = 17) or reported minimal harms. Among studies reporting harms, bleeding was most frequently reported. Bleeding was typically described as minor and limited. Reoperation was noted in seven studies. Few studies described the specific methods they used to collect harms data.

Discussion

Key Findings

Most of the studies included in this review addressed outcomes related to breastfeeding (Table B). Overall, three good-quality[10,11,13] and one fair-quality[12] RCT assessed whether surgical treatment of ankyloglossia improved breastfeeding effectiveness. Maternally reported breastfeeding effectiveness was significantly improved in the treated group compared with the untreated group in both RCTs that evaluated it either as a primary[12] or secondary[11] outcome. Only one of three RCTs that used blinded independent observers found significantly improved breastfeeding effectiveness among frenotomized infants immediately postprocedure.[13] A third RCT evaluated the mother's breastfeeding self-efficacy and found a significant improvement from baseline in the frenotomy group 5 days postprocedure.[10] In all, some evidence suggests that maternally reported breastfeeding outcomes improved, but data are unavailable to assess the durability of effects.

These same studies had disparate findings about whether frenotomy decreased maternal nipple pain during breastfeeding. Only the RCT performed on infants at 6 days of age showed a significant reduction in maternal pain.[13] Those performed on infants a few weeks older did not report either an immediate[11] or 5-day[10] reduction in pain. The difference between earlier frenotomy and later frenotomy on nipple pain may relate to cumulative trauma on the breast from several additional weeks with inefficient latch from tongue-tied infants.

We identified three studies examining feeding outcomes other than breastfeeding: one RCT,[12] one-poor quality retrospective cohort study,[16] and one case series.[17] Bottle-feeding and ability to use the tongue to eat ice cream and clean the mouth improved more in treatment groups in comparative studies. Bottle feedings to supplement breast feeding decreased over time in the case series.

Following breastfeeding outcomes, outcomes related to speech were most often reported in the ankyloglossia literature. Two poor-quality cohort studies[16,18] reported an improvement in articulation and intelligibility with ankyloglossia treatment, but benefits in word and sentence accuracy and intelligibility and fluent speech were unclear. One poor-quality RCT reported improved articulation in patients treated with Z-frenuloplasty compared with horizontal-to-vertical frenuloplasty.[19] Numerous noncomparative studies reported a speech benefit after

treating ankyloglossia; however, these studies primarily discussed modalities, with safety, feasibility, or utility as the main outcome, rather than speech itself.[23,26-28]

Few studies addressed social concerns. One retrospective cohort study noted improvements in using the tongue to clean the teeth and for licking in the treatment group compared with untreated participants.[16] In two comparative studies reporting on tongue mobility, mobility improved in treated patients.[18,19]

Harms of surgical interventions included minor bleeding, which was typically self-limiting, and need for reoperation, which was rare. Minor bleeding is not an unexpected occurrence in this type of surgical intervention. Eighteen studies reported that no significant harms were observed.

Strength of Evidence

Breastfeeding Outcomes

Very few higher quality comparative studies have addressed the effectiveness of surgical interventions to improve breastfeeding outcomes. In those few studies, mothers consistently reported improved breastfeeding effectiveness, but outcome measures were heterogeneous and very short term. Future studies could provide additional data to confirm or change the measure of effectiveness; thus, we consider the strength of evidence to be low at this time. We considered the strength of evidence (confidence in the estimate of effect) to be low for an immediate reduction in nipple pain. Improvements were reported in the current studies, but additional studies are needed to confirm and support these results. Only one poor-quality cohort study addressed effects on the length of breastfeeding; thus, we considered the strength of evidence to be insufficient.

Other Feeding Outcomes

With only two comparative studies, both with significant study limitations, existing data are insufficient to draw conclusions about the benefits and harms of surgical interventions for infants and children with ankyloglossia on medium- and long-term feeding outcomes. The studies used different populations and measured different outcomes.

Speech Outcomes

Given the lack of good-quality studies and limitations in the measurement of outcomes, we considered the strength of the evidence for the effect of surgical interventions to improve speech and articulation to be insufficient.

Social Concerns Related to Tongue Mobility

With only one poor-quality comparative study, strength of evidence related to the ability of treatment for ankyloglossia to alleviate social concerns is currently insufficient. Also, with only three comparative studies with small sizes and limitations in the measurement of outcomes related to tongue mobility, we considered the strength of evidence for the effect of surgical interventions to improve the short-term outcome of mobility to be insufficient.

Harms

We considered the strength of evidence for minimal and short-lived bleeding as a minor harm of surgical interventions as moderate based on an expanded search for harms reports in addition to the comparative data. We considered the strength of evidence for reoperation and pain as

harms to be insufficient, given the small number of outcomes available for analysis. We acknowledge that harms are not systematically reported, and thus there may be substantial underreporting.

Table B. Strength of evidence for studies addressing surgical approaches for ankyloglossia

Outcome; Number of Studies and Quality (Total Participants)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding/Strength of Evidence
Breastfeeding Outcomes						
Nipple pain RCT: 3 good,[10,11,13] 1 poor[14] (251) Retrospective cohort: 1 poor[15] (367)	Low	Inconsistent	Direct	Imprecise	Undetected	Low SOE for an immediate reduction in nipple pain postprocedure due to inconsistent results across small studies.
Breastfeeding effectiveness RCTs: LATCH—2 good,[10,11] 1 poor[14] (193) IBFAT—1 good[13] (58) BSES-SF—1 fair[10] (107) Retrospective cohort: 1 poor[15] (367)	Low	Inconsistent	Direct	Imprecise	Undetected	Low SOE for improved breastfeeding. Mothers consistently reported improved breastfeeding effectiveness, but outcome measures were heterogeneous and very short term. Observer-rated measures did not show significant improvements. Future studies could provide additional data to confirm or change the measure of effectiveness.
Length of breastfeeding Retrospective cohort: 1 poor[15] (367)	High	NA	Direct	Imprecise	Undetected	Insufficient SOE due to the high risk of bias of the 1retrospective study
Other Feeding Outcomes						
Feeding outcomes RCT: 1 poor[12] (57) Retrospective cohort: 1 poor[16] (104)	High	Consistent	Indirect	Imprecise	Undetected	Insufficient SOE for all feeding outcomes, given small number of participants, lack of standard outcome measures, and poor quality of studies.

Table B. Strength of the evidence for studies addressing surgical approaches for ankyloglossia (continued)

Outcome Number of Studies and Quality (Total Participants)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding/Strength of the Evidence
Speech Outcomes						
Speech and articulation Retrospective cohort: 1 poor[16] (104) Prospective cohort: 1 poor[18] (23)	High	Inconsistent	Indirect	Imprecise	Undetected	Insufficient SOE based on 2 poor-quality cohort studies.
Oral motor skills Retrospective cohort: 1poor[16] (104) Prospective cohort: 1 poor[18] (23)	High	Consistent	Indirect	Imprecise	Undetected	Insufficient SOE based on 2 poor-quality cohort studies.
Social Outcomes						
Social concerns Retrospective cohort: 1 poor[16] (104)	High	NA	Indirect	Imprecise	Undetected	Insufficient SOE based on 1 poor-quality cohort study.
Tongue mobility RCT: 1 poor[19] (16) Retrospective cohort: 1 poor[18] (15)	High	Consistent	Direct	Imprecise	Undetected	Insufficient SOE based on 2 small poor-quality studies.

Table B. Strength of the evidence for studies addressing surgical approaches for ankyloglossia (continued)

Outcome Number of Studies and Quality (Total Participants)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding/Strength of the Evidence
Harms						
Bleeding RCT: 1 poor[11] (60) Case series: 14 poor[17,22,25,28-38], 2 good[27,39] (963)	High	Consistent	Direct	Imprecise	Suspected	Moderate SOE for minimal and short-lived bleeding based on an extensive search for harms reports in addition to the comparative data. Studies consistently reported minimal to no bleeding.
Reoperation RCT: 1 poor[10] (107) Retrospective cohort: 1 poor[15] (367) Case series:1 good,[39] 4 poor[23,24,40,41] (4,080)	High	Consistent	Direct	Imprecise	Suspected	Insufficient SOE due to very small numbers for the outcome.
Pain Case series: 2 good[27,42] (84)	High	Consistent	Indirect	Imprecise	Suspected	Insufficient SOE for minimal short-lived pain in infants. No studies reported excessive crying or an inability to feed soon after the intervention, but pain is arguably difficult to assess in infants, so outcomes were indirect and from poor-quality or noncomparative studies.

BSES –SF = Breastfeeding Self-Efficacy Scale-Short Form; IBFAT = Infant Breastfeeding Assessment Tool; LATCH = Latch, Audible swallowing, Type of nipple, Comfort, Hold; NA = not applicable; RCT = randomized controlled trial; SOE = strength of evidence.

Applicability

Newborns referred for treatment of ankyloglossia were born primarily at tertiary-care centers and recognized as having difficulty with breastfeeding concomitant with ankyloglossia. The frenotomy procedure itself is not technically difficult and is likely performed similarly across birthing sites; however, the criteria by which the decision is made to perform frenotomy are less clear. Moreover, newborns of mothers not choosing to breastfeed may not be recognized as having and/or diagnosed with ankyloglossia, as breastfeeding difficulties were used as an indicator to evaluate for ankyloglossia. At minimum, the studies in this report apply only to

infants with both ankyloglossia and feeding difficulties; data on ankyloglossia absent feeding difficulties were unavailable.

In these studies, various clinicians were involved in making the ankyloglossia diagnoses. However, assessment of breastfeeding difficulty and diagnostic criteria for ankyloglossia were not universally described. Lack of a consistent objective measure to define and classify this condition may limit the reproducibility of findings. Furthermore, the age of patients in these studies varied from a median of 6 days of age in one study[13] up to a mean of 33 days of age (range, 6 to 115) in another study.[11] Applicability of findings to older infants cannot be gleaned from these data, nor can durability of results.

Frenotomy was the only intervention employed in the good-quality RCTs.[10,11,13] However, the specifics of the procedure were variably reported. The degree of posterior extension of the frenulum incision was not clearly defined and appears to be at the discretion and clinical expertise of the clinician. Also, the severity of the ankyloglossia was inconsistently reported, making interstudy generalizations difficult and, more importantly, limiting the broader applicability of findings.

The comparators used were sham surgery[11,13] and no intervention.[10] Both "no intervention" and "sham surgery" are perhaps misnomers, however, since these infant-mother dyads underwent usual care, which could include, but is not limited to, lactation consultation, supportive care, and bottle-feeding advice.

The population studied in the question of benefit of ankyloglossia repair for social concerns included children and adults with wide variation in ages.

Research Gaps

A critical unknown at this point is a good description of the natural history of ankyloglossia by severity, including long-term risk of feeding, social, and speech production difficulties. Future studies should consider direct comparisons of alternative treatments, as currently available literature addressed only the comparison of frenotomy with sham. In order to conduct these studies, it would be helpful if the field could agree on a standardized approach to identifying and classifying ankyloglossia; this would also improve our ability to synthesize the data across studies.

Given variation in outcomes that may be associated with earlier versus later frenotomy, future studies should assess timing of frenotomy to determine whether more significant reduction in maternal pain is achievable by earlier treatment and whether mothers are more apt to breastfeed longer if the frenotomy is done earlier.

A significant gap in research is in understanding the durability of outcomes. Good-quality comparative studies evaluated breastfeeding effectiveness immediately[11,13] or within 5 days of frenotomy;[10] however, none adequately assessed whether effectiveness and other outcomes (e.g., changes in maternal nipple pain) were maintained months or, if appropriate, years later. Longer term followup of both treated infants and controls is needed. Because of the paucity of available data on other feeding outcomes, this entire research question represents a gap and a potential area for future research.

Similarly, substantially more research is needed to consider whether treatment of ankyloglossia in infancy prevents future speech production difficulties, as well as whether treatment later in life with frenotomy leads to improvement when speech problems arise. To conduct this research effectively, methods for evaluating risk and presence of speech production difficulties will need to be standardized, and outcomes agreed on. Understanding of the natural

history of speech concerns in children with ankyloglossia is lacking, as are comparative studies that use standardized measurement tools for speech outcomes.

No standard definitions of tongue mobility or established norms for mobility exist, and further research is needed to determine such parameters. Social concerns are difficult to measure objectively, so there will likely always be a subjective component to social outcomes. Larger studies that assess both treated and untreated individuals could provide useful data to minimize the potential bias found in the existing literature. Similarly, future research in objective measurement tools or validated self-report tools is needed.

Conclusions

A small body of evidence suggests that frenotomy may be associated with improvements in breastfeeding as reported by mothers, and potentially in nipple pain. However, with small, inconsistently conducted studies, strength of evidence is low to insufficient, preventing us from drawing firm conclusions at this time. Research is lacking on nonsurgical interventions, as well as on outcomes other than breastfeeding, particularly speech and dental outcomes. In particular, there is a lack of evidence on significant long-term outcomes, such as exclusive breastfeeding at 6 months of age or at 1 year of age, growth, and other measures of health outcomes. Harms are minimal and rare; the most commonly reported harm is self-limited bleeding. Future research is needed on a range of issues, including prevalence and incidence of ankyloglossia and problems with the condition. The field is currently challenged by a lack of standardized approaches to assessing and studying the problems of infants with ankyloglossia.

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Introduction

Background

Ankyloglossia

Ankyloglossia is a congenital condition in which a neonate is born with an abnormally short, thickened, or tight lingual frenulum that restricts mobility of the tongue. Ankyloglossia may be associated with other craniofacial abnormalities, but is also often an isolated anomaly.[1] It variably causes reduced anterior tongue mobility and has been associated with functional limitations in breastfeeding, swallowing, articulation, orthodontic problems including malocclusion, open bite, and separation of lower incisors, mechanical problems related to oral clearance, and psychological stress. Reported rates of ankyloglossia in one review including studies of infants, children, and adults ranged from 0.1 to 10.7 percent,[2] but definitive incidence and prevalence statistics are difficult to obtain because there criterion standard or clinically practical diagnostic criteria.

Anterior ankyloglossia is defined as tongue-tie with a prominent lingual frenulum and/or restricted tongue protrusion with tongue tip tethering. The diagnosis of posterior ankyloglossia is considered when the lingual frenulum is not very prominent on inspection but is thought to be tight on manual palpation or is found to be abnormally prominent, short, thick, or fibrous cord-like with the use of the grooved director. Although treatment is similar in anterior and posterior cases, posterior ankyloglossia is more subtle in presentation. Usually, clinicians recognize the anterior frenulum as the cause of ankyloglossia; however, an infant can have ankyloglossia even without obvious abnormalities of the anterior frenulum. Anterior ankyloglossia has been found more commonly in males and posterior ankyloglossia in females.[3] Posterior ankyloglossia is more likely to require revision surgery due to the relative difficulty of accurate diagnosis and treatment.

Estimates in the literature of the number of infants with ankyloglossia who have feeding difficulties are based on small case series without control groups. Mechanistically, infants with restrictive ankyloglossia cannot protrude their tongues over the gum line to contact their lips to form a proper latch and therefore use their jaws to keep the maternal nipple in the mouth for breastfeeding. Adequate tongue mobility is required, and infants with ankyloglossia often cannot overcome their deficiency with conservative measures such as positioning and latching techniques.[2] Ineffective latch associated with ankyloglossia is hypothesized to underlie breastfeeding problems in these infants including failure to thrive, maternal nipple damage, maternal breast pain, poor milk supply, maternal breast engorgement, and refusing the breast.[2]

Consensus on ankyloglossia's role in breastfeeding difficulties is lacking. A minority of surveyed pediatricians (10%) and otolaryngologists (30%) believe it commonly affects feeding, while 69 percent of lactation consultants feel that it frequently causes breastfeeding problems.[4] Therefore, depending on the audience, enthusiasm for its treatment varies. Currently, the U.K. National Health Service (NHS) and the Canadian Paediatric Society (CPS) recommend treatment only if it interferes with breastfeeding.[5] Unfortunately, a standard definition of "interference" with breastfeeding is not provided, leaving room for interpretation and variation in treatment thresholds. The absence of data on the natural history of untreated ankyloglossia creates even more uncertainty. Some propose that a short frenulum elongates spontaneously due to progressive stretching and thinning of the frenulum with age and use.[1] However, there are no

prospective longitudinal data on the fate of the congenitally short lingual frenulum. Without this information it is difficult to inform parents fully about the long-term implications of ankyloglossia, which complicates the decision making process.

Although most ankyloglossia research is focused on the infant and breastfeeding issues, concerns beyond infancy include speech-related issues, such as difficulty with articulation, and social concerns related to limited tongue mobility. Individuals with untreated ankyloglossia may experience difficulty with licking foods such as ice cream, kissing, drooling, playing wind instruments, and licking the lips. Self- esteem or psychological issues may also be a concern for affected older patients.

Treatment Strategies

Surgical Approaches

Surgical modalities include frenotomy, frenulectomy, and tongue tie release surgery. These interventions are often used interchangeably in the literature. In general, a lingual frenotomy involve clipping or cutting of the lingual frenulum using the proceduralist's fingers, a grooved tongue director, or other instrument to lift the tongue, which puts the tension on the frenulum and using straight scissors to divide the frenulum, generally without sedation. The ensuing wound does not typically require repair. Laser frenotomy or frenulotomy has also been described,[6] and proponents argue that its use is more exact and provides better hemostasis than standard frenotomy or frenulotomy.

Frenuloplasty is more technically involved than frenotomy or frenulotomy. It generally refers to rearranging tissue or adding grafts after making incisions and closing the resultant wound in a specific pattern to lengthen the anterior tongue. Specific types of frenuloplasty include Z-frenuloplasty, which involves making a longitudinal incision along the length of the lingual frenulum combined with perpendicular incisions at tongue tip and floor of the mouth. These cuts create a Z-type incision. Submucosal flaps are then elevated, and transposed flaps are sutured closed, resulting in increased tongue length and mobility. A second type of frenuloplasty involves a horizontal division at the base of the frenulum where a harvested buccal mucosal graft is inserted and affixed to fill the defect created by the incision. Horizontal-to-vertical frenuloplasty is a third type in which a horizontal incision is created at mid-frenulum to release the tethering fibrotic band. The incision is then converted to a vertical orientation and closed with sutures to effectively elongate the anterior tongue. Frenuloplasty is most commonly performed under a general anesthetic and used in older infants and children or in more complex frenulum repairs.

Nonsurgical Approaches

Nonsurgical approaches include speech therapy and lactation interventions and observation to determine if intervention is warranted (Table 1).

Table 1. Nonsurgical treatment approaches

Intervention	Description
Complementary and alternative procedures	Diverse group of therapies not conventionally practiced by physicians or allied health professionals (e.g., craniosacral therapy).
Lactation intervention	Counseling and recommendations from a lactation consultant for better, easier or more efficient breast-feeding. Focus on latching technique and infant and maternal positioning on breast.
Physical therapy/occupational therapy	Approaches to reduce tension in and stretch neck, back, and strap muscles to improve range of motion. This includes myofascial release and other manual techniques.
Speech therapy/oromotor therapy	Exercises and techniques intended to develop awareness, strength, coordination and mobility of the oral muscles including the tongue, lip, and palate. Evaluation and treatment of swallowing and speech disorders using specific exercises and procedures.
Observation	Supportive therapy for mother without any treatment approach and observation for improvement through natural history of the condition process.

Several measures have been developed to assess or describe ankyloglossia. Structured assessments can also be used to assess the effectiveness of breastfeeding. Table 2 outlines measures used in the studies reported in this review.

Table 2. Structured assessments and screening tools used in ankyloglossia literature

Measure	Description
Degree of Ankyloglossia	
Coryllos criteria	Scale for categorizing ankyloglossia based on proximity of frenulum attachment to tongue tip: Type 1=frenulum attached to tip of tongue. Type 2=frenulum attached 2-4 millimeters behind tongue tip on or behind alveolar ridge. Type 3=mid-tongue attachment. Type 4=attachment at base of tongue. Type 4 is associated with more difficulty with bolus swallowing and more significant symptoms.
Hazelbaker Assessment Tool for Lingual Frenulum Function (HATLFF)	Measure of ankyloglossia extent and severity that include items to assess the appearance and function of the tongue and frenulum. Lower scores indicate more severe ankyloglossia. HATLFF is scored: 0-14 with14=perfect; 11=acceptable if appearance item score is 10; <11=impaired function (frenotomy should be considered if management fails; frenotomy is necessary if appearance item score is <8). HATLFF score of 6-12=mild to moderate tongue-tie; <6=severe tongue-tie.[7, 8]
Breastfeeding Effectiveness	
Breastfeeding Self-Efficacy Scale (BSES)	Measure of maternal breastfeeding confidence that uses a 5-point (1=not at all confident to 5=always confident) Likert scale to assess agreement with statements such as "I can always position my baby correctly at my breast." BSES scores range from 33-165 on the 33-item instrument [9] and 14-70 on the 14-item BSES-Short Form.[10] Higher overall scores indicate higher levels of breastfeeding self-efficacy.
Infant Breastfeeding Assessment Tool (IBFAT)	Measure of clinician or maternally rated perception of 4 items related to effectiveness of and satisfaction with a feeding (readiness to feed, rooting, latching on, sucking) rated on a 3-point scale (e.g., 3=rooted effectively at once, 0=did not root). Higher scores indicate greater perceived effectiveness. IBFAT scores range from 0-12; 12=vigorous and effective feeding.[11]

Table 2. Structured assessments used in ankyloglossia literature (continued)

Measure	Description
Latch, Audible swallowing, Type of nipple, Comfort, Hold (LATCH)	Measure of effectiveness of latch to the breast, feeding, comfort for mother, and maternal positioning rated on 3 levels with higher scores indicating greater effectiveness. LATCH score ≤8=breastfeeding difficulties.[12]

Scope and Key Questions

Scope of Review

This systematic review provides a comprehensive review of potential benefits of treatments (surgical and nonsurgical) as well as harms associated with those therapies in individuals with ankyloglossia and tight labial frenulum (lip-tie) concomitant with ankyloglossia. We assess outcomes related to breast and bottle-feeding and related to tongue tie in later life (e.g., orthodontic and dental issues, speech, self-esteem).

Key Questions

We have synthesized evidence in the published literature to address the following Key Questions (KQs):

KQ1. What are the benefits of various treatments in breastfeeding newborns and infants with ankyloglossia intended to improve breastfeeding outcomes? Surgical treatments include frenotomy (anterior and/or posterior), frenuloplasty (transverse to vertical frenuloplasty), laser frenulectomy/frenulotomy, and Z-plasty repair. Nonsurgical treatments include complementary and alternative medicine therapies (e.g. craniosacral therapy), lactation intervention, physical/occupational therapy, oral motor therapy, and stretching exercises/therapy.

KQ2a. What are the benefits of various treatments in newborns, infants, and children with ankyloglossia intended to prevent, mitigate, or remedy attributable medium and long-term *feeding* sequelae including trouble bottle feeding, spilling and dribbling, difficulty moving food boluses in the mouth and deglutition?

KQ2b. What are the benefits of various treatments in infants and children with ankyloglossia intended to prevent, mitigate, or remedy attributable medium and long term *other* sequelae including articulation disorders, poor oral hygiene, oral and oropharyngeal dysphagia, sleep disordered breathing, orthodontic issues including malocclusion, open bite due to reverse swallowing, lingual tipping of the lower central incisors, separation of upper central incisors, crowding, narrow palatal arch, and dental caries?

KQ3. What are the benefits of various treatments for ankyloglossia in children through 18 years of age intended to prevent or address social concerns related to tongue mobility (i.e., speech, oral hygiene, excessive salivation, kissing, spitting while talking, and self-esteem)?

KQ4. What are the benefits of simultaneously treating ankyloglossia and concomitant tight labial frenulum (lip-tie) in infants and children through age 18 intended to improve or remedy breastfeeding, articulation, orthodontic and dental, and other feeding outcomes? What are the relative benefits of treating only ankyloglossia when tight labial frenulum (lip-tie) is also diagnosed?

KQ5. What are the harms of treatments for ankyloglossia or ankyloglossia with concomitant lip-tie in neonates, infants, and children through age 18?

Table 3 outlines the population, intervention, comparator, outcomes, timing, and setting characteristics for each KQ.

Table 3. PICOTS

PICOTS	Criteria
Population	• KQ1: Breastfeeding newborns with ankyloglossia • KQ2 and KQ3: Infants and children with ankyloglossia • KQ4: Infants and children (newborns through18 years of age) with ankyloglossia and concomitant tight labial frenulum (lip-tie) KQ5: Children through age 18 treated for ankyloglossia or ankyloglossia and concomitant lip-tie.
Intervention(s)	• Surgical interventions, including frenotomy (anterior or posterior), frenuloplasty, laser frenulectomy and Z-plasty repair • Nonsurgical treatments include complementary and alternative medicine (CAM) therapies (e.g., craniosacral therapy), lactation intervention, and speech therapy (for children ages 2 to 18 years), physical/occupational therapy, oral motor therapy, and stretching exercises/therapy
Comparator	• Other surgical approach • Non-surgical interventions including lactation intervention, speech therapy, physical/occupational therapy oral motor therapy, and stretching exercises/therapy • Observation • Complementary and alternative medicine (CAM) therapies (e.g. craniosacral therapy) • Placebo (sham therapy)
Outcomes	• Breastfeeding, including latch, nipple pain, nipple excoriations, nipple infections (mastitis), weight gain, aerophagia, swallowing function, failure to thrive, milk transfer, low milk supply, breastfeeding cessation/duration of breastfeeding • Other feeding issues, including difficulty bottle feeding, moving food boluses in the mouth, deglutition, spilling and dribbling, reflux, dysphagia • Articulation • Speech (e.g., speech fluency, effort with speech, speech intelligibility) • Sleep disordered breathing (sleep apnea) • Oral hygiene • Excessive salivation • Orthodontic problems, including malocclusion, open bite due to reverse swallowing, lingual tipping of lower central incisors, separation of upper central incisors, crowding, and narrow palatal arch, dental caries • Psychological (e.g., self-esteem) • Harms, including excessive bleeding, airway obstruction, pain, transient poor feeding secondary to discomfort, dysphagia, complications related to dysphagia such as aspiration pneumonia, surgical site infection, nerve damage, salivary gland damage, ranulae, scarring, soft tissue damage, oral aversion, readherence, and need for further surgery/revision
Timing	• Short-term (breastfeeding) • Long-term (feeding) speech, psychological, oral hygiene
Setting	• Inpatient or outpatient pediatric care, operating room, newborn nursery or NICU, ENT clinic, primary care outpatient, dental office, breastfeeding medicine clinic

CAM = Complementary and alternative medicine; ENT = ear, nose and throat; KQ = Key Question; NICU = neonatal intensive care unit; PICOTS = population, intervention, comparator, outcomes, timing, setting

Analytic Framework

Figure 1 depicts KQs 1, 4, and 5 within the context of the PICOTS (Population, Intervention, Comparator, Outcomes, Timing, Setting) described in the document. The figure examines surgical and nonsurgical treatments in newborns and infants to improve breastfeeding outcomes. Intermediate outcomes include maternal nipple pain, ability to latch and maintain latch, tongue mobility, and aerophagia. Final outcomes include duration of breastfeeding, failure to thrive, infant weight gain and oral and oropharyngeal dysphagia. Harms (KQ5) may occur at any point after the intervention is received.

Figure 1. Analytic framework for ankyloglossia in neonates and infants

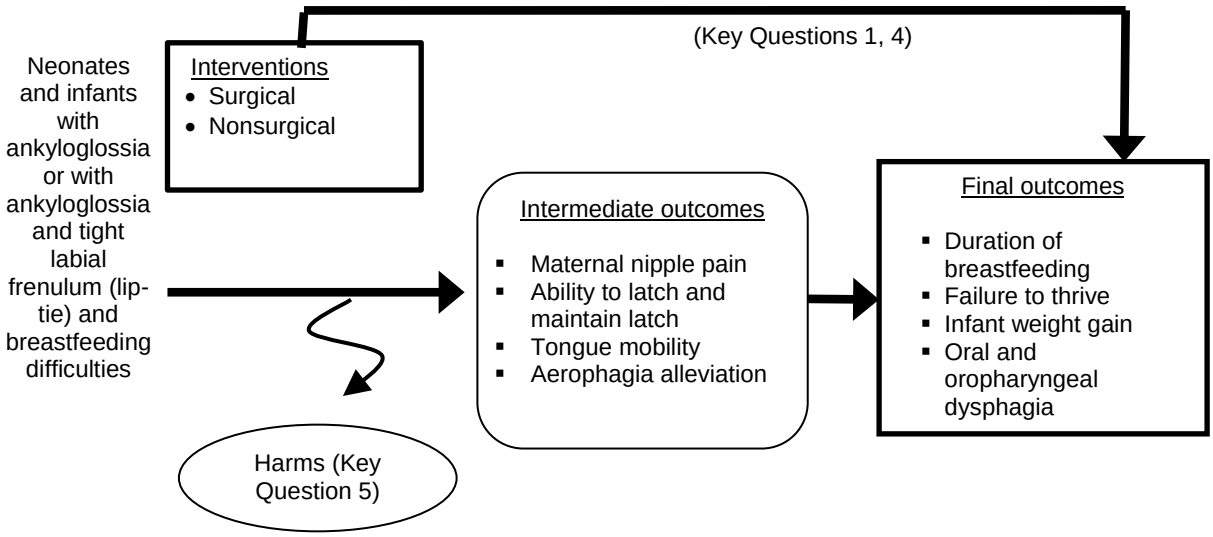
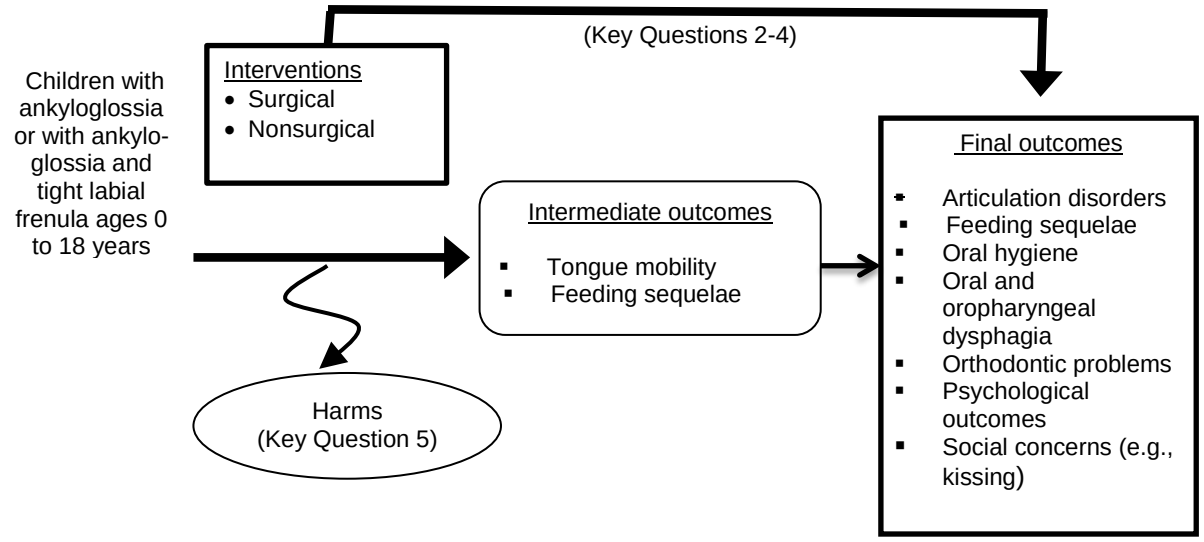


Figure 2 depicts KQs 2, 3, 4, and 5 within the context of the PICOTS described in the document. The figure examines surgical and nonsurgical treatments in infants and children with ankyloglossia (KQ2, KQ3) or ankyloglossia with concomitant tight labial frenulum (lip-tie) (KQ4). The intermediate outcome is tongue mobility and final health outcomes include articulation disorder, oral hygiene, oral and oropharyngeal dysphagia, orthodontic problems, psychological outcomes and social concerns including kissing. Harms (KQ5) may occur at any point after the intervention is received.

Figure 2. Analytic framework for ankyloglossia in infants and children through 18 years of age



Organization of This Report

The Methods section describes our processes including our search strategy, inclusion and exclusion criteria, approach to review of abstracts and full publications, and methods for extraction of data into evidence tables, and compiling evidence. We also describe our approach to grading the quality of the literature and to describing the strength of the body of evidence.

The Results section presents the findings of the literature search and the review of the evidence by KQ, synthesizing the findings across strategies.

The Discussion section of the report discusses the results and expands on the methodologic considerations relevant to each KQ. We also outline the current state of the literature and challenges for future research in the field.

The report includes a number of appendices to provide further detail on our methods and the studies assessed. The appendixes are as follows:

- Appendix A. Search Strategies
- Appendix B. Abstract and Full-Text Screening Forms
- Appendix C. Excluded Studies
- Appendix D. Evidence Tables
- Appendix E. Quality Assessment Forms
- Appendix F. Quality Scoring Results
- Appendix G. Case Reports Harms
- Appendix H. Conference Abstracts
- Appendix I. Applicability Tables

We also include a list of abbreviations and acronyms at the end of the report.

Uses of This Evidence Report

We anticipate this report will be of primary value to organizations that develop guidelines for clinical practitioners and to health care providers who take care of infants and children through 18 years of age with ankyloglossia. Interested organizations would include the American Academy of Pediatrics, the Pediatric Academic Societies (PAS), the Academy of Breastfeeding

Medicine(ABM), the American Academy of Pediatric Dentistry (AAPD), the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), the American Speech-Language-Hearing Association (ASHA), the International Lactation Consultant Association (ILCA), Lactation Consultants of Australia and New Zealand (LCANZ), the College of Lactation Consultants of Western Australia (CLCWA), the American Orthodontic Society (AOS) and the American Association of Orthodontists (AAO), the NHS and other organizations and societies for pediatric care. Ankyloglossia is diagnosed and treated by an array of physicians and allied health professionals, but this most commonly includes pediatricians, otolaryngologists, dentists, and lactation consultants. This report supplies practitioners and researchers up-to-date information about the current state of evidence, and assesses the quality of studies that aim to determine the outcomes of treatments for ankyloglossia. It will be of interest to parents concerned about the health of their infants and facing treatment choices around care for their children with ankyloglossia.

Researchers can obtain a concise analysis of the current state of knowledge in this field. They will be poised to pursue further investigations that are needed to advance research methods, develop new treatment strategies, and optimize the effectiveness and safety of clinical care infants and children through 18 years of age with ankyloglossia.

Methods

In this chapter, we document the procedures that the Vanderbilt Evidence-based Practice Center used to produce a Comparative Effectiveness Review on the approaches to treatment for ankyloglossia. These procedures follow the methods suggested in the Agency for Healthcare Research and Quality (AHRQ) Effective Health Care Program "Methods Guide for Effectiveness and Comparative Effectiveness Reviews."[13]

Topic Refinement and Review Protocol

The topic for this report was nominated by the American Academy of Pediatrics in a public process using the Effective Health Care Web site. Working from the nomination, we drafted the initial Key Questions (KQs) and analytic framework and refined them with input from key informants representing the fields of pediatric care, pediatric otolaryngology, breastfeeding and lactation, dentistry, occupational therapy, and speech therapy. All members of the research team were required to submit information about potential conflicts of interest before initiation of the work. No members of the review team had any conflicts.

After review from AHRQ, the questions and framework were posted online for public comment. No changes to the questions or framework were recommended. We also developed population, interventions, outcomes, timing, and settings (PICOTS) criteria for intervention KQs.

We identified technical experts on the topic to provide assistance during the project. The Technical Expert Panel (TEP), representing the fields of pediatric care, pediatric otolaryngology, breastfeeding and lactation, dentistry, and speech-language pathology, contributed to the AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential customers and users of its products. Thus, the TEP was both an additional resource and a sounding board during the project. The TEP included nine members serving as technical or clinical experts. To ensure robust, scientifically relevant work, we called on the TEP to review and provide comments as our work progressed. TEP members participated in conference calls and discussions through e-mail to:

- Help to refine the analytic framework and KQs at the beginning of the project;
- Discuss the preliminary assessment of the literature, including inclusion/exclusion criteria; and
- Provide input on the information and domains included in evidence tables.

The final protocol was posted to the AHRQ Effective Health Care Web site.[14]

Literature Search Strategy

Search Strategy

To ensure comprehensive retrieval of relevant studies of therapies for children with ankyloglossia or ankyloglossia with concomitant tight labial frenulum (lip-tie), we used four key databases: the MEDLINE® medical literature database via the PubMed® interface, the PsycINFO® psychology and psychiatry database, the Cumulative Index of Nursing and Allied Health Literature (CINAHL®) and EMBASE (Excerpta Medica Database), an international biomedical and pharmacological literature database via the Ovid® interface. Search strategies applied a combination of controlled vocabulary (Medical Subject Headings (MeSH), PsycINFO headings, CINAHL medical headings, and Emtree headings, respectively) to focus specifically

on concepts related to ankyloglossia and its treatment as well as treatment harms. Literature searches were not restricted to a year range (i.e., searches were from inception of the database to the present) given the need to capture variations in practice patterns and trends in breastfeeding over time.

We included studies published in English only as a review of non-English citations retrieved by our MEDLINE search identified few studies of relevance. Appendix A lists our search terms and strategies and the yield from each database. Searches were executed between September 2013 and August 2014**.**

We carried out hand searches of the reference lists of recent systematic reviews or meta-analyses of therapies for ankyloglossia; the investigative team scanned the reference lists of articles included after the full-text review phase for studies that potentially could meet our inclusion criteria.

As we did not review medications or devices, we did not request Scientific Information Packets or regulatory information. We reviewed abstracts presented at annual meetings of key scientific societies including the American Association of Pediatrics (AAP), the Pediatric Academic Societies (PAS), the Academy of Breastfeeding Medicine (ABM), the American Academy of Pediatric Dentistry (AAPD), the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), the American Speech-Language-Hearing Association (ASHA), the International Lactation Consultant Association (ILCA), Lactation Consultants of Australia and New Zealand (LCANZ), the College of Lactation Consultants of Western Australia (CLCWA), the American Orthodontic Society (AOS) and the American Association of Orthodontists (AAO). We identified relevant theses and dissertations through ProQuest Dissertations and Theses (PQDT).

Inclusion and Exclusion Criteria

Table 4 lists the inclusion/exclusion criteria we used based on our understanding of the literature, key informant and public comment during the topic-refinement phase, input from the TEP, and established principles of systematic review methods.

Table 4. Inclusion and exclusion criteria

Category	Criteria
Study population	Inclusion: Children ages 0-18 with ankyloglossia or ankyloglossia with concomitant tight labial frenulum (lip-tie); Exclusion: Studies with participants with Van der Woude syndrome, Pierre Robin syndrome, Down syndrome, or craniofacial abnormalities were excluded as were studies of premature babies (<37 weeks of gestation[15])
Publication languages	Inclusion: English Exclusion: Non-English
Admissible evidence (study design and other criteria)	Included study designs RCTs, prospective and retrospective cohort studies, nonrandomized controlled trials, prospective and retrospective case series, and cross over studies Case reports to assess harms Other criteria Original research studies providing sufficient detail regarding methods and results to enable use and aggregation of the data and results Studies must address one or more of the following: • Surgical interventions (simple anterior frenotomy, frenulotomy, or frenectomy, laser frenotomy, frenulotomy, or frenulectomy, posterior frenulectomy, Z-plasty repair) • Nonsurgical treatments include complementary and alternative medicine therapies (e.g. craniosacral therapy, myofascial release, and other chiropractic therapies), lactation intervention , speech therapy, physical therapy, oral motor therapy and stretching exercises/therapy • Baseline and outcome data (including harms) related to interventions for ankyloglossia Relevant outcomes must be able to be extracted from data in the papers Data must be presented in the aggregate (vs. individual participant data)

RCT = randomized controlled trial.

Study Selection

Once we identified articles through the electronic database searches and hand-searching, we examined abstracts of articles to determine whether studies met our criteria. Two reviewers separately evaluated the abstracts for inclusion or exclusion, using an Abstract Review Form (Appendix B). If one reviewer concluded that the article could be eligible for the review based on the abstract, we retained it. Following abstract review, two reviewers independently assessed the full text of each included study using a standardized form (Appendix B) that included questions stemming from our inclusion/exclusion criteria. Disagreements between reviewers were resolved by a senior reviewer. All abstract and full text reviews were conducted using the DistillerSR online screening application (Evidence Partners Incorporated, Ottawa, Ontario). Excluded studies, and the reasons for exclusion, are presented in Appendix C. Reviewers included three clinicians with expertise in pediatrics and/or otolaryngology and two expert systematic reviewers.

Data Extraction

The staff members and clinical experts who conducted this review jointly developed the evidence tables. We designed the tables to provide sufficient information to enable readers to

understand the studies and to determine their quality; we gave particular emphasis to essential information related to our key questions. Two evidence table templates were employed to facilitate the extraction of data based on study type; one form was designed for case series and one to accommodate all types of comparative studies. We based the format of our evidence tables on successful designs used for prior systematic reviews.

The team was trained to extract data by extracting several articles into evidence tables and then reconvening as a group to discuss the utility of the table design. We repeated this process through several iterations until we decided that the tables included the appropriate categories for gathering the information contained in the articles. All team members shared the task of initially entering information into the evidence tables. A second team member also reviewed the articles and edited all initial table entries for accuracy, completeness, and consistency. The two data extractors reconciled disagreements concerning the information reported in the evidence tables. The full research team met regularly during the article extraction period and discussed global issues related to the data extraction process. In addition to outcomes related to intervention effectiveness, we extracted all data available on harms. Harms encompass the full range of specific negative effects, including the narrower definition of adverse events.

The final evidence tables are presented in their entirety in Appendix D. Studies are presented in the evidence tables alphabetically by the last name of the first author. A list of abbreviations and acronyms used in the tables appears at the beginning of that appendix.

Data Synthesis

We considered the possibility of conducting a meta-analysis, but the small number of the studies, the study designs and the heterogeneity of interventions and outcomes made a meta-analysis inappropriate. We completed evidence tables for all included studies, and data are presented in summary tables and analyzed qualitatively in the text.

Quality (Risk of Bias) Assessment of Individual Studies

We used four tools to assess quality of individual studies: the Cochrane Risk of Bias Tool for Randomized Controlled Trials,[16] a cohort study assessment instrument and a tool for case series, both adapted from RTI Item Bank questions,[17] and a four-item harms assessment instrument for cohort studies derived from the McMaster Quality Assessment Scale of Harms (McHarm) for Harms Outcomes[18] and the RTI Item Bank.[17]

The Cochrane Risk of Bias tool is designed for the assessment of studies with experimental designs and randomized participants. Fundamental domains include sequence generation, allocation concealment, blinding, completeness of outcome data, and selective reporting bias. The RTI Item Bank-based cohort instrument was used to assess the quality of nonrandomized studies (e.g., cohort and case-control studies). Questions assess selection and follow up of study groups, the comparability of study groups, and the ascertainment of outcomes of interest for cohort studies. The case series tool assesses attrition, blinding, appropriateness of outcome measures, and reporting bias. The harms assessment tool documents whether harms were predefined and pre-specified and if standard scales were applied. We did not assess the quality of case reports, which we used solely for harms data. All four tools are presented in Appendix E.

Quality assessment of each study was conducted by two team members independently using the forms presented in Appendix E. Any discrepancies were adjudicated through discussion between the assessors to reach consensus or via a senior reviewer. Investigators did not rely on the study design as described by authors of individual papers; rather, the methods section of each

paper was reviewed to determine which rating tool to employ. The results of these tools were then translated to the AHRQ standard of "good," "fair," and "poor" quality designations as described below.

Determining Quality Ratings

- We required that randomized controlled trials (RCTs) receive a positive score (i.e., low risk of bias for RCTs) on all questions used to assess quality to receive a rating of good (equivalent to low risk of bias). RCTs had to receive at least five positive scores to receive a rating of fair (moderate risk of bias), and studies with less than or equal to four positive ratings were considered poor quality (high risk of bias). We designated an "unclear" rating on an individual question as a positive rating as long as the consensus of the investigators assessing quality was that study outcomes were not likely to be biased by the factor.
- We required that cohort studies receive positive scores on all elements to receive a rating of good, less than or equal to two negative ratings for fair, and greater than two negative scores for a rating of poor quality.
- Case series, or pre-post studies, have inherently high risk of bias. Nonetheless, prospective case series that enroll participants consecutively and control for potentially confounding factors may provide more evidence to support comparative studies. We assessed case series using questions identified in the AHRQ Effective Health Care program's "Methods Guide for Effectiveness and Comparative Effectiveness Reviews"[13] but did not assign a quality level for these studies as it would be inappropriate to assess them on the same scale as prospective cohort and RCT designs. Rather, the elements on which they were scored and the results are presented in Appendix F.
- For harms assessment we required that studies receive a positive score (i.e., an affirmative response) on all four questions to receive a rating of good. Studies had to receive three positive scores to receive a rating of fair, and studies with less than three positive scores received a rating of poor.

Strength of the Body of Evidence

We applied explicit criteria for rating the overall strength of the evidence for each key intervention-outcome pair for which the overall risk of bias is not overwhelmingly high. We established concepts of the quantity of evidence (e.g., numbers of studies, aggregate ending-sample sizes), the quality of evidence (from the quality ratings on individual articles), and the coherence or consistency of findings across similar and dissimilar studies and in comparison to known or theoretically sound ideas of clinical or behavioral knowledge.

The strength of evidence evaluation is that stipulated in the Effective Health Care Program's "Methods Guide for Effectiveness and Comparative Effectiveness Reviews"[13] and in the updated strength of evidence guide[19] which emphasizes the following five major domains: study limitations (low, medium, high level of limitation), consistency (inconsistency not present, inconsistency present, unknown or not applicable), directness (direct, indirect), and precision (precise, imprecise), and reporting bias. Study limitations are derived from the quality assessment of the individual studies that addressed the KQ and specific outcome under consideration. Each key outcome for each comparison of interest is given an overall evidence grade based on the ratings for the individual domains.

The overall strength of evidence was graded as outlined in Table 5. Two senior staff independently graded the body of evidence; disagreements were resolved as needed through discussion or third-party adjudication. We recorded strength of evidence assessments in tables, summarizing results for each outcome.

Table 5. Strength of evidence grades and definitions*

Grade	Definition
High	**We are very confident that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has few or no deficiencies. We believe that the findings are stable, i.e., another study would not change the conclusions.
Moderate	**We are moderately confident that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.
Low	**We have limited confidence that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has major or numerous deficiencies (or both). We believe that additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.
Insufficient	**We have no evidence, we are unable to estimate an effect, or we have no confidence in the estimate of effect for this outcome**. No evidence is available or the body of evidence has unacceptable deficiencies, precluding reaching a conclusion.

* Excerpted from Berkman et al., 2013.[19]

Applicability

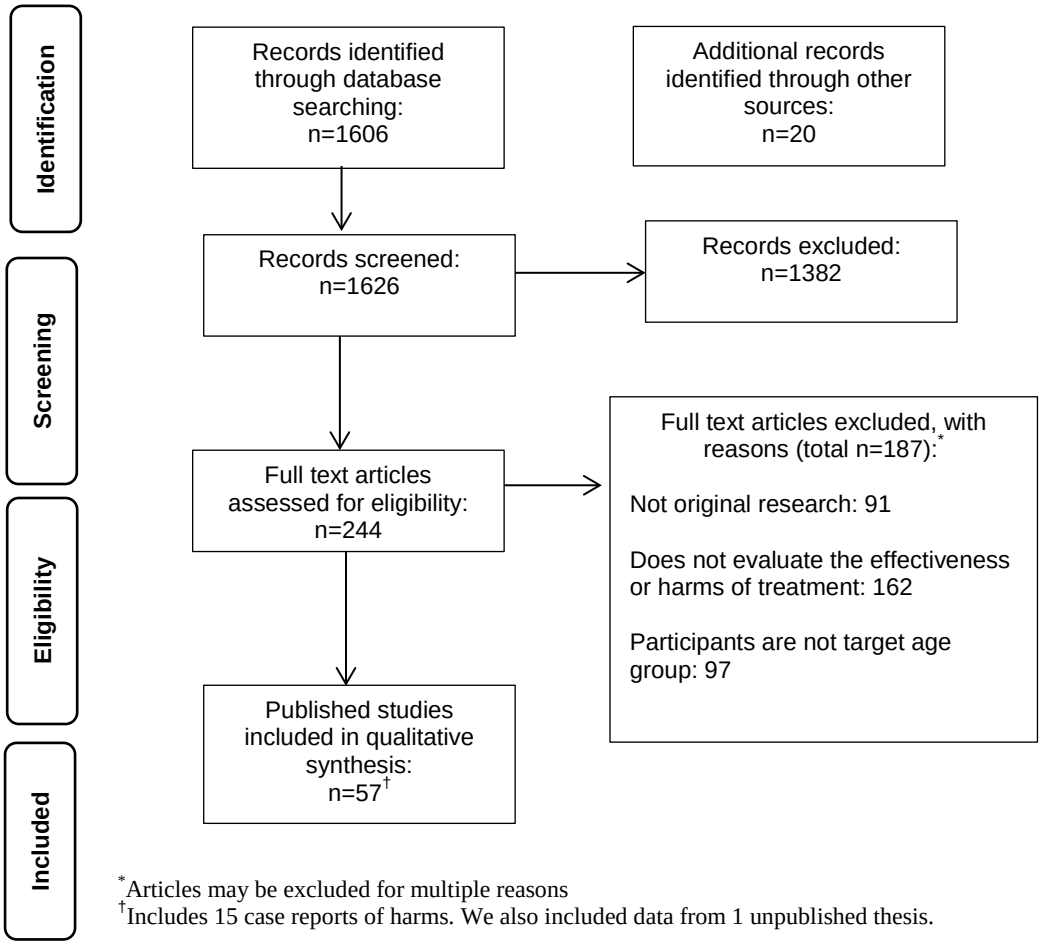
We assessed the applicability of findings reported in the included literature to the general population of children with ankyloglossia by determining the population, intervention, comparator, and setting in each study and developing an overview of these elements for each intervention category. We anticipated that areas in which applicability would be especially important to describe would include the severity of ankyloglossia in the study population, the age range of the participants, and the setting in which the intervention took place. We also attempted to capture information about the clinical provider including specialty and training. We describe any needs related to the setting, including anesthesia, surgical environment, materials for non-surgical interventions, etc.

Results

Results of Literature Searches

We identified 1,626 nonduplicative titles or abstracts with potential relevance, with 244 proceeding to full text review (Figure 3). We excluded 187 studies at full-text review, which yielded 57 published studies included in the review. We also included one unpublished thesis in our results, thus the report summarizes data from 58 unique publications.

Figure 3. Disposition of articles identified by the search strategy



*Articles may be excluded for multiple reasons
†Includes 15 case reports of harms. We also included data from 1 unpublished thesis.

Description of Included Studies

The 58 unique publications included in the review comprise six randomized controlled trials (RCTs), three assessed as good quality[7, 8, 20] for outcomes related to breastfeeding effectiveness and maternal pain related to breastfeeding. One RCT was rated as poor quality for breastfeeding effectiveness and pain outcomes.[21] One RCT was of poor quality for outcomes of tongue protrusion, frenulum length, and articulation/intelligibility,[22] and we rated one RCT as fair quality for measures of breast and bottle feeding.[23] The literature also includes three cohort studies (all poor quality[24-26]), 33 case series,[3, 6, 27-57] and 15 case reports (one of which reports

two cases and one of which reports five cases).[58-72] We also included one unpublished thesis (not quality rated). Table 6 outlines study characteristics.

Because case series do not include comparison groups, they do not provide comparative effectiveness data but were read to determine if they generally provided support for comparative data and as an additional source of harms. We used case reports to seek harms data only. We considered all comparative studies (RCTs and cohort studies) as poor quality for harms outcomes. We considered the quality for harms outcomes as good in four case series[49-52] and poor in 26.[3, 6, 27-48, 54, 56]

Table 6. Overview of comparative studies included

Characteristic	RCTs	Cohort Studies	Prospective Case Series	Retrospective Case Series	Total Literature
	(n=6)	(n=3)	(n=21)	(n=12)	(n=42)*
Intervention					
Frenotomy	3	3	3	5†	14†
Frenulotomy	0	0	6	1	7
Frenectomy	0	0	2	0	2
Frenuloplasty	0	0	3	2†	5†
Horizontal-to-vertical frenuloplasty	1††	0	1**	0	2††
Four-flap Z-frenuloplasty	1††	0	0	0	1††
Z-plasty with partial myotomy	0	0	0	1	1
Laser excision	0	0	2	0	2
Tongue-tie division (non-specified)	2	0	4	4	10
Length of last followup					
Immediately after intervention	1	1	2	1	5
≤1 month	0	0	7	1	8
>1 to ≤3 months	2	0	5	3	10
>3 to ≤6 months	1	0	1	2	4
>6 to ≤12 months	1	0	0	0	1
>12 months	1	2	2	1	6
Not reported/unclear	0	0	4	4	8
Provider					
Family practitioner	0	0	1	0	1
Pediatrician	0	0	1	1	2
Otolaryngologist	1	2	4‡	2	9
Otolaryngologist consultant or lactation consultant	0	0	1	0	1
Lactation consultant or pediatric surgeon	2	0	0	1	3
Neonatologist or pediatric dentist	1	1	1	0	3
General surgeon	0	0	4	2	6
Pediatric surgeon	0	0	3‡‡	1	4
Not reported/unclear	2	0	6	5	13

Table 6. Overview of comparative studies included (continued)

Characteristic	RCTs	Cohort Studies	Prospective Case Series	Retrospective Case Series	Total Literature
Study population					
United States/Canada	2	2	5	4	13
Europe	3	0	8	5	16
Asia	0	0	2	2	4
Other	1	1	6	1	9
Total N participants	324	473	1142	3846***	5785

N=number; RCT=randomized controlled trial.

* Literature also includes 15 case reports used for harms data and one unpublished thesis.

** Four children had horizontal to vertical frenuloplasty; one child had frenulotomy.

*** 2590 children in one study had tongue-tie division but the number responding to a follow-up survey was not clearly reported; therefore, these children are not included in the total participant count.

ǂ Providers included otolaryngologist in 54 cases and nurse in 51 cases.

ǂǂ Providers included pediatric surgeons, pediatricians, otolaryngologists, dentists, dermatologists, family practitioners, physician lactation consultants, and unspecified physicians

†One retrospective case series addressed frenotomy and frenuloplasty[48]

†† One RCT compared horizontal-to-vertical frenuloplasty to four-flap Z-frenuloplasty[22]

KQ (Key Question) 1. Benefits of Interventions To Improve Breastfeeding Outcomes

Key Points

- Results for reduction in nipple pain immediately after surgery were inconsistent, and potentially associated with how early after birth surgery occurred, with the one good quality study with positive results including the youngest infants.
- Frenotomy was associated with significantly improved maternally reported breastfeeding effectiveness immediately post-procedure compared with sham in two RCTs[7, 20], but inconsistent evidence that it improved infant's latch and breastfeeding effectiveness compared with no intervention. Results on whether frenotomy prolonged duration of breastfeeding were unclear and not consistent.
- No comparative study identified expressly evaluated the role of non-surgical interventions in improving breastfeeding effectiveness.

Overview of the Literature

Twenty-nine studies provided data on breastfeeding outcomes after surgical treatments for ankyloglossia. Only six included a comparison group and could provide information on comparative effectiveness. These studies included five randomized controlled trials conducted either in the United Kingdom (n=3),[8, 20, 23]United States (n=1),[7] or Israel (n=1)[21] and one retrospective cohort study conducted in the United States.[25] We rated three RCTs as good quality for outcomes related to breastfeeding effectiveness and pain related to breastfeeding.[7, 8, 20] One RCT was rated as fair[23] and one as poor quality for breastfeeding effectiveness and pain outcomes,[21] and we rated the cohort study as poor quality. The remainder of the studies were

case series and therefore used to identify harms (n=23). Case series were conducted in the United Kingdom (n=11),[28, 29, 32, 35, 36, 39, 41, 49, 50, 53, 57] United States (n=5),[3, 31, 44, 45, 56] Australia (n=3),[30, 38, 40] Finland (n=1),[48] Israel (n=2),[52, 55] and Canada (n=1).[27]

In the studies that provided breastfeeding outcomes, ankyloglossia was only identified in the presence of breastfeeding difficulties. It was diagnosed by clinician examination in all comparative studies but using different methods. In three studies, clinicians diagnosed it from exam without defining clear diagnostic criteria.[20, 23, 25] In others, ankyloglossia was defined as breastfeeding difficulties combined with either 1) Hazelbaker Assessment Tool of Lingual Frenulum Function (HATLFF) score between 6 and 12 and Latch, Audible swallowing, Type of nipple, Comfort, Hold (LATCH) score ≤ 8[8], or 2) abnormal HATLFF (cut-off not defined).[7]

Two RCTs compared frenotomy to sham surgery,[7, 20] one to usual care,[8] one to intensive lactation consultation,[23] and one used a crossover design to compare frenotomy followed by sham surgery to sham surgery followed by frenotomy with assessment of breastfeeding after each order of intervention (i.e., frenotomy and sham).[21] Similarly, the retrospective cohort study compared frenotomy to usual care.[25] The frenotomy procedure was explicitly described by three of five RCTs and the cohort study. In all descriptions, the frenulum was divided with straight scissors: straight iris (1),[25] blunt tipped (2),[20, 23] unspecified (1).[7] Two RCTs mentioned frenotomy without specifying how it was technically performed.[8, 21] The cohort study was the only comparative study that described systematic use of anesthetic (i.e., viscous lidocaine) prior to ankyloglossia division;[25] however, when case series were considered, a total of four of 25 studies reported use of some anesthetic before surgery.[3, 25, 31, 49] In the sham procedure, infants were removed from their parents to a separate room for the same amount of time as those receiving the procedure.

Detailed Analysis

Overview by Study Design for All Breastfeeding Outcomes

Randomized Controlled Studies

Five RCTs addressed the benefits of treating ankyloglossia with frenotomy on breastfeeding outcomes among neonates and infants who had breastfeeding difficulties (Table 7). The first good quality RCT was single-blinded and randomly assigned infants causing maternally reported nipple pain or difficulty breastfeeding with concomitant and significant ankyloglossia diagnosed by lactation consultant based on HATLFF criteria to frenotomy (n=30) or a sham procedure (n=28).[7] Infants in this study were young (mean 6.0 ± 6.9 days), and had a gender distribution of approximately 2:1 male: female in both treatment groups. Primary outcomes were 1) nipple pain assessed using the Montreal Pain Questionnaire (MPQ-SF); 2) objective breastfeeding effectiveness using Infant Breastfeeding Assessment Tool (IBFAT); and 3) lingual frenulum function via the HATLFF appearance and function scores. Mothers assessed pain outcomes and were blinded to their infant's treatment group.

Mothers whose infants had frenotomy reported significantly less nipple pain immediately following the procedure (mean MQP-SF: 4.9 ± 1.46 vs. 13.5 ± 1.5, $p<0.001$), which remained significantly less than the sham group until the 4-week assessment. Moreover, the mean IBFAT score was higher among frenotomized infants than those undergoing the sham procedure (11.6 ± 0.81 vs. 8.07 ± 0.86, $p=0.026$) immediately post-procedure, but was no different from the sham group at 2-week postoperative evaluation.

A second good quality RCT randomized infants less than 4 months of age with breastfeeding problems and ankyloglossia to either frenotomy (n=30) or sham procedure (n=30). There was nearly identical distribution of males and females (~2:1) and mean ages between groups (33 vs. 28 days).[20] The primary outcome was objectively observed improvement in breastfeeding effectiveness using a score adapted from LATCH and IBFAT, and the secondary outcome was maternally reported improvement in breastfeeding immediately after intervention. Treatment allocation was blinded to both the parents and independent outcome assessor.

No difference in breastfeeding improvement was reported by trained objective observers immediately following intervention (50% [13/26] vs. 40% [12/30]). In contrast, mothers whose infants had frenotomy reported significantly improved breastfeeding compared with those in the sham group (78% [21/27] vs. 47% [14/30] $p<0.02$). There was no immediate difference in the reduction in maternal reported pain scores between the frenotomy and sham groups (mean -2.5 ± 1.9 and -1.3 ± 1.5, p=0.13). Although the study reports that they re-assessed outcomes at 3 months, the data are not provided by treatment group.

A third good quality RCT randomized term infants with breastfeeding difficulties and ankyloglossia (HATLFF score between 6 – 12 and LATCH score ≤ 8) to either frenotomy (n=55) or no intervention (n=52).[8] All dyads consulted with a lactation consultant prior to randomization. Infants with severe ankyloglossia (defined as HATLFF < 6) were excluded and offered immediate frenotomy. At randomization, the median age was 11 days (IQR 8 – 14) and 11 days (IQR 8 – 16) in the frenotomy and control groups, respectively (p=0.94). This study did not report on gender of enrolled infants, but matched infants on age and birth order. Primary outcomes assessed 5-days and 8 weeks post-procedure included 1) change in maternal pain using VAS and 2) LATCH score. Secondary outcomes were method of feeding (i.e., bottle vs. breast), percent breastfeeding, and Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF) score. Independent researchers collecting outcomes, but not mothers, were blinded to infant group assignment and performed assessment at the 5-day follow-up visit. The 8-week assessment was limited since 35 of 52 in the comparison group requested frenotomy before that follow-up date due to continued breastfeeding problems. Therefore, the 8-week comparison was between 52 of 55 of the frenotomized infants, and 50 of 52 in the "no intervention" group of whom only eight of 50 (15%) had not had frenotomy at the time of this follow-up assessment.

Five days after the procedure, reductions in pain scores were not significantly greater among mothers whose infants had a frenotomy (median -2 [IQR -3 to 0.4] vs. -1 [-13.5 to 1]). Of note, 17 percent randomized to usual care did not wait 5 days before getting a frenotomy due to painful breastfeeding. Similarly, no significant improvement in median maternal pain was reported 8 weeks post-procedure (median -2 [IQR -3 to -1] vs. -2 [-3.5 to -0.6], p=0.83). Infant outcomes showed no differential median improvement between frenotomy and control group at 5-days for LATCH score (median 1 [IQR 0 – 2] vs. 1 [0 – 2], p=0.52) or IBFAT score (median 0 [IQR -1.8 to 1.0] vs. 0 [IQR 0 – 1]), p=0.36).

In contrast, compared with controls, there was improvement in both median BSES-SF score (median 9 [IQR 1.8 – 12.3] vs. 1 [-4 to 7.5] p=0.0002) and HATLFF score (4.5 [IQR 3.3 – 6] vs. 0 [0 – 2.3], $p<0.001$) 5-days post-intervention in the frenotomy group. Between 5-days and 8 weeks post-intervention, there was less improvement in the median BSES-SF score among frenotomy infants compared with those in the control group, but this difference was not statistically significant (3 [IQR 0 – 13] vs. 10 [2 – 18], p=0.082). The BSES-SF improvement occurred more rapidly after frenotomy in the surgery group than in the control group, but by 8-weeks both groups were nearly equivalent in overall improvement (5-day median + 8-week

median: frenotomy 9 + 3=12 vs. control 1 + 10=11). However, this comparison is difficult to interpret because so many control infants underwent frenotomy between the 5- and 8-week assessments. Crossover to frenotomy may also explain the equivalence of exclusive breastfeeding rates between groups at the 8-week assessment (intervention 82.7% vs. 80%, p=0.73).

A fair quality RCT randomized infants born with ankyloglossia diagnosed within the first 5 months with feeding problems to either frenotomy (n=28) or a control group who had intensive support, advice and help from lactation consultants (n=29).[23] The percentage of the tongue attached by the frenulum was gauged by clinician visualization to be between 0 percent (i.e., none) and 100 percent (i.e., to the tongue tip). This was judged to be 25 percent in six patients, 50 percent in 13, 75 percent in 15, and 100 percent in 23. Infants in both the frenotomy and control group had similar ages (20 vs. 18 days), but gender distribution was only recorded for the frenotomy group where there was a 1:1 ratio of males to females. The primary outcome was maternally reported improvement in breastfeeding. Most (96%) of frenotomized infants had improved feeding with 48 hours compared with 3 percent in the control group. The study was, however, entirely unblinded and all outcomes were by maternal report.

The final poor quality trial randomized full-term healthy for gestational age infants, ages 1 to 21 days, who were referred to a lactation clinic due to maternal nipple pain, and diagnosed with ankyloglossia by a neonatologist to either frenotomy followed by sham procedure (n=15) or vice versa (n=11) with assessment of breastfeeding after each intervention type in both arms.[21] Neither infant ages nor gender distribution was reported. The study's primary outcomes were maternal breastfeeding pain or nipple trauma measured by a standard Visual Analog Scale (VAS) and breastfeeding LATCH scores. Main outcome assessors were the mothers who were blinded to infant treatment group. Comparative group results were not reported, therefore preventing comparative analysis in this review.

Table 7. Breastfeeding effectiveness following surgical procedures

Outcome Measure	Study Study Design/Setting Groups, N Enrollment/ N Final Quality	Age in Days (IQR, Range, Mean, or Mean ± SD)	Baseline Measures	Outcomes at 5 Days	Outcomes at 8 Weeks
LATCH	Emond et al. 2013[8] RCT/Hospital clinic G1: Frenotomy, 55/52 G2: Usual care, 52/50 Quality: Good	Mean at 5 days followup (IQR) G1: 11 (8-14) G2: 11 (8-16)	G1+G2: ≤ 8	Median (IQR) G1: 9 (8-10) G2: 9 (8-10) G1 vs. G2: p= 1.0	Median (IQR) G1: 10 (10-10) G2: 10 (10-10) G1 vs. G2: p= 0.41
	Dollberg et al., 2006[21] RCT G1: Frenotomy, breastfeeding/ sham, breastfeeding, 15/14 G2: Sham, breastfeeding, frenotomy, breastfeeding, 11/11 Quality: Poor	Range of days G1+G2: 1-21	Mean ± SD G1+G2: 6.4±2.3	Mean ± SD G1+ G2: 6.8 ± 2.0 p=0.06 compared with baseline	NA
BSES-SF	Emond et al. 2013[8] RCT/Hospital clinic G1: Frenotomy, 55/52 G2: Usual care, 52/50 Quality: Fair	Mean at 5 days followup (IQR) G1: 11 (8-14) G2: 11 (8-16)	NR	Median (IQR) G1: 54 (43-62) G2: 53 (40.8-61) G1 vs. G2: p= 0.53	Median (IQR) G1: 63 (59-68) G2: 63 (57-69) G1 vs. G2: p= 0.62
IBFAT	Emond et al. 2013[8] RCT/Hospital clinic G1: Frenotomy, 55/52 G2: Usual care, 52/50 Quality: Good	Mean at 5 days follow=up (IQR) G1: 11 (8-14) G2: 11 (8-16)	NR	Median (IQR) G1: 12 (11-12) G2: 12 (11-12) G1 vs. G2: p= 0.76	Median (IQR) G1: 12 (12-12) G2: 12 (12-12) G1 vs. G2: p= 0.58
	Buryk et al. 2011[7] RCT/Newborn nursery or clinic, otolaryngology clinic G1: Frenotomy, 30 G2: Sham procedure, 28 Quality: Good	Mean days ± SD at enrollment G1: 6.2±6.9 G2: 6.0±7.0	IBFAT, mean ± SE G1: 9.3±0.69 G2: 8.5±0.73	Immediately after procedure, mean ± SE G1: 11.6±0.81 G2: 8.07±0.86 G1 vs. G2, p=0.029 Effect size: 0.31	NA

Note: Not all RCTs reported these measures. BSES-SF = Breastfeeding Self-Efficacy Scale-Short Form; G = group; IBFAT = Infant Breastfeeding Assessment Tool; IQR = interquartile range; LATCH = Latch, Audible swallowing, Type of nipple, Comfort, Hold; N = number; NA = not applicable; SD = standard deviation; SE = standard error.

Cohort Studies

A single poor quality retrospective cohort study compared frenotomy to no intervention.[25] It included 367 infants with feeding or latching difficulties that caused maternal pain when breastfeeding, 302 of whom underwent frenotomy. In this cohort, 58.6 percent of infants were male, mean age at ankyloglossia diagnosis was 18 days, and the majority of patients were either Caucasian (70.3%) or African American (15.5%). Ankyloglossia grade was recorded using Coryllos et al. system.[73] Overall, 17.4 percent had type I, 45.5 percent type II, 25.3 percent type III, 18 percent type IV, and 5.8 percent indeterminate. Outcomes were only assessed in the 91 mothers (24.9%) who agreed to participate in a follow-up survey (82 had frenotomy, 9 no intervention), thus limiting its generalizability. Nonetheless, 80.4 percent of interviewed mothers whose infant had undergone frenotomy felt it had benefited their child's ability to feed. Breastfeeding was continued in 82.9 percent of 82 frenotomized infants for a mean 7.09 months total compared with 66.7 percent of nine infants not treated who breastfed a mean 6.28 months total. In all, 17.1 percent and 33.3 percent in the frenotomy and no intervention group stopped breastfeeding due to difficulty or pain due to ankyloglossia. Having a frenotomy in the first week of life versus later did not affect the total months of breastfeeding (mean: ≤7 days 7.11 vs. >7 days 7.06 months; p<0.9).

Case Series

We identified 23 case series that addressed treatments for ankyloglossia on effectiveness of breastfeeding. All studies focused on surgical treatments, which included frenotomy, frenulotomy, or frenuloplasty. None explicitly evaluated non-surgical interventions. By design, none included a comparison group, thereby eliminating the ability to assess comparative effectiveness of surgical approaches, although the studies typically reported improvements in breastfeeding effectiveness after surgery. Harms reported in case series are included in KQ5.

Analysis of Breastfeeding Effectiveness

Immediate Outcomes

Breastfeeding effectiveness was evaluated in four of five RCTs (Table 8).[7, 8, 20, 23] We rated two RCTs as good quality for these outcomes[7, 20] and two as fair quality.[8, 23] Among the three RCTs that used a blinded independent reviewer to assess effectiveness,[7, 8, 20] one reported objective improvement in breastfeeding effectiveness based on IBFAT score immediately post-frenotomy compared with sham treatment (mean 11.6 ± 0.81 vs. 8.07 ± 0.86; p=0.026).[7] In contrast, in two of the three RCTs, the independent blinded observers did not detect a difference in breastfeeding improvement. Outcomes that failed to show a difference in these two RCTs included percent improvement (50% vs. 40%) immediately after intervention[20]and LATCH and IBFAT change 5-days post-intervention (LATCH change: median 1 [IQR 0 – 2] vs. median 1 [IQR 0 – 2], p=0.52 and IBFAT change: 0 [IQR -1.8 to 1.0] vs. 0 [IQR 0 – 1], p=0.36).[8]

Three of four RCTs with usable data used maternally reported improvement in breastfeeding as an outcome,[8, 20, 23] and in one, it was the primary outcome measure of effectiveness.[23] Maternally reported outcomes differed from objective independent assessment reported above. For example, in one RCT, mothers self-reported improved breastfeeding among infants

immediately after frenotomy (78% in the treated group vs. 47% in the comparison group, p<0.02).[20] Similarly, another trial using non-blinded maternally assessed breastfeeding effectiveness reported that 96 percent of frenotomized infants had improved feeding with 48 hours compared with 3 percent in a control group who had intensive lactation consultant support.[23] Finally, one RCT used the BSES-SF as a secondary outcome and found that mothers whose infants had had frenotomy had significantly improved scores 5 days after intervention (median BSES-SF =9 [IQR 1.8 – 12.3] vs. 1 [IQR -4 to 7.5], p=0.0002).[8]

Longer Term Outcomes

Three RCTs[7, 8, 20]and the retrospective cohort study[25] followed up dyads during the first postoperative year. One RCT contacted mothers 3 months after frenotomy, but did not stratify results by treatment group.[20] Overall, 92 percent (54/59) of all patients reported improved feeding, with 56 percent reporting full resolution of breastfeeding difficulties. Moreover, 65 percent (38/59) of infants were being breastfed at 3 months of age, whereas 51 percent (30/59) were continuing to breastfeed at second outcome assessment (4.5 months). The second RCT evaluated results 2-weeks post-operatively and found no difference between those who underwent frenotomy or sham treatment.[7] A third RCT found no difference in breastfeeding effectiveness between groups as measured by LATCH score at an 8-week follow-up survey, but mothers did report nonsignificantly improved BSES-SF scores among frenotomized infants.[8] Of note, 35 of 52 children assigned to the control arm had undergone frenotomy after 5 days. Seventeen of 35 had not had surgery, and two additional infants were lost to followup at 8 weeks.

The retrospective cohort reported that breastfeeding was continued in 82.9 percent of frenotomized infants for a mean 7.09 months total compared with 66.7 percent of infants not treated who breastfed a mean 6.28 months total. In all, 17.1 percent in the frenotomy and 33.3 percent in the no intervention group stopped breastfeeding due to difficulty or pain due to ankyloglossia. Having had frenotomy in the first week of life versus later did not affect the total months of breastfeeding (mean: ≤7 days 7.11 vs. >7 days 7.06 months; p<0.90).

Maternal Pain Outcomes

Among comparative studies, three RCTs, rated as good[7, 8, 20] for pain outcomes, reported on maternal nipple pain outcomes. Of these, one reported significant and immediate improvement in maternally reported nipple pain among mothers of frenotomized infants compared with sham treatment.[7] Both remaining RCTs found nonsignificant reductions in maternally reported nipple pain between the frenotomy and sham groups at immediate[20] and 5-day[8] post-procedure assessments. Of note, 17 percent of infants randomized to no intervention in the study that followed patients out five days[8] requested and received early frenotomy before the data were collected.

Table 8. Breastfeeding-associated pain scores after surgical procedures

Outcome Measure	Study Study Design/Setting Groups, N Enrollment/ N Final Quality	Age in Days	Baseline Measures, Mean ±SD	Followup Measures
Visual Analog Scale	Emond et al. 2013[8] RCT/Hospital clinic G1: Frenotomy, 55/52 G2: Usual care, 52/50 Quality: Good	Mean at 5 days followup (IQR) G1: 11 (8-14) G2: 11 (8-16)	NR	5 days, median (IQR) G1**:** 3 (1-4.3**)** G2**:** 3 (2-6) G1 vs. G2: p=0.13 8 weeks, median (IQR) G1: 0 (0) G2: 0 (0-1) G1 vs. G2: p=0.41
	Berry et al. 2012[20] RCT/Hospital (not specified) G1: tongue-tie division, 30/27 G2: sham procedure, 30/3 Quality: Good	Mean (range) G1: 33 (6-115) G2: 28 (5-111)	G1: 4.1± NR G2: 4.2± NR	Mean immediately after procedure G1: 1.6 G2: 2.9 Mean change ± SD: G1: -2.5 ± 1.9 G2: -1.3 ± 1.5, p=0.13 (95% CI: -0.3 to 2.4)
Short-Form McGill Pain Questionnaire	Buryk et al. 2011[7] RCT/Newborn nursery or clinic, otolaryngology clinic G1: Frenotomy, 30 G2: Sham procedure, 28 Quality: Good	Mean ± SD at enrollment G1: 6.2±6.9 G2: 6.0±7.0	G1: 16.8±10.6 G2: 19.2±9.9	Mean ± SD immediately after procedure G1: 4.9±1.46 G2: 13.5±1.5 G1 vs. G2: p<0.001 Effect size: 0.38

G=group; IQR=interquartile range; N=number; NR=not reported; RCT=randomized controlled trial; SD=standard deviation.

KQ2a. Benefits of Treatments To Mitigate Feeding Sequelae

Key Points

- Existing data are insufficient to draw conclusions about the benefits of surgical interventions for infants and children with ankyloglossia on medium- and long-term feeding outcomes other than breastfeeding. The studies used different populations and measured different outcomes.

Overview of the Literature

We identified three studies examining medium- and long-term benefits related to feeding outcomes and sequelae of various interventions for infants and children with ankyloglossia (Table 9).[23, 24, 35] One was an RCT[23] (fair quality for feeding outcomes) and one was a poor

quality retrospective cohort study[24]; the remaining study was a case series.[35] All studies were single center or single surgeon studies. Two studies were conducted in the United Kingdom[23, 35] and one study in the United States.[24]

Detailed Analysis

Comparative data were included in two studies.[23, 24] A detailed description of the included fair quality RCT study design and population are reported in the detailed analysis for KQ1. In summary, the study[23] randomized infants born with ankyloglossia and diagnosed within the first 5 months with feeding problems to either frenotomy (n=28) or a control group who had intensive support, advice and help from lactation consultants (n=29). Outcomes were based solely on maternal-report within 48-hours of randomization. However, in the RCT the control group was offered – and the majority elected to receive –frenotomy within 48 hours of randomization to the comparison group, so the outcomes do not reflect "medium to long term" feeding outcomes. This study was included herein, because it includes data on bottle-feeding efficiency. Outcomes related directly to breastfeeding are presented in KQ1.

Among pre-treatment bottle fed infants, 76 percent had major problems with dribbling, and 71 percent had "excess wind" (gas). Mothers reported significant improvement in feeding in all eight who received the frenotomy and in none who did not. The interval to ascertainment of outcomes was not specifically reported, but outcomes were obtained within the first 4 weeks of life.

The retrospective cohort study compared parent-reported (typically maternal) outcomes at age 3 years for children born in 2010 who 1) received frenotomy for tongue-tie (n=71; frenotomy group), 2) were offered but declined frenotomy for tongue-tie (n=15; no frenotomy group), and 3) children without ankyloglossia (n=18; control group).[24] Three questions rated on a 5-point Likert scale were used to assess a child's difficulty (a) cleaning his or her teeth with the tongue, (b) licking the outside of his or her lips, and (c) eating ice cream. With respect to answers on each of the questions, the frenotomy group performed better than the no frenotomy group at age 3 years and did not differ significantly from the comparison group without ankyloglossia. P-values were presented without reporting the central tendency (e.g., median, mean) or variance (IQR, SD) from which they were calculated. Therefore, further comparative description or analysis was not possible.

In the case series of 62 infants, 51 had complete outcome data (11 lost to follow-up).[35] Of these, infant ages ranged from 12 to 35 days at time of referral for frenulotomy by plastic surgeon, and outcomes were assessed prospectively over an 8-month period, on the day of frenulotomy, and at 2-weeks post-procedure at outpatient appointment. Over this period, the number of breastfeeding sessions decreased from 10 ± 0.7 pre-frenulotomy to 7 ± 0.5 post-frenulotomy ($p<0.0001$) and bottle feeding supplementary sessions per day were reduced from nine to two at 2-week follow-up ($p<0.0001$). The authors suggest that this reflects longer-term improvement in feeding efficiency.

Table 9. Feeding sequelae

Study Study Design/Setting Groups, N Enrollment/N Final Quality	Age, Mean Days	Outcomes
Hogan et al. 2005[23] RCT/Outpatient (not specified) G1: Tongue-tie division, 28/28 G2: Usual care and advice from lactation consultants, 29/29 Quality: Fair	G1: 20 G2: 18 Range G1+G2: 3-70	• 96% of G1 infants improved in overall (breast and bottle) feeding (as rated by mothers) compared with 3% in G2 (p<0.001) • Feeding improved in 100% (n=8) of bottle fed infants in G1 vs. 0 in G2 (p<0.001) • Most G2 participants also received frenotomy shortly after randomization
Walls et al. 2014[24] Retrospective Cohort/Outpatient clinic, postpartum ward G1: Frenotomy, 71/71 G2: No surgery, 15/15 G3: No ankyloglossia, 18/18 Quality: Poor	3 years	• More children in G1 vs. G2 improved in oral motor activities including difficulty cleaning teeth with tongue (p=0.0006), difficulty licking outside of lips (p<0.0001), and difficulty eating ice cream (p=0.0003) • Outcomes did not differ significantly between participants in G1 and G3

G=group; N=number; NR=not reported; RCT=randomized controlled trial.

KQ2b. Benefits of Treatments To Prevent Other Sequelae

Key Points

- Two studies reported better articulation among children who had received ankyloglossia treatment compared to those who had not, but results related to word, sentence, and fluent speech were inconsistent.
- Results in two studies comparing children with ankyloglossia who received treatment to children without a history of ankyloglossia were inconsistent.
- One small, poor quality RCT compared two surgical methods and reported that children in a four-flap Z-frenuloplasty group had greater articulation gains than those in the horizontal-to-vertical frenuloplasty group.
- Although a number of case series report positive outcomes related to speech after treating ankyloglossia, most discussed modalities, with safety, feasibility or utility as the main outcome, rather than speech itself.

Overview of the Literature

Ten studies addressed ankyloglossia treatment in children with speech and articulation concerns. One RCT[22] rated as poor quality comparing two different surgical techniques and one

poor quality cohort study[24] were conducted in the United States. An additional poor quality retrospective cohort study was conducted in Israel (Table 10).[26] Of seven case series addressing this question, two were conducted in the United States,[42, 43] one each from the United Kingdom,[51] China,[37] India,[47] Japan,[54] and Korea.[34] No study addressed the effect of ankyloglossia on sleep disordered breathing, dental/occlusal issues, or dysphagia.

Among the comparative studies identified, two of three had speech and articulation assessed by speech-language pathologists,[22, 26] while the third relied on parental report.[24] Professional assessment was performed by speech-language pathologists using the Articulation and Naming Test[26] in one of two studies in which they were the outcome assessors and with the other using consensus between speech-language pathologists.[22] The third study used a non-validated parental survey to determine parent perception of the severity of the child's speech misarticulations.[24]

Detailed Analysis

Cohort Studies

One poor quality retrospective cohort study[24] compared three treatment groups of children who were three years old in 2010 who had: (1) ankyloglossia and frenotomy within the first month of life (n=71), (2) ankyloglossia and whose parents declined frenotomy during the same period (n=21), and (3) a control group of randomly selected 3-year old patients with no history of ankyloglossia (n=18). Three-year old subjects were chosen because that is the age that speech and articulation abnormalities typically present. Pediatric otolaryngologists assessed ankyloglossia using Coryllos criteria in the postpartum ward or during outpatient clinical examination. Parents of all identified patients were then contacted for a telephone survey that consisted of nine questions related to the health care provider who identified restriction, recommendations for surgery, intelligibility of speech to parent(s), impaired speech sounds, deficiencies in oral motor activities, and perceived need for speech therapy. Speech intelligibility was graded on a 5-point Likert scale (1=poor to 5=well-developed).

Overall, 36 of 86 with treated or untreated ankyloglossia had parent-identified speech difficulties. Three-way comparison found statistically improved speech scores among treated versus untreated groups (mean 4.52 ± 0.61 vs. 3.60 ±0.63, $p<0.0001$) and between the control and untreated groups (mean 4.33 ± 0.77 vs. 3.60 ±0.63, $p=0.01$). No difference was found between the treatment and non-ankyloglossia control arms. The authors suggest that these results indicate that frenotomy can improve speech, and that speech outcomes for children after frenulum release are on par with those of children who never had ankyloglossia. However, little information is provided about why children in the untreated group did not receive frenotomy or why certain children were treated, nor were parents unaware of the treatment their child had received making recall bias a clear possibility.

A second poor quality retrospective cohort study recruited children who underwent frenotomy for ankyloglossia between ages of 2 days and 4 weeks and who were 4 to 8 years of age at the time of the study.[26] These children were age-matched to children with untreated ankyloglossia whose parents reported a history of breastfeeding difficulties (nipple pain and/or latching difficulties) and to children with no history of ankyloglossia. All patients were administered the Articulation and Naming Test[74] by two speech-language pathologists who were blinded to the group assignment. Each child's oral anatomy was systematically assessed from a standard oral motor evaluation test and scored.

In all, 23 children (17 males, 6 females) were divided into age-matched groups based on treatment status: treated (n=8; mean age 6.2 ± 1.8), untreated (n=7; mean age 6.2 ± 1.9), and controls (n=8; mean age 5.8 ± 1.9). All were found to have normal oral anatomy on examination. No significant differences were detected between treated and control patients in word, sentence, and fluent speech intelligibility. In contrast, children with untreated ankyloglossia had more articulatory errors than those who had been treated (14.5 ± 10 errors vs. 6.0 ± 4.2 errors).

Relevant case series examined different treatment methods including simple division with scalpel, scissors, and CO2 laser,[51] frenuloplasty,[42, 43, 54] and the addition of genioglossus myotomy.[34] All studies reported positive outcomes and none reported significant harms, but as noted, these studies provide no comparative effectiveness data.

Table 10. Comparative studies with speech outcomes

Study Study Design/Setting Groups, N Enrollment/ N Final Quality	Age in Years	Key Outcomes
Walls et al. 2014[24] Retrospective cohort/Outpatient clinic, postpartum ward G1: Frenotomy, 71/71 G2: Untreated, 15/15 G3: No ankyloglossia, 18/18 Quality: Poor	3 years	• 36 of 86 patients in G1 and G2 were reported by parents to have speech difficulties at age 3 • Using a Likert scale of 1 (poor outcome), 3 (intelligible), 5 (well developed), parents reported (mean ± SD): G1: 4.52 ± 0.61 G2:3.60 ± 0.63 G3: 4.33 ± 0.77 • Parental measures of speech were significantly higher in G1 compared with G2 (p<0.0001) and G2 compared with G3 (p=0.01), but not in G1 compared with G3 (p=0.38)

Table 10. Comparative studies with speech outcomes (continued)

Study Study Design/Setting Groups, N Enrollment/ N Final Quality	Age in Years	Key Outcomes
Dollberg et al. 2011[26] Retrospective cohort/NR G1: Frenotomy, 8/8 G2: Untreated tongue-tie, 7/7 G3: No ankyloglossia, 8/8 Quality: Poor	G1: 6.2 ± 1.8 G2: 6.2 ± 1.9 G3: 5.8 ± 1.9	• Investigators assessed consonant articulation errors, word production accuracy, word intelligibility, sentence intelligibility and fluent-speech intelligibility. • Although differences were observed, including with treated children consistently having fewer problems across measures than untreated children, none of the differences was statistically significant, possibly due to small sample size. There were minimal, nonsignificant differences in the mean number of errors between treated children and those without ankyloglossia: Consonant articulation errors mean ± SD (SEM): G1: 6.0 ± 7.5 (2.7) G2: 7.1 ± 6.9 (2.6) G3: 1.0 ± 2.9 (1.0) G1 vs. G2: p=0.76 (95% CI: -6.96 to 9.19) G1 vs. G3: p=0.11 (95% CI: -1.43 to 11.39) Word production accuracy mean ± SD (SEM): G1: 6.0 ± 4.2 (1.5) G2: 14.5 ± 10.0 (3.7) G1 vs. G2: p=0.076 (95% CI: -1.15 to 18.09) G3: 8.8 ± 11.6 (3.1) G1 v. G3: p=0.53 (95% CI: -12.54 to 7.28) Word intelligibility mean ± SD (SEM): G1: 1.3 ± 0.1 (0.1) G2: 1.7 ± 0.36 (0.1) G1 vs. G2: p=0.33 (95% CI: 0.04 to 0.714) G3: 1.4 ± 0.4 (0.1) G1 vs. G3: 0.50 (95% CI: -0.46 to 0.25) Sentence intelligibility mean ± SD (SEM): G1: 1.3 ± 0.2 (0.1) G2: 1.6 ± 0.46 (0.2) G1 vs. G2: p=0.16 (95% CI: -0.147 to 0.749) G3: 1.4 ± 0.4 (0.1) G1 vs. G3: p=0.46 (95% CI: -0.49 to 0.24) Fluent-speech intelligibility mean ± SD (SEM): G1: 1.5 ± 0.4 (0.1) G2: 1.6 ± 0.5 (0.2) G1 vs. G2: p=0.6 (95%CI: -0.416 to 0.689) G3: 1.2 ± 0.3 (0.1) G1 vs. G3: p=0.229 (95%CI: -0.18 to 0.68)

CI = confidence interval; G = group; N = number; NR = not reported; SD = standard deviation; SEM = standard error of the mean

Comparison of Surgical Approaches

One RCT randomized children presenting to a cleft lip and palate-craniofacial clinic between 1999 and 2003 with a tight frenulum (<15 mm), an articulation or speech problem related to tongue tie, and/or age greater than 3 years to four-flap Z-frenuloplasty or horizontal-to-vertical frenuloplasty.[22] Technical aspects of both surgical procedures were well described. Primary outcomes were changes from pre-operative to follow-up (>10 months) in frenulum length, tongue-protrusion measurements, and speech assessment. Both frenulum length and tongue protrusion were measured pre- and post-operatively by trained independent raters. Each patient had speech evaluations performed by two independent speech-language pathologists.

The study included 16 children with articulation problems, of whom 11 underwent four-flap Z-frenuloplasty (7 male, 4 female) and the remainder (2 male, 3 females) horizontal-to-vertical frenuloplasty. Ages were similar between treatment groups (Z-frenuloplasty: mean 5.7 ± 2.14 vs. horizontal-to-vertical: mean 5.56 ± 1.52). Pre-operatively, children in the Z-frenuloplasty arm had articulation difficulties rated as severe in six (55%) and moderate in five by the speech-language pathologists. Of the five patients in the horizontal-to-vertical frenuloplasty group, three (60%) were rated as severe and two (40%) as moderate. Ten of eleven children in the Z-plasty arm had two orders of magnitude improvement (i.e., severe to mild) and seven had complete resolution of articulation problems. In contrast, no patients in the horizontal-to-vertical group had two order of magnitude improvement or complete resolution. Two had one level improvement in articulation and three had none. Table 11 reports key outcomes in comparative studies.

Table 11. Comparison of surgical approaches

Study Study Design/Setting Groups, N Enrollment/ N Final Quality	Age in Years	Key Outcomes
Heller et al. 2005[22] RCT/Craniofacial clinic G1: Four flap Z-frenuloplasty, 11/11 G2: Horizontal-to-vertical frenuloplasty, 5/5 Quality: Poor	G1: 5.7 ± 2.14 G2: 5.56 ± 1.52	• In the four-flap Z-frenuloplasty group, 6 (55%) participants were rated by a speech-language pathologist as having severe articulation difficulties at baseline; 4 (45%) were rated as having moderate difficulties. • After treatment, 10/11 had 2 orders magnitude improvement; 7 had complete resolution. • In the horizontal-to-vertical group, 3 (60%) participants were rated by a speech-language pathologist as having severe articulation difficulties at baseline; 2 (40%) were rated as having moderate difficulties. • After treatment, 2/5 had 1 order magnitude of improvement; 0 had complete resolution; 3 had no improvement

G = group; N = number; RCT = randomized controlled trial

KQ3. Benefits of Treatments To Prevent Social Concerns Related to Tongue Mobility

Key Points

- Evidence is insufficient to assess the effects of intervention on social concerns related to tongue mobility.
- Studies assessed different surgical interventions and different patient populations with widely varying age ranges.

Overview of the Literature

We identified nine studies that addressed either social concerns[24, 33, 42, 51] and/or tongue mobility.[6, 22, 26, 42, 43, 46, 51] Studies related to the effect of ankyloglossia on social concerns included one poor quality retrospective cohort[24] and three case series[33, 42, 51] that included outcome data for social concerns (e.g., drooling, embarrassment, kissing). The retrospective cohort was conducted in the United States[24] and case series in the United Kingdom,[51]United States,[42] and Brazil.[33] None reported objective measurements of social concerns; instead each used parent- or patient-report to measure improvement. Subject age ranges varied significantly with the cohort study concentrating on 3 year old children[24]and case series including wider age ranges.[33, 42, 51] The studies employed different surgical techniques and used different terminology without technical explanation: laser excision,[6, 51] frenotomy,[24, 33, 34] frenectomy,[6, 33] and horizontal-to-vertical frenuloplasty.[42, 43] Two studies described novel approaches to ankyloglossia repair, frenuloplasty with buccal mucosal graft,[46] and four flap Z-frenuloplasty.[22]

Studies assessing the effect of ankyloglossia treatment on tongue mobility included a single RCT from the United States (rated as poor quality for outcomes related to tongue mobility),[22]a poor quality retrospective cohort study[26] from Israel, and five case series: three from the United States[42, 43, 46] and one each from the United Kingdom,[51] and Brazil.[6] One of two comparative studies objectively measured frenulum length and tongue protrusion,[22] while the other used speech-language pathologists to rate children's tongue movement.[26]

Detailed Analysis

Social Concerns

One comparative study addressed the effect of ankyloglossia treatment on social concerns unrelated to speech.[24] This retrospective cohort study enrolled 3-year old patients who received a frenotomy in infancy (n =71) and age- matched children with untreated ankyloglossia (n=15) and a control group of children without ankyloglossia (n=18). This study design and patient population is described in detail in KQ2 as it relates to feeding outcomes and in KQ2b with respect to speech outcomes. In short, parents were contacted in a telephone survey developed by a speech-language pathologist using a Likert scale to detect improvement in 1) difficult cleaning teeth with tongue, 2) difficulty licking outside of lips, and 3) difficulty eating ice cream.

Compared with individuals with non-treated ankyloglossia, those that were treated had significantly less difficulty cleaning the teeth with the tongue ($p = 0.0006$), licking the outside of their lips ($p < 0.0001$) and eating ice cream ($p = 0.0003$). Similarly, control patients had significantly less difficulties with these tasks compared with untreated children ($p<0.05$). Unfortunately, the central tendency and variance from which these p-values were derived were

not presented in the manuscript. Because this study was retrospective and included only parent report, both recall bias and confounding by indication are likely.

In one case series of older patients (mean age 29.8 ± 10.0 years), pre- and post-procedure patient survey was used to determine improvement.[42] Seven of 15 participants reported embarrassment due to their ankyloglossia. In the six patients who elected to undergo frenuloplasty (mean age 17.3 ± 3.2 years), all reported improvement in tongue function in at least three of six areas which included: licking ice cream, licking lips, cleaning teeth, kissing, and playing a wind instrument. Another case series reported subjective improvement in oral hygiene (n=18/21) after laser frenectomy.[51] Limiting these findings was the absence of pre-procedure status of these patients in these domains and how each was assessed. In addition to not including a comparison group of any type, case series are strongly affected by selection bias and are, by nature, not comparative studies.

Tongue Mobility

We identified two comparative studies that provided data on tongue mobility (Table 12).[22, 26] One RCT enrolled 16 children (mean age 5.7±2.14) randomized to either four-flap Z-frenuloplasty or horizontal-to-vertical frenuloplasty.[22] A thorough review of its study design is described in KQ2b in relation to speech outcomes. Authors measured frenulum length and tongue protrusion using a string to record the distance from the lower dentition to tongue tip during maximum protrusion of the tongue. The string was then transferred to a ruler for measurement in millimeters (mm). Three trained raters measured each patient's tongue protrusion.

The study reported improved tongue tip mobility in all 11 patients who underwent Z-frenuloplasty. The mean frenulum length in this group was 49.4 ± 16.6mm, which was significantly longer than pre-operatively (11.9 ± 6.1 mm, $p<0.001$). Thus, the mean gain in length was 37.5 ± 13.5 mm. In contrast, mean frenulum length for horizontal-to-vertical frenuloplasty was 22.6 ± 7.02 from 11.4 ± 3.36 mm, which was significantly longer, but less so than in the comparison group. Both groups were able to protrude the tongue past the inferior dentition. Mean gains in tongue protrusion for Z-frenuloplasty and horizontal-to-vertical frenoplasty were 36.2 ± 7.6 mm and 13.2 ± 2.6 mm, respectively. Measurements in both groups were significantly improved from baseline (p values <0.01).

The retrospective cohort study compared outcomes among children with ankyloglossia that was treated with frenotomy (n=8), untreated children with ankyloglossia (n=7) and a control group without a history of ankyloglossia (n=8). Design of this cohort is summarized as part of KQ2b in relation to speech outcomes. In terms of tongue mobility, speech-language pathologists examined each child's oral anatomy and tongue movements by performing 10 different exercises as part of a standardized oral motor evaluation test: protrusion, elevation, left and right movements, licking of lower and upper lips, clicking, touching hard palate, elevation of mid-tongue toward the hard palate). Each task was scored from 0 (normal) to 1 (for distorted movement or inability to perform task). Untreated individuals had more difficulties in tasks of tongue movement (11.4 ± 7.6 uncompleted tasks) compared with treated children (3.7 ± 4.2). Children with no history of tongue-tie had the lowest rate of uncompleted tasks (1.2 ± 1.6).

Five case series reported improvements in mobility and elevation.[6, 42, 43, 46, 51] Two case series assessing the safety of CO2 laser (total n=36) concluded that it was safe and effective alternative to conventional release.[6, 51] Both studies reported improvement in tongue mobility after repair but one[6] described greater improvement if the patient received speech therapy prior to release. A

third case series in participants (mean age 8 at surgery, 15 with ankyloglossia and two with short labial frenulums) reported improvements in tongue mobility in the 3-4 months following surgery in an unspecified number of participants.[46] For most of these studies there was minimal explanation of expectations for normal tongue mobility. For the few studies with objective measurements, the total sample size (n= 52) was too small and the ages too varied to establish normative data.

Table 12. Outcomes of interventions for social concerns related to tongue mobility

Author, Year Study Design/Setting Groups, N at Enrollment/Followup Quality	Age, Years, Mean ± SD	Key Outcomes
Social Concerns		
Walls et al. 2014[24] Retrospective cohort/Outpatient clinic, postpartum ward G1: Frenotomy, 71/71 G2: Untreated, 15/15 G3: No ankyloglossia, 18/18 Quality: Poor	3	• More parents in G1 vs. G2 reported improvements in difficulty in cleaning teeth with tongue (p=0.0006), difficulty licking outside of lips (p<0.0001), and difficulty eating ice cream (p=0.0003) • No significant differences between G1 and G3
Tongue Mobility		
Heller et al. 2005[22] RCT/Craniofacial clinic G1: Four flap Z-frenuloplasty, 11/11 G2: Horizontal –to-vertical frenuloplasty, 5/5 Quality: Poor	G1: 5.7 ± 2.14 G2: 5.56 ± 1.52	• Mean frenulum length increased from mean 11.9 ± 6.1 mm to 49.4 ± 16.6 mm (p<.0001) in G1 and from 11.4 ± 3.36 mm to 22.6 ± 7.02 (p=0.02) in G2 • Mean gain in tongue protrusion of 36.2 ± 7.6 mm (range 23-45 mm) in G1 (p<.0001); mean gain for G2 was 13.2 ± 2.6 (range 9-16) mm (p=0.0003) • Study did not define optimal ranges for tongue mobility
Dollberg et al. 2011[26] Retrospective cohort/NR G1: Frenotomy, 8/8 G2: Untreated tongue-tie, 7/7 G3: No ankyloglossia, 8/8 Quality: Poor	G1: 6.2 ± 1.8 G2: 6.2 ± 1.9 G3: 5.8 ± 1.9	• Children in G2 had more difficulties in tasks of tongue movement compared with G1 (11.4 ± 7.6 uncompleted tasks in G2 vs. 3.7 ± 4.3 in G1, p=0.12, 95% CI: -0.26 to 0.18) • Differences between G1 and G3 were not significant

G=group; mm=millimeters; N=number; RCT=randomized controlled trial; SD=standard deviation.

KQ4. Benefits of Simultaneously Treating Ankyloglossia and Concomitant Lip-Tie

We identified no studies that presented outcomes specifically for infants or children treated simultaneously for ankyloglossia and lip tie. One study reported that some of the participants also had lip-tie, but the outcomes were not presented separately for this subset.[31]

KQ5. Harms of Treatments for Ankyloglossia or Ankyloglossia With Concomitant Lip-Tie in Neonates, Infants, and Children Through Age 18

Key Points

- Most studies that reported harms information explicitly noted that no significant harms were observed (n=17) or reported minimal harms, most commonly self-limited bleeding, which would be expected with oral surgery.

Overview of the Literature

We identified 46 studies addressing harms (31 RCTs, cohort studies, or case series and 15 case reports). One RCT conducted in the United Kingdom reported minor harms of surgery and need for reoperation.[8] A single retrospective cohort study conducted in the United States reported harms (scarring).[25]. Twelve of 33 case series reported minor harms: four from the United States,[3, 31, 42, 46] four from the United Kingdom,[29, 49-51] one from Brazil,[6] one from Finland,[48] one from Israel,[52]and one from China[37] Seventeen studies (13 case series, four RCTs) specifically noted that no harms were observed. We included case reports specifically to address harms; details of the 15 case reports yielding harms data are in Appendix G.

Detailed Analysis

Data on harms were only available for studies of surgical interventions. Given the paucity of comparative data on this topic, we also sought case series and case reports to ensure that we captured possible evidence of harms associated with treatment. Of six RCTs, four reported that there were no harms, one was silent on the subject, and one study reported that 64 percent of participants had a small white patch at the base of the frenulum (likely healing slough) that took approximately 7 days to heal and four of 99 (4%) required a reoperation.[8] Among the three cohort studies, two did not address harms. In the one cohort study that reported harms, eight of 302 (2.6%) participants had a recurrence due to scarring or incomplete clipping that required reoperation.[25] Harms were described in 11 of 33 case series. Minor bleeding occurred in six and infant distress/pain was described as affecting 2 of 36 infants (5.6%) in another.[49] Rates of reoperation ranged from 0.1 percent[37] to 27 percent[31], with a need for reoperation occurring in a total of five case series. One case series reported mild wound cicatrization following frenuloplasty involving use of buccal mucosa grafts.[46] Another case series reported no complications after CO2 laser excision, but in patient surveys two of 21 disagreed with the statement "no pain" and one of 21 disagreed with the statement "no blood."[51]

To ensure that we did not miss potential harms of surgical intervention, we searched for case reports of harms and identified 15,[58-72] details of which are presented in Appendix G. Among 15 case reports (two of which reported multiple cases[58, 72]), there were two cases of surgical site infection, three cases of reoperation and four reports of swelling and pain. One case reported post-surgical mucocele in a 12-year-old patient.[59] Only two cases, in Nigeria, sustained harms to the degree that they were hospitalized for bleeding; in these cases, the authors indicated that the procedure was done by inexperienced clinicians and that this likely accounted for the excessive bleeding.[60]

Gray Literature

Conference Abstracts

We searched for conference paper and poster abstracts from recent national and international societies and associations related to pediatrics, nursing, breastfeeding medicine, lactation, otolaryngology, dentistry, orthodontics, speech and hearing. Conference abstracts predominantly addressed prevalence of ankyloglossia, investigation into incidence of anterior versus posterior rates of tongue-tie, rates of surgical treatment interventions, and case reports of successful surgical interventions to address breastfeeding issues. Results reported in abstracts generally aligned with our findings, with abstracts noting maternally reported improvements in breastfeeding effectiveness and nipple pain (Appendix H).

Dissertations and Theses

Although we did not identify any relevant dissertations in our search, one TEP member who recently completed a master's degree at the University of Liverpool allowed us to use findings from her unpublished thesis. She conducted a retrospective survey of parents in the United States of children who had had frenotomy for ankyloglossia either before or after age 12 weeks (Table 13).[75] The survey included questions related to breastfeeding effectiveness and pain, supplemental bottle feeding, feeding with solid food, knowing and pronouncing words, and oral hygiene and was sent to parents of children treated between 2006 and 2011 at a single institution. Findings supported the published literature in reporting improvements after frenotomy in maternally reported outcomes. This study adds to the published literature in assessing early versus late outcomes, finding improved outcomes associated with early treatment. Because it is not a published study, we did not include it in our strength of evidence assessment but provide the results here.

Findings included data from 125 children with ankyloglossia who received frenotomy, 51 of whom were treated before 12 weeks of age (early treatment) and 74 who were treated after (late treatment). All children in the early treatment group were diagnosed within 90 days of birth, while 43 of the late treatment arm were diagnosed by 90 days, eight by 180 to 365 days, and 15 at >365 days of age.

Breastfeeding Outcomes

Children in the early treatment group had a longer duration of breastfeeding compared with the later treatment group. Within the early treatment group, about a third either did not have a latch issue or it was resolved prior to frenotomy, while in 45 percent of the cases the issue was resolved with frenotomy. Nonetheless, in almost a quarter (23.5%), latch issues led to abandonment of breastfeeding. In the late treatment group, however, most (82%) either never had a latch issue or it resolved before the frenotomy, with only 1.4 percent having latch resolved via frenotomy. Pain was resolved after frenotomy in about a third (33.3%) of the early treatment group, whereas about half either did not have pain or it had resolved prior to frenotomy in this group. Among infants diagnosed and treated late, mothers reported that most (89%) did not have pain or that it resolved prior to frenotomy.

Other Feeding Outcomes

In terms of latching to a bottle, in the early treatment group, 75.5 percent either had no issue or had it resolve prior to treatment. Twenty-four percent had problems with latch to a bottle resolved with frenotomy.

Speech Outcomes

Speech issues were unique (as expected) to children with a later treatment. Among these children, pronunciation issues were resolved in in 43.1 percent (n=31/72) of the cases.

Other Outcomes

In this study, no children in the early frenotomy group had oral hygiene issues, compared to 15 in late treatment arm. Issues resolved with frenotomy in 18.1 percent (n=13/122) of children in this group.

Table 13. Outcomes reported in unpublished thesis*

Outcome	Issues With:	Not Breastfed or Not an Issue or Issue Resolved Without Frenotomy N (% of Group)	Issue Resolved With Frenotomy N (% of Group)	Issue Did Not Resolve With Frenotomy N (% of Group)	Issue Resulted in Abandoning Breastfeeding N (% of Group)
Breast-feeding	**Latch to mother's nipple**				
	Early group	16/51 (31.4)	23/51 (45.1)		12/51 (23.5)
	Late group	61/74 (82.4)	1/74 (1.4)		12/74 (16.2)
	All	77/125 (61.6)	24/125 (19.2)		24/125 (19.2)
	Issues with maternal pain				
	Early group	27/51 (52.9)	17/51 (33.3)		7/51 (13.7)
	Late group	65/73 (89.0)	1/73 (1.4)		7/73 (9.6)
	All	92/124 (74.2)	18/124 (14.5)		14/124 (11.3)
	Breastfeeding in reasonable amount of time				
	Early group	22/49 (44.9)	17/49 (34.7)		10/49 (20.4)
	Late group	60/73 (82.2)	0/73 (0)		13/73 (17.8)
	All	82/122 (67.2)	17/122 (13.9)		23/122 (18.9)
	Supplemental bottle feeds				
	Early group	46/51 (90.2)	4/51 (7.8)		1/51 (2.0)
	Late group	69/74 (93.2)	0/74 (0)		5/74 (6.8)
	All	115/125 (92)	4/125 (3.2)		6/125(4.8)

Table 13. Outcomes reported in unpublished thesis* (continued)

Outcome	Issues with:	Not Breastfed or not an Issue or Issue Resolved Without Frenotomy N (% of Group)	Issue Resolved With Frenotomy N (% of Group)	Issue Did Not Resolve With Frenotomy N (% of Group)	Issue Resulted in Abandoning Breastfeeding N (% of Group)
Other Feeding Outcomes	**Latch to bottle**				
	Early group	37/49 (75.5)	12/49 (24.4)	0/49 (0)	
	Late group	64/73 (87.7)	7/73 (9.6)	2/73 (2.7)	
	All	101/122 (82.8)	19/122 (15.6)	2/122 (1.6)	
	Spoon feeding				
	Early group	50/51 (98)	0/51 (0)	1/51 (2)	
	Late group	69/73 (94.5)	4/73 (5.5)	0/73 (0)	
	All	119/124 (96)	4/124 (3.2)	1/124 (0.8)	
	Solid feeding				
	Early group	49/50 (98)	0/50 (0)	1/50 (2)	
	Late group	68/74 (91.9)	6/74 (8.1)	0/74 (0)	
	All	117/124 (94.4)	6/124 (4.8)	1/124 (0.8)	
Speech and Other Outcomes	**Pronunciation**				
	Early group	48/48 (100)	0/48 (0)	0/48 (0)	
	Late group	32/72 (44.4)	31/72 (43.1)	9/72 (12.5)	
	All	80/120 (66.7)	31/120 (25.8)	9 /120 (7.5)	
	Oral hygiene				
	Early group	50/50 (100)	0/50 (0)	0/50 (0)	
	Late group	57/72 (79.2)	13/72 (18.1)	2/72 (2.8)	
	All	107/122 (87.7)	13/122 (10.7)	2/122 (1.6)	

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G = group; N = number.

Discussion

We identified 57 published studies for this review, six of which were randomized controlled trials (RCTs), three were cohort studies, and the remainder case series (n=33) and case reports (n=15). The analysis and discussion concentrate on comparative studies (RCTs and cohorts), as these studies were used for strength of evidence assessment. Case series were included in the results only to ensure that the full range of available literature is made available to the end users of this report. Harms were reported from all included studies as well as a specific search for case reports.

Three RCTs were assessed as good[7, 8, 20] and one as fair[23] quality for outcomes related to breastfeeding effectiveness and associated maternal pain. One RCT was rated as poor quality for breastfeeding effectiveness and pain outcomes.[21] One RCT addressing tongue protrusion, frenulum length, and speech outcomes was rated as poor quality for those outcomes,[22] and we rated one RCT as fair quality for measures of bottle feeding.[23] We rated all three cohort studies as poor quality.[24-26]

We assessed the quality of harms reporting in RCTs and cohort studies as poor and as good in four case series[49-52] and poor in 23.[3, 6, 27-29, 31, 32, 34, 35, 37-40, 42-45, 48-51, 54, 56] We also included data from one unpublished thesis (not quality scored).

Key Findings and Strength of Evidence

KQ (Key Question) 1. Benefits of Interventions Intended To Improve Breastfeeding Outcomes

Key Findings

Overall, three good[7, 8, 20] and one fair[23] quality RCTs assessed whether treatment of ankyloglossia improved breastfeeding effectiveness. While only one of three RCTs that used blinded independent observers found significantly improved breastfeeding effectiveness among frenotomized infants immediately post-procedure,[7] maternally reported breastfeeding effectiveness was significantly improved in the treated group compared with untreated in two of two RCTs that evaluated it either as a primary[23] or secondary[20] outcome. A third RCT evaluated the mother's breastfeeding self-efficacy and found a significant improvement from baseline in the frenotomy group 5-days post-procedure.[8] In all, there is some evidence that maternally reported breastfeeding outcomes improve. Comparative data are lacking to assess the durability of effects.

These same studies had disparate findings about whether frenotomy decreased maternal nipple pain during breastfeeding. Only the RCT performed on infants at 6 days of age showed a significant reduction in maternal pain.[7] Those performed on infants a few weeks older did not report either an immediate[20] or 5-day[8] reduction in pain. The difference between earlier frenotomy and later frenotomy on nipple pain may relate to cumulative trauma on the breast from several additional weeks with inefficient latch from tongue-tied infants.

Strength of the Evidence

Few comparative studies have addressed the effectiveness of surgical interventions to improve breastfeeding outcomes. Mothers consistently reported improved breastfeeding effectiveness, but outcome measures were heterogeneous and most were short term. Future

studies could provide additional data to confirm or change the measure of effectiveness; thus we consider the strength of the evidence (confidence in the estimate of effect) to be low at this time.

We also considered the strength of the evidence to be low for an immediate reduction in nipple pain. Improvements were reported in the current studies, but additional studies are needed to confirm and support these results. Only one poor quality cohort study addressed effects on the length of breastfeeding; thus, we considered the strength of the evidence to be insufficient (Table 14).

Table 14. Strength of the evidence for studies addressing surgical approaches for ankyloglossia and breastfeeding outcomes

Outcome Number of Studies and Quality (Total Participants)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding/Strength of the Evidence
Nipple pain RCT: 3 good, [7, 8, 20] 1 poor[21] (251) Retrospective cohort: 1 poor[25] (367)	Low	Inconsistent	Direct	Imprecise	Undetected	Low SOE for an immediate reduction in nipple pain post-procedure due to inconsistent results across small studies.
Breastfeeding effectiveness RCTs-LATCH: 2 good,[8, 20] 1 poor [21] (193) IBFAT: 1 good[7] (58) BSES: 1 fair[8] (107) Retrospective cohort: 1 poor[25] (367)	Low	Inconsistent	Direct	Imprecise	Undetected	Low SOE for improved breastfeeding. Mothers consistently reported improved breastfeeding effectiveness, but outcome measures were heterogeneous and most were short term. Observer-rated measures did not show effectiveness. Future studies could provide additional data to confirm or change the measure of effectiveness.
Length of breastfeeding Retrospective cohort: 1 poor[25] (367)	High	NA	Direct	Imprecise	Undetected	Insufficient SOE due to the high risk of bias of the one retrospective study

BSES = Breastfeeding Self-Efficacy Score; IBFAT = Infant Breastfeeding Assessment Tool; LATCH = Latch, Audible swallowing, Type of nipple, Comfort, Hold; NA = not applicable; RCT = randomized controlled trial; SOE = strength of the evidence.

KQ2a. Benefits of Treatments To Mitigate Feeding Sequelae

Key Findings

We identified three studies examining feeding outcomes other than breastfeeding: one RCT,[23] one poor quality retrospective cohort study,[24] and one case series.[35] All three studies were single center or single surgeon studies. Bottle feeding and ability to use the tongue to eat ice cream and clean the mouth improved more in treatment groups in comparative studies. Supplementary bottle feedings decreased over time in the case series.

Strength of the Evidence

With only two comparative studies, both with significant study limitations, existing data are insufficient to draw conclusions about the benefits of surgical interventions for infants and children with ankyloglossia on medium- and long-term feeding outcomes. The studies used different populations and measured different outcomes (Table 15).

Table 15. Strength of the evidence for studies addressing surgical approaches and feeding outcomes

Outcome Number of Studies and Quality (Total Participants)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding/Strength of the Evidence
Feeding outcomes RCT: 1 poor[23](57) Retrospective cohort: 1 poor [24](104)	High	Consistent	Indirect	Imprecise	Undetected	Insufficient SOE for all feeding outcomes given small number of participants, lack of standard outcome measures, and poor quality of studies.

RCT = randomized controlled trial; SOE = strength of the evidence.

KQ2b. Benefits of Treatments To Prevent Other Sequelae

Key Findings

Speech concerns were the second most prevalent topic in the ankyloglossia literature, after breastfeeding. A speech-language pathologist measured speech outcomes in two studies[22, 26] with the third using parent report.[24] No studies included data related to sleep disordered breathing, occlusal issues and dysphagia in the non-breastfeeding child. Two cohort studies attempted to assess the effectiveness of frenotomy, [24, 26] and one compared two surgical approaches to frenotomy. [22]

Two poor quality cohort studies[24, 26] reported an improvement in articulation and intelligibility with ankyloglossia treatment, but benefits in word, sentence and fluent speech were unclear. The one poor quality RCT reported improved articulation in patients treated with Z-frenuloplasty compared to horizontal-to-vertical frenuloplasty.[22] Numerous non-comparative studies reported a speech benefit after treating ankyloglossia; however these studies primarily discussed modalities, with safety, feasibility or utility as the main outcome, rather than speech itself.[33, 34, 37, 42, 43, 47, 48, 51]

Strength of the Evidence

Given the lack of good quality studies and limitations in the measurement of outcomes, we considered the strength of the evidence for the effect of surgical interventions to improve speech and articulation to be insufficient (Table 16).

Table 16. Strength of the evidence for studies addressing surgical approaches and other outcomes

Outcome Number of Studies and Quality (Total Participants)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding/SOE
Speech and articulation Retrospective cohort: 1 poor[24] (104) Prospective cohort: 1 poor[26] (23)	High	Inconsistent	Indirect	Imprecise	Undetected	Insufficient SOE based on 2 poor quality cohort studies
Oral motor skills Retrospective cohort: 1 poor [24](104) Prospective cohort: 1 poor[26] (23)	High	Consistent	Indirect	Imprecise	Undetected	Insufficient SOE based on 2 poor quality cohort studies

SOE = strength of the evidence.

KQ3. Benefits of Treatments To Prevent Social Concerns Related to Tongue Mobility

Key Findings

Only one poor quality comparative, retrospective cohort study assessed outcomes related to social concerns other than speech.[24] It reported significantly improved ability to clean teeth with tongue, licking outside of lips, and eating ice cream in the treatment group compared with untreated participants. The intermediate outcome of improved tongue movement or mobility after ankyloglossia repair was assessed in two comparative studies—one poor quality RCT[22] and one poor quality cohort study.[26] The RCT assessed tongue mobility using two different surgical techniques for treating ankyloglossia and found that both approaches significantly improved tongue mobility, but that Z-frenuloplasty was superior.[22] In the cohort study, individuals with untreated ankyloglossia had the worst tongue mobility followed in order by children with treated ankyloglossia, and those with no history of ankyloglossia.[26]

Strength of the Evidence

With only one poor quality comparative study, strength of the evidence related to the ability of treatment for ankyloglossia to alleviate social concerns is currently insufficient. Also, with only three comparative studies with small sizes and limitations in the measurement of outcomes related to tongue mobility, we considered the strength of the evidence for the effect of surgical interventions to improve the short-term outcome of mobility to be insufficient (Table 17).

Table 17. Strength of the evidence for studies addressing surgical approaches and social concerns related to tongue mobility

Outcome Number of Studies and Quality (Total Participants)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding/SOE
Social concerns Retrospective cohort: 1 poor[24] (104)	High	NA	Indirect	Imprecise	Undetected	Insufficient SOE based on 1 poor quality cohort study
Tongue mobility RCT: 1 poor[22] (16) Retrospective cohort: 1 poor[26] (15)	High	Consistent	Direct	Imprecise	Undetected	Insufficient SOE based on 2 small, poor quality studies

RCT = randomized controlled trial; NA = not applicable; SOE = strength of the evidence.

KQ4. Benefits of Simultaneously Treating Ankyloglossia and Lip-Tie

We did not identify any studies addressing this question.

KQ5. Harms of Treatments for Ankyloglossia or Ankyloglossia With Concomitant Lip-Tie in Neonates, Infants, and Children Through Age 18

Key Findings

We identified all possible harms reported within comparative studies and case series that potentially provided effectiveness data. We also sought case reports of harms. With this approach, we reported harms from 51 studies that reported that they had looked for harms, either reporting actual harms or specifically indicating that they found none. These included five RCTs, one cohort study, 28 case series, and 15 case reports. We considered all comparative studies (RCTs and cohort studies) as poor quality for harms outcomes. We considered the quality for harms outcomes as good in four case series[49-52] and poor in 24.[3, 6, 27-48]Most studies that reported harms information explicitly noted that no significant harms were observed (n=18) or reported minimal harms. Among studies reporting harms, bleeding and the need for reoperation were

most frequently reported. Bleeding was typically described as minor and limited. Few studies described what specific methods they used to collect harms data.

Strength of the Evidence

We considered the strength of the evidence for minimal and short-lived bleeding as a harm of surgical interventions as moderate based on an expanded search for harms reports in addition to the comparative data. We considered the strength of the evidence for reoperation and pain as harms to be insufficient given the small number of studies that included these outcomes (Table 18).

Table 18. Strength of the evidence for studies addressing harms of surgical approaches

Outcome ***Number of Studies and Quality (Total Participants)***	**Study Limitations**	**Consistency**	**Directness**	**Precision**	**Reporting Bias**	**Finding/SOE**
Bleeding RCT: 1 poor[20] (60) Case series: 14 poor[6, 27-29, 32, 34, 35, 38-40, 42-45], 2 good [50, 51] (963)	High	Consistent	Direct	Imprecise	Suspected	Moderate SOE for minimal and short-lived bleeding based on an extensive search for harms reports in addition to the comparative data. Studies consistently reported minimal to no bleeding.
Reoperation RCT: 1 poor[8] (107) Retrospective cohort: 1 poor[25] (367) Case series:1 good,[50] 4 poor[3, 31, 37, 48] (3577)	High	Consistent	Direct	Imprecise	Suspected	Insufficient SOE due to very small numbers of the outcome reported at all in studies.
Pain Case series: 2 good[49, 51] (84)	High	Consistent	Indirect	Imprecise	Suspected	Insufficient SOE for minimal, short-lived pain in infants. No studies reported excessive crying or an inability to feed soon after the intervention, but pain is arguably difficult to assess in infants, so outcomes were indirect and from poor quality or noncomparative studies.

RCT = randomized controlled trial; SOE = strength of the evidence.

Findings in Relationship to What Is Already Known

Few recent reviews assessed outcomes of ankyloglossia treatment,[2, 5, 76, 77] and our findings generally align with those prior reviews, concluding that current evidence is drawn from a small literature base with inconsistent findings related to the benefits of ankyloglossia treatments for increasing breastfeeding effectiveness or reducing maternally reported nipple pain. In a review focused solely on frenotomy and breastfeeding, the authors rated most of the seven studies evaluating frenotomy as poor quality (mean score of 24.4, range 9-40 on a 47-point scale).[76] Studies included one RCT, and all used different outcome-measures to assess effects of frenotomy. Outcomes (breastfeeding mechanics, nipple pain, rate of breastfeeding, sucking, weight gain) all improved post-procedure, and no studies reported significant adverse effects. Another review and meta-analysis addressing frenotomy and breastfeeding included four RCTs and 12 observational studies and concluded that moderate quality evidence supports the effectiveness of frenotomy for improving latching and nipple pain.[77] The risk ratio for overall improvement in latching was 2.88 (95% confidence interval [CI]: 1.82 to 4.57) in meta-analysis of four RCTs, and the mean difference in pain scores was -5.10 (95% CI: -5.60 to -4.59) in meta-analysis of three RCTs. The review noted that no major complications were reported in the studies analyzed.

In a review addressing diagnosis and treatment and including 10 studies assessing effects of treatment on breastfeeding outcomes, breastfeeding mechanics and related outcomes typically improved.[2] Four studies of tongue mobility and three of speech problems also reported improvement. The review notes insufficient evidence related to choice of procedure, timing of procedure, or surgical versus conservative management; however, the investigators did not include any quality metrics for included studies.

A fourth recent review assessed outcomes related to breastfeeding and speech.[5] The 20 studies included ranged from level 4 case series to randomized controlled trials, and concluded that there is both objective and subjective evidence that frenotomy benefits breastfeeding (facilitated breastfeeding, enhanced milk transfer to the infant, and contributed to protecting maternal nipple and breast health), but tempered this by recognizing that there were a limited number of studies available with high quality evidence. Outcomes in four studies addressing speech articulation reported few definitive improvements following treatment. This review did not evaluate non-surgical management or broader outcomes.

Applicability

We set inclusion criteria intended to identify studies with applicability to newborns, infants, and children with ankyloglossia. Studies differed in terms of study population and outcome measures. Most studies were non-comparative, and lack of direct comparisons of treatment options further hinders the ability to understand what findings will best extrapolate to a specific newborn or infant or decisions about care protocols. Overall the data on breastfeeding and maternal breast pain that are available may be applicable to newborns with ankyloglossia with concomitant feeding problems. There is no evidence to suggest that the data would be applicable to infants with ankyloglossia who do not present with feeding problems. Appendix I contains applicability tables for individual KQs.

Applicability of Studies With Breastfeeding Outcomes

Newborns referred for treatment of ankyloglossia were born primarily at tertiary care centers and recognized as having difficulty with breastfeeding concomitant with ankyloglossia. The frenotomy procedure itself is not technically difficult and is likely performed similarly across birthing sites; what is less clear is whether the diagnostic criteria by which the decision is made to perform the procedure are similar across practice settings. Moreover, newborns of mothers not choosing to breastfeed may not be recognized as having and/or diagnosed with ankyloglosssia as breastfeeding difficulties were used as an indicator to evaluate for ankyloglossia. Interestingly, two studies[7, 8] reported that all patients had lactation consultation prior to enrollment without significant improvement in feeding. Arguably, this limits the applicability of their results to newborns that had failed to improve adequately with such consultation.

In these studies, various clinicians were involved in making the ankyloglossia diagnoses; however, assessment of breastfeeding difficulty and diagnostic criteria for ankyloglossia were not universally described. Lack of a consistent objective measure to define and classify this condition may limit the reproducibility of findings. Furthermore, patients in these studies were between a median 6 days of age[7] and up to a mean 33 days of age (range 6 to 115) in another study.[20] Applicability to findings in older infants cannot be gleaned from these data; nor can durability of results.

Frenotomy was the only intervention employed in the good quality RCTs.[7, 8, 20] However, the specifics of the procedure were variably reported. As such the degree of posterior extension of the frenulum incision was not clearly defined and appears to be at the discretion and clinical expertise of the clinician. Also, the severity of the ankyloglossia was inconsistently reported, making inter-study generalizations difficult and, more importantly, limiting the broader applicability of findings.

The comparators used were sham surgery[7, 20] and usual care.[8] These outcomes are identical except in regards to blinding and outcome assessment. Both no intervention and sham surgery are perhaps misnomers, however, since these infant-mother dyads underwent usual care, which could include, but is not limited to, lactation consultation, supportive care, and bottle-feeding advice. Finally, there is insufficient evidence from available literature to assess the applicability of frenotomy on durability of breastfeeding.

Applicability of Studies With Other Feeding Outcomes

Only one study with comparative poor quality retrospective cohort data addressed other feeding outcomes.[24] The study's intervention group received frenotomy for ankyloglossia, which was identified within the first month of life, and was compared to dyads who were also offered, but declined, frenotomy for the same indication in the same time period. Although this is a common decisional dilemma for parents of infants with congenital ankyloglossia, in usual clinical care, surgical intervention is not considered unless congenital ankyloglossia co-occurs with breast- or other feeding problems. Furthermore, there are several biases inherent in this treatment decision. First, those with "worse" ankyloglossia are more likely to get treated. Second, mothers who more strongly want to breastfeed may opt for division. Mothers who would rather pump or bottle feed with formula would more likely chose observation. Third, practitioners' presentation of the evidence may sway the decision, thus perpetuating their personal bias about effectiveness of frenotomy on improving breastfeeding and reducing

maternal pain. Additionally, the study was conducted in an academic medical center in large, urban area with ankyloglossia severity graded by pediatric otolaryngologists. Therefore, applicability of its findings and observations may not translate to other care environments (i.e. community hospital, rural) and many usual clinical care settings may not include practitioners from this sub-specialty, instead relying more on pediatricians, lactation consultants, family practitioners, or dentists.

Applicability of Studies With Speech Outcomes

Comparative studies providing data on speech outcomes were all rated as poor quality and included a randomized controlled trial[22] and two retrospective cohort studies.[24, 26] The RCT compared two different frenuloplasty approaches for treatment of children of a mean age of approximately 6 years with a tight frenulum effecting articulation or intelligibility[22] and found that children treated with either four-flap Z-frenuloplasty and horizontal-to-vertical frenuloplasty had significant improvement in articulation as judged by trained speech-language pathologists. Applicability of these findings is limited due to the small sample size, inadequate characterization of candidate children, and that specialist pediatric craniofacial surgeons performed these surgeries at an urban tertiary care center. "Usual sites" where ankyloglossia is diagnosed and treated would have a difficult time extrapolating these findings considering the limitations.

Similarly, the cohort studies were performed solely in urban tertiary care centers. One assessed outcomes on 3-year old children treated for ankyloglossia as neonates compared to those who had untreated ankyloglossia, and a control group without a history of ankyloglossia.[24] Pediatric otolaryngologists made the diagnosis using standardized diagnostic criteria. The reason that infants presented for treatment of ankyloglossia was not identified. Further limiting the applicability is that these patients were all cared for at a tertiary care facility and outcomes were assessed using a non-validated parent reported telephone survey. Thus, there was no objective evaluation of speech. Parents of children with ankyloglossia would have a higher index of concern for speech issues than those whose children never had been diagnosed with tongue mobility restriction. The second poor quality retrospective cohort with a relatively small sample size (n=23) of children a mean of roughly 6 years of age that were similarly divided into those with treated ankyloglossia, untreated ankyloglossia, and a control group.[26] It was performed at a tertiary care facility in an Israeli urban center. Unfortunately, its applicability is limited similarly to that previously described except that speech-language pathologists objectively assessed speech using a standardized assessment tool. Both retrospective studies lacked explanations about the rationale for initial surgical intervention or reason parent chose not to intervene.

Applicability of Studies With Social Outcomes

The population studied in the question of benefit of ankyloglossia repair for social concerns included children and adults with wide variation in ages. Studies were rated as poor quality, were retrospective, and few in number. Outcomes in one were assessed by parental report and subject to recall bias[24] and social outcomes assessed were limited to licking lips, cleaning teeth with tongue and eating ice cream. Thus, the social concerns or implications of these issues are unclear. No other comparative study considered social concerns. In addition, at least two case series did consider the impact of ankyloglossia on kissing and playing a wind instrument[42] and drooling and oral hygiene.[33] Limiting these findings was the absence of preprocedure status of these patients in these domains and how each was assessed. In addition to not including a

comparison group of any type, case series are strongly affected by selection bias and are, by nature, not comparative studies. Moreover, patients were selected either by retrospective chart review or as they presented to otolaryngology clinics. Only surgical interventions were studied and no two studies measured the same outcomes. Typically, social concerns were measured as a secondary outcome. The setting was typically the outpatient setting, within academic medical centers.

Implications for Clinical and Policy Decision Making

A small body of evidence suggests that frenotomy may be associated with mother-reported improvements in breastfeeding and possibly reduction in nipple pain, when feeding difficulties are present. At this point, the evidence is fairly inconclusive on effectiveness for most outcomes. However, there does seem to be stronger evidence that harms are minimal to none, Thus, given the mixed evidence, clinicians and families will likely need to make individual decisions about pursuing intervention for ankyloglossia-related feeding and speech production difficulties. Importantly, no research evidence exists to assess any non-surgical interventions, so clinical and policy decision making will necessarily occur in the absence of evidence for nonsurgical interventions.

Limitations of the Comparative Effectiveness Review Process

This review included only studies published in English. However, our scan and review of non-English references revealed that high percentage of non-eligible items. Specifically, we determined that 502 of the 520 foreign language references identified in MEDLINE (search conducted in February 2014) would be excluded based on our criteria. Of the 18 potential includes, six appeared, from the information in the abstract and/or title to be eligible for inclusion; 12 did not include abstracts or sufficient information from the title to make an inclusion decision. Two of these appeared to be case reports and neither gave clear indications on whether harms of interventions were addressed. Given the high percentage of non-eligible items in this scan (97%), we feel that excluding non-English studies did not introduce significant bias into the review.

While we focused the review on comparative studies (studies including an intervention and a comparison group), we provide summaries of case series data to supplement the comparative findings given the small number of studies addressing ankyloglossia interventions. We further specifically sought case reports of any harms associated with ankyloglossia intervention. This approach may provide particularly useful information about harms as we found little evidence of serious harm of surgical interventions, though harms reporting was limited.

Limitations of the Evidence Base

The evidence base for the benefits of treatment in ankyloglossia is very limited. Overall, the evidence base consists of a few small studies that use varied outcomes and provide little information to adequately characterize participants. Infants vary in age at treatment from 6 to 33 days and in reasons for presentation. Studies are focused on neonates and infants who present because of breastfeeding difficulties, and while improving breastfeeding success is an important goal, by definition, this means data are unavailable on infants with ankyloglossia but without feeding difficulties in infancy. The degree to which these infants are likely to go on to develop

either feeding, speech or social impediments is inadequately understood. No study effectively assessed mid- and long-term comparative outcomes of frenotomy making it difficult to predict whether mother-reported improvements early in infancy led to longer term breastfeeding. In particular, there is a lack of evidence on significant long-term outcomes such as exclusive breast-feeding at six month of age or at one year of age, growth and other measures of health outcomes. Furthermore, studies are entirely lacking that compare surgical intervention to well-described skilled lactation consultation and other breastfeeding report. Although complementary and alternative methods of care are used in some practices, no studies are available. In addition, the literature base may be subject to publication bias. Most controlled studies reported only positive outcomes, and we identified no negative trials.

Finally, we found no comparative effectiveness data on nonsurgical interventions, although they are in use in clinical care, and in surgical studies, case series predominated, providing little comparative data.

Research Gaps

Breastfeeding Outcomes

Future studies should consider direct comparisons of alternative treatments as currently available literature only addressed the comparison of frenotomy to sham. In order to conduct these studies, it would be helpful if the field could agree upon on standardized approach to identifying and classifying ankyloglossia; this would also improve our ability to synthesize the data across studies.

A critical unknown at this point is a good description of the natural history of ankyloglossia by severity, including long term risk of feeding, social and speech production difficulties. Studies should also consistently report measures of severity.

Given variation in outcomes that may be associated with earlier versus later frenotomy, future studies should assess timing of frenotomy to determine whether more significant reduction in maternal pain is achievable by earlier treatment and whether mothers are more apt to breastfeed longer if done earlier.

A final gap in research is in understanding the durability of outcomes. Good quality comparative studies evaluated breastfeeding effectiveness immediately[7, 20] or within 5 days of frenotomy.[8] However, none adequately assessed whether effectiveness and other outcomes (e.g., changes in maternal nipple pain) were maintained months or, if appropriate, years later. Longer term follow up of both treated infants and controls is needed.

Other Feeding Outcomes

Because there is such a paucity of available data on other feeding outcomes, this entire research question represents a gap and a potential area for future research.

Speech and Other Outcomes

Similarly, substantially more research is needed to consider whether treatment of ankyloglossia in infancy prevents future speech production difficulties as well as whether treatment later in life with frenotomy leads to improvement when speech problems arise. To conduct this research effectively, methods for evaluating risk and presence of speech production difficulties will need to be standardized, and outcomes agreed upon. Understanding of the natural

history of speech concerns in children with ankyloglossia is lacking as are comparative studies that utilize standardized measurement tools for speech outcomes.

Social Concerns Related to Tongue Mobility

No standard definitions of tongue mobility or established norms for mobility exist, and further research is needed to determine such parameters. Social concerns are difficult to measure objectively so there will likely always be a subjective component to social outcomes. Larger studies that assess both treated and untreated individuals could provide useful data to minimize the potential bias found in the existing literature. Similarly, future research in objective measurement tools, or validated self-report tools, is needed.

Harms Reporting

Few studies prespecified harms or provided details of harms collection. Harms were not systematically reported, and therefore there may be substantial underreporting. Minor, limited bleeding and need for re-operation were reported in some studies, but methods for collecting harms in studies overall were poorly reported. Future studies would benefit from explicit description of methods for harms collection, including estimating blood loss, and assessment and explicit reporting.

Conclusions

A small body of evidence suggests that frenotomy may be associated with improvements in breastfeeding as reported by mothers, and potentially in nipple pain, but with small studies, inconsistently conducted, strength of the evidence is low to insufficient, preventing us from drawing firm conclusions at this time. Research is lacking on nonsurgical interventions as well as on outcomes other than breastfeeding, particularly speech and dental outcomes. In particular, there is a lack of evidence on significant long-term outcomes such as exclusive breast-feeding at six month of age or at one year of age, growth and other measures of health outcomes. Harms are minimal and rare; the most commonly reported harm is self-limited bleeding. Future research is needed on a range of issues, including prevalence and incidence of ankyloglossia and problems with the condition. The field is currently challenged by a lack of standardized approaches to assessing and studying the problems of infants with ankyloglossia.

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Abbreviations and Acronyms

AAP: American Academy of Pediatrics
AAPD: American Academy of Pediatric Dentistry
AAO: American Association of Orthodontists
AAO-HNS: American Academy of Otolaryngology – Head and Neck Surgery
ABM: Academy of Breastfeeding Medicine
AF: Analytic framework
AHRQ: Agency for Healthcare Research and Quality
AOS: American Orthodontic Society
ASHA: American Speech-Language-Hearing Association
BSES: Breastfeeding Self-Efficacy Scale
BSES-SF: Breastfeeding Self-Efficacy Scale Short Form
CAM: Complementary and alternative medicine
CER: Comparative Effectiveness Review
CINAHL: Cumulative Index of Nursing and Allied Health Literature
CLCWA: College of Lactation Consultants of Western Australia
CPS: Canadian Paediatric Society
ENT: Ear, Nose & Throat
EMBASE: Excerpta Medica Database
EPC: Evidence-based Practice Center
HATLFF: Hazelbaker Assessment Tool of Lingual Frenulum Function
IBFAT: Infant Breastfeeding Assessment Tool
ILCA: International Lactation Consultant Association
IQR: Interquartile range
KI: Key Informant
KQ: Key Question
LATCH: Latch, Audible swallowing, Type of nipple, Comfort, Hold
LCANZ: Lactation Consultants of Australia and New Zealand
MPQ-SF: Montreal Pain Questionnaire
NHS: National Health Service
MeSH: Medical Subject Headings
NICU: Neonatal intensive care unit
PAS: Pediatric Academic Societies
PICOTS: Population, Intervention, Comparator, Outcomes, Timing, Setting
PQDT: ProQuest Dissertations & Theses
RCT: Randomized controlled trial
SF-MQP: Short Form McGill Pain Questionnaire
SRDR: Systematic Review Data Repository
TEP: Technical Expert Panel
VAS: Visual Analog Scale for Pain

Appendix A. Search Strategies

Table A-1. PubMed search strategies

Search terms		Search results
#1	("Mouth Abnormalities"[Mesh:noexp] OR "Tongue Diseases/congenital"[Mesh:noexp] OR "Tongue/abnormalities"[Mesh] OR "Lingual Frenum"[Mesh] OR "Lip Diseases/congenital"[Mesh:noexp] OR "Lip/abnormalities"[Mesh] OR "Labial Frenum"[Mesh] OR "Ankyloglossia"[Supplementary Concept] OR "ankyloglossia"[tiab] OR (("tongue"[tiab] OR "lip"[tiab] OR "lingual"[tiab] OR "linguae"[tiab] OR "labial"[tiab] OR "maxillary"[tiab]) AND ("frenum"[tiab] OR "fraenum"[tiab] OR "frenulum"[tiab] OR "frena"[tiab] OR "frenula"[tiab])) OR (("tongue"[tiab] OR "lip"[tiab] OR "maxillary"[tiab]) AND ("tie"[tiab] OR "tied"[tiab])))	3501
#2	("Therapeutics"[Mesh] OR "therapy"[Subheading] OR "Treatment Outcome"[Mesh] OR "therapy"[tiab] OR "therapies"[tiab] OR "therapeutic"[tiab] OR "therapeutics"[tiab] OR "outcome"[tiab] OR "outcomes"[tiab] OR "Oral Surgical Procedures"[Mesh] OR “surgical”[tiab] OR “surgery”[Subheading] OR “surgery”[tiab] OR "frenulotomy"[tiab] OR "frenulectomy"[tiab] OR "frenotomy"[tiab] OR "frenectomy"[tiab] OR "frenuloplasty"[tiab] OR "z-plasty"[tiab] OR "h-plasty"[tiab] OR "laser"[tiab] OR "Rehabilitation of Speech and Language Disorders"[Mesh] OR "Speech Disorders "[Mesh] OR "Language Development Disorders "[Mesh] OR "speech therapy"[tiab] OR "speech therapies"[tiab] OR "language therapy"[tiab] OR "language therapies"[tiab] OR "oral motor therapy"[tiab] OR "oral motor therapies"[tiab] OR "Complementary Therapies"[Mesh] OR cam[sb] OR "complementary medicine"[tiab] OR "complementary therapy"[tiab] OR "complementary therapies"[tiab] OR "alternative medicine"[tiab] OR "alternative therapy"[tiab] OR "alternative therapies"[tiab] OR "cam"[tiab] OR "craniosacral therapy"[tiab] OR "cranial sacral therapy"[tiab] OR "myofascial release"[tiab] OR "myofascial therapy"[tiab] OR "rolfing"[tiab]) OR (“unsafe”[tiab] OR “safety”[tiab] OR “harm”[tiab] OR “harms”[tiab] OR “harmful”[tiab] OR “complication”[tiab] OR “complications”[tiab] OR “risk”[tiab] OR “risks”[tiab] OR “side-effect”[tiab] OR “side-effects” [tiab]OR ((undesirable OR adverse) AND (effect OR effects OR reaction OR reactions OR event OR events OR outcome OR outcomes))OR” sequelae” [tiab] OR “sequela” [tiab] OR ((postoperative OR surgical OR “post operative” OR “post surgical”) AND (complication OR complications)) OR “adverse effects”[Subheading] OR “complications”[Subheading] OR “contraindications”[Subheading])	10219702
#3	#1 AND #2	2065
#4	#3 AND eng[la]	1496
#5	#4 NOT (editorial[pt] OR letter[pt] OR comment[pt] OR review[pt] OR news[pt] OR historical article[pt] OR practice guideline[pt] OR meta-analysis[pt])	1252

Key: [Mesh: noexp] exact medical subject heading, not including the terms nested beneath it; [MeSH] medical subject heading; [Supplmentary Concept] indexing terms for chemicals, substances and rare diseases; [tiab] keyword in title or abstract; [sh] subheading; [la] language; [pt] publication type.

Table A-2. CINAHL search strategies

Search terms		Search results
S1	((MH "Mouth Abnormalities") OR (MH "Tongue Diseases") OR (MH "Tongue /AB") OR (MH "Lip Diseases") OR (MH "Lip/AB") OR (MH "Frenum (Oral)") OR (MH "Ankyloglossia") OR "ankyloglossia" OR (("tongue" OR "lip" OR "lingual" OR "linguae" OR "labial" OR "maxillary") AND ("frenum" OR "fraenum" OR "frenulum" OR "frena" OR "frenula")) OR (("tongue" OR "lip" OR "maxillary") AND ("tie" OR "tied")))	864
S2	((MH "Therapeutics+") OR (MH "Treatment Outcomes+") OR "therapy" OR "therapies" OR "therapeutic" OR "therapeutics" OR "outcome" OR "outcomes" OR (MH "Surgery, Oral+") OR "frenulotomy" OR "frenulectomy" OR "frenotomy" OR "frenectomy" OR "frenuloplasty" OR "z-plasty" OR "h-plasty" OR "laser" OR "surgery" OR "surgical" OR (MW "su") OR (MH "Speech Disorders+") OR (MH "Communicative Disorders+") OR (MH "Language Disorders+") OR (MH "Rehabilitation, Speech and Language+") OR "speech therapy" OR "speech therapies" OR "language therapy" OR "language therapies" OR "oral motor therapy" OR "oral motor therapies" OR (MH "Alternative Therapies+") OR "complementary medicine" OR "complementary therapy" OR "complementary therapies" OR "alternative medicine" OR "alternative therapy" OR "alternative therapies" OR "cam" OR "craniosacral therapy" OR "cranial sacral therapy" OR "myofascial release" OR "myofascial therapy" OR "rolfing")	1269326
S3	S1 AND S2	497
S4	S3 AND limiters: English language	495
S5	S4 AND limiters: Exclude MEDLINE records	96

Key: MH CINAHL medical subject heading; MW CINAHL subheading

Table A-3. PsycINFO search strategies

Search terms		Search results
#1	(SU.EXACT.EXPLODE("Mouth (Anatomy)") OR SU.EXACT.EXPLODE("Tongue") OR SU.EXACT.EXPLODE("Lips (Face)") OR IF("ankyloglossia" OR (("tongue" OR "lip" OR "lingual" OR "linguae" OR "labial" OR "maxillary") AND ("frenum" OR "frenum" OR "fraenum" OR "frenulum" OR "frena" OR "frenula")) OR (("tongue" OR "lip" OR "maxillary") AND ("tie" OR "tied"))))	2022
#2	(SU.EXACT.EXPLODE("Treatment") OR (IF("therapy" OR "therapies" OR "therapeutic" OR "therapeutics" OR "outcome" OR "outcomes" OR "frenulotomy" OR "frenulectomy" OR "frenotomy" OR "frenectomy" OR "frenuloplasty" OR "z-plasty" OR "h-plasty" OR "laser" OR "surgery" OR "surgical" OR "speech therapy" OR "speech therapies" OR "language therapy" OR "language therapies" OR "oral motor therapy" OR "oral motor therapies" OR "complementary medicine" OR "complementary therapy" OR "complementary therapies" OR "alternative medicine" OR "alternative therapy" OR "alternative therapies" OR "cam" OR "craniosacral therapy" OR "cranial sacral therapy" OR "myofascial release" OR "myofascial therapy" OR "rolfing")))	684785
#3	#1 AND #2	235

#4	#3 AND LA(English)	220
#5	#4 with peer reviewed and scholarly journals selected	207

Key: SU.EXACT.EXPLODE subject term

Table A-4. EMBASE search strategies

Search terms		**Search results**
#1	tongue disease/cn or tongue disease*.tw. or tongue abnormalit*.tw. or ankyloglossia/ or ankyloglossia.tw. or lip malformation/cn or lip malformation*.tw. or lip disease/cn or lip disease*.tw. or ((tongue/ or tongue.tw. or lip/ or lip*.tw. or labial.tw. or lingual.tw.) and (frenum.tw. or fraenum.tw. or frena.tw. or frenulum.tw. or frenula.tw.)) or ((tongue.tw. or lip/ or maxillary.tw.) and (tie.tw. or tied.tw. or ties.tw.))	1229
#2	th.fs. or therapy/ or therapy.tw. or therapies.tw. or therapeutic*.tw. or treatment outcome/ or treatment outcome*.tw. or outcome*.tw. or oral surgery/ or oral surger*.tw. or surgical.tw. or su.fs. or surgery.tw. or frenulotom*.tw. or frenulectom*.tw. or frenotom*.tw. or frenectom*.tw. or frenuloplast*.tw. or z plasty/ or z plasty.tw. or h plasty.tw. or laser surgery/ or speech rehabilitation/ or speech rehabilitation.tw. or speech disorder/ or speech disorder*.tw. or developmental language disorder/ or language development disorder*.tw. or speech therapy/ or speech therap*.tw. or language therap*.tw. or oral motor therap*.tw. or complementary therap*.tw. or cam.tw. or complementary medicine*.tw. or alternative medicine/ or alternative medicine*.tw. or alternative therap*.tw. or craniosacral therapy/ or craniosacral therap*.tw. or myofascial therap*.tw. or myofascial release.tw. or manipulative medicine/ or rolfing/ or rolfing.tw. or (Unsafe.tw. or safety/ or safety.tw. or harm.tw. or harms.tw. or harmful.tw. or complication/ or complication*.tw. or risk/ or risk*.tw. or side effect/ or side effect*.tw. or contraindication*.tw. or ((undesirable.tw. or adverse.tw.) and (effect.tw. or effects.tw. or reaction.tw. or reactions.tw. or event.tw. or events.tw. or outcome.tw. or outcomes.tw.)) or sequelae.tw. or sequela.tw. or ((postoperative.tw. or surgical.tw. or post operative.tw. or post surgical.tw.) and (event.tw. or events.tw. or outcome.tw. or outcomes.tw.)) or si.fs. or co.fs.)	8617400
#3	1 AND 2	730
#4	Limit 3 to English	585
#5	Limit 4 to human	541
#6	5 not (review.pt. or editorial.pt. or letter.pt. or note.pt. or short survey.pt. or conference paper.pt. or meta analysis/ or practice guideline/ or systematic review/)	431
#7	5 Exclude MEDLINE journals	25

Key: / Emtree heading; .tw. abstract, title and drug trade name; /cn congenital; .fs. subheading;
si.fs. side effects subheading; th.fs. therapy subheading; su.fs. surgery subheading; co.fs. complications subheading;
p.t. publication type

Appendix B. Abstract and Full-Text Screening Forms

Table B-1. Abstract screening questions

Ref ID	**Reviewer name**		
1. Does the study address the treatment of ankyloglossia and/or concomitant lip-tie or harms of treatment/no treatment (conservative management)? If "No" please skip to #4.	Yes	No	Cannot Determine
2. Is the study original research? (excludes reviews, commentary, editorials, letters; includes systematic reviews and meta analyses)	Yes	No	Cannot Determine
3. Does the study population include infants or children up to age 18?	Yes	No	Cannot Determine
4. If excluded, should the study be retained for any of the following reasons: Background/discussion Review of references Study population has congenital craniofacial malformation, Pierre Robin and/or cleft lip/palate Other _____	Yes	No	Cannot Determine
Comment			

Table B-2. Full-text screening questions

Ref ID	**Reviewer name**	
1. Is the study original research? (excludes narrative reviews, commentary, editorials, letters; includes systematic reviews and meta analyses)	Yes	No
2. Does the study evaluate the effectiveness of treatment for ankyloglossia and/or concomitant lip-tie OR is this a study or case report that provides data on harms of treatment?	Yes	No
3. Does the study population include infants or children up to age 18?	Yes	No
4. If excluded, should the study be retained for any of the following reasons: Background/discussion Review of references Study population has congenital craniofacial malformation, Pierre Robin and/or cleft lip/palate Other _____	Yes	No
Comment		

Appendix C. Excluded Studies

Abstract Review Exclusion Reasons

X-1 Does not address treatment of ankyloglossia and/or concomitant lip-tie or harms of treatment/no treatment

X-2 Not original research

X-3 Participants not in target age range

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8. Watt OM. Lingual thyroid; complicating general anaesthesia. Anaesthesia. 1959 Apr;14(2):162-7. PMID: 13637370; X-1
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5228693; X-1

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Full-Text Review Exclusion Reasons

X-4 Not original research
X-5 Does not evaluate effectiveness of treatment for ankyloglossia and/or concomitant lip-tie or is not a case series reporting on harms of treatments for ankyloglossia and/or concomitant lip-tie.
X-6 Participants are not target age group

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Appendix D. Evidence Table

Table D-1. Evidence table

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Amir et al., 2005[1] **Country:** Australia **Enrollment period:** Aug 2002 to July 2003 **Funding:** NR **Design:** Case series	**Intervention:** Frenotomy: Use index finger and thumb of non-dominant hand to stabilize and visualize lingual frenulum. Frenulum is divided by 2-3 mm with small sterile scissors, adjacent to tongue taking care to avoid vascular tissue. Encouraged to breast feed immediately after procedure. **Groups, n (%):** **G1:** intervention, 35/46 (76%) **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** None **Other non-surgical therapies:** NR **Setting of therapy:** hospital ward (n=4) or breastfeeding clinic (n=28) **Treatment duration:** Days / weeks **Last follow-up post-treatment:** phone interview 3 months post-treatment **N at enrollment:** **G1:** 66 at assessment **N at follow-up:** **G1:** 46 **Consultation with lactation consultant:** **G1:** Yes, referral	**Inclusion criteria:** • Infants presenting to breastfeeding service assessed with HATLFF • Impaired lingual function • Frenulum visualized to be thin membrane • Parents gave informed consent **Exclusion criteria:** • Score did not recommend release of frenulum (n=11) **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at assessment, mean (range):** **G1:** 18 (3-98) **Gender, n (%):** Male: **G1:** 29/46 (63) at assessment 22 males in frenotomy group Female: **G1:** 13 females in frenotomy group **Race/ethnicity:** NR **Indication for therapy, n (%):** Most important presenting problem Attachment to the breast **G1:** 12 (44) Nipple pain: **G1:** 6 (22) Prolonged feeding: **G1:** 5 (19) Poor weight gain: **G1:** 2 (7) Frequent feeding: **G1:** 1 (4) Nipple damage:	**Length of lingual frenulum when tongue is lifted:** **G1:** NR Mean HATLFF function score (n=35) **G1:** 10.9 ± 0.57 Mean appearance score **G1:** 5.9 ± 1.5 **Maternal:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:**NR **Maternal, n (%):** No difference in breastfeeding **G1:** 6/35 (17) Better attachment to breast: **G1:** 18/35 (51) Improved sucking: **G1:** 20/35 (57) Less pain: **G1:** 9/35 (26) Weight improved **G1:** 6/35 (17) Other difference: **G1:** 2/35 (44) No longer breastfeeding: n=3 **Infant:** **G1:** NR **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** No problems reported when mothers were queried. **Harms Detailed:** NA **Timing of harms:** NA

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		G1: 1 (4) **Other characteristics:** Family history: Yes **G1:** 7 No **G1:** 36 Missing: **G1:** 3 **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR		

Comment: Maternal satisfaction also reported.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Argiris et al., 2011[2] **Country:** UK **Enrollment period:** Aug 2008 to Oct 2008 **Funding:** NR **Design:** Case series (prospective audit)	**Intervention:** Middle finger or index finger were used to lift infant tongue making tongue tie visible. Floor of mouth often compressed with gauze to prevent submandibular duct injury. Tongue tie was divided with blunt pair of scissors. Manual pressure with gauze administered to control blood loss. **Groups, n:** **G1:** intervention, 46 **Type of professional performing treatment:** otolaryngologist consultant or lactation consultant **Anesthesia used in surgical intervention:** No anesthetic or analgesic **Other non-surgical therapies:** NR **Setting of therapy:** Main OR then kept in peds ward for observation postop before discharge **Treatment duration:** NA **Last follow-up post-treatment:** 6 weeks post-treatment **N at enrollment:** **G1:** 46 **N at follow-up:** **G1:** 46 **Consultation with lactation consultant, n (%):** **G1:** 46 (100)	**Inclusion criteria:** •Presented with breastfeeding difficulties •Diagnosed with tongue-tie by lactation nurse consultant or ENT **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, weeks at intervention, mean:** **G1:** 4 (range 1 day to 12 weeks **Gender, n:** Male: **G1:** 33 Female: **G1:** 13 **Race/ethnicity:** NR **Indication for therapy:** breastfeeding difficulties **Other characteristics:** NR **Type of ankyloglossia, n (%):** Mild tongue tie (bound by thin mucous membrane **G1:** 20 (43) Severe tongue tie –tongue fused to floor of mouth **G1:** 23 (57) **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal, %:** Sore nipples **G1:** 63 Damaged nipples: **G1:** 43 Coming on/off of breast, %: **G1:** 50 **Pain score, mean ± SD** **G1:** 6.63/10 ± 2.46 **Infant, %:** Poor latch **G1:** 67 Not satisfied after feeding **G1:** 30 Poor weight gain **G1:** 22 **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal, %:** Immediate improvement in breastfeeding **G1:** 70 Breastfeeding at follow-up, n (%) **G1:** 41/46 (89) Major improvement at followup, %: **G1:** 87% Reduced nipple pain, n (%): **G1:** 19 (40) **Pain score, mean ± SD** **G1:** 1.47/10 ± 1.34 **Change in pain score p-value:** p< 0.01 **Infant:** Improved latch, n (%) **G1:** 36 (78) More effective suck **G1:** 30 (64) **Child:** **G1:** NR **Need for reoperation:** **G1:** 3/46 **Harms:** Yes **Harms Details:** Blood loss, %: **G1:** 52 No correlation with degree of ankyloglossia **Timing of harms:** Immediate

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Ballard et al., 2002[3] **Country:** USA **Enrollment period:** Jan 1998 to June 2001 **Funding:** Service grant from the March of Dimes, Ohio Chapter, Cincinnati Children's Hospital Medical Center, and University Hospital, Inc, members of the Health Alliance of Greater Cincinnati. **Design:** Prospective Case series	**Intervention:** The infant is placed supine with the elbows held flexed securely close to the face and the assistant's index finger on the chin for stabilization. The tongue is lifted gently with a sterile, grooved retractor so as to expose the frenulum. With sterile iris scissors, the frenulum is divided by approximately 2 to 3 mm at its thinnest portion, between the tongue and the alveolar ridge, into the sulcus just proximal to the genioglossus muscle. **Groups:** **G1:** Frenuloplasty **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** Usually used if >4mo, type not specified **Other non-surgical therapies:** NR **Setting of therapy:** Hospital Inpatient & outpatient lactation center **Treatment duration:** NR **Last follow-up post-treatment:** post-operative day #3 phone call, some followed for 5 days **N at enrollment:** **G1:** 127 **N at follow-up:** **G1:** 123 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Breast feeding infants with short or tight lingual frenulum who might benefit from surgery based on clinical assessment and HATLFF score **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days or months at intervention:** **G1:** Median (25th, 75th percentile) age at presentation with poor latch was significantly lower than with maternal nipple pain: 1.2 days (0.7, 2.0) versus 2.0days (1.0, 12.0), respectively (p = 0.007). **Gender, ratio:** Boys:Girls: 1.5:1 **Race/ethnicity:** NR **Indication for therapy:** Breastfeeding problems **Other characteristics:** Family history of tongue-tie: Positive: n= 26 **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** Nipple pain levels based on an analog scale of 1 (extremely mild) to 10 (severe pain),: Mean ± SD: 6.9 ± 2.31 **Inpatients, n (%)** Nipple pain: **G1:** 32/88 (36.4) **Outpatients, n (%):** Nipple pain: **G1:** 21/35 (60) Moderate to severe nipple trauma with or without infection: 21 mothers Recurrent mastitis= 4 Suppressed lactation= 4 **Infant:** **G1:** Inpatients, n (%) Poor latch: 56 /88 (63.6) Outpatients, n (%): Poor latch: 14/35 (40) Failure to thrive: 6 (poor latch=4, nipple pain=2) **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** Nipple pain levels based on an analog scale of 1 (extremely mild) to 10 (severe pain), Mean ± SD: 1.2 ± 1.52 (p < .0001) Comfortable breast feeding: 31/35 mothers Stopped breastfeeding: 3 **Infant: HATLFF** **G1:** Function score: 7.9 ± 1.86 Appearance score: 4.9 ± 1.81 There was significant correlation between function and appearance: r= 0.49, P<0.001. With ooor latch: Mean function score: 7.8 ± 1.88 Appearance score: 4.8 ± 1.87 With maternal nipple pain, Function score: 8.0 ± 1.85 Appearance score: 5.0 ± 1.76 The score differences not significant 5 failure to thrive (FTT) infants resumed breastfeeding and achieved a normal rate of growth within 3 to 5 days after the procedure. One severe failure to thrive patient

				advised by own pediatrician to start formula **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** None observed **Harms Details:** NA **Timing of harms:** Immediate & 3 days after Rx via phone call

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Berry et al., 2012[4] **Country:** UK **Enrollment period:** October 2003 to April 2004 **Funding:** NR (Authors report no competing financial interests) **Study Design:** RCT, blinded	**Intervention:** Tongue-tie division: The tongue-tie was put on a stretch with left index finger and holding lower lip clear with thumb. Tie was divided completely with sharp, blunt ended sterile scissors. And floor of mouth compressed with sterile gauze swabs. Baby immediately returned to mother. Feeding was reassessed. Infants who had been allocated to non-division were then taken to have procedure performed **Groups:** **G1:** Tongue-tie division **G2:** Sham tongue-tie division **Type of professional performing treatment:** Lactation consultant or pediatric surgeon **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NA **Setting of therapy:** Hospital (clinic not specified) **Treatment duration:** NA **Last followup post-treatment:** Three most post-treatment **N at enrollment:** **G1:** 30 **G2:** 30	**Inclusion criteria:** • Age < 4 months • Symptoms of breastfeeding problem • Tongue-tie present **Exclusion criteria:** • Bottle fed • Declined to participate • Infant failed to feed **Age, days or months at first diagnosis:** NR **Age at baseline, days, mean (range):** **G1:** 33 (6-115) **G2:** 28 (5-111) **Gender, n:** Male: **G1:** 21 **G2:** 19 **Race/ethnicity:** NR **Indication for therapy, n (%):** Difficulty with latch: **G1:** 23 (77) **G2:** 24 (80) Nipple pain/trauma: **G1:** 20 (67) **G2:** 19 (63) Inefficient feeding: **G1:** 19 (63) **G2:** 18 (60) All 3 indications: **G1:** 10 (33) **G2:** 9 (30) **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NA	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** Breastfeeding pain score, mean: **G1:** 4.1 **G2:** 4.2 **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** Breastfeeding pain score, mean: **G1:** 1.6 **G2:** 2.9 Change in pain score, mean ± SD: **G1:** -2.5 ± 1.9 **G2:** -1.3 ± 1.5 **G1 vs G2:** p=0.13 (95% CI: -0.3, 2.4) **Infant:** **Immediate** Improved breastfeeding maternal report, n (%) **G1:** 21 (78) **G2:** 14 (47) **G1 vs G2**: p< 0.02 95% CI (6-51%) Improved feeding objective observer, n (%): **G1:** 13/26 (50) **G2:** 12 (40) **G1 vs G2, p=ns** Mean age of babies whose mothers reported full resolution of feeding problem were 8 days younger than those reporting no improvement (26 vs. 34d) None reported worse feeding **3-month follow-up, n (%):** Improved feeding maternal report: **G1+ G2:** 54/59 (92) Full resolution of feeding problems: **G1+ G2:** 33/59 (56) No improvement in feeding:

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
	N at followup: **G1:** 27 **G2:** 30 **Consultation with lactation consultant:** NR			**G1+ G2:** 5/59 (8) **Breastfeeding at 3 months:** **G1+ G2:** 38/59 (65) **Breastfeeding at second phone call (mean age 4.5 months), n (%):** **G1+ G2:** 30/59 (51) **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** Yes **Harms Details, n (%):** Small amount of bleeding following procedure: **G1+ G2:** 3 (5) "None of complications were significant" and all infants with complications were feeding better at 1 day after division **Timing of harms:** **G1:** Immediate

Comments: Parents and single observer who independently assessed outcomes were blinded to group.
All mothers contacted would choose to have the tongue tie divided again if they were in the same situation in the future.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Blekinsop, 2003[5] **Country:** UK **Enrollment period:** Retrospective audit: January 2002 to June 2002 Prospective audit: 2003 **Funding:** NR **Study Design:** Case series	**Intervention:** Frenulotomy: membrane stripped with sterile blunt edged scissors and baby immediately fed **Groups:** **G1:** Intervention **Type of professional performing treatment:** Pediatric surgeon or lactation consultant **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** Hospital **Treatment duration:** NR **Last followup post-treatment:** 2 weeks **N at enrollment:** **G1:** 21 **N at followup:** **G1:** 20 **Consultation with lactation consultant, (%):** **G1:** Yes, (100)	**Inclusion criteria:** • Babies referred for frenotomy during time period **Exclusion criteria:** NR **Age, days or weeks at first diagnosis, range:** 1 day to 6 weeks **Age, days or months at intervention:** NR **Gender:** Male: **G1:** NR Female: **G1:** NR **Race/ethnicity:** **G1:** NR **Indication for therapy:** Breastfeeding issues **Other characteristics:** NA **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal, n:** Stopped breastfeeding due to reduced milk supply: **G1:** 7 **Infant, n (%):** Feeding difficulty Fully resolved: **G1:** 10/20 (50) Significantly improved: **G1:** 8/20 (40) Slightly improved: **G1:** 2/20 (10) **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** No post treatment complications reported **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Buryk et al., 2011[6] **Country:** US **Enrollment period:** Dec 2007 to Dec 2008 **Funding:** U.S. gov't; authors report no financial disclosures **Design:** RCT Single blinded	**Intervention:** Frenotomy: tongue elevated and frenulum exposed with grooved director. Frenulum tissue was crushed with straight clamp to provide anesthesia and frenulum was incised with straight scissor. On occasion, direct pressure with fingertips needed to be applied for hemostasis **Groups:** **G1:** Frenotomy **G2:** sham procedure **Type of professional performing treatment:** otolaryngologist **Anesthesia used in surgical intervention:** No **Other non-surgical therapies:** NR **Setting of therapy:** Newborn nursery, newborn care clinic, and otolaryngology clinic **Treatment duration:** 5 minutes **Last follow-up post-treatment:** 12 months **N at enrollment:** **G1:** 30 **G2:** 28 **N at follow-up:** At twelve months **G1 + G2:** 44 **Consultation with lactation consultant, n (%):** **G1:** 30 (100) **G2:** 28 (100)	**Inclusion criteria:** • Maternal report of nipple pain or difficulty breastfeeding combined with significant ankyloglossia diagnosed by lactation consultant (100% agreement with ENT assessment at time of procedure) using HATLFF **Exclusion criteria:** • Infant older than 30 days • Craniofacial abnormalities, including cleft lip or palate • Neurologically compromised infants • Any other contraindications to maternal breastfeeding **Age, days at enrollment, mean ± SD (range):** **G1+G2:** 6.0 ± 6.9 (1 – 35) **G1:** 6.2 ± 6.9 **G2:** 6.0 ± 7.0 **Age, days at intervention, mean ± SD:** **Mean age:** 6.7 days (one child at 2 weeks) **Gender, n (%):** Male: **G1:** 19 (63) **G2:** 19 (68) Female: **G1:** 11 (37) **G2:** 9 (32) **Indication for therapy:** Maternal report of nipple pain or difficult breastfeeding and HATFLL **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** **G1:** 0 **G2:** 0	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G1:** NR **Maternal:** Nipple pain assessed by SF-MQP (Short form McGill Pain Questionnaire), mean ± SD: **G1:** 16.8 ± 10.6 **G2:** 19.2 ± 9.9 Breastfeeding rates: NR **Infant:** IBFAT, mean ± SE **G1:** 9.3 ± 0.69 **G2:** 8.5 ± 0.73 **HATFLL appearance score, mean ± SD** **G1:** 6.0 ± 1.6 **G2:** 5.7 ± 2.2 **HATFLL function score, mean ± SD** **G1:** 9.4 ± 2.6 **G2:** 8.4 ± 2.0 **Child:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2**: NR **Maternal:** Nipple pain, immediately after procedure SF-MPQ: **G1:** 4.9 ± 1.46 **G2:** 13.5 ± 1.5 p value G1 vs G2: p<0.001 Effect size: 0.38 Breastfeeding rates, n (%): Two months: **G1+G2:** 36/58 (66) Six months: **G1+G2:** 23/58 (44) Twelve months **G1+G2:** 14/58 (28) **Infant:** IBAT, mean ± SE **G1:** 11.6 ± 0.81 **G2:** 8.07 ± 0.86 **G1 vs. G2:** p=0.029 effect size: 0.31 **Child:** NR **Need for reoperation:** NR **Harms:** No complications from the procedure in any infants **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Choi et al., 2011[7] **Country:** Korea **Enrollment period:** 2005 to 2010 **Funding:** NR **Study Design:** Case series	**Intervention:** Z-plasty combined with partial midline genioglottus myotomy Pull tongue tip in cephalic direction and release the lingual frenulum close to tongue base using a scalpel. Then mucosal layer of tongue is opened and contracted genioglossus muscle exposed. Pull tongue and cut only the predominantly tightened muscle portion horizontally using electrocautery and release. Dissect mucosal flap to prevent mucosal contracture, release mucosal layer 1 cm long at tongue base through z-plasty and close with 5-0 Vicryl suture **Groups:** **G1:** Intervention **Type of professional performing treatment:** Surgeon-not specified (Corresponding author in plastic and reconstructive surgery) **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** NR **Treatment duration:** NA **Last followup post-treatment:** Up to 6 months post-treatment overall range 3 months to 2 years	**Inclusion criteria:** NR **Exclusion criteria:** • Other congenital anomalies or with oral disease or anomaly **Age, days or months at first diagnosis, mean ± SD:** NR **Age, years at intervention, (range):** **G1:** 1-10 **Gender:** Male to female ratio: **G1:** 2.3:1 **Race/ethnicity:** NR **Indication for therapy:** Unclear Speech impediments Sucking and breastfeeding problems also mentioned in intro **Other characteristics** Family history: **G1:** 20% **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR **Need for reoperation:** **G1:** NR (No patient had scar contracture during f/u) **Harms:** No **Harms Details:** No signs and symptoms that may typically result from a genioglossus myotomy procedure such as limited tongue movement or aggravated speech or articulation problems were seen. No aggravated scar contracture or speech problem post-therapy **Timing of harms:** NA

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
	N at enrollment: **G1:** 106 **N at followup:** **G1:** 106 **Consultation with lactation consultant:** NR			

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Dave et al., 2013 [8] **Country:** India **Enrollment period:** 6/2010 to 9/2012 **Funding:** None **Design:** Case series	**Intervention:** Surgery details not reported. Tongue tie release surgery **Groups:** **G1:** Tongue-tie release surgery **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** Speech therapy **Setting of therapy:** Outpatient & inpatient department of otorhinolaryngology **Treatment duration:** NR **Last follow-up post-treatment:** Immediately post-treatment **N at enrollment:** **G1:** 7 **N at follow-up:** **G1:** 7 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Dysglossia with articulation disorder **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days or months at intervention, N :** **G1:** Up to 12 years: 5 13-19 years: 2 **Gender, n (%):** Male: **G1:** 5/7 (71.4) Female: **G1:** 2/7(28.6) **Race/ethnicity:** NR **Indication for therapy:** Dysglossia **Other characteristics:** All 7 patients were given speech therapy post-operatively **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** defects of linguadental and alveolar sounds as well as sibilants viz. ‘d’, ‘t’, ‘l’, ‘s’, ‘z’, (n=7)	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** All improved (100%) satisfactorily **Need for reoperation:** **G1:** NR **Harms:** NR **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Dollberg et al., 2014[9] **Country:** Israel **Enrollment period:** 3/2010 to 10/2010 **Funding:** NR **Design:** Prospective case series	**Intervention:** Follow-up study after frenotomy. Procedure not described **Groups** **G1:** Frenotomy **Type of professional performing treatment:** Physician **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** Hospital or office **Treatment duration:** NR **Last follow-up post-treatment:** 6 months (phone interview) **N at enrollment:** **G1:** 264 **N at follow-up:** **G1:** 244 **Consultation with lactation consultant, (%):** **G1:** yes (100)	**Inclusion criteria:** • All mothers of infants who had breastfeeding difficulties • Term infants with no congenital anomalies **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, median (range):** **G1:** 14 (1-135) **Gender, n (%):** Male: **G1:** 143 (59) Female: **G1:** 101 (41) **Race/ethnicity:** NR **Indication for therapy:** Maternal nipple soreness nipple pain with / without bruising Latching difficulties (repeated, frequent detachments of the infant from the breast) Inability to feed, falling asleep on the breast and other latching problems **Other characteristics:** Problems with breast feeding with previous offspring, 61.5% (64/104) First Born: 129 (53%) **Type of ankyloglossia:** **G1:** Coryllos type of tongue-tie, % I. 13 II. 31 III. 24 IV. 32 Coryllos type by gender, %, (M:F ratio): I. 79% M, 21% F (3.7:1) II. 57% M, 43% F (1.3:1) III. 62% M, 38% F (1.6:1)	**Length of lingual frenulum when tongue is lifted:** **G1:** Visual description of frenular thickness, n, (%): Thin: 105 (43) Thick: 96 (40) Graded (thin distally and thick proximally): 42 (17) Notched tongue tip: 78 (32) Tongue elevation above midmouth: 51 (21) **Maternal, n (%):** **G1:** Sore maternal nipples (VAS),: 203 (83) Nipple pain with bruising: 152 (62) Nipple pain without bruising: 92 (38) Latching difficulties 134 (55) **Infant:** Maternal perception of infant's pain, median (range) **G1:** 3 (0–10) **Child:** **G1:** NR	Length of lingual frenulum when tongue is lifted: **G1:** NR Maternal, n (%): Breast feeding difficulties: **G1:** Improvement: 180 (75) Significant improvement: 131 (54) No improvement: 48 (20) Worsening: 7 (3) Nipple wounds: **G1:** 50 /130 (38) reported wound disappearance Disappearance of nipple bruises (days), median (range) **G1:** 4 (1–15) Infant, n (%): **G1:** 217/244 (89) were still being breastfed at the 2-week follow-up Fully breastfed: 160 (74) Received more than half of their meals as breastmilk: 28 (13) Fed half or fewer of their meals as breastmilk: 29 (13) At 3-month follow-up: Still breastfeeding: 165 (68) Fully breastfed: 134/165 (81) At 6 months follow-up: Still breastfeeding:

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		IV. 49% M, 51% F (1:1) **Ankyloglossia with concomitant lip tie:** NR		137 of 244 (56) No statistically significant predictor in terms of history of breastfeeding of siblings, symptom (e.g., pain, bruising), or anatomy-- e.g.,Coryllos type and thickness of the frenulum) for improvement in breastfeeding **G1:** Mothers reported that fibrin deposition over the wound disappeared within a median of 9 days (range, 2–14 days). Infant's crying duration post-frenotomy in minutes, n (%): < 1 = 192 (79) 1–5 = 49 (20) > 5 = 3 (1) Child: **G1:** NR Need for reoperation: **G1:** NR Harms: Yes Harms Details: **G1:** Minimal discomfort & minimal **G1:** Bleeding Bleeding time, median(range): 1 (0-6) minutes Acetaminophen use, n (%): **G 1 :** 44 (18) Timing of harms: immediate

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Dollberg et al., 2011 [10] **Country:** Israel **Enrollment period:** NR **Funding:** NR **Design:** Prospective Cohort	**Intervention:** NR **Groups:** **G1:** Frenotomy **G2:** Untreated tongue-tie **G3:** No tongue-tie/controls **Type of professional performing treatment:** Neonatologist or pediatric dentist **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** NR **Treatment duration:** NR **Last follow-up post-treatment:** Immediately post-treatment **N at enrollment:** **G1:** 8 **G2:** 7 **G3:** 8 **N at follow-up:** **G1:** 8 **G2:** 7 **G3:** 8 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Children who underwent frenotomy of tongue-tie during infancy who were at time of study between 4 – 8 years old • Age-matched children with untreated tongue-tie whose parents reported a history of breastfeeding difficulties (e.g. nipple pain during nursing, difficulties in latching or both) • Children with no tongue-tie as controls **Exclusion criteria:** NR **Age, days or months at first diagnosis:** NR **Age, days or months at intervention, range:** **G1:** 2 days- 4 weeks **G2:** NA **G3:** NA **Current age, years: mean ± SD :** **G1:** 6.2 ± 1.8 **G2:** 6.2 ± 1.9 **G3:** 5.8 ± 1.9 **Gender, n:** Male: **G1+G2+G3:** 17 Female: **G1+G2+G3:** 6 **Race/ethnicity:** NR **Indication for therapy:** NR **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **G3:** NR **Maternal:** **G1:** NR **G2:** NR **G3:** NR **Infant:** **G1:** NR **G2:** NR **G3:** NR **Child:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **G3:** NR **Maternal:** **G1:** NR **G2:** NR **G3:** NR **Infant:** **G1:** NR **G2:** NR **G3:** NR **Child:** Tongue movement (oromotor test) Mean ± SD (95% CI): **G1:** 3.7 ± 4.3 (1.5) **G2:** 11 ± 7.6 (2.9) p=0.122, (-0.025, 0.179) **G3:** 1.2 +/-1.6 (0.5) **G1 v. G3:** p=0.28 (-0.023 – 0.073) Consonant articulation errors: **G1:** 6.0 ± 7.5 (2.7) **G2:** 7.1 ± 6.9 (2.6) p=0.76 (-6.96, 9.19) **G3:** 1.0 +/- 2.9 (1.0)**G1 v. G3:** p=0.11 (-1.43 – 11.39) Word production accuracy: **G1:** 6.0 ± 4.2 (1.5) **G2:** 14.5 ± 10.0 (3.7) p=0.076 (-1.150, 18.09) **G3:** 8.8 +/- 11.6 (3.1) **G1 v. G3:** p=0.53 (-12.54 – 7.28) Word intelligibility: **G1:** 1.3 ± 0.1 (0.1) **G2:** 1.7 ± 0.36 (0.1) p=0.33 (0.04, 0.714) **G3**: 1.4 +/- 0.4 (0.1) **G1 v. G3:** 0.50 (-0.46 – 0.25) Sentence

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
				intelligibility: **G1:** 1.3 ± 0.2 (0.1) **G2:** 1.6 ± 0.46 (0.2) p=0.16 (-0.147, 0.749) **G3:** 1.4 +/- 0.4 (0.1) **G1 v. G3:** p=0.46 (-0.49 – 0.24) Fluent-speech intelligibility: **G1:** 1.5 ± 0.4 (0.1) **G2:** 1.6 ± 0.5 (0.2) P=0.6 (-0.416, 0.689) **G3:** 1.2 +/- 0.3 (0.1) **G1 v. G3:** p=0.229 (-0.18 – 0.68) **Need for reoperation:** **G1:** NR **G2:** NR **Harms:** NR **Harms Details:** NA **Timing of harms:** NA **Gap between lower incisors at age 4 – 8 years:** NR **Frenotomy** N=1 **Non-frenotomy** N=1

Comment: See related paper Dollberg et al, 2006

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Dollberg et al., 2006[11] **Country:** Israel **Enrollment period:** Dec 2001 to Sept. 2004 **Funding:** NR **Design:** RCT	**Intervention:** Frenotomy, followed by careful hemostasis (i.e. mild pressure for several seconds to several minutes) **Groups:** **G1:** frenotomy followed by breastfeeding, then sham followed by breastfeeding **G2:** sham followed by breastfeeding, then frenotomy followed by breastfeeding **Type of professional performing treatment:** neonatologist or pediatric dentist **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** Lactation clinic at maternity hospital **Treatment duration:** NA **Last follow-up post-treatment:** Immediately post-treatment **N at enrollment:** **G1:** 15 **G2:** 11 **N at follow-up:** **G1:** 14 **G2:** 11 **Consultation with lactation consultant, (%):** Yes (100)	**Inclusion criteria:** • Full-term healthy appropriate for gestational age infants • Age 1 to 21 days • Referred for lactation clinic for nipple pain • Diagnosis of ankyloglossia by neonatologist (ankyloglossia defined as: inability of infant to protrude tip of tongue over lower gum line while tip was tied to floor of mouth by tight cord of frenulum and tongue became heart shaped) **Exclusion criteria:** • One exclusion due to failure of blinding **Gestational Age, weeks, mean ± SD:** **G1+ G2:** 39.8 ± 1.2 **Age, days at intervention, range:** **G1+ G2:** 1-21 **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** Nipple pain **Other characteristics:** family history in first degree relatives, n: **G1+ G2:** 4/25 Gestational weight: 3205 g (SD +/- 830) **Type of ankyloglossia, n:** Tongue protusion beyond alveolar ridge **G1+ G2:** 3/25 No tongue protrusion beyond alveolar ridge **G1+ G2:** 22/25 Anterior crease of tongue **G1+ G2:** 15/25 **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** NR **Maternal:** Breastfeeding pain or nipple trauma (standard visual analog pain scale up to 10 points) mean ± SD **G1+ G2:** 7.1 ± 1.9 **Infant:** Breastfeeding latch score (LATCH score), mean ± SD **G1+ G2:** 6.4 ± 2.3 **Child:** NR	**Length of lingual frenulum when tongue is lifted:** NR **Maternal:** Breastfeeding pain or nipple trauma, mean ± SD **G1+ G2: 5.3** ± 2.2 p=0.001 compared to baseline **Infant:** Breastfeeding latch score (LATCH score), mean ± SD **G1+ G2:** 6.8 ± 2.0 p=0.06 compared to baseline **Child:** NR **Need for reoperation:** NR **Harms:** Mentioned no unexpected bleeding **Harms Details:** Authors reported no significant side effects and bleeding (a few drops) was controlled within seconds in all cases. Infant crying lasted a few seconds. **Timing of harms:** Immediate

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Edmunds, et al., 2013[12] **Country:** Australia **Enrollment period:** NR **Funding:** None and no conflicts of interest **Study Design:** Case series	**Intervention:** Phenomenological study of breastfeeding mothers; first interview at diagnosis and follow-up interview 2 weeks later 7/10 underwent frenotomy **Groups:** **G1:** Intervention **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** Public health service breastfeeding clinic **Treatment duration:** NA **Last followup post-treatment:** 2 weeks **N at enrollment:** **G1:** 10 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Infants initially diagnosed with tongue-tie **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** G1: 3 days-3 weeks **Age, days or months at intervention, mean ± SD:** NR **Gender, n (%):** NR **Race/ethnicity:** NR **Indication for therapy, n (%):** **G1:** NR **Other characteristics:** Family history: **G1:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean, median:** **G1:** NR **Maternal:** **G1:** Breastfeeding concerns/difficulty **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean, median:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** NR **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Emond, et al., 2013[13] **Country:** UK **Enrollment period:** October 2011 to June 2013 **Funding:** NIHR (part of NHS) **Study Design:** RCT	**Intervention:** Frenotomy **Note:** Control group were offered frenotomy after 5 days **Groups:** **G1:** Intervention **G2:** Usual care control **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies, n (%):** NR **Setting of therapy:** Hospital clinic **Treatment duration:** NR **Last followup post-treatment:** Followup at 5 days, and then 8 weeks post-treatment **N at enrollment:** **G1:** 55 **G2:** 52 **Consultation with lactation consultant, (%):** **G1:** Yes (100) **G2:** Yes (100)	**Inclusion criteria:** • Term babies with a tongue-tie experiencing breast feeding problems • HATLFF score between 6-12 and LATCH score ≤ 8 **Exclusion criteria:** • Infant age ≥ 2 weeks old • Prematurity < 37 weeks • Congenital orofacial malformations • Infant weight loss (> 10% of birth weight) • Severe tongue-tie (HATLFF < 6) offered immediate frenotomy **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at 5 day followup, median (IQR):** **G1:** 11 (8-14) **G2:** 11 (8-16) **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** Breastfeeding difficulties **Other characteristics:** Family history: NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **Maternal:** Breastfeeding pain, nipple excoriations, low milk supply, breast feeding cessation, etc (specify method and results, mean, median, %) **G1:** NR **G2:** NR **Infant:** Feeding method at assessment, n (%) Bottle **G1:** 1 (1.8) **G2:** 0 Bottle and breast **G1:** 10 (18.2) **G2:** 5 (9.6) Breast only **G1:** 44 (80) **G2:** 47 (90.4) OR 2.35 (0.76 to 7.31) p= 0.13 **Child:** **G1:** NR **G2:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **Maternal, median (IQR):** At 5 days followup Pain VAS score: **G1:** 3 (1-4.3) **G2:** 3 (2-6) **G1 vs G2:** p= 0.13 Change between baseline and 5 days Pain VAS score: **G1:** -2 (-3 to 0.4) **G2:** -1 (-13.5 to 1) **G1 vs G2:** p< 0.09 At 8 week follow-up Pain Visual Analogue Scale score (VAS): **G1:** 0 (0) **G2:** 0 (0-1) **G1 vs G2:** p= 0.41 Change between 5 days and 8 weeks Pain VAS score: **G1:** -2 (-3 to -1) **G2:** -1 (-3.5 to -0.61) **G1 vs G2:** p< 0.83 **G1:** NR **G2:** NR **G3:** NR **Infant, median (IQR):** At 5 days follow-up LATCH score: **G1:** 9 (8-10**)** **G2:** 9 (8-10) **G1 vs G2:** p= 1.0 IBAT score: **G1:** 12 (11-12**)** **G2:** 12 (11-12) **G1 vs G2:** p= 0.76 Self-efficacy score: **G1:** 54 (43-62**)** **G2:** 53 (40.8-61) **G1 vs G2:** p= 0.53 HATLFF score: **G1:** 13.5 (11-16) **G2:** 8 (7-11)

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
				G1 vs G2: p< 0.0001 **Change in scores between baseline and 5 days** **From 0-5 days:** HATLFF score **G1:** 4.5 (3.3 to 6) **G2:** 0 (0 to2.3) **G1 vs G2:** p< 0.0001 LATCH score: **G1:** 1 (0 to2**)** **G2:** 1 (0 to 2) **G1 vs G2:** p= 0.52 IBAT score: **G1:** 0 (-1.8 to1.0) **G2: 0** (0-1) **G1 vs G2:** p= 0.36 Self-efficacy score (BSES-SF): **G1:** 9 (1.8 to 12.3) **G2:** 1 (-4 to 7.5) **G1 vs G2:** p= 0.0002 **Feeding method, n (%):** Bottle: **G1:** 5 (9.4) **G2:** 8 (15.5) Bottle and breast: **G1:** 13 (24.5**)** **G2:** 6 (11.5) Breast only: **G1:** 35 (66**)** **G2:** 38 (73) OR 1.40 (0.60 to 3.22) p= 0.43 At 8 week follow-up LATCH score: **G1:** 10 (10-10) **G2:** 10 (10-10) **G1 vs G2:** p= 0.41 IBAT score: **G1:** 12 (12-12) **G2:** 12 (12-12) **G1 vs G2:** p= 0.58 Self-efficacy score (BSES-SF): **G1:** 63 (59-68) **G2:** 63 (57-69) **G1 vs G2:** p= 0.62

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
				Infant weight, kg: **G1:** 5 (5-6) **G2:** 5 (5-6) **G1 vs G2:** p= 0.54 **Change in scores between 5 days and 8 weeks:** Self-efficacy score (BSES-SF): **G1:** 3 (0 to 13) **G2:** 10 (2 to 18) **G1 vs G2:** p= 0.082 **Feeding method, n (%):** Bottle: **G1:** 9 (17.3) **G2:** 10 (20) Bottle and breast: **G1:** 13 (25) **G2:** 8 (116) Breast only: **G1:** 30 (57.7) **G2:** 32 (64) OR 1.30 (0.59 to 2.89) p= 0.51 **Child:** **G1:** NR **G2:** NR **Need for reoperation, n (%):** **G1+G2:** 4/99 (4) **Harms:** No adverse events reported **Harms Details:** Small white patch at base of frenulum reported at 5 days, took median 7 days to heal (range 1-30) **G1+ G2:** 63 (64) **Timing of harms:** Immediate

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Finigan, 2014 [14] **Country:** UK **Enrollment period:** Oct 2007 to Sept 2012 **Funding:** NR **Design:** Case series (retrospective audit)	**Intervention (description):** Ffrenulotomy: No description **Groups, n (%)** **G1:** intervention **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies, n (%):** NR **Setting of therapy:** Hospital clinic **Treatment duration:** NR **Last follow-up post-treatment:** varied **N at enrollment:** **G1:** 2590 **N at 3 month follow-up:** **G1:** 21% **Consultation with lactation consultant, n (%):** **G1:** NR	**Inclusion criteria:** Parents who chose frenulum division surgery **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** **G1:** NR **Age, days or months at intervention, mean ± SD:** **G1:** NR **Gender, n (%):** NR **Race/ethnicity:** **G1:** NR **Indication for therapy:** NR **Other characteristics:** NR **Type of ankyloglossia:** Anterior, n (%): **G1:** NR Posterior, n (%): **G1:** NR **Ankyloglossia with concomitant lip tie, n (%):** **G1:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean, median** **G1:** NR **Maternal:** Breastfeeding pain, nipple excoriations, low milk supply, breast feeding cessation, etc **G1:** NR **Infant:** Breastfeeding latch, bottle feeding difficulty, failure to thrive, tongue mobility, weight gain, etc **G1:** NR **Child:** Speech, articulation, psychosocial, orthodontic, oral hygiene, tongue mobility, etc. **G1:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean, median** **G1:** NR **Maternal:** Reported immediate improvement in feeding (likert 1-10 scale) **G1:** 96% No improvement (included babies who were asleep, mothers with low milk supply and mothers with very sore nipples) **G1:** 4% 24-48 hour telephone follow-up Reported improvement in feeding **G1:** 71% No improvement (majority in this category did not respond to call) **G1:** 29% 3 month follow-up Continued to breastfeed **G1:** 43% (of the 21% who responded) Moved to bottle feeding, n=5 Mixed feed, n=12 **Infant:** Breastfeeding latch, bottle feeding difficulty, failure to thrive, tongue mobility, weight gain, etc. **G1:** NR **Child:** Speech, articulation, psychosocial, orthodontic, oral hygiene, tongue mobility, etc. **G1:** NR **Need for reoperation:** **G1:** NR

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
				Harms: NR **Timing of harms:** NR

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Fiorotti et al., 2004[15] **Country:** Brazil **Enrollment period:** NR **Funding:** FAEP/FCM-UNICAMP, CAPES **Design:** Case series	**Intervention:** Stretched tongue upward during the application of the CO2 laser so that depth of incision could be controlled. CO2 laser applied (with 2mm spot size applied continuously at 6W and with an intensity of 191W/cm2) perpendicular to the lingual frenulum and the fibrous cord was vaporized. **Groups:** **G1:** Frenectomy using carbon-dioxide laser **Type of professional performing treatment:** Otolaryngologist **Anesthesia used in surgical intervention:** Yes: 1) 10% lidocaine spray, 2) 1.8 ml of 2% lidocaine without vasoconstrictor into mobile portion of frenulum near tip of tongue and into fixed portion in the lingual region of inferior incisors **Other non-surgical therapies:** **G1:** speech therapy (some had speech therapy before surgery, n not reported) **Setting of therapy:** Outpatient ENT clinic **Treatment duration minutes, mean ± SD (range):** **G1:** 16 ± 2.80 (15-25) **Last follow-up post-treatment:** 15 days after surgery **N at enrollment:** **G1:** 15 **N at follow-up:** **G1:** 15 **Consultation with lactation consultant:** NR	**Inclusion criteria:** NR **Exclusion criteria:** NR **Age, days or months at first diagnosis:** NR **Age (years) at intervention, mean ± SD (range):** **G1:** 6.89 ± 3.38; (2-15) **Gender, n:** Male: **G1:** 10 Female: **G1:** 5 **Race/ethnicity:** NR **Indication for therapy:** Respiration abnormality; difficulties in speech sounds; damaging oromyofunctional habits (thumb sucking, pacifier sucking), inadequate postural habits or discomfort during feeding **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** Speech-articular alterations: yes=10; no=5 Breathing: G1: Nasal: 9 Buccal:5 Mixed: 1	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** greater control and motor capacity of tongue reported by those with prior speech therapy (NOT QUANTIFIED) Speech therapy improved tongue mobility **Recovery of normal habits with (days) mean ± SD (range):** **G1:** 4.2 ± 0.77 (4–7) **Need for reoperation:** **G1:** NR **Harms:** None **Harms Details:** NA **Timing of harms:** Immediate & 15 days after

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Geddes et al., 2008 [16] **Country:** Australia **Enrollment period:** NR **Funding:** Medela AG **Design:** Case series	**Intervention:** Frenulotomy: lifted tongue with fingers to examine frenulum and ensure it was thin and devoid of blood vessels. Using sterile iris scissors, small cut made at anterior portion of frenulum extending just past the genioglossus muscle. Infant encouraged to breastfeed after procedure **Groups:** **G1:** intervention **Type of professional performing treatment:** Pediatric surgeon **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** Breastfeeding clinic **Treatment duration:** NA **Last follow-up post-treatment, days mean ± SD (range):** **G1:** 13 ± 6 (7-29) **N at enrollment:** **G1:** 24 **N at follow-up:** **G1:** 24 **Consultation with lactation consultant, (%):** **G1:** Yes (100)	**Inclusion criteria:** • Mothers with healthy full term infants experiencing breastfeeding difficulties • Received breastfeeding advice and follow-up but not resolved **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, mean ± SD:** **G1:** 33 ± 28 **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** Breastfeeding difficulties **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR 2 of the mothers not in lactation	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal mean ± SD:** LATCH score **G1:** 7.9 ± 1.4 Pain score **G1:** 3.6 ± 3.0 Nipple shield, n **G1:** 4/24 **Twenty-four hour milk production, measured by test-weigh method, mean** **G1:** 409 (n=8) **Infant mean ± SD:** Milk intake **G1:** 50.5 ± 29.1 g Milk transfer, mL/min **G1:** 5.6 ± 3.0 g **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal mean ± SD:** LATCH score **G1:** 9.4 ± 0.8 p<0.05 Pain score **G1:** 0.5 ± 1.2 p<0.05 Nipple shield, N **G1:** 1/24 **Twenty-four hour milk production, measured by test-weigh method, mean** **G1:** 615 (n=8) **Duration of breastfeeding, months mean ± SD** **G1:** 11.3 ± 5.2 (n=16) **Infant:** Milk intake **G1:** 69.1 ± 31.9 g p<0.01 Milk transfer, mL/min **G1:** 10.5 ± 5.5 g p<0.01 **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** No complications reported **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Godley et al., 1994[17] **Country:** USA **Enrollment period:** 10/1988 to 2/1992 **Design:** Case series	**Intervention:** Frenulum divided horizontally below the undersurface of the tongue, a buccal mucosal graft harvested and the graft sutured into the sublingual wound **Groups:** **G1:** Frenuloplasty with Full thickness Buccal Mucosal Graft **Type of professional performing treatment:** Surgeon **Anesthesia used in surgical intervention:** Yes (General) **Other non-surgical therapies:** NR **Setting of therapy:** Hospital **Treatment duration:** 1 hour **Last follow-up post-treatment:** 3-4 months after surgery **N at enrollment:** **G1:** 15/17 with ankyloglossia **N at follow-up:** **G1:** 15 with ankyloglossia **Consultation with lactation consultant:** NR	**Inclusion criteria:** NR **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, years at intervention, mean (range):** **G1:** 8 (1-35) **Gender, n (%):** Male: **G1:** 10 (58.8) Female: **G1:** 7 (41.2) **Race/ethnicity:** NR **Indication for therapy:** Diagnosis of ankyloglossia **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR*	**Length of lingual frenulum when tongue is lifted (mm), mean:** **G1:** 3.7 mm **Maternal:** **G1:** NR **Infant:** **G1:** Restricted tongue mobility **Child:** **G1:** Restricted tongue mobility	**Length of lingual frenulum when tongue is lifted (cm), mean, median:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** Mobility of the tongue improved **Child:** **G1:** Mobility of the tongue improved **Need for reoperation:** **G1:** NR **Harms:** Yes **Harms Details:** **G1:** 3 minor post- operative complications Graft loss=1 Swollen delayed graft take=1 Wound dehiscence=1 Wound cicatrization=3 **Timing of harms:** Immediate & 3-4 months After surgery

Comment: * 2/17 with short maxillary labial frenulum

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Griffiths et al., 2004[18] **Country:** UK **Enrollment period:** 12/1999 to 12/2001 **Funding:** NR **Design:** Prospective case series	**Intervention:** Tongue tie put on the stretch with left index finger while holding the lower lip clear with left thumb. The tie was divided completely with sharp, blunt-ended, sterile scissors, and the floor of the mouth was compressed with a paper towel or gauze. **Groups:** **G1:** Simple division of tongue-tie **Type of professional performing treatment:** Neonatal, pediatric surgeon **Anesthesia used in surgical intervention:** No **Other non-surgical therapies:** NR **Setting of therapy:** Outpatient **Treatment duration:** Days / weeks **Last follow-up post-treatment:** 3 months after Rx **N at enrollment:** **G1:** 215 **N at follow-up:** **G1:** 215 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Infants younger than 3 months with a tongue tie and mother wanting to breastfeed but experiencing difficulty despite professional support. **Exclusion criteria:** NR **Age, days or months at first diagnosis:** NR **Age, days or months at intervention:** **G1:** 19 days **Gender:** Male/ Female ratio: 2:1 **Race/ethnicity:** NR **Indication for therapy:** 192/215 (88%) of infants had difficulty latching 167 (77%) mothers had painful, sore, or bleeding nipples 156 (72%) had “continuous” feeding cycle 112 (52%) had all three **Other characteristics:** Family history of tongue-tie: 44% 111 had tried bottle-feeding—either expressed breast milk (n = 104) or formula (n = 7)—of whom 85 (76%) had found it easy. Tongue-tie parameters, n (%): **G1:** Thickness Diaphanous 138 (64) Medium 59 (27) Thick 20 (9) Shape, n (%): Dimple 112 (52) Heart 88 (41) Pointed 17 (7) Percentage of tongue	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** Painful, sore, or bleeding nipples: 167 (77%) Mother-infant pairs with all 3 symptoms: 112 (52) Expressing and cup- or bottlefeeding: 104 (48) Use of nipple shield with professional guidance: 95 (44%) **Infant:** **G1:** Difficulty in latching on to the breast: 192/215 (88%) Those with a “continuous” feeding cycle: 156 (72) **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** Feeding postdivision, mean (%): 83 (70) breastfed for 3 months 92 (43) felt no immediate difference 32/53 mothers of awake infants (60) breastfed for 3 months. 173 (80%) feeding better by maternal assessment at 24 hours. 40 (19) Unchanged feeds 2 Increased difficulty feeding **At 3 months post division, n (%):** **G1:** Breastfed for at least 3 months: 138 (64) Breastfed for 6 to 12 weeks after division: 11 (5) Fed for less than 6 weeks: 68 (32) 72 (37%) had not started solids “Awful feeders” on breast, bottle, and with solids: 2(1) **Tongue extension:** **G1:** Yes: 204 (95) No: 4 (2 breastfed for 3 months)

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		anchored by tissue, n (%) 100 124 (57) 75 54 (25) 50 26 (12) 25 11 (5) Overall 215 (100) **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR		**Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** Yes **Harms Details:** **G1:** No serious complication. An increased cry after division: 128 (60) Duration of cry, n (%): 5 seconds or less: 56 (44) 20 seconds or less: 183 (85) More than 1 minute: 2 (1) Mean duration of cry: 15 seconds, median: 10 seconds Bleeding: Few drops of blood: 113 (52) Any bleeding: 131 (61) Small amount: 18 (9) Ulcer under the tongue > 48 hours: n=4 Mild complication: 6 (3) **Timing of harms:** Immediate

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Heller et al., 2005[19] **Country:** USA **Enrollment period:** 1999 to 2003 **Funding:** NR **Design:** RCT	**Intervention:** 4-Flap Z-Frenuloplasty: 2 flaps were marked on one side at the tip of the tongue, and 2 more on the other side at the tongue base. After incisions made, flaps were transposed and then sutured. Horizontal- to-vertical frenuloplasty: Scissors were used to separate the deep tissue to release the tight muscular layers, and hemostasis was achieved with a Bovie cauterizer. With retraction of the single hook, the horizontal wound was converted to a vertical wound that was closed with interrupted 4–0 chromic sutures. **Groups:** **G1:** 4-Flap Z-Frenuloplasty **G2:** Horizontal- to-vertical frenuloplasty **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** Yes **Other non-surgical therapies:** Discussion section also notes “exercises” were prescribed **Setting of therapy:** Multidisciplinary team at the Cleft Lip and Palate–Craniofacial Clinic **Treatment duration:** NR **Last follow-up post-treatment:** **G1:** 1.3 years (10-35 months) **G2:** 1.5 years (10-41 months) **N at enrollment:** **G1:** 11 **G2:** 5	**Inclusion criteria:** had a tight frenulum <15 mm Had articulation and speech problems related to the tongue-tie Older than 3 years of age **Exclusion criteria:** developmental delay were syndromic, or had significant oral pathology **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, mean ± SD :** **G1:** 5.7 ± 2.14 **G2:** 5.56 ± 1.52 **Gender, n (%):** Male: **G1:** 7 (77.8) **G2:** 2 (22.2) Female: **G1:** 4 (57.1) **G2:** 3 (42.9) **Race/ethnicity:** NR **Indication for therapy:** Articulation & Speech problems **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean ± SD:** **G1:** 11.9 ± 6.1 mm **G2:** 11.4 ± 3.36 mm **Maternal:** **G1:** NR **G2:** NR **Infant:** **G1:** NA **G2:** NA **Child:** Tongue protrusion: **G1:** -0.64 ± 1.91 mm **G2:** -0.6 ± 1.14 mm Articulation difficulties, n (%): Severe: **G1:** 6 (55) **G2:** 3 (60) Moderate articulation difficulties: **G1:** 5 (45) **G2:** 2 (40)	**Length of lingual frenulum when tongue is lifted (cm), mean ± SD:** **G1:** 49.4 ± 16.6 mm **G2:** 22.6 ± 7.02 mm **Maternal:** **G1:** NR **G2:** NR **Infant:** **G1:** NA **G2:** NA **Child:** Mean Frenulum length Gain: **G1:** 37.5 **±** 13.5 mm, (increase of 315% from the baseline mean), p<0.0001 **G2:** 11.2 ± 4.5 (increase of 98% from baseline mean), p<0.02 Tongue protrusion: **G1:** 35.54 ± 9.03 mm **G2:** 12.6 ± 1.7 Mean tongue protrusion Gain: **G1:** 36.2 ± 7.2 mm (p<0.0001) **G2:** 13.2 ± 2.6 mm (p=0.0003) **Speech/articulation, n (%):** Significant improvement in articulation errors of at least 2 orders: **G1:** 10 (91) **G2:** 0 One order of improvement: **G1:** 0 **G2:** 2 (40) Complete resolution of

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
	N at follow-up: **G1:** 11 **G2:** 5 **Consultation with lactation consultant:** NR			speech problems: **G1:** 7 (64) **G2:** 0 No improvement in speech: **G1:** 1 (9) **G2:** 3 (60) **Need for reoperation:** **G1:** NR **G2:** NR **Harms:** None **Harms Details:** NA **Timing of harms:** Surgical or post-operative

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Hogan et al., 2005[20] **Country:** UK **Enrollment period:** March 2002 to July 2002 **Funding:** NR **Design:** RCT	**Intervention:** Tongue-tie division: tongue-tie put on a stretch with left index finger while holding lower lip clear with left thumb. Tie divided completely with sharp blunt end sterile scissors and floor of mouth compressed with gauze. Returned to mother for feeding after the procedure. Control group received intensive support, advice and help from lactation consultants. If no improvement after 48 hours they were offered division. **Groups:** **G1:** tongue-tie division **G2:** breastfeeding control group **Type of professional performing treatment:** lactation consultants, pediatric surgeon **Anesthesia used in surgical intervention:** None used **Other non-surgical therapies:** List reported by group **Setting of therapy:** Outpatient **Treatment duration:** NA **Last follow-up post-treatment:** Telephone follow-up at 24 hours, weekly for 4 weeks and after 4 months **N at enrollment:** **G1:** 28 **G2:** 29 **N at follow-up:** **G1:** 28 **G2:** 29 **Consultation with lactation consultant, n (%):** **G1:** 28 (100) **G2:** 29 (100)	**Inclusion criteria:** • Infants born with tongue-tie during 5 month period • Feeding problems **Exclusion criteria:** • Wanted immediate division • Feeding problems resolved **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at randomization, mean (range):** **G1:** 20 **G2:** 18 **G1+ G2:** (3-70) **Gender, n (%):** Male: **G1:** 14 **G2:** NR Female: **G1:** 14 **G2:** NR **Race/ethnicity:** NR **Indication for therapy, n (%):** Breastfed babies Latching problems **G1:** 17 (85) **G2:** 16 (80) Sore nipples **G1:** 16 (80) **G2:** 16 (80) Continuous feeds **G1:** 9 (45) **G2:** 12 (60) Top-up feeds **G1:** 6 (30) **G2:** 8 (40) Bottle-fed Slow bottle feeds **G1:** 5 (62) **G2:** 8 (88) Dribbling **G1:** 5 (62)	**Length of lingual frenulum when tongue is lifted (cm), mean, median:** Length of tongue tie, n: **25%:** 5 breast fed and 1 bottlefed **50%:** 11 breast fed and 2 bottlefed **75%:** 9 breast fed and 6 bottlefed **100%:** 15 breast fed and 8 bottlefed **Maternal:** Painful, damaged nipples, n (%) **G1+ G2:** 32/40 (80) Mastitis **G1+ G2:** 6/40 (15) **Infant:** Breastfeeding latch problems, n (%) **G1+ G2:** 33/40 (82) **Child:** NR	**Length of lingual frenulum when tongue is lifted:** NR **Maternal:** **G1:** NR **G2:** NR **Infant:** Improvement in feeding, n (%) **G1:** 27/28 (96) **G2:** 1/29 (3) The remaining 28 mothers in G2 all requested tongue-tie division. Following this 27/28 improved. **Child:** NR **Need for reoperation:** NR **Harms:** Yes **Harms Details:** No problems with infection or bleeding, either primary or secondary **Timing of harms:** immediate

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		G2: 7 (77) Excess wind **G1:** 2 (25) **G2:** 2 (25) **Other characteristics:** Breastfeeding **G1:** 20 **G2:** 20 Bottle feeding **G1:** 8 **G2:** 9 **Type of ankyloglossia:** See length of tongue tie **Ankyloglossia with concomitant lip tie:** NR		

Comment: Authors noted most babies cried for only a few seconds until they were given a feed.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Hong et al., 2010 [21] **Country:** US **Enrollment period:** July 2007 to July 2009 **Funding:** NR **Design:** Case series, retrospective	**Intervention:** Frenotomy **Groups:** **G1:** intervention **Type of professional performing treatment:** Pediatric ENT **Anesthesia used in surgical intervention:** Yes (20% Benzocaine topical) **Other non-surgical therapies:** NR **Setting of therapy:** Outpatient pediatric ENT clinic **Treatment duration:** Days / weeks **Last follow-up post-treatment:** Immediately post-treatment **N at enrollment:** **G1:** 341 **G1a:** 322 anterior **G1b:** 19 posterior **N at follow-up:** **G1:** 341 **Consultation with lactation consultant, (%):** **G1:** Yes (80)	**Inclusion criteria:** • Patients seen in pediatric ENT clinic for ankyloglossia (identified using ICD.9 code for ankyloglossia and CPT code for outpatient frenotomy **Exclusion criteria:** NR **Age, days or months at first diagnosis:** NR **Age, weeks at presentation, median (range):** **G1:** 2.7 (1 day to 24 weeks) **Gender, n (%):** **G1a:** Male: 221 (68.6) Female: 101 (31.4) **G1b:** Male: 7 (36.8) Female: 12 (63.2) **Race/ethnicity:** NR **Indication for therapy:** Breastfeeding **G1b:** 89% nipple pain **G1b:** 84% latching on difficulties **G1b:** 80% prolonged feeds **G1b:** 16% (n=3) poor weight gain **Other characteristics:** NR **Type of ankyloglossia:** Anterior, n: **G1a:** 322 Posterior, n: **G1b:** 19 **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR Improved breastfeeding noted. **Child:** **G1:** NR **Need for reoperation:** Revision procedure, n (%) **G1a:** 12 (3.7) **G1b:** 4 (21.1) **G1a vs G1b:** p=0.008 **Harms:** NR **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Khoo et al., 2009 [22] **Country:** UK **Enrollment period:** June 2007 to July 2008 **Funding:** NR **Design:** Case series	**Intervention:** Frenulotomy: tongue tie put on a stretch using sterile notched tongue elevator and divided using curved blunt strabismus scissors **Groups:** **G1:** intervention **Type of professional performing treatment:** Surgeon **Anesthesia used in surgical intervention:** None Required **Other non-surgical therapies:** Reviewed in the clinic after appropriate intervention from qualified lactation consultants had failed to improve feeding difficulties **Setting of therapy:** TBD clinic in hospital **Treatment duration:** Days / weeks **Last follow-up post-treatment:** Immediately post-treatment **N at enrollment:** **G1:** 62 **N at follow-up:** **G1:** 62 **Consultation with lactation consultant, (%):** **G1:** Yes (100)	**Inclusion criteria:** • Intervention from qualified lactation consultant failed to improve feeding difficulties • Symptomatic tongue-tie confirmed on examination **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, mean ± SD (%):** **G1:** < 90 days (100) **G1:** 23.5 ± 17.1 **Gender, n (%):** Male: **G1:** 42 (68) Female: **G1:** 20 (32) **Race/ethnicity:** NR **Indication for therapy, n (%):** Poor latch **G1:** 52 (84) Prolonged jaundice **G1:** 6 (11) Noisy feeding **G1:** 39 (63) Infant frustration **G1:** 50 (81) Infant not satisfied after feed **G1:** 27 (44) (e.g., breastfeeding, other feeding issues, speech, psychosocial) **Other characteristics, n (%):** Family history: **G1:** 19 (33) **Type of ankyloglossia, n (%):**	**Length of lingual frenulum when tongue is lifted:** 25% of tongue, n (%): **G1:** 7 (22) 50% of tongue, n (%): **G1:** 19 (30) 75% of tongue, n (%): **G1:** 15 (24) To tip of tongue, n (%): **G1:** 21 (34) **Maternal, n (%):** Nipple pain **G1:** 52 (84) Nipple trauma **G1:** 32 (52) **Infant mean ± SD:** Number feeds per day **G1:** 7.4 ± 2.4 Length of feed (minutes) **G1:** 41.6 ± 27.5 Time between feeds/min **G1:** 161.1 ± 44.3 Overall difficulty (0 to 10 scale) **G1:** 6.1 ± 2.7 **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean, median:** **G1:** NR **Maternal:** **G1:** NR **Infant:** Number feeds per day **G1:** 6.4 ± 1.5 p< 0.005 Length of feed (minutes) **G1:** 24.1 ± 17.4 p< 0.001 Time between feeds/min **G1:** 197.0 ± 45.3 p< 0.001 Overall difficulty (0 to 10 scale) **G1:** 1.9 ± 2.6 p< 0.001 **Child:** **G1:** NR **Need for reoperation:** NR **Harms:** Minor bleeding **Harms Details:** NA **Timing of harms:** NR

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		Movement Able to protrude tongue beyond lower gum line **G1:** 18 (31) Able to elevate tongue **G1:** 15 (24) **Ankyloglossia with concomitant lip tie:** NR		

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Klockars et al., 2009[23] **Country:** Finland **Enrollment period:** 1996 to 2006 **Funding:** No financial conflict of interest **Design:** Case series	**Intervention:** Frenotomy / Frenuloplasty procedure not described **Groups:** **G1:** intervention **G1a:** 1-23 months **G1b:** 2-5 years **G1c:** 6-12 years **G1d:** 13-18 years Frenotomy (no or local anesthesia), n (%) **G1:** 100/296 (34) **G1a:** 32/67 (48) **G1b:** 43/143 (30) **G1c:** 22/74 (30) **G1d:** 3/12 (25) Frenotomy (general anesthesia) **G1:** 46/296 (16) **G1a:** 14/67 (21) **G1b:** 21/143 (15) **G1c:** 9/74 (12) **G1d:** 2/12 (17) Frenuloplasty (no or local anesthesia) **G1:** 15/296 (5) **G1a:** 1/67 (1) **G1b:** 1/143 (1) **G1c:** 6/74 (8) **G1d:** 7/12 (58) Frenuloplasty (general anesthesia) **G1:** 135/296 (46) **G1a:** 20/67 (30) **G1b:** 78/143 (55 **G1c:** 37/74 (50) **G1d:** 0/12 (0) **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** Varied **Other non-surgical therapies:** List reported by group **Setting of therapy:** NR **Treatment duration:** NR **Last follow-up post-treatment:** Varied. See age at query	**Inclusion criteria:** • Children who received frenotomy or frenuloplasty because of tongue-tie identified from hospital records based on WHO ICD code Q38.1 and NOMESCO classification (surgical procedure EJC20) **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, years at intervention, median (range):** **G1:** 4 (newborn to 18) **Age, years at query, median (range):** **G1:** 11 (9 months to 27) **Gender, n (%):** Male: **G1:** 216 (68) Female: **G1:** 101 (32) **Race/ethnicity:** NR **Indication for therapy, n (%):** Speech/articulation problems **G1:** 101/159 (64) Restricted movement **G1:** 28/159 (18) Lactation/nutrition problems **G1:** 13/159 (8) Different combinations of speech and nutrition problems **G1:** 8/159 (5) **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** Benefit (from operation) type not specified **Infant:** **G1:** Benefit (from operation) type not specified **Child:** Benefit from operation: (Type not specified) **Maternal/Infant/child, n (%):** Benefit from surgery: **G1:** 133/159 (84 %) probable or partial benefit: 9 No benefit from operation: **G1:** 7/159 (4%) Could not estimate possible benefit: **G1:** 19/159 (12%) **Need for reoperation, n:** **G1:** 48/317 including 4 who had 3 surgeries and 1 who had 4 By type of initial procedure and age group, n (%) Total, n (%) **G1:** 31/296 (10) **G1a:** 4/67 (6) **G1b:** 14/143 (10) **G1c:** 12/74 (16) **G1d:** 1/12 (8) Frenotomy (no or local anesthesia), n (%) **G1:** 29/100 (29)

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
	N at enrollment: **G1:** 317 **N at follow-up:** **G1:** 296 (information available for initial operation technique and anesthesia use) **Consultation with lactation consultant:** NR			**G1a:** 4/32 (13) **G1b:** 13/43 (30) **G1c:** 12/22 (55) **G1d:** 0 (0) Frenotomy (general anesthesia) **G1:** 1/46 (2) **G1a:** 0/14 (0) **G1b:** 0/21 (0) **G1c:** 0/9 (0) **G1d:** 1/2 (50) Frenuloplasty (no or local anesthesia) **G1:** 1/15 (1) **G1a:** 0/1 (0) **G1b:** 1/1 (100) **G1c:** 0/6 (0) **G1d:** 0/7 (0) Frenuloplasty (general anesthesia) **G1:** 0/135 (0) **G1a:** 0/20 (0) **G1b:** 0/78 (0) **G1c:** 0/0 (0) **G1d:** 0 (0) **Harms:** No immediate or long term postoperative effects Nearly 1/3 of patient operated on under local/no anesthesia needed reoperation **Harms Details:** N/A **Timing of harms:** N/A

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Lalakea et al., 2003[24] **Country:** USA **Enrollment period:** 3/1997 to 7/2000 **Funding:** NR **Design:** Prospective case series (Part II of study)	**Intervention:** Horizontal to vertical frenuloplasty with acetaminophen 650mg for analgesia as needed followed with a series of tongue mobility exercises for 1 month after surgery **Groups:** **G1:** Frenuloplasty **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** Yes (Local anesthesia) **Other non-surgical therapies:** NR **Setting of therapy: Hospital** (Head and Neck surgery clinic or county hospital) **Treatment duration:** NR **Last follow-up post-treatment:** 3 months post-treatment **N at enrollment:** **G1:** 6/15 (for part II) **N at follow-up:** **G1:** 6 **Consultation with lactation consultant:** **G1:** NR	**Inclusion criteria:** Primary complaint of ankyloglossia Ankyloglossia as an incidental finding (as manifested by restricted tongue mobility and tight frenulum with or without notching of the tongue tip), History of ankyloglossia in adolescence or adulthood **Exclusion criteria:** Coexisting oral pathology that might affect oral mechanics or speech articulation (eg., cleft palate) **Age, days or months at first diagnosis, mean ± SD:** NR **Age, years at intervention, mean ± SD (range):** **G1:** 17.3 ± 3.2 years (14-23) **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** Uncorrected ankyloglossia with speech problems & mechanical limitation such as difficulty licking the lips **Other characteristics:** family history: 8/15 (53%) **Type of ankyloglossia:** Anterior: **G1:** NR Posterior: **G1:** NR Mild: 4/14 Moderate: 9/14 Severe:1/14 **G1:** Frenulum Thin: 8/14 Thick: 6/14 Rolling or curling of tongue: 3/14 **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** NR **Maternal:** **G1:** NA **Infant:** **G1:** NA **Child:** Tongue protrusion: **G1:** 14.8 mm Tongue elevation: **G1:** 13.7 mm **G1:** Limited tongue motion: 2/6 Notched or heart-shaped tongue: 3/6 (50%) Limitation in Eating ice cream: 2 Licking lips;1 Cleaning teeth:1	**Length of lingual frenulum when tongue is lifted:** NR **Maternal:** **G1:** NA **Infant:** **G1:** NA **Child:**1 month after surgery: Tongue protrusion: **G1:** 24 mm Tongue elevation: **G1:** 26.7 mm **G1:** Tongue protrusion: mean gain : 9.2 ± 8.3 mm ($p<0.05$) Tongue elevation: mean gain of 13 ± 4mm ($p<0.001$) Side-to side motion of tongue: normal (100%) Persistence of notching of tongue tip: 3 (100%) Gains in, n (%): Eating ice cream: 4 (67) Licking lips: 6 (100) Cleaning teeth:4 (67) Kissing: 3/3 (100) Play wind instrument: 1/2 (50) Speech: 2 (33.3) **Need for reoperation:** **G1:** NR **Harms:** No surgical complications Minor pain requiring no or minimal analgesia

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
				Harms Details: NA **Timing of harms:** immediate

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Marchesan et al., 2012[25] **Country:** Brazil **Enrollment period:** 2010 **Funding:** NR **Study Design:** Case series	**Intervention:** Frenectomy **Groups:** **G1:** Intervention **Type of professional performing treatment:** Otolaryngologist **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** NR **Treatment duration:** NA **Last followup post-treatment:** 30 days post-treatment **N at enrollment:** **G1:** 10 **N at followup:** **G1:** 10 **Consultation with lactation consultant:** **G1:** NR	**Inclusion criteria:** • Subjects who had never undergone speech therapy or lingual frenulum surgery evaluated by speech-language pathologists • Suspected frenulum alteration • No hearing impairment, mental retardation and/or motor or genetic syndromes • Both lingual frenulum and oral functions altered **Exclusion criteria:** • See above **Age, days or months at first diagnosis:** NR **Age, years at intervention, range:** **G1:** 2-33 **Gender, n (%):** Male: **G1:** 8 (80) Female: **G1:** 2 (20) **Race/ethnicity:** NR **Indication for therapy:** Both lingual frenulum and oral functions altered **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NA **Infant:** **G1:** NA **Child, n (%):** Shape of tongue altered: **G1:** 6 (60) Speech alteration: **G1:** 8/10 (80)	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NA **Infant:** **G1:** NA **Child, n (%):** Shape of tip of tongue improved **G1:** 6/6 (100) Mouth opening improved during speech **G1**: 6/8 (75) Speech alteration improved **G1:** 4/8 (50) Difficulties in tongue protrusion and cleaning of oral cavity as well as drooling and open mouth were solved after surgery **Need for reoperation:** NR **Harms:** NR **Harms Details:** NA **Timing of harms:** NA

Comment: Results presented by patient in Table 1. Note two subjects are > age 18.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Masaitis et al., 1996 [26] **Country:** USA **Enrollment period:** 18 months **Funding:** NR **Design:** Prospective case series	**Intervention:** First the lingual frenulum was isolated and then using straight iris scissors, the membranous frenulum was clipped about 1cm. **Groups:** **G1:** Frenotomy **Type of professional performing treatment:** Pediatrician **Anesthesia used in surgical intervention:** No **Other non-surgical therapies:** NR **Setting of therapy:** Medical center **Treatment duration:** NR **Last follow-up post-treatment:** Within 1st week after procedure and at 3 months **N at enrollment:** **G1:** 36 **N at follow-up:** **G1:** 36 **Consultation with lactation consultant, n (%):** G1: 36 (100)	**Inclusion criteria:** • All Primiparous and multiparous women from Mother-Baby Program with breastfeeding problems (through intraoral exam, maternal breast exam, breastfeeding assessment and verbal history) **Exclusion criteria:** NR **Age, days at first diagnosis:** **G1:** 1- 24 days **Age, days or months at intervention, mean ± SD:** **G1:** 5.7 days (range: 1-24 days); median 3 days **Gender, n (%):** Male: **G1:** 20 (55.6) Female: **G1:** 16 (44.4) **Race/ethnicity:** NR **Indication for therapy, n:** Incidence of indications: 1. Tongue does not cross alveolar ridge (29/36) 2. Heart shaped tongue (29/36) 3. Poor attachment at breast (27/36) 4. Injured nipples (maternal) (27/36) 5. Frenulum attached to tip of tongue (24/36) 6. Previous breastfeeding failure (maternal) 9/36) 7. Inadequate weight gain (7/36) 8. Clicking sound with nursing (4/36) 9. Breast abscess (1/36) 24/36 had same cluster of most frequent occurring items: heart shaped tongue, not able to extend past lower gum line, and injured nipples **Other characteristics:**	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** Current feeding method, n (%): Breastfeeding, 1st week: **G1:** 32 (89) 3 months: **G1:** 19 (53) Only 2 mothers who weaned early (2/13) did so owing to continuous difficulty with breastfeeding. Other reasons included: maternal work (n=7), bottle easier (n=3), did not nurse 1st baby (n=3), physician recommendation to supplement with bottle weight gain mother switched (n=1), insufficient milk supply (n=1), frenotomy procedure at 12 days "too late" to reestablish breastfeeding (n=1) Bottle feeding: 1st week: **G1:** 4 (11) 3 months: **G1:** 17 (47) **Infant: G1:** Range of motion of the tongue improved in all 36 infants Range of motion of tongue: Normal: 1st week: **G1:** 33 (92) 3 months: **G1:** 36 (100)

		Family history: 21/36 (58%) had relatives with ankyloglossia Parity: First time mothers: 22/36 Of bottle fed infants at 3 months, 14/17 had frenotomies after 4 days (5 – 24). Of breastfeeding group at 3 months, 16/19 had their frenotomies under age of 4 days **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR		Better than previously: 1 week: 3 (8) 3 months: 0 Problems resolved: Yes, completely: 1 week: **G1:** 27 (75) 3 months: **G1:** 36 (100) Partially: **G1:** 1 week: 7 (19) 3 months: 0 No: **G1:** 1 week: 2 (6) 3 months: 0 Rate of infant growth: appropriate: 1 week: **G1:** 34 (94%) 3 months: **G1:** 36 (100) Slow: 1 week: G1: 2 (6) 3 months: 0 Choosing procedure again if needed at: 1 week: 100% (36/36) 3 months: 100% (36/36) **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** No complications nor any excessive bleeding **Harms Details:** NA **Timing of harms:** Immediate

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Messner et al., 2002[27] **Country:** USA **Enrollment period:** 6/1997 to 6/2001 **Funding:** NR **Design:** Case series	**Intervention:** NR **Groups, n** **G1**: Frenuloplasty (horizontal to vertical) (n=29) OR Frenotomy (n=1) **Type of professional performing treatment:** NR **Anesthesia used in surgical intervention:** **G1:** Yes General (n=26) Local (n=4) 11/26 had frenuloplasty in conjunction with another procedure **Other non-surgical therapies, n (%):** Tongue exercises for 1 month after surgery **G1:** 20 /24 (83.3) **Setting of therapy:** Otolaryngology clinics **Treatment duration:** NR **Last follow-up post-treatment:** 3.1 months (7 days to 8.5 months) **N at enrollment:** **G1:** 30 **N at follow-up:** **G1:** 28 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • primary complaint of ankyloglossia or if the ankyloglossia was an incidental finding • Tight lingual frenulum with associated feeding, speech or social difficulties or if they were anticipated to develop • aged 1 to 12 years **Exclusion criteria:** • cleft palate, generalized developmental delay **Age, days or months at first diagnosis, mean:** **G1:** 1.9 years (11 diagnosed at < 1 year of age) **Age, days or months at intervention, mean:** **G1:** 4.1 yrs. **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** Tight lingual frenulum with associated feeding, speech, or social difficulties **Other characteristics:** Family history: 3/30 (10%) Attempted breastfeed: 25 Unable to breastfeed: 4/25 (3 with Latching problem: 1 with nipple pain) 20/26 parents (child's age 2 or older) reported child's speech adversely affected Difficulty with Ice cream: 7 Difficulty with wind instrument: 1 Difficulty licking lips: 8 Difficulty cleaning teeth: 2 Cuts under tongue: 1 Difficulty with speech: 20 **Type of ankyloglossia:**	**Length of lingual frenulum when tongue is lifted (cm), mean, median** Tongue elevation (measured interincisal distance with mouth maximally open, while maintaining contact of tongue tip with upper dentition): **G1:** 5.2 ± 5.6 mm Tongue Protrusion (maximum protrusion of tongue past lower teeth): **G1:** 14.2 ± 5.5 mm Tongue Mobility: **G1:** 2.3 (on a scale of 1 to 5) **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** Abnormal articulation: **G1:** 11 /15 (73.3%) Speech intelligibility (parent assessment): **G1:** 3.4 (on a scale of 1 to 5)	**Length of lingual frenulum when tongue is lifted (cm), mean, median** Tongue elevation: **G1:** 22 ± 8.7 mm ($p < 0.01$) Tongue Protrusion: **G1:** 25.8 ± 7.8 mm ($p < 0.01$) Tongue Mobility: **G1:** 4.6 (on a scale of 1 to 5), ($p < 0.01$) Mean gain in tongue elevation: **G1:** 17.1 ± 8.5 mm Mean Gain Tongue protrusion: **G1:** 11.3 ± 9.1 mm **Maternal, n (%):** Satisfaction with frenotomy/frenuloplasty: Less than completely satisfied : **G1:** 2/29 (6.9) Very or extremely satisfied: **G1:** 27/29 (93.1) **Infant:** **G1:** NR **Child, n (%):** Improved articulation: **G1:** 9 /11 (82) Persistent articulation difficulties: **G1:** 2 (18) Speech

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		NR **Ankyloglossia with concomitant lip tie:** NR		intelligibility: **G1:** 4.2 (on a scale of 1 to 5), p <0.01 **Need for reoperation:** **G1:** NR **Harms:** No complications observed **Harms Details:** NA **Timing of harms:** Immediate (surgical & postoperative)

Comment: 21/26 children aged 2+ underwent formal speech evaluation 15/21 had documented articulation errors believed to be d/t decreased tongue mobility 6/21 had age appropriate speech. All with abnormal speech were able to protrude tongue past lower incisionrs, with protrusion measurements ranging from 3 – 25 mm (mean 14.9mm). No stat difference between patients with abnormal and normal speech measurements for tongue protrusion or interincisal distance).

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Mettias et al., 2013[28] **Country:** UK **Enrollment period:** May 2010 to June 2011 **Funding:** NR **Study Design:** Case series	**Intervention:** Tongue tie division: Chin depressed with thumb of right hand to open mouth. Frenulum lubricated and numbed with lidocaine gel. Tongue-tie put on a stretch using index and middle fingers and divided using curved blunt scissors. Division completed by blunt fingertip dissection. Baby returned to mother for immediate breast feeding **Groups:** **G1:** Intervention **Type of professional performing treatment:** Otolaryngologist **Anesthesia used in surgical intervention:** Lignocaine gel 2% **Other non-surgical therapies:** List reported by group **Setting of therapy:** Outpatient clinic **Treatment duration:** NA **Last followup post-treatment:** Telephone questionnaire **N at enrollment:** **G1:** 63 **N at followup:** **G1:** 36 **Consultation with lactation consultant:** **G1:** referred by lactation Average referral time was 7.8 days from delivery	**Inclusion criteria:** NR **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, weeks at intervention, mean ± SD:** **G1:** 4.1 ± 3.2 **Gender, %:** Male: **G1:** 49.2 Female: **G1:** 50.8 **Race/ethnicity:** NR **Indication for therapy (%):** Difficulty breastfeeding: **G1:** 66.7 Poor growth: **G1:** 11.1 Limitation in tongue movement: **G1:** 22.2 Breast problems including cracking and sore nipples: **G1:** 27.7 Asymptomatic: **G1:** 13.9 **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** See indications for therapy **Infant:** **G1:** See indications for therapy **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Outcomes, n (%):** Preoperative problems were resolved: 36 (96.8) Reported delayed diagnosis and referral time: 9 (25) **Harms:** Yes (for n=36) **Harms Details, n (%):** Infant distress or discomfort (pain form procedure) **G1:** 2 (5.6) Mild bleeding on day of surgery stopped spontaneously: **G1:** 1 (2.8) Ulceration **G1:** 1 (2.8) n=2 mothers couldn't resume breastfeeding. No complications: **G1:** 32 (88.9) **Timing of harms:** NR

Comment: Some results presented in figures only. It is not clear when the follow-up questionnaire was administered.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Miranda et al., 2010 [29] **Country:** UK **Enrollment period:** 8 months **Funding:** NR **Design:** Case series, prospective data collection	**Intervention:** Frenulotomy: surgeon places two fingers on either side of frenulum to open mouth and lift tongue. Sharp sterile scissors used to release the frenulum. Piece of gauze used to absorb any mild sanguinous exudates **Groups:** **G1:** intervention **Type of professional performing treatment:** Surgeon **Anesthesia used in surgical intervention:** None **Other non-surgical therapies:** NR **Setting of therapy:** outpatient (only for neonates) **Treatment duration:** 30 seconds **Last follow-up post-treatment:** 2 weeks post-procedure **N at enrollment:** **G1:** 62 **N at follow-up:** **G1:** 51 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Diagnosis of ankyloglossia • Breastfeeding difficulty resistant to initial lactation consultant management **Exclusion criteria:** • Non-plastic surgery pediatric patients **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, mean ± SD :** **G1:** 12-36 days **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** Breastfeeding **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted::** **G1:** NR **Maternal, n (%):** Nipple pain **G1:** 27/51 (53) Nipple cracking: **G1:** 19/51 (37) Nipple bleeding **G1:** 11/51 (22) **Infant, n (%):** Poor latch: **G1:** 28/51 (55) Breastfeeding sessions/24 hours, mean ± SD: **G1:** 10 ± 0.7 Bottle feeding supplementary sessions/24 hours, mean ± SD **G1:** 9 ± 0.6 **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal, n (%):** Breastfeeding improvements **G1:** (63) Reporting improvements Nipple pain: **G1:** 27/51 (100) Nipple cracking: **G1:** 19/51 (100) Nipple bleeding: **G1:** 11/51 (100) Pain score improvement: **G1:** 83% **Infant:** Weight gain n, (%) **G1:** 51/51 (100) Poor latch improvement **G1:** 28/51 (89) Two weeks post Breastfeeding sessions/24 hours, mean ± SD **G1:** 7 ± 0.5 p< 0.0001 Bottle feeding supplementary sessions/24 hours, mean ± SD **G1:** 2 ± 0.7 p< 0.0001 **Child:** **G1:** Weight gain occurred in 100% (51/51) of neonates at 2 weeks post-frenulotomy, of which 90% (46/51) gained in centile, 6%(3/51) remained at the same centile

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
				and 4%(2/51) dropped 7.5 centiles. Neonates therefore gained 15 1.2 centiles (41st-56th) 1.4 males and 18 2.0 for females. **Need for reoperation:** NR **Harms:** No complications **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: O'Callahan et al., 2013[30] **Country:** US **Enrollment period:** December 2006 to March 2011 **Funding:** Middlesex hospital **Study Design:** Case Series	**Intervention:** Frenotomy; Infants swaddled and immobilized. Use of metal grooved elevator held with thumb and index fingers while middle finger maintained pressure on lower gum to keep jaw open (reverse "chop-stick" maneuver). Blunt-tipped curved scissors used to clip thin diaphanous membrane if present, mucosa at thinnest part of frenular protrusion near underside of tongue, and shiny white submucosal band if present. Maxillary frenotomy consisted of lifting infant lip with gauze and clipping parallel to gum with wide clamp and then cutting through crushed tissue. Hemostasis achieved by applying direct pressure using gauze for 2-4 minutes **Groups:** **G1:** Intervention **Type of professional performing treatment:** Pediatrician **Anesthesia used in surgical intervention:** Yes topical 20% benzocaine and three drops of 22% sucrose; NOTE: use of benzocaine no longer recommended in children under 2 as of April 2, 2011 **Other non-surgical therapies:** NA **Setting of therapy:** Pediatric clinic	**Inclusion criteria:** • Women whose infants underwent frenotomy asked to complete web-based questionnaire between December 2010 and May 2011 **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, mean (range):** **G1:** 35 (2-332) Age 2-30 days, n (%) **G1:** 131 (44) **G1a:** 60 (38) **G1b:** 71 (50) 31-60 days **G1:** 89 (30) **G1a:** 54 (35) **G1b:** 35 (25) 61-90 days **G1:** 36 (12) **G1a:** 24 (15) **G1b:** 12 (9) 91 to 323 days **G1:** 43 (14) **G1a:** 19 (12) **G1b:** 24 (17) **Gender, n (%):** Male: **G1:** 162 (51) **G1a:** 80 (51) **G1b:** 82 (58) Female: **G1:** 137 (49) **G1a:** 77 (49) **G1b:** 60 (43) **Race/ethnicity:** NR **Indication for therapy:** NR **Other characteristics:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal , n (%):** Mother sought breastfeeding consultation prior to frenotomy evaluation **G1a:** 153 (98) Maternal breastfeeding difficulties prior to frenotomy (i.e.nipple skin damage and/or bleeding, misshapen nipple, compression/stripe mark on nipple after breastfeeding, low milk supply, plugged ducts, and/or mastitis): **G1a:** 146 (93) **Infant, n (%):** Breastfeeding difficulties prior to frenotomy evaluation (i.e.latching issues, poor weight gain, weight loss, prolonged feedings, use of a bottle, chewing or lipsticking, and/or clicking sounds while nursing): **G1a:** 156 (99) Nipple pain **G1a:** 118 (75) Latching problems **G1a:** NR **Child:** Speech difficulty: **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal :** Exclusive breastfeeding post intervention, % **G1a:** 92 Duration months mean ± SD, (range) **G1a:** 14 ± 10.2 (0.5-54) Note n=46 did not provide duration data **Infant , n (%):** No nipple pain:: **G1a:** 64% P< 0.001 compared to baseline **Child:** **G1:** NR **Need for reoperation, n (%):** Multiple frenotomies **G1a:** 43 (27) **Harms, %:** 3 infants required cauterization with silver nitrate for persistent oozing No complications or negative side effects **G1a:** 94 Undergoing frenotomy was worth the emotional and physical discomfort to mother and infant **G1a:** 93 **Harms Details:** NA **Timing of harms:** NR

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
	Treatment duration: **G1:** NA **Last followup post-treatment:** Varied **N at enrollment:** **G1:** 299 Survey respondents, n: **G1a:** Yes, 157 **G1b:** No, 142 **Consultation with lactation consultant:** NR	**Type of ankyloglossia:** Anterior, (Type 1 and Type 2), n (%): **G1:** 47 (16) **G1a:** 18 (12) **G1b:** 29 (20) Type III, n (%): **G1:** 107 (36) **G1a:** 52 (33) **G1b:** 55 (39) Type IV, n (%) **G1:** 145 (49) **G1a:** 87 (55) **G1b:** 58 (41) **Ankyloglossia with concomitant lip tie, n (%):** **G1:** 72 (37) **G1a:** 44 (44) **G1b:** 28 (29)		

Comment: Authors reported that half of the infants with latch issues as the presenting problem reported no issues after the intervention (N's were not reported). No new latching issues emerged.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Puthussery et al., 2011 [31] **Country:** UK **Enrollment period:** NR **Funding:** NR **Design:** Case series	**Intervention:** Laser excision: carbon dioxide laser with 10.6 µ.m wavelength and power of 4 W at 25J/cm^2 in continuous mode. Vertical incision made to release frenulum. **Groups, n:** **G1:** intervention, 21 **Type of professional performing treatment:** A single surgeon **Anesthesia used in surgical intervention:** Yes (general or local) for surgery. Also local with 2% lidocaine and 1:80,000 adrenaline infiltrated at the end of surgery for postoperative pain control and patients were discharged with analgesics PRN. **Other non-surgical therapies:** NR **Setting of therapy:** Day stay unit of hospital **Treatment duration:** NR **Last follow-up post-treatment:** Day 1, 7 and one month post-treatment **N at enrollment:** **G1:** 21 **N at follow-up:** **G1:** 21 **Consultation with lactation consultant:** NR	**Inclusion criteria:** NR **Exclusion criteria:** NR **Age, days or months at first diagnosis:** NR **Age, years at intervention, range:** **G1:** 3-30 **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** Speech problems (n=10) Feeding problems (n=3) Oral hygiene issues (n=8) **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted :** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child: (parents and child filled out survey together)** Improved speech Strongly agree or agree: **G1:** 14/21 Improved tongue movement Strongly agree or agree: **G1:** 18/21 Improved oral hygiene Strongly agree or agree **G1:** 16/21 **Need for reoperation:** **G1:** NR **Harms:** Yes **Harms Details:** Authors report no complications and no patients had bleeding or swelling that caused problems with airway or feeding. No pain: **G1:** 2/21 disagree, 2/21 neutral No bleeding: **G1:** 1/21 disagree, 1/21 neutral No swelling: **G1:** 0/21 disagree, 1/21 neutral **Timing of harms:** Unclear at which time-point the survey was administered.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Ridgers, et al., 2009[32] **Country:** UK **Enrollment period:** NR (16 month period listed in abstract; 24 month period listed in text) **Funding:** NR **Study Design:** Case series	**Intervention:** Division of tongue tie: mother holds baby, surgeon inserts left middle finger into baby's mouth between alveolar ridges, retracts the upper and lower lips with index finger and thumb of same hand. Wait until baby cries, as tongue is raised surgeon snips the excess fibrous tissue if tongue-tie assessed as significant. **Groups:** **G1:** Intervention **Type of professional performing treatment:** Surgeon **Anesthesia used in surgical intervention:** None **Other non-surgical therapies:** NR **Setting of therapy:** Inpatient lactation and breastfeeding clinic **Treatment duration:** NA **Last followup post-treatment:** Immediately post-treatment and 4 weeks after **N at enrollment:** **G1:** 220 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Infants with feeding difficulties and tongue ties **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, median (range):** **G1:** 10 (3-70) **Gender, n (%):** Male: **G1:** 141 (64) Female: **G1:** 79 (36) **Race/ethnicity:** NR **Indication for therapy, n (%):** Difficult attachment: **G1:** 95 (43) Nipple soreness: **G1:** 86 (39) Frequent feeds: **G1:** 57 (26) Infant not attaching: **G1:** 40 (18) Protracted feeds: **G1:** 40 (18) Dribbles on bottle: **G1:** 18 (8) Poor milk supply: **G1:** 17 (8) Infant never attached: **G1:** 9 (4) Mastitis: **G1:** 9 (4) **Other characteristics, n (%):** Family history: **G1:** 90 (41)	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant, n (%):** Feeding problems full resolved: **G1:** 168 (67) Improved **G1:** 47 (21) No change **G1:** 5 (2) **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** **G1:** Yes **Harms Details:** Minor bleeding, n (%) **G1:** 4 (2) Infant distress (crying) **Timing of harms:** Immediate or within 10-20 seconds for crying- stopped completely within maximum of two minutes for bleeding

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		Feeding Breast only: **G1:** 130 (59) Bottle only: **G1:** 35 (16) Combination: **G1:** 55 (25) **Type of ankyloglossia:** Anterior, n (%): Unable to protrude tongue beyond alveolar ridge or bottom lip; thick fibrous band and notching of tip on attempted protrusion: **G1:** 150 (68) Partial extrusion with significant feeding difficulties: **G1:** 44 (20) Unrestricted tongue movement but definite band visible: **G1:** 26 (12) **Ankyloglossia with concomitant lip tie:** NR		

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Riskin et al., 2014 [33] **Country:** Israel **Enrollment period:** Jan 2005 to Dec 2010 **Funding:** NR **Design:** Retrospective cohort	**Intervention (description)** Frenotomy **Groups, n (%)** **G1a:** intervention **G1b:** No intervention **Type of professional performing treatment:** Pediatric surgeons (38.5%), pediatricians (10.8%), otolaryngologists (7.7%), dentists (7.7), dermatologists (6.1%), family practitioners (3.1%) **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies, n (%):** NR **Setting of therapy:** NR **Treatment duration:** NR **Last follow-up post-treatment:** Varied **N at enrollment:** **G1:** 239 **N at follow-up:** **G1:** 183 Received frenotomy **G1a:** 65 (35.5) No frenotomy **G1b:** 118 (64.5) **Consultation with lactation consultant, n (%):** **G1:** 110 (60.1) Lactation support in hospital **G1a:** 41/65 (63.1) **G1b:** 69/118 (58.59)	**Inclusion criteria:** Newborns delivered at Bnai Zion medical center at gestational age ≥ 37 weeks diagnosed with tongue tie Diagnosis made by physicians, nurses or lactation consultants and confirmed by senior neonatologist at discharge **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** **G1:** NR **Age, days or months at intervention, mean ± SD:** **G1:** NR **Age, years at interview, mean ± SD :** **G1:** 3.2 ± 1.3 **Gender, n (%):** Male: **G1:** (62.8) Female: **G1:** (37.2) **Race/ethnicity:** Jewish **G1:** 81.5% Arab **G1:** 18.5% **Indication for therapy:** Purpose of frenotomy Alleviate breastfeeding problems **G1a:** 40/65 (61.5) Alleviate breastfeeding problems only **G1a:** 19/65 (29.2) Alleviate breastfeeding + future speech problems **G1a:** 21/65 (32.3) Speech problems **G1a:** 20/65 (30.8) Other purposes	**Length of lingual frenulum when tongue is lifted (cm), mean, median** **G1:** NR **Maternal:** Breastfeeding problems in first month of life Pain or sore nipples **G1:** 51 (29.5) Latch **G1:** 51 (27.9) Congestion (breast engorgement) **G1:** 39 (21.3) Insufficient milk supply **G1:** 30 (16.4) Inflammation or mastitis **G1:** 13 (7.1) Other unspecified problems **G1:** 13 (7.1) Spontaneous report of problems **G1a:** 38/65 (58.5) **G1b:** 40/118 (33.9) G1a vs G1b: p=0.002 Reported problems on specific questions Congestion **G1a:** 19 (29.2) **G1b:** 20 (16.9) G1a vs G1b: p=0.08 **Latch** **G1a:** 25 (38.5) **G1b:** 26 (22.0) G1a vs G1b: p=0.03 Lengthy breastfeedings **G1a:** 13 (20.0) **G1b:** 12 (10.2) G1a vs G1b: p=0.10 Infant exhaustion **G1a:** 12 (18.5) **G1b:** 7 (5.9) G1a vs G1b: p=0.02 Pain or sore nipples **G1a:** 24 (36.9) **G1b:** 27 (22.9) G1a vs G1b: p=0.06	**Length of lingual frenulum when tongue is lifted (cm), mean, median** **G1:** NR **Maternal:** Reported improvement after frenotomy Alleviate breastfeeding problems **G1a:** 23/26 (88.5) Alleviate breastfeeding problems only **G1a:** 12/23 Alleviate breastfeeding + future speech problems **G1a:** 11/23 Speech problems **G1a:** 2/26 (7.7) Other purposes **G1a:** 1/26 (3.8) No improvement **G1a:** 10/65 (15.4) Could not tell **G1a:** 29/65 (44.6) **Infant:** Breastfeeding latch, bottle feeding difficulty, failure to thrive, tongue mobility, weight gain, etc. (specify method and results, mean, median, %) **G1:** NR **Child:** Speech, articulation, psychosocial, orthodontic, oral hygiene, tongue mobility, etc. (specify assessment method and results, mean, median, %) **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** NR

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		G1a: 4/65 (6.2) No reason given **G1a:** 1/65 (1.5) **Other characteristics n (%):** First degree relative with anklyoglossia **G1:** 64 (35) **Type of ankyloglossia:** Anterior, n (%): **G1:** NR Posterior, n (%): **G1:** NR **Ankyloglossia with concomitant lip tie, n (%):** **G1:** NR	Inflammation or mastitis **G1a:** 8 (12.3) **G1b:** 5 (4.2) G1a vs G1b: p=0.08 **Insufficient milk supply** **G1a:** 11 (16.9) **G1b:** 19 (16.1) G1a vs G1b: p=0.95 **Poor weight gain** **G1a:** 8 (12.3) **G1b:** 7 (7.9) G1a vs G1b: p=0.22 Other unspecified problems **G1a:** 6 (9.2) **G1b:** 7 (5.9) G1a vs G1b: p=0.60 **Infant:** Infant's exhaustion **G1:** 25 (14.4) Lengthy breastfeedings **G1:** 25 (14.4) Poor weight gain **G1:** 15 (8.2) **Child:** Reported speech problem **G1:** 19/183 (10.3) True rate speech problem (age > 2 years old at time of interview **G1:** 19/159 (11.9)	**Timing of harms:** NA

LATCH = Latch, Audible swallowing, Type of Nipple, Comfort, Hold; HATLFF = Hazelbaker Assessment Tool for Lingual Frenulum Function; BSES= Breastfeeding Self-Efficacy Scale; IBAT = Infant Breastfeeding Assessment Tool; VAS = Visual Analog Scale for Pain; MPQ = McGill Pain Questionnaire

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Rose et al., 2014[34] **Country:** UK **Enrollment period:** 1 year period **Funding:** NR **Design:** Case series	**Intervention (description):** Frenulotomy **Groups, n (%)** **G1:** intervention **Type of professional performing treatment:** (e.g., **G1a:** ENT physician **G1b:** ENT nurse **Anesthesia used in surgical intervention:** No **Other non-surgical therapies, n (%):** NR **Setting of therapy:** outpatient tongue-tie clinic **Treatment duration:** 20 minutues **Last follow-up post-treatment:** Immediately post-treatment **N at enrollment:** **G1:** 162 **N at follow-up:** **G1:** 105 **G1a:** 54 **G1b:** 51 **Consultation with lactation consultant, n (%):** **G1:** NR	**Inclusion criteria:** Parents of patients treated for tongue-tie in < 6 month old at either ENT or nurse led outpatient clinic regardless of breast feeding problems **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** **G1:** NR **Age, days or months at intervention, range :** **G1:** 7 days to 5 months (77% < 1 month) **Gender, n (%):** Male: **G1a:** 28 **G1b:** 29 Female: **G1a:** 26 **G1b:** 22 **Race/ethnicity:** **G1:** NR **Indication for therapy:** Varied **Other characteristics:** NR **Type of ankyloglossia: Anterior, n (%):** **G1:** NR **Posterior, n (%):** **G1:** NR **Ankyloglossia with concomitant lip tie, n (%):** **G1:** NR	**Length of lingual frenulum when tongue is lifted** **G1:** NR **Maternal:** Breastfeeding, n (%) **G1a:** 38 (70) **G1b:** 26 (51) Difficulty breastfeeding, n (%) **G1a:** 34/38 (89) **G1b:** 23/26 (88) **Infant:** Breastfeeding latch, bottle feeding difficulty, failure to thrive, tongue mobility, weight gain, etc. (specify method and results, mean, median, %) **G1:** NR **Child:** Speech, articulation, psychosocial, orthodontic, oral hygiene, tongue mobility, etc. (specify assessment method and results, mean, median, %) **G1:** NR	**Length of lingual frenulum when tongue is lifted** **G1:** NR **Maternal:** Immediate improvement in breastfeeding, n (%) **G1a:** 21/34 (62) **G1b:** 16/23 (70) No improvement in breastfeeding, n (%) **G1a:** 2/34 (6) **G1b:** 1/23 (4) Too early to tell if improvement in breastfeeding, n (%) **G1a:** 11/34 (32) **G1b:** 6/23 (26) Satisfaction scores: Overall experience (median scores): **G1a, G1b:** 10 **Infant:** Breastfeeding latch, bottle feeding difficulty, failure to thrive, tongue mobility, weight gain, etc. (specify method and results, mean, median, %) **G1:** NR **Child:** Speech, articulation, psychosocial, orthodontic, oral hygiene, tongue mobility, etc. (specify assessment method and results, mean, median, %) **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** NR **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Sethi et al., 2013[35] **Country:** UK **Enrollment period:** February 2008 to February 2011 **Funding:** NR **Study Design:** Prospective case series	**Intervention:** Frenulotomy: Sterile iris scissors with blunt tips used to divide the frenulum and parent was able to attempt breastfeeding almost immediately after **Groups:** **G1:** Intervention **Type of professional performing treatment:** Otolaryngologist **Anesthesia used in surgical intervention:** No **Other non-surgical therapies:** NR **Setting of therapy:** Outpatient ENT **Treatment duration:** NA **Last followup post-treatment:** At least 5 months after procedure by telephone **N at enrollment:** **G1:** 85 **N at followup:** **G1:** 52 **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Presence of tongue-tie assessed by senior authors based on tongue protrusion, ability to suckle finger, length, elasticity and tongue shape **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, mean (range):** **G1:** 19 (3-120) **Gender, n:** Male: **G1:** 35 Female: **G1:** 17 **Race/ethnicity:** NR **Indication for therapy:** Referrals from midwives (n=25) lactation consultants (n=20) pediatricians (n=4) and GPs (n=3) All mothers had experienced problems breastfeeding **Other characteristics :**NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal, n:** Sore nipples **G1:** 6/52 **Infant, n:** Poor latch **G1:** 49/52 Continual feeding **G1:** 18/52 Poor weight gain **G1:** 10/52 Excess wind **G1:** 2/52 **Feeding at baseline** Exclusively breastfeeding **G1:** 28/52 Supplementing with expressed breast milk **G1:** 22/52 Exclusively formula fed **G1:** 2/52 **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal, n:** Immediate improvement in breastfeeding: **G1:** 16/52 Improvement within 24 hours: **G1:** 8/52 Improvement within 1 week: **G1:** 13/52 Improvement within 2 weeks: **G1:** 3/52 No Improvement : **G1:** 12/52 **Infant, n:** Feeding after frenotomy Exclusively breastfeeding **G1:** 20/52 Supplementing with expressed breast milk: **G1:** 19/52 Exclusively formula fed: **G1:** 13/52 **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** NR **Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Srinivasan et al., 2006[36] **Country:** Canada **Enrollment period:** August 2004 to February 2005 **Funding:** No financial support and authors report no conflicts of interest **Study Design:** Case series	**Intervention:** Frenotomy: index and middle fingers of one hand used to isolate the frenulum, while other hand performed frenotomy under direct vision. An incision of 2 to 5 mm made using sterile scissors, severing the entire fibrous part of the frenulum. Sterile swabs used to compress any bleeding. Baby returned to mother for immediate breast feeding. **Groups:** **G1:** Frenotomy + counseling **Type of professional performing treatment:** Family practitioners **Anesthesia used in surgical intervention**: NR **Other non-surgical therapies:** List reported by group **Setting of therapy:** Breastfeeding clinic **Treatment duration:** NA **Last followup post-treatment:** Questionnaire after three months **N at enrollment:** **G1:** 27 **N at followup:** **G1:** 25 **Consultation with lactation consultant, (%):** **G1:** 100	**Inclusion criteria:** • Mothers with infants < 12 weeks • Intend to begin or continue breastfeeding • Frenotomy decision rule for breast feeding infant (see comment below) • Understand either English or French **Exclusion criteria:** • Babies with congenital anomalies or other developmental delay • Mothers unwilling to participate **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, mean ± SD (range):** **G1:** 19 ± 19 (2-71) **Gender, n (%):** Male: **G1:** 18 (66.7) Female: **G1:** 9 (29.6) **Race/ethnicity:** NR (“various”) **Indication for therapy:** Patients were referred to clinic for symptoms such as maternal nipple pain, latching difficulties, and/or poor infant weight gain. One subject had vasospasm of the nipple. Two subjects diagnosed with decreased milk supply. **Other characteristics:** NA **Type of ankyloglossia:** NR	**Length of lingual frenulum when tongue is lifted:** NR **Maternal, mean ± SD (range):** Short Form McGill Pain Questionnaire (includes both PRI and PPI): Nipple pain: Pain Rating Index (PRI) score: **G1:** 13.7 ± 10.9 (0-37 Present Pain Index (PPI) score: **G1:** 2.2 ± 1.3 (0-5) **Infant:** Breastfeeding latch, mean ± SD: **G1:** 6.7 ± 1.2 **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** NR **Maternal, mean ± SD (range):** Nipple pain: Pain Rating Index score: **G1:** 2.2 ± 3.1 (0-11) **Decrease in mean score:** 11.4 (p<0.0001, 95% CI: -15.544, -7.345) **Pain scores based on quality of latch postfrenotomy (compared subjects who had optimal latches postfrenotomy vs. those that did not):** Mean improvement in PRI (Optimal latch): 13.2 (95% CI -18.069 - -8.385) Mean improvement in PRI (Suboptimal latch): 7.9 (95% CI -16.512 - -0.735) Mean difference in PRI between subjects with optimal and suboptimal latches: 5.3 (p=0.21; 95% CI -3.277 – 13.944) Mean improvement in PPI (Optimal latch): 1.8 (95% CI – 2.379 - -1.287) Mean improvement in PPI (Suboptimal latch): 0.8 (95% CI -1.618 – 0.062) Mean difference in PPI between subjects with optimal and suboptimal latches: 1.1 (p=0.03, 95% CI 0.134 – 1.977)

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		Ankyloglossia with concomitant lip tie: NR		**Infant:** Breastfeeding latch, Mean ± SD **G1:** 9.2 ± 0.9 Improvement in mean score, 2.5 (p< 0.0001, 95% CI, 2.038, 2.925) Breastfeeding after three months, n (%): **G1:** 21/27 (77.8) (reasons for stopping: persistent nipple pain, breast infection, personal reasons) Pain free after three months, n (%) **G1:** 23/25 (92) % felt frenotomy had helped: 22/25 (88%) **Child:** NR **Need for reoperation:** NR **Harms:** No complications noted during or after frenotomy. No extended incidents of bleeding requiring active management, no infant fever, and no hospital admission. **Harms Details:** NA **Timing of harms:** 3 months

Comment: Frenotomy Decision Rule: Mother with nipple pain/trauma while breastfeeding AND/OR inability to maintain latch AND/OR poor weight gain in the infant (<15 g/d), AND A visible membrane anterior to the base of the tongue, which restricts tongue movement, leading to: An inability to touch the roof of the mouth, OR An inability to cup an examining finger, OR An inability to protrude the tongue past the gum line
Note: Authors also report improvement in pain based on quality of latch.

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Steehler et al., 2012[37] **Country:** USA **Enrollment period:** April 2006 to February 2011 **Funding:** NR **Study Design:** Retrospective cohort	**Intervention:** Infant swaddled and held upright. Topical viscous lidocaine applied to lingual frenulum exposed with cotton applicators or Tongue Tie groove director. Scissors used to release the frenulum. Posterior limit is anterior genioglossus muscle. Infant immediately breastfed following procedure **Groups:** **G1:** Frenotomy **G2:** No intervention **Type of professional performing treatment:** NR (Pediatric otolaryngologist reviewed the diagnosis) **Anesthesia used in surgical intervention:** Yes (topical viscous Lidocaine) **Other non-surgical therapies:** NR **Setting of therapy:** NR **Treatment duration:** NR **Last followup post-treatment:** 3 months to 5 years after treatment **N at enrollment:** From chart review **G1:** 302 **G2:** 62 **N at followup:** Mothers who then	**Inclusion criteria:** • Medical records of neonates and infants seen for feeding and latching difficulties along with pain when breastfeeding due to suspected ankyloglossia. Dx confirmed by peds ORL **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** **G1+G2:** 18 days **Age, days or months at intervention, mean ± SD:** NR **Gender, n (%):** Male: **G1+G2:** 216 (58.9) Female: **G1+G2:** 151 (14.1) **Indication for therapy:** Feeding difficulties, latch problems, pain with breast feeding **Other characteristics:** Family history, n (%): **G1+G2:** Yes 127 (34.6) No 194 (52.9) Unknown 46 (12.5) Race Caucasian: **G1+G2:** 258 (70.3) African-American: **G1+G2:** 57 (15.5) Hispanic: **G1+G2:** 16 (4.4) Multiethnic: **G1+G2:** 12 (3.3) Indian: **G1+G2:** 10 (2.7) Asian: **G1+G2:** 6 (1.6)	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **Maternal:** **G1:** NR **Infant:** Delayed speech articulation **G1:** NR **G2:** NR **Child:** Shape of tongue altered **G1:** NR **G2:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **Maternal, n (%):** Only includes participants in phone survey: Continued to breastfeed after diagnosis of ‘‘tongue tie,” n (%) : **G1:** NA **G2:** 6 (66.7) Total months breastfeeding after diagnosis of ‘‘tongue tie’’: **G1:** NA **G2:** 6.28 Breastfeeding discontinued due to difficulty or pain from ‘‘tongue tie,” n (%) **G1:** 14 (17.1) **G2:** 3 (33.3) Continued to breastfeed after frenotomy, n (%): **G1:** 68 (82.9) **G2:** NA Total months breastfeeding after frenotomy: **G1:** 7.09 **G2:** NA Within 1st week of life: **G1:** 7.11 months After 1st week of life: **G1:** 7.06 months p=not significant **Infant, n (%):** Child’s ability to feed (maternal survey report): **G1:** 66 (80.4) **G2:** NA

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
	agreed to participate in f/u phone survey: **G1:** 82 **G2:** 9 **Consultation with lactation consultant:** NR	Arabic: **G1+G2:** 4 (1.1) Persian: **G1+G2:** 2 (0.5) Filipino: **G1+G2:** 1 (0.3) Unknown: **G1+G2:** 1 (0.3) **Type of ankyloglossia:** Anterior, n (%): **G1+G2:** 64 (17.4) Posterior, n (%): **G1+G2:** 18 (4.9) Type 1 **G1+G2:** 64 (17.4) Type 2 **G1+G2:** 167 (45.5) Type 3 **G1+G2:** 93 (25.3) Type 4 **G1+G2:** 18 (4.9) Insufficient data **G1+G2:** 25 (6.8) **Ankyloglossia with concomitant lip tie:** NR		Within 1st week of life; **G1:** 37/43 (86) After 1st week of life: **G1:** 29/39 (74.3) P<0.003 Based on type of ankyloglossia: 1: 13/16 (81.3) 2: 31/38 (83.8) 3: 18/21 (85.7) 4: 1/3 (33.3) **Child:** Age (in months) when beginning solid foods **G1:** 5.8 **G2:** 6 **Need for reoperation:** **G1:** 8 **Harms:** Yes **Harms Details, n (%):** Recurrent ankyloglossia secondary to scarring; 8 (2.6%) **Timing of harms:** NR

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Toner et al., 2014 [38] **Country:** U.S. **Enrollment period:** 2003-2008 **Funding:** NR **Design:** Retrospective Case series	**Intervention (description)** Frenotomy. Oral cavity exposed with downward pressure on mandible. Tongue elevated with grooved director or cotton-tipped applicator and attachment of frenulum to undersurface of tongue is cut. Mild digital pressure sometimes applied to stop bleeding. **Groups, n (%)** **G1:** intervention **Type of professional performing treatment:** otolaryngologist **Anesthesia used in surgical intervention:** Yes, (52%) Topical lidocaine applied to frenulum and undersurface of tongue **Other non-surgical therapies, n (%):** NR **Setting of therapy:** Outpatient clinic **Treatment duration:** DNR **Last follow-up post-treatment:** Varied from a few months up to 6 years after procedure **N at enrollment:** **G1:** 55 **N at follow-up:** **G1:** 25 **Consultation with lactation consultant, n (%):** **G1:** NR	**Inclusion criteria:** Infants who had frenotomy in ORL office between 2003-2008 **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD :** **G1:** NR **Age, days or months at intervention, mean ± SD :** **G1:** NR **Gender, n (%):** NR **Race/ethnicity:** **G1:** NR **Indication for therapy:** Difficulty nursing in the first week of life **Other characteristics:** NR **Type of ankyloglossia: Anterior, n (%):** **G1:** NR **Posterior, n (%):** **G1:** NR **Ankyloglossia with concomitant lip tie, n (%):** **G1:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean, median** **G1:** NR **Maternal:** **G1:** NR **Infant:** Difficulty latching for breastfeeeding **G1:** 76% Breastfeeding **G1:** 19 (76) Bottle feeding **G1:** 4 (16) Both breast and bottle fed **G1:** 2 (8) **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted (cm), mean, median** **G1:** NR **Maternal, n (%):** Post-procedure improvement: Immediate: **G1:** 21 (84) 3-4 months after: G1: 1 (4) Time unknown: G1: 1(4) Family satisfaction with office procedure, 5 point scale Very satisfied **G1:** 23 (92) Somewhat satisfied **G1:** 2 (8) **Infant, n (%):** **G1:** NR **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** No reported complications **Timing of harms:** NR

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Wallace et al., 2006[39] **Country:** UK **Enrollment period:** Aug 2003 to Feb 2005 **Funding:** NR **Design:** Case series	**Intervention:** Tongue tie division: Index and middle finger placed under tongue in infant's mouth on either side of lingual frenulum to stretch it and divided with sterile iris scissors, being careful not to damage submandibular ducts. Infant promptly returned to mother for breastfeeding. **Groups:** **G1:** intervention **Type of professional performing treatment:** Otolaryngologist **Anesthesia used in surgical intervention:** No **Other non-surgical therapies:** NR **Setting of therapy:** Outpatient clinic **Treatment duration:** NR **Last follow-up post-treatment:** Varied **N at enrollment:** **G1:** 11 **N at follow-up:** **G1:** 10 **Consultation with lactation consultant, (%):** **G1:** Yes (100)	**Inclusion criteria:** • Infants with breast feeding difficulties associated with tongue tie identified by lactation consultants **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days at intervention, median (range):** **G1:** 10 (2-31) **Age, months at follow-up, median (range):** **G1:** 10 (3-20) **Gender, n (%):** Male: **G1:** 9/11 Female: **G1:** 2/11 **Race/ethnicity:** NR **Indication for therapy:** Breastfeeding **Other characteristics:** NR **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** Sore nipples, n **G1**: 6/10 **Infant:** Poor latch, n **G1:** 9/10 Continual feeding cycle **G1:** 5/10 **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal, n:** Breastfed for at least 4 months **G1:** 6/10 Failed to establish breastfeeding after division **G1:** 2/10 **Infant:** Improvements in breastfeeding immediately **G1:** 4/10 Improvements in breastfeeding 1-14 days **G1:** 3/10 No improvements **G1:** 3/10 **Child:** **G1:** NR **Need for reoperation:** **G1:** NR **Harms:** NR **Harms Details:** NA **Timing of harms:** NR

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Walls et al., 2014[40] **Country:** USA **Enrollment period:** January 2010 to December 2010 **Funding:** NR **Study Design:** Retrospective Cohort	**Intervention:** Frenotomy completed within the first month of life in 102 three year old children. No details of procedure reported **Groups:** **G1:** Frenetomy **G2:** No surgery **G3:** Control **Type of professional performing treatment:** Otolaryngologist **Anesthesia used in surgical intervention:** NR **Other non-surgical therapies:** NR **Setting of therapy:** Outpatient clinic or postpartum ward **Treatment duration:** NR **Last followup post-treatment:** 3 years **N at enrollment:** **G1:** 71 **G2:** 15 **G3:** 18 **Consultation with lactation consultant, %:** **G1:** 64% had been referred to ORL from lactation consultants **G2:** 64% had been referred to ORL from lactation consultants **G3:** 64% had been referred to ORL from lactation consultants	**Inclusion criteria:** • Medical records of 3 year old patients with a past history of ankyloglossia who had received frenotomy within the first month of life • Three-year old patients with a past history of ankyloglossia but declined the frenetomy procedure during the same time period • Control Group compiled from the medical records of randomly assigned three-year old patients without a past history of ankyloglossia during the same time period **Exclusion criteria:** • Did not discuss why they excluded the charts of 31 frenotomy and 6 no intervention patients from the study **Age, days at first diagnosis:** **G1:** 9 days **G2:** 9 days **G3**: NA **Age, days or months at intervention:** **G1:** first month of life **G2:** NA **G3:** NA **Gender, n (%):** Male: **G1/G2/G3:** 62 (59) Female: **G1/G2/G3:** 42 (41) **Race/ethnicity:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **G3:** NR **Maternal:** **G1:** NR **G2:** NR **G3:** NR **Infant:** **G1:** NR **G2:** NR **G3:** NR **Child, n:** Speech difficulty: **G1+G2:** 36	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **G2:** NR **G3:** NR **Maternal:** **G1:** NR **G2:** NR **G3:** NR **Infant:** **G1:** NR **G2:** NR **G3:** NR **Child:** Speech outcome (Likert scale): Mean ± SD : **G1:** 4.52 ± 0.61 **G2:** 3.60 ± 0.63 **G3:** 4.33 ± 0.77 Group differences-speech outcomes (Wilcoxon rank sum): **G1 vs. G2:** p<0.0001 **G1 vs. G3:** p=0.38 **G2 vs. G3:** p=0.01 Improved Oral motor activities (Fischer Exact): Difficulty cleaning teeth with tongue: **G1/G2:** p=0.0006 **G1/G3:** p=1.0000 **G2/G3**: p=0.0120 Difficulty licking outside of lips: **G1/G2:** p<0.0001 **G1/G3**: p=0.1120 **G2/G3**: p=0.0053 Difficulty eating ice cream: **G1/G2**: p=0.0003 **G1/G3**: p=0.58 **G2/G3**: p=0.0015 **Need for reoperation:** **G1:** NR **Harms:** NR

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
		G2: NR **G3:** NR **Indication for therapy:** Diagnosis of ankyloglossia **Other characteristics:** Family history: **G1+G2+G3:** 27 (32) **Type of ankyloglossia:** Coryllos criteria, n (%): **G1:** 20 (23) **G2:** 44 (51) **G3:** 22 (26) **Anklyoglossia with concomitant lip tie:** NR		**Harms Details:** NA **Timing of harms:** NA

Table D-1. Evidence table continued

Study Description	Intervention	Inclusion / Exclusion Criteria / Population	Baseline Measures	Outcomes
Author: Yeh, 2008 [41] **Country:** Taiwan **Enrollment period:** 1980 to 2006 **Funding:** NR **Design:** Case series	**Intervention:** Tongue tie division: for infants, tongue is lifted superiorly by doctor's middle finger or middle and index fingers. With other hand, divides tongue tie using blunt tipped scissors. Cut is made incomplete to avoid injury to tongue, leaving small portion of frenulum intact. This portion then released by gentle push with a gauze sponge. Post division with compression with gauze sponge for 5 minutes routinely used to control bleeding was used early in doctors experience but later considered unnecessary. For patients with more teeth: tongue elevated upward with tongue depressor and doctor places scissors alongside lingual frenulum. If not too thick and vascular, about 2/3s of frenulum released by a quick cut. **Groups:** **G1:** intervention **Type of professional performing treatment:** pediatric surgeon **Anesthesia used in surgical intervention:** No **Other non-surgical therapies:** List reported by group **Setting of therapy:** Outpatient clinic **Treatment duration:** NA **Last follow-up post-treatment:** 3 months post-treatment **N at enrollment:** **G1:** 2620 infants and 158 children **N at follow-up:** **G1:** 2620 infants and 158 children **Consultation with lactation consultant:** NR	**Inclusion criteria:** • Treated for tongue tie by author • No family history bleeding disorders **Exclusion criteria:** NR **Age, days or months at first diagnosis, mean ± SD:** NR **Age, days or months at intervention, mean ± SD:** NR **Gender:** NR **Race/ethnicity:** NR **Indication for therapy:** NR **Other characteristics:** No family history of bleeding disorders **Type of ankyloglossia:** NR **Ankyloglossia with concomitant lip tie:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR	**Length of lingual frenulum when tongue is lifted:** **G1:** NR **Maternal:** **G1:** NR **Infant:** **G1:** NR **Child:** **G1:** NR **Need for reoperation:** **G1:** 3 **Harms:** Yes **Harms Details:** Post division bleeding occurred in most cases, it was usually very mild and would stop spontaneously within a couple of minutes. None required hemostasis by prolonged compression or electrocautery. Indentation of tongue tip and recurrence of tongue-tie- repeat surgery in operating room under general anesthesia **Timing of harms:** Immediate and 3 month followup

Table D-2. Abbreviations in evidence table

µm	Micrometers
BSES-SF	Breastfeeding Self-Efficacy Scale – Short Form
CI	Confidence Interval
CM	Centimeters
CPT	Current Procedural Terminology
ENT	Otolaryngologist
g/d	Weight Velocity
HATLFF	Hazelbaker Assessment Tool for Lingual Frenulum Function
IBAT	Infant Breastfeeding Assessment Tool
ICD	International Classification of Diseases
IQR	Interquartile Range
J/cm^2	Joules per Area
LATCH	Latch, Audible swallowing, Type of Nipple, Comfort, Hold;
mL/min	Milliliters per Minute
MM	Millimeters
MPQ	McGill Pain Questionnaire
NA	Not Applicable
NOMESCO	Nordic Medico-Statistical Committee
NR	Not Reported
NS	Not Statistically Significant
ORL	Otorhinolaryngology
PRI	Pain Rating Index
PPI	Present Pain Intensity
RCT	Randomized, Controlled Trials
SD	Standard Deviation
SE	Standard error
SF-MQP	Short Form McGill Pain Scale
VAS	Visual Analog Scale for Pain
W/cm^2	Power per Area
WHO	World Health Organization

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Appendix E. Quality Assessment Forms

Table E-1. Cochrane Collaboration modified tool for assessing risk of bias, Part I

REF ID:				**Reviewer:**	
Domain	***Description***	***High risk of bias***	***Low risk of bias***	***Unclear risk of bias***	***Reviewer Assessment***
Selection bias ***Random sequence generation***	Described the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. **Reviewer Comments:**	Selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence.	Random sequence generation method should produce comparable groups	Not described in sufficient detail	**Judgment: Random Sequence generation** □ **High** □ **Low** □ **Unclear**
Selection bias ***Allocation concealment***	Described the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrollment. **Reviewer Comments:**	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.	Intervention allocations likely could not have been foreseen in advance of, or during, enrollment	Not described in sufficient detail	**Judgment: Allocation concealment** □ **High** □ **Low** □ **Unclear**
Reporting Bias ***Selective reporting***	State how the possibility of selective outcome reporting was examined by the authors and what was found. **Reviewer Comments:**	Reporting bias due to selective outcome reporting.	Selective outcome reporting bias not detected	Insufficient information to permit judgment of 'Low risk' or 'High risk'. (*It is likely that the majority of studies will fall into this category.)*	**Judgment: Selective reporting** □ **High** □ **Low** □ **Unclear**
Other bias ***Other sources of bias***	Any important concerns about bias not addressed above. If particular questions/entries were pre-specified in the study's protocol, responses should be provided for each question/entry. **Reviewer Comments:**	Bias due to problems not covered elsewhere in the table.	No other bias detected	There may be a risk of bias, but there is either: Insufficient information to assess whether an important risk of bias exists; or Insufficient rationale or evidence that an identified problem will introduce bias.	**Judgment: Other sources of bias** □ **High** □ **Low** □ **Unclear**

Table E-2. Cochrane Collaboration modified tool for assessing risk of bias for RCTs, Part II

REF ID:

Outcome(s):

Domain	***Description***	***High risk of bias***	***Low risk of bias***	***Unclear risk of bias***	***Reviewer Assessment***
Performance bias ***Blinding (participants and personnel)***	Described all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provided any information relating to whether the intended blinding was effective. **Reviewer Comments:**	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.	Blinding was likely effective.	Not described in sufficient detail	**Judgment: Blinding (participants and personnel)** □ **High** □ **Low** □ **Unclear**
Detection bias ***Blinding (outcome assessment)***	Described all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provided any information relating to whether the intended blinding was effective. **Reviewer Comments:**	Detection bias due to knowledge of the allocated interventions by outcome assessors.	Blinding was likely effective.	Not described in sufficient detail	**Judgment: Blinding (outcome assessment)** □ **High** □ **Low** □ **Unclear**
Attrition bias ***Incomplete outcome data***	Described the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. Stated whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported. **Reviewer Comments:**	Attrition bias due to amount, nature or handling of incomplete outcome data.	Handling of incomplete outcome data was complete and unlikely to have produced bias	Insufficient reporting of attrition/exclusions to permit judgment of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided)	**Judgment: Incomplete outcome data** □ **High** □ **Low** □ **Unclear**

Table E-3. Cohort study assessment

Questions to Assess the Risk of Bias			
1. Do the inclusion/exclusion criteria vary across the comparison groups of the study?	No	Yes	Comments
2. Does the strategy for recruiting participants into the study differ across groups?	No	Yes	Comments
3. Is the selection of the comparison group inappropriate, after taking into account feasibility and ethical considerations?	No	Yes	Comments
4. Was the outcome assessor not blinded to the intervention or exposure status of participants?	No	Yes	Comments
5. Were valid and reliable measures, implemented consistently across all study participants used to assess inclusion/exclusion criteria, intervention/exposure outcomes, participant health benefits and harms, and confounding?	No	Yes	Comments
6. Was the length of followup different across study groups?	No	Yes	Comments
7. In cases of high loss to followup (or differential loss to followup), was the impact assessed (e.g., through sensitivity analysis or other adjustment method)?	No	Yes	Comments
Questions to Assess Confounding			
8. Any attempt to balance the allocation between the groups or match groups (e.g., through stratification, matching, propensity scores)?	No	Yes	Comments
9. Were the important confounding variables taken into account in the design and/or analysis (e.g., through matching, stratification, interaction terms, multivariate analysis, or other statistical adjustment such as instrumental variables)?	No	Yes	Comments
Questions to Assess Precision			
10. Are the statistical methods used to assess the primary benefit outcomes inadequate?	No	Yes	Comments
11. Are the statistical methods used to assess the main harm or adverse event outcomes inadequate?	No	Yes	Comments

Based on cohort questions from: Viswanathan M, Berkman ND, Dryden DM, et al. Assessing Risk of Bias and Confounding in Observational Studies of Interventions or Exposures: Further Development of the RTI Item Bank [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2013 Aug. Available from: http://www.ncbi.nlm.nih.gov/books/NBK154461/

Table E-4. Minimum criteria to assess risk of bias in case series

Selection bias and confounding					
1. Were the important confounding and modifying variables taken into account in the design and analysis?	Yes	No	NA	NR	Comments
Performance bias					
2. Was any impact from a concurrent intervention or an unintended exposure that might bias results ruled out by the researchers?	Yes	No	NA	NR	Comments
3. Was the study free from variations from the study protocol that could compromise the conclusions of the study?	Yes	No	NA	NR	Comments
Attrition bias					
4. Was there a low rate of differential or overall attrition? (note: low≤20%)	Yes	No	NA	NR	Comments
5. Attrition did not result in a difference in group characteristics between baseline and follow-up	Yes	No	NA	NR	Comments
Detection bias					
6. Were the outcome assessors blinded to the intervention or exposure status of participants?	Yes	No	NA	NR	Comments
7a. Are the inclusion/exclusion criteria clearly stated? (note: consider whether level of detail would allow for replication)	Yes	No	NA	NR	Comments
7b. Were the measures implemented consistently across all study participants?	Yes	No	NA	NR	Comments
8a. Are interventions/exposures assessed using appropriate measures?	Yes	No	NA	NR	Comments
8b. Were the interventions implemented consistently across all study participants?	Yes	No	NA	NR	Comments
9a. Are primary outcome measurement approaches clearly described? List outcome. Outcome 1:	Yes	No	NA	NR	Comments
Outcome 2:					
Outcome 3:					
Outcome 4:					
Outcome 5:					
Outcome 6:					
9b. Are primary outcomes assessed using appropriate measures? List outcome. Outcome 1:	Yes	No	NA	NR	Comments
Outcome 2:	Yes	No	NA	NR	Comments
Outcome 3:	Yes	No	NA	NR	Comments

Outcome 4:	Yes	No	NA	NR	Comments
Outcome 5:	Yes	No	NA	NR	Comments
Outcome 6:	Yes	No	NA	NR	Comments
9b. Was outcome assessment implemented consistently across all study participants?	Yes	No	NA	NR	Comments
10a.Are confounding variables assessed using appropriate measures?	Yes	No	NA	NR	Comments
10b. Was assessment of confounding variables implemented consistently across all study participants?	Yes	No	NA	NR	Comments
11. Did the study account for secular trends and regression to the mean?	Yes	No	NA	NR	Comments
Reporting bias					
12a.Are the potential outcomes pre-specified by the researchers?	Yes	No	NA	NR	Comments
12b. Are harms pre-specified by the researchers?	Yes	No	NA	NR	Comments
13. Are all pre-specified outcomes reported?	Yes	No	NA	NR	Comments
13a. Are all pre-specified harms reported?	Yes	No	NA	NR	Comments

Table E-5. Harms risk-of-bias assessment

RefID: _____ Reviewer:_____

Question	Yes	No	Comments
Were the harms predefined using standardized or precise definitions?	Yes	No	Comments
Are all pre-specified harms reported?	Yes	No	Comments
Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection?	Yes	No	Comments
Are the statistical methods used to assess the main harm or adverse event outcomes adequate?	Yes	No	Comments

Based on questions from: Viswanathan M, Berkman ND, Dryden DM, et al. Assessing Risk of Bias and Confounding in Observational Studies of Interventions or Exposures: Further Development of the RTI Item Bank [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2013 Aug. Available from: http://www.ncbi.nlm.nih.gov/books/NBK154461/ and Santaguida P., Raina P. McMaster Quality Scale of Harms (McHarm) for primary studies: Manual for use of the McHarm. [Hamilton, ON: McMaster University, n.d.].

Appendix F. Quality Scoring Results

Table F-1. RCT quality score results

Author, Year	Sequence Generation	Allocation Concealment	Selective Reporting	Other Bias	Blinding of Participants/ Personnel	Blinding of Outcome Assessment	Incomplete Outcome Data	Risk of Bias Rating for Outcome
Studies assessing HATLFF*								
Emond et al. 2013[1]	Low	Low	Low	Low	Low	Low	Low	Good
Buryk et al. 2011[2]	Low	Low	Low	Low	Low	Low	Low	Good
Studies assessing LATCH†								
Emond et al. 2013[1]	Low	Low	Low	Low	Low	Low	Low	Good
Berry et al. 2012[3]	Low	Low	Low	Low	Low	Low	Low	Good
Dollberg et al. 2006[4]	Low	Low	High	Unclear	High	Low	Low	Poor
Studies assessing IBFAT††								
Emond et al. 2013[1]	Low	Low	Low	Low	Low	Low	Low	Good
Berry et al. 2012[3]	Low	Low	Low	Low	Low	Low	Low	Good
Buryk et al. 2011[2]	Low	Low	Low	Low	Low	Low	Low	Good
Studies assessing BSES§								
Emond et al. 2013[1]	Low	Low	Low	Low	High	Low	Low	Fair
Studies assessing								

Author, Year	Sequence Generation	Allocation Concealment	Selective Reporting	Other Bias	Blinding of Participants/ Personnel	Blinding of Outcome Assessment	Incomplete Outcome Data	Risk of Bias Rating for Outcome
pain scores								
Emond et al. 2013[1]	Low	Low	Low	Low	Low	Low	Low	Good
Berry et al. 2012[3]	Low	Low	Low	Low	Low	Low	Low	Good
Buryk et al. 2011[2]	Low	Low	Low	Low	Low	Low	Low	Good
Dollberg et al. 2006[4]	Low	Low	High	Unclear	High	Low	Low	Poor
Studies assessing infant weight gain								
Emond et al. 2013[1]	Low	Low	Low	Low	Unclear	Low	Low	Fair
Studies assessing frenulum length								
Heller et al. 2005[5]	Unclear	Unclear	Low	Unclear	Low	Unclear	Low	Poor

Author, Year	Sequence Generation	Allocation Concealment	Selective Reporting	Other Bias	Blinding of Participants/ Personnel	Blinding of Outcome Assessment	Incomplete Outcome Data	Risk of Bias Rating for Outcome
Studies assessing tongue protrusion								
Heller et al. 2005[5]	Unclear	Unclear	Low	Unclear	Low	Unclear	Low	Poor
Studies assessing speech								
Heller et al. 2005[5]	Unclear	Unclear	Low	Unclear	Unclear	Unclear	Low	Poor
Studies assessing feeding (breast and bottle) measured by observers								
Hogan et al. 2005[6]	Unclear	Low	Low	Low	High	Low	Low	Fair

*HATLFF=Hazelbaker Assessment Tool for Lingual Frenulum Function
‡LATCH=Latch, Audible swallowing, Type of Nipple, Comfort, Hold
††IBFAT=Infant Breastfeeding Assessment Tool
§BSES= Breastfeeding Self-Efficacy Scale

Table F-2. Cohort quality score results

Author, Year	Inclusion/exclusion criteria across groups	Recruitment strategy across groups	Selection of the comparison group	Outcome assessor blinding	Valid & reliable measures across study participants	Length of followup different across groups	Assessment of impact of high loss to followup	Balancing allocation between groups/matching groups	Accounting for confounding factors	Adequacy of statistical methods to assess primary outcomes	Adequacy of statistical methods to assess harms or adverse events	Rating
Walls et al. 2014[7]	-	+	+	-	-	+	NA	-	-	+	+	Poor
Steehler et al. 2012[8]	+	+	+	-	-	-	-	-	-	+	+	Poor
Dollberg et al. 2011[9]	-	+	+	-	-	+	NA	+	-	-	-	Poor

NA=not applicable

Table F-3. Case series quality score results

Author, Year	Confounding and modifying variables accounted	Concurrent intervention/unintended exposure ruled out	Study free from variations from protocol	Low rate (≤20%) attrition	Attrition did not result in difference in groups baseline & followup	Outcome assessors blinded	Clearly stated inclusion/exclusion criteria	Measures implemented consistently	Appropriate measures for assessing interventions/exposures	Interventions implemented consistently	Outcome: Latch	Appropriate measures for outcome assessment	Outcome: Nipple Pain	Appropriate measures for outcome assessment	Outcome: breastfeeding	Appropriate measures for outcome assessment	Outcome: feeding outcomes	Appropriate measures for outcome assessment	Outcome: infant growth	Appropriate measures for outcome assessment	Outcome: speech	Appropriate measures for outcome assessment	Outcome: Tongue mobility, protrusion	Appropriate measure for outcome assessment	Outcome: Oral hygiene	Appropriate measure for outcome assessment	Outcome: reoperation	Appropriate measure for outcome assessment	Outcome: Beneficial	Appropriate measure for outcome assessment	Consistent implementation of outcome assessment	Appropriate measures for confounding variables assessment	Consistent assessment of confounding variables	Secular trends and regression to the mean accounted for	Pre-specified potential outcomes	Pre-specified harms	Reporting of all pre-specified outcomes	Reporting of all pre-specified harms
Dollberg et al. 2014[10]	-	NA	+	+	NA	-	+	+	+	+					+	+															+	NR	NR	-	+	+	+	+
Finigan et al. 2014[11]	-	-	NR	-	NR	-	-	NR	+	NR							+	+													+	-	NA	NA	+	-	+	NA
Ito et al. 2014[12]	-	+	NR	+	NA	-	+	+	+	-											+	+									+	-	NA	NA	+	-	+	NA
Riskin et al. 2014[13]	-	-	NR	-	NR	NA	+	+	+	NA	+	+	+	+	+	+			+	+											+	-	-	-	+		+	

Author, Year	Rose et al. 2014[14]	Toner et al. 2014[15]	Dave et al. 2013[16]	Edmunds et al. 2013[17*]	O'Callahan et al. 2013[18]
Confounding and modifying variables accounted	-	-	-	-	-
Concurrent intervention/unintended exposure ruled out	-	-	-	-	-
Study free from variations from protocol	R N	R N	R N	+	+
Low rate (≤20%) attrition	-	-	+	+	-
Attrition did not result in difference in groups baseline & followup	R N	R N	A N	A N	-
Outcome assessors blinded	-	-	R N	-	-
Clearly stated inclusion/exclusion criteria	+	-	-	-	+
Measures implemented consistently	+	R N	R N	+	+
Appropriate measures for assessing interventions/exposures	+	+	R N	-	+
Interventions implemented consistently	R N	R N	+	A N	+
Outcome: Latch					
Appropriate measures for outcome assessment					
Outcome: Nipple Pain					
Appropriate measures for outcome assessment					
Outcome: breastfeeding					+
Appropriate measures for outcome assessment					+
Outcome: feeding outcomes	+				
Appropriate measures for outcome assessment	+				
Outcome: infant growth					
Appropriate measures for outcome assessment					
Outcome: speech			-		
Appropriate measures for outcome assessment			R N		
Outcome: Tongue mobility, protrusion					
Appropriate measure for outcome assessment					
Outcome: Oral hygiene					
Appropriate measure for outcome assessment					
Outcome: reoperation					
Appropriate measure for outcome assessment					
Outcome: Beneficial	+	+			
Appropriate measure for outcome assessment	+	+			
Consistent implementation of outcome assessment	+	+	R N	R N	+
Appropriate measures for confounding variables assessment	-	-	-	-	-
Consistent assessment of confounding variables	A N	A N	A N	-	-
Secular trends and regression to the mean accounted for	A N	A N	A N	A N	A N
Pre-specified potential outcomes	+	+	-	-	+
Pre-specified harms	-	-	-	-	-
Reporting of all pre-specified outcomes	+	+	A N	+	+
Reporting of all pre-specified harms	A N	A N	A N	+	R N

Author, Year	Mettias et al. 2013[19]	Sethi et al. 2013[20]	Marchesan et al. 2012[21]	Argiris et al. 2011[22]	Cho et al. 2011[23]
Confounding and modifying variables accounted	-	-	-	-	-
Concurrent intervention/unintended exposure ruled out	-	-	-	NR	-
Study free from variations from protocol	-	+	+	+	-
Low rate (≤20%) attrition	-	-	+	NA	+
Attrition did not result in difference in groups baseline & followup	NR	NR	NA	NA	NA
Outcome assessors blinded	-	-	-	-	-
Clearly stated inclusion/exclusion criteria	-	-	+	+	-
Measures implemented consistently	+	+	+	+	+
Appropriate measures for assessing interventions/exposures	+	+	+	+	-
Interventions implemented consistently	+	+	+	+	+
Outcome: Latch				+	
Appropriate measures for outcome assessment				+	
Outcome: Nipple Pain				+	
Appropriate measures for outcome assessment				+	
Outcome: breastfeeding	+	-		+	
Appropriate measures for outcome assessment	+	+		+	
Outcome: feeding outcomes					
Appropriate measures for outcome assessment					
Outcome: infant growth					
Appropriate measures for outcome assessment					
Outcome: speech					-
Appropriate measures for outcome assessment					-
Outcome: Tongue mobility, protrusion			-		
Appropriate measure for outcome assessment			-		
Outcome: Oral hygiene					
Appropriate measure for outcome assessment					
Outcome: reoperation					
Appropriate measure for outcome assessment					
Outcome: Beneficial					
Appropriate measure for outcome assessment					
Consistent implementation of outcome assessment	+	-	NR	+	NR
Appropriate measures for confounding variables assessment	-	NA	-	NR	-
Consistent assessment of confounding variables	-	NA	-	NA	-
Secular trends and regression to the mean accounted for	-	-	NA	NA	-
Pre-specified potential outcomes	+	+	-	+	-
Pre-specified harms	+	-	-	-	-
Reporting of all pre-specified outcomes	+	+	NA	+	NA
Reporting of all pre-specified harms	+	NA	NA	NA	NA

Author, Year	Puthussery et al. 2011[24]	Hong et al. 2010[25]	Miranda et al. 2010[26]	Khoo et al. 2009[27]	Klockars et al.
Confounding and modifying variables accounted	-	-	-	-	-
Concurrent intervention/unintended exposure ruled out	-	-	+	-	-
Study free from variations from protocol	+	+	+	NA	+
Low rate (≤20%) attrition	+	+	+	NA	-
Attrition did not result in difference in groups baseline & followup	NA	NA	NR	NA	NR
Outcome assessors blinded	-	-	-	-	-
Clearly stated inclusion/exclusion criteria	-	+	+	-	+
Measures implemented consistently	+	+	+	+	+
Appropriate measures for assessing interventions/exposures	+	+	+	+	+
Interventions implemented consistently	+	+	+	+	NR
Outcome: Latch			-		
Appropriate measures for outcome assessment			NA		
Outcome: Nipple Pain			-		
Appropriate measures for outcome assessment			NA		
Outcome: breastfeeding		-	-	+	
Appropriate measures for outcome assessment		NR	NA	+	
Outcome: feeding outcomes					
Appropriate measures for outcome assessment					
Outcome: infant growth					
Appropriate measures for outcome assessment					
Outcome: speech	+				
Appropriate measures for outcome assessment	+				
Outcome: Tongue mobility, protrusion	+				
Appropriate measure for outcome assessment	+				
Outcome: Oral hygiene					
Appropriate measure for outcome assessment					
Outcome: reoperation		+			+
Appropriate measure for outcome assessment		+			+
Outcome: Beneficial					-
Appropriate measure for outcome assessment					-
Consistent implementation of outcome assessment	+	+	+	+	+
Appropriate measures for confounding variables assessment	-	NA	NA	NR	-
Consistent assessment of confounding variables	-	-	NA	NR	-
Secular trends and regression to the mean accounted for	NA	-	NA	NA	-
Pre-specified potential outcomes	+	+	+	+	+
Pre-specified harms	+	+-	-	-	-
Reporting of all pre-specified outcomes	+	+	+	+	+
Reporting of all pre-specified harms	+	NA	NA	NA	NA

Author, Year	2009[28]	Ridgers et al. 2009[29]	Geddes et al. 2008[30]	Yeh. 2008[31]	Srinivasan et al. 2006[32]
Confounding and modifying variables accounted		-	NR	-	-
Concurrent intervention/unintended exposure ruled out		-	NR	-	+
Study free from variations from protocol		+	+	NR	+
Low rate (≤20%) attrition		+	+	+	+
Attrition did not result in difference in groups baseline & followup		NA	NA	NA	NA
Outcome assessors blinded		-	-	-	-
Clearly stated inclusion/exclusion criteria		-	+	-	+
Measures implemented consistently		+	+	+	+
Appropriate measures for assessing interventions/exposures		+	+	NR	+
Interventions implemented consistently		+	+	+	+
Outcome: Latch			+		+
Appropriate measures for outcome assessment			+		+
Outcome: Nipple Pain			+		+
Appropriate measures for outcome assessment			+		+
Outcome: breastfeeding			+		+
Appropriate measures for outcome assessment			+		+
Outcome: feeding outcomes		+			
Appropriate measures for outcome assessment		+			
Outcome: infant growth					
Appropriate measures for outcome assessment					
Outcome: speech					
Appropriate measures for outcome assessment					
Outcome: Tongue mobility, protrusion					
Appropriate measure for outcome assessment					
Outcome: Oral hygiene					
Appropriate measure for outcome assessment					
Outcome: reoperation				+	
Appropriate measure for outcome assessment				+	
Outcome: Beneficial					
Appropriate measure for outcome assessment					
Consistent implementation of outcome assessment		-	+	+	+
Appropriate measures for confounding variables assessment		-	NA	-	NA
Consistent assessment of confounding variables		NA	NA	-	NA
Secular trends and regression to the mean accounted for		-	NA	-	-
Pre-specified potential outcomes		-	+	-	+
Pre-specified harms		-	-	-	-
Reporting of all pre-specified outcomes		NA	+	NA	+
Reporting of all pre-specified harms		NA	NA	NA	-

Author, Year	Blenkinsop. 2003[33]	Wallace et al. 2006[34]	Amir et al. 2005[35]	Heller et al. 2005[5]	Griffiths. 2004[36]
Confounding and modifying variables accounted	-	-	-	-	-
Concurrent intervention/unintended exposure ruled out	NR	-	-	-	+
Study free from variations from protocol	+	-	-	-	+
Low rate (≤20%) attrition	+	+	-	+	+
Attrition did not result in difference in groups baseline & followup	NA	NA	NR	NA	+
Outcome assessors blinded	-	-	-	-	-
Clearly stated inclusion/exclusion criteria	-	-	+	-	+
Measures implemented consistently	+	+	+	NR	+
Appropriate measures for assessing interventions/exposures	+	+	+	NR	+
Interventions implemented consistently	+	+	+	+	+
Outcome: Latch					
Appropriate measures for outcome assessment					
Outcome: Nipple Pain					
Appropriate measures for outcome assessment					
Outcome: breastfeeding	-	+	+		+
Appropriate measures for outcome assessment	-	+	+		+
Outcome: feeding outcomes					
Appropriate measures for outcome assessment					
Outcome: infant growth					
Appropriate measures for outcome assessment					
Outcome: speech				-	
Appropriate measures for outcome assessment				-	
Outcome: Tongue mobility, protrusion					+
Appropriate measure for outcome assessment					+
Outcome: Oral hygiene					
Appropriate measure for outcome assessment					
Outcome: reoperation					
Appropriate measure for outcome assessment					
Outcome: Beneficial					
Appropriate measure for outcome assessment					
Consistent implementation of outcome assessment	+	+	+	+	+
Appropriate measures for confounding variables assessment	-	-	-	NR	+
Consistent assessment of confounding variables	-	NR	-	NA	+
Secular trends and regression to the mean accounted for	-	AN	-	-	-
Pre-specified potential outcomes	+	+	+	-	+
Pre-specified harms	-	-	-	-	-
Reporting of all pre-specified outcomes	+	+	+	NA	+
Reporting of all pre-specified harms	AN	AN	AN	AN	AN

Author, Year	Lalakea et al. 2003[37]	Ballard et al. 2002[38]	Messner et al. 2002[39]	Masaitis et al. 1996[40]
Confounding and modifying variables accounted	-	-	-	-
Concurrent intervention/unintended exposure ruled out	+	-	-	NA
Study free from variations from protocol	+	+	+	+
Low rate (≤20%) attrition	+	+	+	+
Attrition did not result in difference in groups baseline & followup	NA	NA	NA	NR
Outcome assessors blinded	-	-	-	NA
Clearly stated inclusion/exclusion criteria	+	-	+	-
Measures implemented consistently	+	-	+	+
Appropriate measures for assessing interventions/exposures	+	+	+	+
Interventions implemented consistently		+	+	+
Outcome: Latch		+		
Appropriate measures for outcome assessment		+		
Outcome: Nipple Pain		+		
Appropriate measures for outcome assessment		+		
Outcome: breastfeeding		+		+
Appropriate measures for outcome assessment		+		+
Outcome: feeding outcomes				
Appropriate measures for outcome assessment				
Outcome: infant growth				-
Appropriate measures for outcome assessment				+
Outcome: speech		+	+	
Appropriate measures for outcome assessment		+	+	
Outcome: Tongue mobility, protrusion	+		+	+
Appropriate measure for outcome assessment	+		+	+
Outcome: Oral hygiene				
Appropriate measure for outcome assessment				
Outcome: reoperation				
Appropriate measure for outcome assessment				
Outcome: Beneficial				
Appropriate measure for outcome assessment				
Consistent implementation of outcome assessment	+	+	+	+
Appropriate measures for confounding variables assessment	NR	NR	+	NA
Consistent assessment of confounding variables	NA	-	NA	NA
Secular trends and regression to the mean accounted for	-	-	NR	-
Pre-specified potential outcomes	+	+	+	+
Pre-specified harms	-	-	+	-
Reporting of all pre-specified outcomes	+	+	+	+
Reporting of all pre-specified harms	NA	NA	NA	NA

Author, Year	Confounding and modifying variables accounted	Concurrent intervention/unintended exposure ruled out	Study free from variations from protocol	Low rate (≤20%) attrition	Attrition did not result in difference in groups baseline & followup	Outcome assessors blinded	Clearly stated inclusion/exclusion criteria	Measures implemented consistently	Appropriate measures for assessing interventions/exposures	Interventions implemented consistently	Outcome: Latch	Appropriate measures for outcome assessment	Outcome: Nipple Pain	Appropriate measures for outcome assessment	Outcome: breastfeeding	Appropriate measures for outcome assessment	Outcome: feeding outcomes	Appropriate measures for outcome assessment	Outcome: infant growth	Appropriate measures for outcome assessment	Outcome: speech	Appropriate measures for outcome assessment	Outcome: Tongue mobility, protrusion	Appropriate measure for outcome assessment	Outcome: Oral hygiene	Appropriate measure for outcome assessment	Outcome: reoperation	Appropriate measure for outcome assessment	Outcome: Beneficial	Appropriate measure for outcome assessment	Consistent implementation of outcome assessment	Appropriate measures for confounding variables assessment	Consistent assessment of confounding variables	Secular trends and regression to the mean accounted for	Pre-specified potential outcomes	Pre-specified harms	Reporting of all pre-specified outcomes	Reporting of all pre-specified harms
Godley. 1994[41]	-	+	NR	+	NA	-	-	NR	+	+													-	-							NR	-	NA	-	-	-	NA	Na

*No discrete outcomes measured;
NA=Not applicable; NR=Not reported

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Appendix G. Case Reports Harms

Table G-1. Harms of frenectomy described in case reports

Study and Country	Age	Bleeding	Pain	Surgical Site Infection	Swelling /edema	Need for further surgery	Ranulae	Other/comments
Santos et al. 2012[1] Brazil	12 years					✓	✓	Mucocele post-surgery
Cunha et al. 2008[2] Brazil	3 months	✓						
Fleiss et al.1990[3] U.S.	13 years							Lisp post-surgery
Tuli et al. 2010[4] India	5 years					✓		
Reddy et al. 2014[5] India	NR		✓		✓			

Table G-2. Harms of frenotomy described in case reports

Study and Country	Age	Bleeding	Pain	Surgical Site Infection	Swelling /edema	Need for further surgery	Ranulae	Other/comments
Opara et al. 2012[6] Nigeria (case 1)	1 day	✓						Continued bleeding for one day post intervention; sepsis
Opara et al. 2012[6] Nigeria (case 2)	3 days	✓						Continued bleeding for three days post-intervention
Mathewson et al. 1966[7] U.S.	16 years							Scar band formed post-surgery

Table G-3. Harms of frenulectomy described in case reports

Study and Country	Age	Bleeding	Pain	Surgical Site Infection	Swelling /edema	Need for further surgery	Ranulae	Other/comments
Isaiah et al. 2013[8] U.S.	2 years			✓	✓			Fever and drooling
Nicholson 1991[9] Australia	44 hours							Slight bruising under tongue for three to four days.

Table G-4. Harms of frenuloplasty described in case reports

Study and Country	Age	Bleeding	Pain	Surgical Site Infection	Swelling /edema	Need for further surgery	Ranulae
Sirinoglu et al. 2013[10] Turkey	3 years				✓		
Chu et al. 2009[11] U.S.	4 weeks	✓					
Lin et al. 2009[12] U.S.	13 years		✓	✓	✓		

Table G-5. Harms of frenulotomy described in case reports

Study and Country	Age	Bleeding	Pain	Surgical Site Infection	Swelling /edema	Need for further surgery	Ranulae
Berg. 1990[13] U.S.	12.5 weeks	✓					
Huggins. 1990[14] U.S.	2 weeks	✓					
Good. 1987[15] U.S.	7 months	✓					

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Appendix H. Conference Abstracts

We searched for abstracts/proceedings within PubMed, CINAHL, EMBASE, Web of Science, Science Direct and websites and journal publications of pediatric, dental, orthodontic and lactation societies and organizations from 1980 to the present. Organizations included the Academy of Breastfeeding Medicine (ABM), American Academy of Pediatric Dentistry (AAPD), American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS), American Association of Orthodontists (AAO), American Association of Pediatrics (AAP), American Orthodontic Society (AOS), American Speech-Language-Hearing Association (AHSA), College of Lactation Consultants of Western Australia (CLCWA), International Lactation Consultant Association (ILCA), Lactation Consultants of Australia and New Zealand (LCANZ), and Pediatric Academic Societies (PAS).

We identified over 20 abstracts, a number of which reported on incidence or prevalence rates or rates of surgical procedures or provided summaries of studies included in the full review. Abstracts that address outcomes related to breastfeeding, feeding, and speech or social concerns are outlined in H-1.

Table H-1. Relevant conference abstracts

Abstract	Key outcomes
4th Congress of the European Academy of Paediatric Societies, Istanbul, Turkey, 2012.	
Post E. et al. "Snipping of a tongue-tie in neonates" with ankyloglossia and breastfeeding problems: Outcomes and complications.	• 117/132 (89%) mothers whose infant (<3 months of age) underwent frenotomy reported breastfeeding improvements (latch and decreased nipple pain). Specific assessment tools are not reported. • 12/132 (9%) mothers reported no improvement • Minor brief bleeding post intervention and pain were reported in five patients .
Matthews E. et al. An audit of impacts of frenulectomy in breast feeding.	• Results of a questionnaire administered to mothers approximately three weeks after infant (mean age of 6.6 weeks) underwent frenulectomy. Mothers reported decreased latch difficulties (reduction from 16/26 (62%) to 2/26 (8%)) and nipple/breast pain (from 13/26 (50%) to 5/26(19%)). Breastfeeding exclusively increased to 61% (16/26) from pre-intervention 46% (12/26).
4th British Academic Conference in Otolaryngology, Glasgow, UK, 2012	
Dhillon B. Audit of division of tongue ties in a single consultant's clinic.	• 77% of mothers (90/118) reported improved breast feeding immediately following infant tongue tie division.
10th World Conference of Perinatal Medicine. Punta del Este, Uruguay, 2011.	
Alvarez V. et al. Breastfeeding and tongue tie.	• 69/75 infants referred for frenotomy due to breastfeeding difficulties underwent procedure. • Mothers reported immediate improved breastfeeding. No associated complications occurred.

Abstract	Key outcomes
Annual Scientific Meeting of the British Association of Oral and Maxillofacial Surgeons (BAOMS) 2011 Nice France.	
Cottom H. Division of ankyloglossia- Its effectiveness in improving associated breastfeeding difficulties.	• All 40 mothers whose infants were referred for frenulotomy reported improvement in breastfeeding evaluated on a scale of zero (impossible) to 10 (no feeding problems) and 40% reported total resolution.
2009 International Lactation Consultant Association (ILCA) Conference	
Felc Z. Ankyloglossia: incidence and effect of neonatal frenotomy on breastfeeding.	• 60/3383 consecutively screened infants experienced breastfeeding problems due to ankyloglossia. Thirty-five of the sixty infants (58%) underwent frenotomy. In 24/35 (68.6%) of the infants, latch, milk transfer, nipple pain improved. No complications occurred.

Appendix I. Applicability Tables

Table I-1. Applicability for KQ 1

Domain	Description of applicability of evidence
Population	Studies examining the effectiveness of ankyloglossia treatment had significant differences in population. Specifically, there was age heterogeneity between the 3 good quality trials: ranging from group means of 28d and 33d for patients treated with frenotomy versus sham in one study[1], an overall median 6d +/- 6.9 in another [2], and group medians 11d (IQR 8 – 14) and 11d (IQR 8 – 16) in the third.[3] Gender distribution was ~2:1 in 2 trials,[1, 2] and not reported in the third. [3] Finally, ankyloglossia severity was only rated in 1 trial, which also excluded the most severe cases (HATLFF > 6), thus potentially biasing its results toward the null hypothesis[3].
Intervention	All comparative studies assessed the role of surgical intervention. Procedural specifics were consistent across studies although tongue-tie division terminology differed (i.e. frenotomy, frenulotomy). No comparative study considered alternative treatments for ankyloglossia and its effect on breastfeeding.
Comparators	Two comparators were used: sham[1, 2] and no intervention[3]. These are synonymous except in relation to blinding of participants since no intervention was performed even in either group. No treatment is a common alternative to frenotomy and therefore its use is broadly applicable to the overall population at risk for ankyloglossia and its sequelae.
Outcomes	There was fair homogeneity among outcome measures used in these studies, which consisted of assessment of breastfeeding effectiveness and maternal nipple pain. However, the means of measuring breastfeeding effectiveness differed among studies. In one RCT, effectiveness was assessed both by maternal-report and objective observer immediately after frenotomy or sham.[1] A second RCT employed an objective observer to assess breastfeeding effectiveness (IBFAT) compared to sham immediately post-procedure.[2] The third RCT had an objective observer score breast latch using the LATCH and IBFAT outcome measures.[3] Nipple pain was assessed using either a visual analog scale (VAS) or the Short-form Montreal Pain Questionnaire (SF-MPQ). While VAS-type scales are commonly used for pain, specific levels may not be widely applicable to other populations of women breastfeeding a newborn with ankyloglossia.
Setting	The setting was variably reported in these studies. Frenotomy were performed in tertiary care hospitals and clinics and performed by pediatric surgeons, lactation consultants, and otolaryngologists. Two of three RCTs were not explicit whether frenotomy was performed as an inpatient or outpatient.

Table I-2. Applicability for KQ 2a

Domain	Description of applicability of evidence compared to question
Population	Neonates born with congenital ankylglossia between January 2010 and December 2010
Intervention	Frenotomy within first month of life
Comparators	Offered but declined frenotomy within first month of life; may or may not have received non-surgical interventions
Outcomes	Paternal (typically maternal) report of the 3 year old's difficulty: (1) cleaning teeth with the tongue, (2) licking the outside of the lips, and (3) eating ice cream
Timing	Outcomes measured at 3 years of age
Setting	Academic medical center hospital in a large, urban area

Table I-3. Applicability for KQ 2b

Domain	Description of applicability of evidence compared to question
Population	The study population primarily consisted of children with tongue-tie and perceived speech impairment, though inclusion criteria were not explicit. There was a small subset of pre-lingual patients who were treated for fear of speech impediment, though no speech concern had been diagnosed at the time of intervention.
Intervention	All interventions in this group were surgical. A variety of surgical techniques were utilized, included simple division with scalpel, scissors, and CO2 laser [4], frenulectomy/frenulotomy,[5] frenuloplasty,[6, 7] and the addition of genioglossus myotomy.[8]
Comparators	The majority of studies were non-comparative case series. Among the comparative studies, two cohort studies compared children with ankyloglossia after surgical management to those with ankyloglossia without surgical management and non-tongue-tied controls. A single RCT compared 4-flap frenuloplasty to horizontal to vertical frenuloplasty
Outcomes	Follow-up intervals ranged from several months to 3 years. Many studies evaluated speech improvement using parental self-report, including one of the cohort studies.[9] The second cohort study[10] measured articulation, and speech understandability with word, sentence and connected speech, as evaluated by blinded speech pathologists.
Setting	The setting was varied and variably reported in these studies. Procedures were performed in nurseries, outpatient clinics and in operating rooms, with no anesthetic, local and general anesthetic all being used. Pediatric surgeons, plastic surgeons and otolaryngologists performed the surgeries. Most studies were based in the United States, with a single study from each India, Korea, China and the United Kingdom.

Table I-4. Applicability for KQ 3

Domain	Description of applicability of evidence for a key question
Population	The population studied in the question of benefit of ankyloglossia repair for social concerns included children and adults with wide variation in ages. The patients were selected either by retrospective chart review or as they presented to otolaryngology clinics.
Intervention	Surgical repair only
Comparators	None
Outcomes	Outcomes measured were not consistent between studies with social concerns measured as a secondary outcome and the types of social outcomes considered were not consistent
Setting	Setting was inconsistently reported but most often surgeries occurred in outpatient settings.

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