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Efficacy of Neonatal Release of Ankyloglossia: A Randomized Trial

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Efficacy of Neonatal Release of Ankyloglossia: A Randomized Trial

WHAT'S KNOWN ON THIS SUBJECT: Ankyloglossia affects 1.7% to 4.8% of all infants. There is evidence that poor latch and maternal nipple pain are more common in infants with ankyloglossia. Some studies have shown that frenotomy benefits these infants; however, significant controversy regarding frenotomy still exists.

WHAT THIS STUDY ADDS: When frenotomy is performed for clinically significant ankyloglossia, there is a clear and immediate improvement in reported maternal nipple pain and infant breastfeeding scores. This study also provides compelling evidence to seek frenotomy when indicated.

abstract

FREE

BACKGROUND: Ankyloglossia has been associated with a variety of infant-feeding problems. Frenotomy commonly is performed for relief of ankyloglossia, but there has been a lack of convincing data to support this practice.

OBJECTIVES: Our primary objective was to determine whether frenotomy for infants with ankyloglossia improved maternal nipple pain and ability to breastfeed. A secondary objective was to determine whether frenotomy improved the length of breastfeeding.

METHODS: Over a 12-month period, neonates who had difficulty breastfeeding and significant ankyloglossia were enrolled in this randomized, single-blinded, controlled trial and assigned to either a frenotomy (30 infants) or a sham procedure (28 infants). Breastfeeding was assessed by a preintervention and postintervention nipple-pain scale and the Infant Breastfeeding Assessment Tool. The same tools were used at the 2-week follow-up and regularly scheduled follow-ups over a 1-year period. The infants in the sham group were given a frenotomy before or at the 2-week follow-up if it was desired.

RESULTS: Both groups demonstrated statistically significantly decreased pain scores after the intervention. The frenotomy group improved significantly more than the sham group ($P < .001$). Breastfeeding scores significantly improved in the frenotomy group ($P = .029$) without a significant change in the control group. All but 1 parent in the sham group elected to have the procedure performed when their infant reached 2 weeks of age, which prevented additional comparisons between the 2 groups.

CONCLUSIONS: We demonstrated immediate improvement in nipple-pain and breastfeeding scores, despite a placebo effect on nipple pain. This should provide convincing evidence for those seeking a frenotomy for infants with signficant ankyloglossia. *Pediatrics* 2011;128:280–288

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KEY WORDS

ankyloglossia, frenotomy, breastfeeding, Hazelbaker, tongue-tie

ABBREVIATIONS

NMCP—Naval Medical Center Portsmouth
HATLFF—Hazelbaker Assessment Tool for Lingual Frenulum Function
ENT—ear, nose, and throat
SF-MPQ—Short-Form McGill Pain Questionnaire
IBFAT—Infant Breastfeeding Assessment Tool

Dr Buryk contributed to the study design, data analysis, and drafting of the manuscript; Dr Bloom contributed to the study design and data collection and also performed the frenotomies; and Dr Shope contributed to the study design, data analysis, and drafting of the manuscript.

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Ankyloglossia, or tongue-tie, is an anatomic variation in which the lingual frenulum is unusually thick, tight, or short. Reported incidence of this condition among newborns in contemporary well-infant nurseries varies from 1.7% to 4.8% with a male-to-female ratio of ~3 to 1.[1,2] Although many infants with ankyloglossia breastfeed without difficulty, previous studies[3,4] have shown that the duration of breastfeeding is shorter in infants with tongue-tie compared with those with normal lingual frenula. It has been well established that breastfeeding promotes and maintains optimal infant health and reduces many childhood illnesses. Furthermore, the American Academy of Pediatrics recommends continuation of breastfeeding throughout the first year of life.[5] However, controversy exists in the medical community as to the significance of ankyloglossia.[6] In addition to difficulty in feeding, studies have evaluated the association of ankyloglossia with speech articulation disorders, poor oral hygiene, and various social issues.[7]

The otolaryngology department at the Naval Medical Center Portsmouth is regularly consulted to perform frenotomy, or release of tongue-tie, on newborns with ankyloglossia who have feeding difficulties or whose mothers have nipple pain during breastfeeding. To develop an evidence-based approach to this problem, we reviewed the literature on the topic. Although most studies found beneficial effects of frenotomy for neonatal ankyloglossia, many lacked reliable and validated tools for defining ankyloglossia or for measuring maternal nipple pain and the adequacy of breastfeeding.[8,9] In addition, some did not use blinding or a control group.[10] Although the results of these initial studies were promising, the methodologic concerns were significant and controversy still exists, according to some authors.[11,12] It is possible that the encouraging results are explained by a significant placebo affect or expected increases in breastfeeding coordination of the infant and mother as both gain more experience. The majority of authors agree that frenotomy in the newborn is a low-risk procedure when performed by trained professionals.[8–10,13–15]

Our goal was to design a study that would adequately answer the question of whether frenotomy was efficacious for neonatal ankyloglossia. Our primary objective was to determine whether frenotomy for infants with ankyloglossia improved maternal nipple pain and the ability to breastfeed. A secondary objective was to determine whether frenotomy improved the length of breastfeeding. We hypothesized that frenotomy would decrease maternal nipple pain, improve breastfeeding scores, and lead to a longer length of breastfeeding.

PATIENTS AND METHODS

Study Design and Setting

The study was a single-blinded, randomized controlled clinical trial of frenotomy for neonatal ankyloglossia. It was conducted at the Naval Medical Center Portsmouth (NMCP) newborn nursery, newborn care clinic, and otolaryngology clinic. The NMCP is a regional military medical center with ~350 newborn deliveries per month. Infants sent home before 48 hours of life are followed-up in the NMCP newborn care clinic within 24 to 48 hours. Infants who stay beyond 48 hours of birth, but who are breastfeeding, are followed-up at 1 week of age in the NMCP newborn care clinic. The study was approved by the institutional review board at the NMCP.

Recruitment and Consent

Newborns in the mother-infant ward and the newborn care clinic at NMCP were referred for possible participation in the following manner. Mothers who were noted to have nipple pain or difficulty breastfeeding were referred to certified lactation consultants. Lactation consultants routinely examined the infants' mouths as part of their assessment. Infants were enrolled if the lactation consultants detected significant ankyloglossia, according to the Hazelbaker Assessment Tool for Lingual Frenulum Function (HATLFF) (described below). Therefore, inclusion criteria were maternal report of nipple pain or difficulty breastfeeding combined with significant ankyloglossia, as judged by the HATLFF. Eligible parents or guardians of all participants provided written informed consent before inclusion. After enrollment, baseline maternal nipple-pain and breastfeeding scores were obtained (described below). Exclusion criteria included being older than 30 days; craniofacial anomalies, including cleft lip or palate; neurologically compromised infants; or any other contraindications to maternal breastfeeding. No patients met exclusion criteria.

Measures

HATLFF Measure for Ankyloglossia

Examiners graded ankyloglossia using the HATLFF, which comprises 2 measures: 5 appearance items (tongue appearance, frenulum elasticity, length of frenulum when tongue lifted, attachment of lingual frenulum to tongue, and attachment of frenulum to alveolar ridge) and 7 function items (tongue lateralization, lift, extension, spread, cupping, peristalsis, and snapback). These are scored 0 to 2 for a total of 10 possible points for appearance and 14 possible points for function (see Appendix 1). Face and content validity were established by Hazelbaker in 1993.[16] More recently, good interrater reliability was established for the appearance items and the first 3 function

items, although the last 4 items did not have good reliability. The HATLFF has excellent reliability for determining the recommendation for a frenotomy, defined as function score higher than 11 with failing lactation management or an appearance score lower than 8.[17] Infants with these score thresholds were defined as having significant ankyloglossia. These were the thresholds we used in this study.[16,17] Lactation consultants and ear, nose, and throat (ENT) surgeons were trained in the use of the HATLFF before the study initiation to increase the interrater reliability.

Maternal Nipple Pain

Mothers rated their nipple pain using the Short-Form McGill Pain Questionnaire (SF-MPQ).[18] The SF-MPQ is an abbreviated version of the McGill Pain Questionnaire, 1 of the most widely used tests for pain.[19] The SF-MPQ takes ~2 to 5 minutes to administer and has 3 sections. The first section consists of a set of 15 words describing sensory and affective aspects of pain, graded on a 0- to 4-point scale. The second section consists of a visual analog scale, and the third section is a 0- to 5-point list of descriptors comprising the present pain intensity measure. These measures are combined for a total possible score of 50, indicating the most severe pain (see Appendix 2). The SF-MPQ combines the use of the visual analog scale and present pain intensity, which are valid and reliable measures of pain intensity, with sensory and affective measures of pain. It has been translated into multiple languages, used in a wide variety of medical conditions, and extensively tested for validity, reliability, and responsiveness to clinically meaningful change.[18,20]

Infant Breastfeeding Assessment Tool

The Infant Breastfeeding Assessment Tool (IBFAT) is completed by the mother and has 4 ordinal response categories scored 0 to 3.[21] The maximum score is 15 (see Appendix 3). The IBFAT has excellent interrater reliability.[21] It seems to be a valid tool also. Higher IBFAT scores over time have been correlated with improved breastfeeding competence, fewer breastfeeding problems, and higher maternal satisfaction with breastfeeding.[22] In addition, higher IBFAT scores at a single feeding are strongly statistically associated with higher measured milk volumes and intake rates.[23] There is some controversy over whether any existing breastfeeding evaluation tools are reliable or valid.[24] However, 1 study[25] that failed to show acceptable reliability and validity of the IBFAT used observers of a videotaped feeding, rather than the mothers, to score the IBFAT, which is contrary to its original intent.

Intervention

After consent and enrollment, subjects were randomly assigned to the frenotomy or sham group using a computerized random-number generator of blocks of 4 created by a statistician and implemented by a research assistant. The parents were blinded to the group in which their infant was enrolled. Subjects were either directly taken to the ENT clinic or scheduled to return at a specific appointment time within 1 to 2 weeks. The time of the intervention was based on the availability of the otolaryngologist and not on the treatment group.

In the ENT clinic, surgical consents were obtained for both sham and frenotomy groups, and a repeat HATLFF assessment was performed by the surgeon. The ENT surgeon's HATLFF score was then used for data analysis. There was 100% agreement between the initial lactation consultant and the ENT surgeon with regard to significant ankyloglossia, with only minor variations in scores. The ENT surgeon performed the assessment before the patient's treatment group was revealed. The frenotomy or sham procedure was performed immediately before the next scheduled breastfeeding. At that time, the infant was taken to a procedure room while the mother remained in the waiting room. The infants in the frenotomy group had the procedure performed, whereas those in the sham group remained in the treatment room for the same length of time the procedure would require (5 minutes).

The experimental procedure was frenotomy. The tongue was elevated and the frenulum exposed with a grooved director. The frenulum tissue was then crushed with a straight clamp to provide anesthesia and decrease bleeding, and the exposed and previously clamped tongue frenulum was incised with a straight scissor. On occassion, direct pressure with the fingertips needed to be applied to achieve hemostasis. The infant usually cried for less than 10 seconds during the procedure.

After the procedure or sham, the patient was returned to the mother and immediately breastfed. The mother was instructed not to look in child's mouth until the breastfeeding and subsequent scoring was complete to protect the blinding of subject group. After breastfeeding, the SF-MPQ and IBFAT assessments were again performed. After the repeat scoring, mothers were informed of their infants' study group. Study subjects were followed-up 2 weeks later in the ENT clinic where the HATLFF, SF-MPQ, and IBFAT tools were again used. Patients who were randomly assigned to the sham group were offered the frenotomy before the 2-week follow-up if they had continued feeding difficulties, as required by our institutional review board and in accordance with the protection of human subjects.

Statistical Analysis

The sample size was based on the pain outcome. We assumed an effect SD of 1.5 and an effect size of 0.41, with $P < .05$ and a power of 80%. Using the Geisser-Greenhouse corrected F test on PASS 2000 software (NCSS, Kaysville, Utah), we determined that 50 subjects would be needed. Accounting for attrition, we sought to enroll 60 subjects. Categorical data were analyzed by using χ^2 analysis. The SF-MPQ and IBFAT scores were analyzed by using repeated-measures analysis of variance. Computed *t* tests were performed for analysis of baseline demographic data. For all tests, $P < .05$ was considered statistically significant. SPSS software (SPSS, Chicago, IL) was used for data analysis.

TABLE 1 Baseline Demographic Data and Outcome Measure Scores

	n	Mean	SD	SE	*P*
Age, d					
Sham	28	6.0	7.0	1.3	.91
Frenotomy	30	6.2	6.9	1.2	
SF-MPQ score					
Sham	28	19.2	9.9	1.9	.36
Frenotomy	30	16.8	10.6	1.9	
IBFAT score	28	8.5	3.8	0.7	.44
Sham					
Frenotomy	30	9.3	3.7	0.7	
Hazelbaker appearance score	28	5.7	2.2	0.4	.63
Sham					
Frenotomy	30	6.0	1.6	0.3	
Hazelbaker function score	28	8.4	2.0	0.3	.08
Sham					
Frenotomy	30	9.4	2.6	0.5	
		Sham	Frenotomy	Total	
Gender					
Girls		9	11	20	
Boys		19	19	38	
Total		28	30	58	

RESULTS

Fifty-eight of 3025 normal newborns (1.9%) met enrollment criteria and were enrolled over a 12-month period from December 2007 to December 2008. Of the infants enrolled, 28 were assigned to sham and 30 to frenotomy. No study subjects who met inclusion criteria refused participation nor did they meet any exclusion criteria. Follow-up continued through December 2009. The mean age of patients at enrollment was 6 days (SD: 6.9 [range 1–35 days]). After random assignment, there were no statistically significant differences in age at time of procedure, SF-MPQ, IBFAT, and HATLFF appearance and function scores (Table 1) at baseline. Both the frenotomy and sham groups demonstrated statistically significant decreases in SF-MPQ scores after the intervention. However, the frenotomy group improved significantly more than the sham group ($P < .001$) (Fig 1). SF-MPQ scores reduced from 16.77 (SD: 1.88) to 4.9 (SD: 1.46) and 19.25 (SD: 1.9) to 13.5 (SD: 1.5) in the frenotomy and sham groups before to immediately after the procedure, respectively, yielding an effect size of 0.38. In addition, IBFAT scores statistically significantly improved in the frenotomy group compared with the sham group ($P = .029$) (Fig 2). IBFAT scores improved from 9.3 (SD: 0.69) to 11.6 (SD: 0.81) in the frenotomy group and were virtually unchanged in the sham group (8.48 [SD: 0.73] to 8.07 [SD: 0.86]) from before to immediately after the procedure, yielding an effect size of 0.31.

Data were analyzed on the basis of intention to treat; however, all but 1 parent in the sham group elected to have the frenotomy at or before the time of the 2-week follow-up. There were no statistically significant differences between treatment groups for SF-MPQ scores after 2 weeks and IBFAT after the postintervention measurement. In addition, there was no difference between groups in the length of breastfeeding ($P = .43$). Overall breastfeeding rates at 2, 6, and 12 months of age were 66% (36 of 58), 44% (23 of 58), and 28% (14 of 58), respectively. There were 1, 6, and 14 total patients lost to follow-up, respectively. Subject attrition did not significantly differ by treatment group. The mothers continued to report decreased SF-MPQ as well as improved IBFAT scores, compared with initial scores throughout the follow-up period. However, after 2 months of age, there were no significant changes in either IBFAT or SF-MPQ scores (Figs 1 and 2). There were no complications from the procedure in any of the infants.

DISCUSSION

The American Academy of Pediatrics recommends that infants breastfeed for the first year of life.[26] This recommendation is based on the evidence for decreased rates of infection, diabetes, obesity, and other medical conditions and on enhanced cognitive development in breastfed infants. Maternal nipple pain and poor infant latch are common reasons for early discontinuation of breastfeeding.[2] There is evidence that ankyloglossia causes both poor latch and nipple pain compared with infants without ankyloglossia.[2,6,10] Studies of frenotomy to relieve neonatal ankyloglossia have consistently shown a benefit.[8–10,13,17,27] However, many opinion articles continue to dispute the utility of this procedure.[11,28]

Some of the controversy is caused by the significant methodologic problems

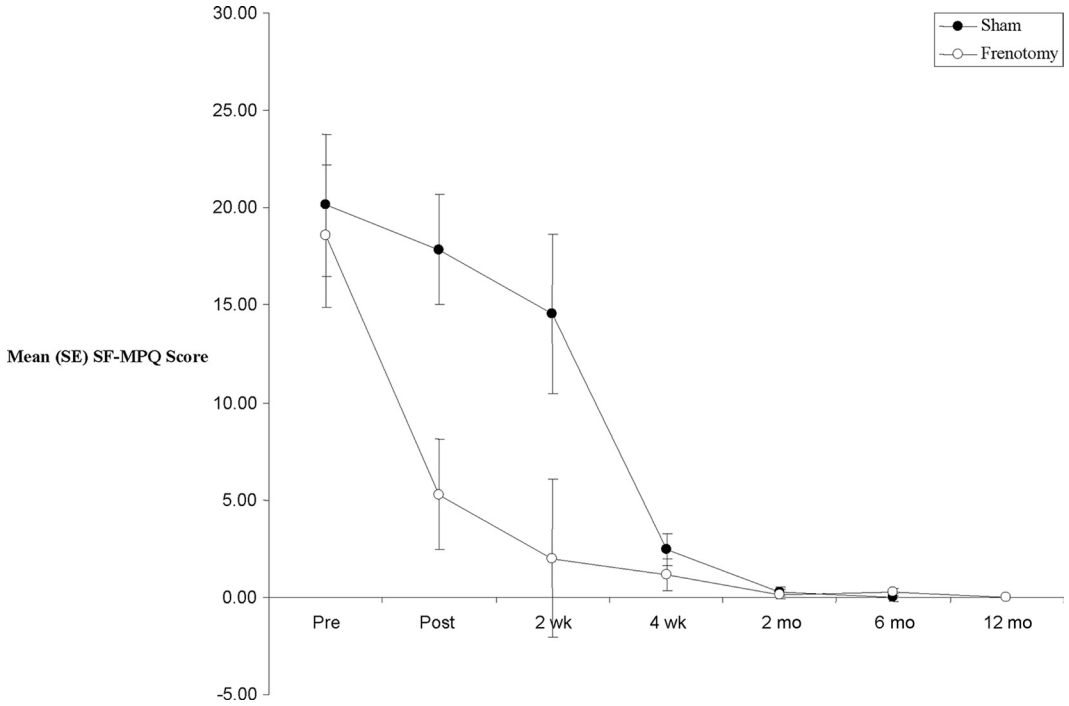

FIGURE 1
SF-MPQ scores before and after the frenotomy versus sham procedure.

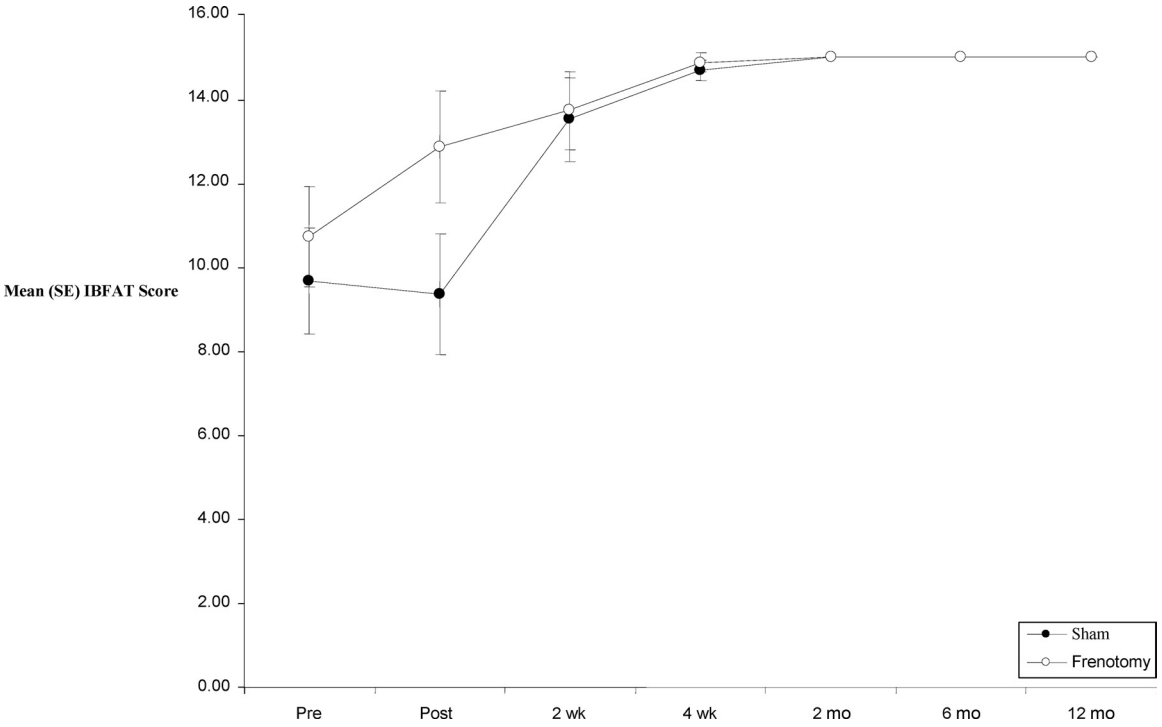

FIGURE 2
IBFAT scores before and after the frenotomy and sham procedure.

of previous studies.[14] Several case series[9,10,17,27] showed the benefit of frenotomy, but the lack of a control group allowed for the possibility that significant biases or the placebo effect could have explained the apparent benefit. To our knowledge, there have been 2 randomized trials[8,13] to date that also address this problem, and each found

frenotomy to be beneficial for breastfeeding infants with ankyloglossia. Only 1 of these studies[13] blinded the parents to the treatment group. However, neither study used validated and reliable tools for grading ankyloglossia or the postfrenotomy outcome measures. Grading ankyloglossia is important because ~50% of breastfeeding infants with ankyloglossia will have no problem breastfeeding.[14]

In this study, we attempted to address these previous methodologic concerns. We used a randomized controlled, blinded design; only enrolled infants with breastfeeding problems; and used validated and reliable tools for grading ankyloglossia and measuring pain and maternal report of breastfeeding adequacy. Using this methodology, we detected a significant placebo effect but also an additive statistically significant treatment effect of immediate improvements in nipple pain and maternal report of breastfeeding adequacy.

The incidence of ankyloglossia in this study was only 1.9%, which is lower than the 3.2% to 10.7% reported in the literature.[2,8,10] We think the lower incidence is because we did not evaluate all infants with ankyloglossia but rather only those who met our entry criteria. We acknowledge the last 4 HATLFF function items did not have good interrater reliability in 1 study.[17] However, our conclusions remained the same regardless of whether these items were included in the analysis. All patients with impairment of function (function score < 11) had appearance scores lower than 10. In Hazelbaker's original study,[16] an appearance score of 8 to 10 indicated a need to consider frenotomy. Therefore, in infants who already have been identified as having difficulty breastfeeding, we think the appearance scores lower than 10 could be used alone to determine whether infants are candidates for frenotomy. Despite the possible concerns with the function items, the HATLFF demonstrated 100% agreement between the lactation consultants and ENT surgeons on the most important issue, which was the decision to perform a frenotomy.

The mean age at time of frenotomy was 6.7 days. These infants, therefore, had time to establish breastfeeding patterns and time for mothers to demonstrate persistent problems with feeding despite lactation interventions. There may be a benefit to allowing a small amount of time to establish breastfeeding before frenotomy because some infants with ankyloglossia will not have breastfeeding problems. We did not evaluate the optimal timing of frenotomy but would suggest that it occur sometime between 2 and 6 days after birth.

We were unable to fully address whether frenotomy increased the length of breastfeeding because the crossover of all but 1 of the sham subjects to the frenotomy group eliminated our control group. Our longitudinal data (Figs 1 and 2) demonstrated that by the 2-month follow-up the mothers had virtually no pain and high IBFAT scores. Our study subjects' breastfeeding rates of 44% and 28% at 6 and 12 months of age, respectively, compare favorably to the national average of 43 and 23%, respectively (Centers for Disease Control and Prevention National Immunization Survey 2006 [www.cdc.gov/breastfeeding/data/nis_data]), despite the loss of nearly one-quarter of our subjects to follow-up by 12 months of age. There is likely to be a selection bias in our study of mothers who were highly motivated to breastfeed because they consented to a surgical procedure for their infants to continue breastfeeding. However, this same bias would be present at any institution that routinely offers frenotomy for ankyloglossia.

Although this study addressed many previous limitations of this area of research, our study had its own limitations. We could not adequately address long-term outcomes of frenotomy because of the significant crossover of sham subjects. It is interesting to note that 1 other randomized trial had the same issue.[8] We do not feel that there is any way to ethically address this issue in a randomized trial. With the preponderance of evidence showing a benefit of frenotomy, withholding the procedure from breastfeeding infants with ankyloglossia and potentially causing them to discontinue breastfeeding would be more harmful than performing a simple frenotomy. Furthermore, we were unable to keep mothers blinded after the first postprocedure feeding, but, again, we feel that this is unavoidable and do not foresee a way to prevent mothers from looking in their infants' mouths.

CONCLUSIONS

When frenotomy is performed for clinically significant ankyloglossia, there is a clear and immediate improvement in reported maternal nipple pain and infant breastfeeding scores. We addressed previous methodological concerns and believe our study, in addition to the other studies on this topic, should now provide compelling evidence for pediatricians, otolaryngologists, oral surgeons, and lactation consultants to seek frenotomy when indicated. As in previous studies, we found the procedure to be rapid, simple, and without complications. Additional studies should be done to determine the optimal timing of frenotomy and the ideal screening tool to detect significant ankyloglossia.

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APPENDIX 1 Hazelbaker Assessment Tool for Lingual Frenulum Function (1998 Version)[17]

Appearance items
- Appearance of tongue when lifted
  - 2: Round OR square
  - 1: Slight cleft in tip apparent
  - 0: Heart shaped
- Elasticity of frenulum
  - 2: Very elastic (excellent)
  - 1: Moderately elastic
  - 0: Little OR no elasticity
- Length of lingual frenulum
  - 2: >1 cm OR embedded in tongue
  - 1: 1 cm
  - 0: <1 cm
- Attachment of lingual frenulum to tongue
  - 2: Attached to floor of mouth OR well below ridge
  - 1: Attached just below
  - 0: Attached at ridge

Function Items
- Lateralization
  - 2: Complete
  - 1: Body of tongue but not tongue tip
  - 0: None
- Lift of tongue
  - 2: Tip to midmouth
  - 1: Only edges to midmouth
  - 0: Tip stays at alveolar ridge or rises to midmouth only with jaw closure
- Extension of tongue
  - 2: Tip over lower lip
  - 1: Tip over lower gum only
  - 0: Neither of above OR anterior or midtongue humps
- Spread of anterior tongue
  - 2: Complete
  - 1: Moderate OR partial
  - 0: Little OR none
- Cupping
  - 2: Entire edge, firm cup
  - 1: Side edges only, moderate cup
  - 0: Poor OR no cup
- Peristalsis
  - 2: Complete, anterior to posterior (originates at the tip)
  - 1: Partial, originating posterior to tip
  - 0: None OR reverse peristalsis
- Snapback
  - 2: None
  - 1: Periodic
  - 0: Frequent OR with each suck

A score of 14 is a perfect score (regardless of the appearance item score); a score of 11 is acceptable if appearance item score is 10; a score of <11 refers to impaired function. Frenotomy should be considered if management fails. Frenotomy is necessary if the appearance item score is <9.
Total score: ___.

APPENDIX 2 R. Melzack's Short-Form Pain Questionnaire (Nipple Pain Scale)

	SF-MPQ (Nipple-Pain Scale)			
	None: 0	Mild: 1	Moderate: 2	Severe: 3
Throbbing				
Shooting				
Stabbing				
Sharp				
Cramping				
Gnawing				
Hot burning				
Aching				
Heavy				
Tender				
Splitting				
Tiring or exhausting				
Sickening				
Fearful				
Punishing cruel				

Evaluative: 0 = no pain; 1 = mild pain; 2 = discomforting; 3 = distressing; 4 = horrible; 5 = excruciating.
Total score (0–50): ___.

APPENDIX 3 IBFAT Scoring System

Check the answer that best describes the baby's feeding behaviors at this feed.

1. To get the baby to begin this feed, did you or the nurse have to:
   a. Just place the baby on the breast as no effort was needed
   b. Use mild stimulation such as unbundling, patting, or burping
   c. Unbundle baby, sit baby back and forward, rub baby's body or limbs vigorously at the beginning and during the feed
   d. Could not be aroused
2. Rooting (definition: at touch of nipple to cheek, baby's head turns toward the nipple, the mouth opens, and baby attempts to fix mouth on the nipple). When the baby was placed at the breast, he/she:
   a. Rooted effectively at once
   b. Needed some coaxing, prompting/encouragement to root
   c. Rooted poorly even with coaxing
   d. Did not try to root
3. How long from placing baby at the breast does he/she latch on and start to feed well (constant sucking through the length of the feed, with some pauses, on either/or both breasts)?
   a. Starts to feed at once, 0–3 minutes
   b. 3–10 minutes
   c. Over 10 minutes
   d. Did not latch on
4. Which of the following phrases best describes the baby's feeding pattern at this feed?
   a. Baby did not suck
   b. Sucked poorly, weak sucking, some sucking for short periods
   c. Sucked fairly well (sucked off and on but needed some encouragement)
   d. Sucked well on one or both breasts
5. How do you feel about the way the baby fed at this feeding?
   a. Very pleased
   b. Pleased
   c. Fairly pleased
   d. Not pleased

Values of 0 to 3 are assigned to responses; 3 represents the best response for each question.
Total score: ___.

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