

# Breastfeeding Improvement Following Tongue-Tie and Lip-Tie Release: A Prospective Cohort Study

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**Objectives/Hypothesis:** Numerous symptoms may arise that prevent mother-infant dyads from maintaining desired breastfeeding intervals. Investigations into treatments that positively influence breastfeeding outcomes allow for improved patient counseling for treatment decisions to optimize breastfeeding quality. This investigation aimed to determine the impact of surgical tongue-tie/lip-tie release on breastfeeding impairment.

**Study Design:** Prospective, cohort study from June 2014 to April 2015 in a private practice setting.

**Methods:** Study participants consisted of breastfeeding mother-infant (0–12 weeks of age) dyads with untreated ankyloglossia and/or tethered maxillary labial frenula who completed preoperative, 1 week, and 1 month postoperative surveys consisting of the Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF), visual analog scale (VAS) for nipple pain severity, and the revised Infant Gastroesophageal Reflux Questionnaire (I-GERQ-R). Breastmilk intake was measured preoperatively and 1 week postoperatively.

**Results:** A total of 237 dyads were enrolled after self-electing laser lingual frenotomy and/or maxillary labial frenectomy. Isolated posterior tongue-tie was identified in 78% of infants. Significant postoperative improvements were reported between mean preoperative scores compared to 1 week and 1 month scores of the BSES-SF ( $F_{(2)} = 212.3$ ;  $P < .001$ ), the I-GERQ-R ( $F_{(2)} = 85.3$ ;  $P < .001$ ), and VAS pain scale ( $F_{(2)} = 259.8$ ;  $P < .001$ ). Average breastmilk intake improved 155% from 3.0 (2.9) to 4.9 (4.5) mL/min ( $P < .001$ ).

**Conclusions:** Surgical release of tongue-tie/lip-tie results in significant improvement in breastfeeding outcomes. Improvements occur early (1 week postoperatively) and continue to improve through 1 month postoperatively. Improvements were demonstrated in both infants with classic anterior tongue-tie and less obvious posterior tongue-tie. This study identifies a previously under-recognized patient population that may benefit from surgical intervention if abnormal breastfeeding symptoms exist.

**Key Words:** Breastfeeding, ankyloglossia, patient outcome assessment, outcome assessment (healthcare), visual analog scale, gastroesophageal reflux.

**Level of Evidence:** 2c

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## INTRODUCTION

The rate of breastfeeding in the United States has been rising over the last 20 years with the increased emphasis on improved health outcomes in breastfed children and the recent impetus for hospitals to meet care standards established by the Baby Friendly Hospital Initiative.<sup>1</sup> Previous research has demonstrated increased breastfeeding failure rate in mothers who intended to

breastfeed in the hospital setting.<sup>2</sup> The causes of breastfeeding cessation are multifactorial and include poor weight gain necessitating supplementation, poor latch, maternal nipple pain, and structural restrictions like ankyloglossia.

Ankyloglossia (either classic anterior tongue-tie or submucosal restriction)<sup>3</sup> and a tethered superior labial frenum (upper lip-tie) cause altered latch and sucking mechanics. The suckling process is complex and multifactorial, and dysfunction may cause diverse signs and symptoms in the breastfeeding dyad. Latch difficulties and suboptimal sucking mechanics may result in inefficient milk transfer, poor weight gain, low milk supply, nipple pain and trauma.

Recently, the Agency for Healthcare Research and Quality (AHRQ) evaluated the existing body of evidence regarding lingual frenotomy and maxillary labial frenectomy, concluding that the strength of outcomes-based evidence supporting those procedures was “generally low to insufficient.”<sup>4</sup> The insufficient research quality is largely due to the lack of randomized controlled trials. Previous studies have examined the impact of lingual frenotomy on maternal pain, improvement in latch

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TABLE I.  
Anatomic Classification Types and Preoperative Frequency for the Overall Cohort (n = 237).

|                                      | Definition                                                            | No. (%)   |
|--------------------------------------|-----------------------------------------------------------------------|-----------|
| Kotlow upper lip-tie classifications |                                                                       |           |
| Class I                              | No significant attachment                                             | 0 (0%)    |
| Class II                             | Attachment mostly into the gingival tissue                            | 2 (1%)    |
| Class III                            | Attachment in front of the anterior papilla                           | 109 (46%) |
| Class IV                             | Attachment into the papilla or extending into hard palate             | 126 (53%) |
| Coryllos tongue-tie classifications  |                                                                       |           |
| Type I                               | Attachment of the frenulum to tip of tongue                           | 12 (5%)   |
| Type II                              | Attachment is 2–4 mm behind tip of tongue/on or behind alveolar ridge | 40 (17%)  |
| Type III                             | Attachment to midtongue/middle of the floor of the mouth              | 76 (32%)  |
| Type IV                              | Attachment against base of tongue, thick and inelastic                | 109 (46%) |

quality, and improvement of breastfeeding complaints. Some breastfeeding specialists have documented an improvement in maternal self-efficacy<sup>5</sup>; this improvement in self-efficacy is an established predictor for continued breastfeeding.<sup>6,7</sup> In children with reflux symptomatology, clinical improvement has been suggested following frenotomy.<sup>8</sup> Due to the complex and multifactorial nature of infant reflux, and because of the lack of published studies trying to determine correlation between tongue-tie and reflux symptoms, further investigation is warranted.

To better elucidate treatment outcomes surrounding these procedures and to help address the AHRQ determination for higher level evidence, we designed a prospective cohort study aimed to test four hypotheses regarding tongue-tie/lip-tie release: 1) Surgical release will improve maternal breastfeeding self-efficacy. 2) Surgical release will improve maternal nipple pain. 3) The procedure will improve milk transfer rates following tongue-tie/lip-tie release. 4) The procedure will improve infant gastroesophageal reflux symptoms.

## MATERIALS AND METHODS

### *Patient Population and Inclusion Criteria*

Study patients were recruited from all dyads who were referred for evaluation for frenotomy if 1) they were currently breastfeeding; 2) the infant was  $\leq 12$  weeks of age and  $\geq 37$  weeks gestational age; and 3) the infant underwent surgical correction for tethered, maxillary labial frenum (upper lip-tie) and/or ankyloglossia (tongue-tie) in a community-based, otolaryngology care center by the principal investigator (B.A.G.). All study protocols and evaluation instruments, informed consent/assent documentation, and data safety monitoring were approved by an institutional review board (Providence Health & Services IRB# 14-031B).

### *Infant Oral Assessment*

All infants were initially evaluated by community lactation consultants before surgical referral as a prerequisite for consultation by the principal investigator. The latch assessment by the lactation consultant was considered in the decision-making process in whether a frenotomy was offered. A targeted head and neck evaluation was performed to determine if restrictions were present, examining for maxillary bony alveolar

notching, blanched frenula with elevation, anatomical restriction of elicited lateral lingual movement (impaired transverse tongue reflex), abnormal floor of mouth elevation with elevation of the tongue, and location of attachment of the frenula. A sucking evaluation was then performed, noting abnormal gum/lip grip pressure, cupping of the tongue against the finger, seal on the finger, and the nature of the sucking tongue movements. Formal scoring using the Assessment Tool for Lingual Frenulum Function staging system was also performed.<sup>9</sup> Standardized classification systems were used to describe frenula anatomy: the Kotlow upper lip-tie classification<sup>10</sup> and Coryllos tongue-tie classification<sup>11</sup> systems as described in Table I. A symptom/complaint checklist was also completed by each mother; the symptoms and frequency of symptom presentation are described in Table II.

### *Surgical Intervention*

Informed consent was obtained from the parent(s), and the patient was moved to a laser-safe operatory suite. A small amount of topical anesthetic cream (EMLA; Actavis Pharma, Parsippany, NJ) was applied with a Q-tip to the surgical site(s).

TABLE II.  
Maternal Complaints at the Time of Study Enrollment.

| Complaint                                             | Prevalence |
|-------------------------------------------------------|------------|
| Poor latching                                         | 81%        |
| Falls asleep while attempting to nurse                | 73%        |
| Creased, flattened, or blanched nipples after nursing | 68%        |
| Gumming or chewing of nipple when nursing             | 67%        |
| Poor or incomplete breast drainage                    | 60%        |
| Slides off nipple when attempting to latch            | 60%        |
| Severe pain when infant attempts to latch             | 59%        |
| Cracked, bruised, or blistered nipples                | 49%        |
| Reflux symptoms                                       | 45%        |
| Unable to hold a pacifier in mouth                    | 40%        |
| Poor weight gain                                      | 32%        |
| Colic symptoms                                        | 24%        |
| Bleeding nipples                                      | 24%        |
| Plugged ducts                                         | 21%        |
| Mastitis or nipple thrush                             | 14%        |
| Infected nipples or breasts                           | 6%         |

The frenotomy procedure was performed with a 1,064-nm InGaAsP semiconductor diode laser (Xlase; Technology4Medicine, San Clemente, CA) with variable pulsed wave and wattage settings, with 0.7 to 0.8 pulsed watts, 200  $\mu$ s on and 100  $\mu$ s off (actual wattage: 0.47–0.53 W) using a 300- $\mu$ m-diameter laser fiber. The tongue was elevated using a grooved director while the laser tip was applied to the frenulum. Starting at the anterior edge of the frenulum (in children with anterior tongue-tie), midline tissue was incised and an approximately 1-mm-deep central window was incised in the mucosa overlying the genioglossus muscle. The window in the mucosa was then extended laterally on both sides to release the mucosa, taking care to not disturb the fascia of the underlying genioglossus muscle. The resulting diamond-shaped wound was considered a full release. Upper lip-tie release involves elevation of the lip with gauze while the maxillary labial frenulum was released off of the alveolar ridge up to the mucogingival junction. The baby was then brought back to the mother and offered the breast, where they either breastfed immediately or fell asleep. Postprocedural stretching exercises are advised to avoid reattachment of tissue by gently elevating the tongue and massaging the wound four to six times per day for several weeks. Acetaminophen was available for analgesia for the first 1 to 2 days as needed, but the majority of infants needed little, if any, analgesia postprocedure.

### **Demographics and Breastfeeding Outcome Measures**

Study enrollment and informed consent were completed subsequent to standard surgical consent, during which parents were asked to provide demographic and medical history information. Study participants completed all study-related outcome assessments prior to surgery, and at 1 week and 1 month after intervention via electronic correspondence using an Internet-based, Health Insurance Portability and Accountability Act of 1996–compliant survey portal (SurveyMonkey, Palo Alto, CA). All infants were followed clinically as to whether a second, adjunctive frenotomy was required. Patients returned to the office routinely at 1 week postprocedure or if symptoms persisted or regressed following initial improvement and were offered a second procedure if restriction was identified.

At each time period parents completed three measures to examine various constructs of breastfeeding: the Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF) (University of Toronto, Toronto, Ontario, Canada), a visual analog scale (VAS) to evaluate breastfeeding pain severity, and the revised Infant Gastroesophageal Reflux Questionnaire (I-GERQ-R) (University of Pittsburgh, Pittsburgh, PA). The BSES-SF is a validated, 14-item survey that measures breastfeeding efficacy and confidence using Likert scale responses between 0 (“Not at all confident”) and 5 (“Very confident”).<sup>12</sup> Scores are summarized (range, 0–70), where higher scores indicate lower breastfeeding impairment and higher confidence. The I-GERQ-R is a validated, 13-item survey with strong internal consistency designed to evaluate the severity of gastroesophageal reflux symptomatology in infants.<sup>13</sup> The I-GERQ-R utilizes ordinal response scales to measure the severity of symptoms associated with infant gastroesophageal reflux disease (GERD). Scoring involves the summarization of 12 items (score range, 0–42), where lower scores reflect lower symptom severity.

### **Measurement of Breastfeeding Efficiency**

A subset of infants was evaluated by an international board-certified lactation consultant to calculate breastfeeding

rates (milliliters/minute) within 1 week prior to the intervention and 1 week after. These rates were calculated by measuring pre- and postfeeding weights during a specific time interval.

### **Exclusion Criteria**

Study participants were considered lost to follow-up if breastfeeding outcome survey evaluations were not completed within the 1 month study follow-up period; they were not included in the analysis. Additional exclusions were made for infants with life-threatening comorbid conditions, those with previous treatment for tongue-tie or lip-tie by another provider, infants born from multiple births, and mothers with previous breast surgery or insufficient glandular tissue.

### **Sample Size Requirements, Data Collection, and Statistical Analyses**

Sample size estimations were determined using testing for differences in dependent mean values for breastfeeding outcome measures between preoperative and 1 month postoperative scores. Assuming a two-tailed test, a .05  $\alpha$  level, an 80% power, a conventional within-subject Pearson correlation coefficient ( $R_p = 0.50$ ), and an equal standard deviation value of 10.9, a total of 233 subjects were required to detect a mean difference of at least 2.0 points on the BSES-SF (~3% difference in total score).<sup>12</sup>

Study data were safeguarded by removal of protected health information and the assignment of unique study identification numbers for patient dyads. A password-protected, relational database (Access; Microsoft Corp., Redmond, WA) was utilized. Statistical comparisons were completed with commercial software (SPSS version 22; IBM Corp., Armonk, NY). Distributions were verified for ordinal or continuous scale measures using graphical analyses. Differences in mean outcome measures between matched pairs of study time points were evaluated using either paired samples  $t$  test or Wilcoxon signed rank statistics. To evaluate level 3 within-subjects effects over time,  $F$  test statistics within repeated measures analysis of variance with Greenhouse-Geisser corrections were used to evaluate significant differences in all breastfeeding outcome measures. To better account for baseline differences, relative mean improvement (RMI) percentages were calculated for discrete pairings of each outcome measure using the algorithm: (1 month follow-up score – preoperative score)/preoperative score  $\times 100$  and averaged. All statistical comparisons assumed a conventional 0.05 type I error probability.

## **RESULTS**

### **Baseline Enrollment and Final Study Cohort**

A total of 237 participant families were enrolled between June 2014 and April 2015. Preoperative anatomic classification is shown in Table I. Final cohort demographic factors included an average infant mean age of 4.4 (standard deviation = 3.6) weeks, with a majority of infants between 0 to 4 weeks ( $n = 139$ ; 59%), compared to 5 to 8 weeks of age ( $n = 60$ ; 25%) and 9 to 12 weeks of age ( $n = 38$ ; 16%). Most infants (86%) were of white/Caucasian ethnicity, and just over half (56%) were male. One hundred seventy-eight subjects underwent hospital births (75%) compared to home births ( $n = 32$ ; 14%) or birthing center deliveries ( $n = 27$ ; 11%). A majority of infants were delivered vaginally ( $n = 198$ ; 84%). One hundred seventy-eight (75%) infants

TABLE III.  
Overall Preoperative and All Postoperative Average Outcome Measure Scores (n = 237).

| Breastfeeding Outcome Measures | Preoperative | 1 Week                   | 1 Month                  | F Test Statistic,<br>df = 2 | P Value* |
|--------------------------------|--------------|--------------------------|--------------------------|-----------------------------|----------|
|                                | Mean (SD)    | Postoperative, Mean (SD) | Postoperative, Mean (SD) |                             |          |
| BSES-SF total score            | 43.9 (12.6)  | 52.3 (11.4)              | 56.5 (10.8)              | 212.3                       | <.001    |
| I-GERQ-R total score           | 16.5 (6.1)   | 13.2 (5.0)               | 11.6 (4.9)               | 85.3                        | <.001    |
| VAS pain score                 | 4.6 (2.7)    | 2.2 (1.8)                | 1.5 (1.7)                | 259.8                       | <.001    |

\*P values reflect overall significance between all within-subjects time points using repeated measures analysis of variance F test results.

BSES-SF = Breastfeeding Self-Efficacy Scale-Short Form; df = degrees of freedom; I-GERQ-R = revised Infant Gastroesophageal Reflux Questionnaire; SD = standard deviation; VAS = visual analog scale;

underwent surgical treatment of both upper lip-tie and tongue-tie. One infant (0.4%) received only lip-tie release, whereas 58 (25%) received only tongue-tie corrective procedures. A total of eight (3%) of patients received a second lingual frenotomy within the study duration for either lack of improvement of symptoms or regression of symptoms after initial improvement. No complications were reported following any procedure.

### Postoperative Improvement in Breastfeeding Outcome Measures

Highly significant within-subject improvement was seen in all outcomes measured at 1 week following surgical procedures, and the improvement between 1 week and 1 month continued to be significant (Table III). Significant improvement was reported between preoperative and 1 week BSES-SF total scores ( $t = -13.9$ ;  $P < .001$ ; RMI = 25%), I-GERQ-R total scores ( $t = 8.8$ ;  $P < .001$ ; RMI = 14%), and VAS pain scores ( $t = 16.3$ ;  $P < .001$ ; RMI = 48%). Continued significant postoperative

improvement was reported, between 1 week and 1 month follow-up evaluations in BSES-SF total scores ( $t = -8.0$ ;  $P < .001$ ; RMI = 11%), I-GERQ-R total scores ( $t = 4.9$ ;  $P < .001$ ; RMI = 7%), and VAS pain scores ( $t = 5.9$ ;  $P < .001$ ; RMI = 28%).

In the subset of participant families studied (n = 60), milk transfer rate significantly improved on average ( $P < .001$ ; RMI = 155%) from 3.0 (2.9) mL/min prior to release to 4.9 (4.5) mL/min (postoperative range, 1.1–33.3 mL/min) at 1 week postprocedure.

### Postoperative Improvement Across Patient Subgroups

Subgroup analysis was performed to investigate the role of infant age, sex, and tongue/lip anatomic classification on outcomes. There was significant improvement in maternal breastfeeding self-confidence, maternal nipple pain, and infant reflux symptoms in every tested variable (Tables IV–VI).

TABLE IV.  
Average Preoperative and Postoperative Improvement in BSES-SF Total Scores Across Participant Subgroups.

| Subgroups                           | Preoperative | 1 Week                   | 1 Month                  | F Test Statistic, df = 2 (P Value) | RMI* |
|-------------------------------------|--------------|--------------------------|--------------------------|------------------------------------|------|
|                                     | Mean [SD]    | Postoperative, Mean [SD] | Postoperative, Mean [SD] |                                    |      |
| Age: 0–4 weeks                      | 43.4 [12.7]  | 51.7 [11.4]              | 55.6 [11.0]              | 127.3 (<.001)                      | 38%  |
| Age: 5–8 weeks                      | 44.3 [12.5]  | 53.8 [10.9]              | 59.7 [8.1]               | 74.7 (<.001)                       | 46%  |
| Age: 9–12 weeks                     | 45.0 [12.9]  | 52.0 [12.5]              | 54.8 [13.0]              | 18.2 (<.001)                       | 29%  |
| Males                               | 43.9 [12.7]  | 52.3 [11.7]              | 56.6 [11.2]              | 113.2 (<.001)                      | 39%  |
| Females                             | 43.9 [12.5]  | 52.3 [11.1]              | 56.5 [10.4]              | 99.4 (<.001)                       | 38%  |
| Kotlow lip classification type      |              |                          |                          |                                    |      |
| Class III                           | 43.3 [12.8]  | 52.8 [10.9]              | 56.7 [11.2]              | 113.8 (<.001)                      | 41%  |
| Class IV                            | 44.6 [12.3]  | 52.0 [11.5]              | 56.5 [10.2]              | 98.3 (<.001)                       | 36%  |
| Coryllos tongue classification type |              |                          |                          |                                    |      |
| Type I                              | 50.1 [11.4]  | 59.1 [8.2]               | 59.7 [11.0]              | 6.9 (.015)                         | 24%  |
| Type II                             | 44.1 [11.2]  | 53.5 [10.7]              | 58.7 [8.5]               | 54.6 (<.001)                       | 43%  |
| Type III                            | 43.4 [12.6]  | 51.4 [11.3]              | 55.0 [11.7]              | 62.1 (<.001)                       | 35%  |
| Type IV                             | 43.5 [13.2]  | 51.7 [11.9]              | 56.4 [10.9]              | 93.3 (<.001)                       | 40%  |
| Procedure type                      |              |                          |                          |                                    |      |
| Tongue                              | 45.1 [12.4]  | 53.6 [11.7]              | 57.6 [11.9]              | 46.1 (<.001)                       | 35%  |
| Both tongue and lip                 | 43.5 [12.7]  | 51.9 [11.4]              | 56.2 [10.5]              | 164.6 (<.001)                      | 40%  |

\*RMI between preoperative and 30-day follow-up scores; higher scores on BSES-SF survey indicate improvement.

BSES-SF = Breastfeeding Self-Efficacy Scale-Short Form; df = degrees of freedom; RMI = relative mean improvement; SD = standard deviation.

TABLE V.  
Average Preoperative and Postoperative Improvement in I-GERQ-R Total Scores Across Participant Subgroups.

| Subgroups:                          | Preoperative, Mean [SD] | 1 Week Postoperative, Mean [SD] | 1 Month Postoperative, Mean [SD] | F Test Statistic, <i>df</i> = 2 (P Value) | RMI* |
|-------------------------------------|-------------------------|---------------------------------|----------------------------------|-------------------------------------------|------|
| Age: 0–4 weeks                      | 15.0 [5.5]              | 13.1 [4.8]                      | 12.3 [5.0]                       | 19.9 (<.001)                              | 12%  |
| Age: 5–8 weeks                      | 19.3 [6.5]              | 14.0 [5.9]                      | 10.8 [4.3]                       | 67.6 (<.001)                              | 39%  |
| Age: 9–12 weeks                     | 17.2 [6.1]              | 12.3 [4.2]                      | 10.7 [5.0]                       | 23.6 (<.001)                              | 33%  |
| Males                               | 16.3 [5.8]              | 13.0 [4.9]                      | 11.3 [5.1]                       | 51.9 (<.001)                              | 24%  |
| Females                             | 16.7 [6.5]              | 13.4 [5.2]                      | 12.1 [4.6]                       | 33.5 (<.001)                              | 19%  |
| Kotlow lip classification type      |                         |                                 |                                  |                                           |      |
| Class III                           | 17.0 [5.9]              | 13.3 [5.0]                      | 12.1 [4.8]                       | 43.8 (<.001)                              | 21%  |
| Class IV                            | 16.0 [6.3]              | 13.1 [5.0]                      | 11.3 [5.0]                       | 41.8 (<.001)                              | 23%  |
| Coryllos tongue classification type |                         |                                 |                                  |                                           |      |
| Type I                              | 14.9 [6.8]              | 12.2 [6.5]                      | 9.8 [6.6]                        | 7.6 (.004)                                | 37%  |
| Type II                             | 15.9 [5.2]              | 13.1 [4.8]                      | 11.2 [4.5]                       | 12.1 (<.001)                              | 23%  |
| Type III                            | 16.6 [6.8]              | 12.8 [5.0]                      | 11.5 [4.6]                       | 33.5 (<.001)                              | 21%  |
| Type IV                             | 16.8 [5.9]              | 13.6 [5.0]                      | 12.2 [5.0]                       | 33.9 (<.001)                              | 20%  |
| Procedure type                      |                         |                                 |                                  |                                           |      |
| Tongue                              | 15.4 [5.4]              | 12.4 [4.4]                      | 11.1 [5.5]                       | 18.1 (<.001)                              | 22%  |
| Both tongue and lip                 | 16.9 [6.3]              | 13.4 [5.2]                      | 11.9 [4.7]                       | 67.4 (<.001)                              | 22%  |

\*RMI between preoperative and 30-day follow-up scores; lower scores on I-GERQ-R survey indicate improvement.

*df* = degrees of freedom; I-GERQ-R = revised Infant Gastroesophageal Reflux Questionnaire; RMI = relative mean improvement; SD = standard deviation.

## DISCUSSION

Improving breastfeeding duration and exclusivity rates optimizes infant health by decreasing the incidence of numerous health conditions while simultaneously providing maternal health benefits. In 2010, a pediatric cost analysis of the potential financial impact of breastfeeding rates concluded that the United States could save

\$13 billion annually if 90% of families complied with recommendations of exclusive breastfeeding for 6 months.<sup>14</sup> Approximately 80% of mothers initiate breastfeeding, but a large percentage either stop breastfeeding completely or do not maintain exclusivity for the recommended duration.<sup>15</sup> Numerous factors contribute to early cessation of breastfeeding.<sup>2,16</sup> Previous studies have

TABLE VI.  
Average Preoperative and Postoperative Improvement in VAS Pain Scores Across Participant Subgroups.

| Subgroups                           | Preoperative, Mean [SD] | 1 Week Postoperative, Mean [SD] | 1 Month Postoperative, Mean [SD] | F Test Statistic, <i>df</i> = 2 (P Value) | RMI |
|-------------------------------------|-------------------------|---------------------------------|----------------------------------|-------------------------------------------|-----|
| Age: 0–4 weeks                      | 5.2 [2.7]               | 2.4 [1.8]                       | 1.8 [1.8]                        | 171.6 (<.001)                             | 61% |
| Age: 5–8 weeks                      | 4.2 [2.7]               | 1.9 [1.9]                       | 1.4 [1.6]                        | 58.3 (<.001)                              | 67% |
| Age: 9–12 weeks                     | 3.3 [2.4]               | 1.6 [1.6]                       | 0.9 [1.3]                        | 35.1 (<.001)                              | 73% |
| Males                               | 4.8 [2.7]               | 2.2 [1.8]                       | 1.7 [1.9]                        | 131.0 (<.001)                             | 58% |
| Females                             | 4.5 [2.7]               | 2.1 [1.9]                       | 1.4 [1.6]                        | 135.2 (<.001)                             | 72% |
| Kotlow lip classification type      |                         |                                 |                                  |                                           |     |
| Class III                           | 4.8 [2.8]               | 2.5 [1.9]                       | 1.7 [1.9]                        | 101.3 (<.001)                             | 61% |
| Class IV                            | 4.6 [2.7]               | 1.9 [1.7]                       | 1.4 [1.6]                        | 163.9 (<.001)                             | 67% |
| Coryllos tongue classification type |                         |                                 |                                  |                                           |     |
| Type I                              | 3.0 [2.3]               | 1.3 [1.7]                       | 0.7 [1.3]                        | 9.0 (.005)                                | 76% |
| Type II                             | 4.7 [2.6]               | 2.2 [1.9]                       | 1.3 [1.8]                        | 39.5 (<.001)                              | 61% |
| Type III                            | 4.5 [2.8]               | 2.3 [2.0]                       | 1.7 [1.7]                        | 65.4 (<.001)                              | 60% |
| Type IV                             | 4.9 [2.7]               | 2.2 [1.7]                       | 1.6 [1.7]                        | 152.7 (<.001)                             | 67% |
| Procedure type                      |                         |                                 |                                  |                                           |     |
| Tongue                              | 4.1 [2.9]               | 2.1 [1.8]                       | 1.4 [1.8]                        | 47.2 (<.001)                              | 64% |
| Both tongue and lip                 | 4.8 [2.7]               | 2.2 [1.8]                       | 1.6 [1.7]                        | 211.9 (<.001)                             | 64% |

\* RMI between preoperative and 30-day follow-up scores; lower scores on VAS indicate improvement.

*df* = degrees of freedom; RMI = relative mean improvement; SD = standard deviation; VAS = visual analog scale.

demonstrated that congenital ankyloglossia can hinder breastfeeding success and that frenotomy results in improvement.<sup>3,17,18</sup> In May 2015, the AHRQ determined that these studies were not of sufficient quality to conclude that frenotomy was beneficial in the setting of ankyloglossia. Our study is the first prospective cohort study to employ complementary, validated outcome measures to evaluate the effect of frenotomy on issues that affect breastfeeding success.

One of the most significant findings is that 78% of the infants who presented with breastfeeding symptoms in this referral sample had an isolated posterior tongue-tie (class III or class IV ankyloglossia). This large percentage of posterior tongue-ties likely reflects several factors: 1) the lactation community's increased awareness of the clinical entity as a cause for breastfeeding issues, and 2) potential treatment of anterior ankyloglossia in the community by primary care providers. We demonstrate that babies with posterior tongue-tie significantly improve postfrenotomy, similar to what is seen in babies with classic anterior tongue-tie. The implications of these findings are significant due to the fact that previous estimates for the incidence of ankyloglossia (4%–10%) refer mainly to anterior ankyloglossia.<sup>19–21</sup> Admittedly, the consideration to treat babies with posterior tongue-tie may represent a paradigm shift in our current understanding of frenotomy but does represent a new population of infants who could potentially benefit from this procedure. More importantly, it demonstrates a new population of babies who may otherwise wean because of difficulty in diagnosing lingual restriction that is palpable but not visible.

It is important to understand that maxillary labial restriction can also affect latch quality. A shortened labial frenulum prevents appropriate flanging of the upper lip. Additionally, a common clinical observation following lip-tie release is that the baby can open the mouth wider, facilitating a deeper latch, although this improvement can also be seen in children who undergo lingual frenotomy without maxillary labial frenectomy. The attachment location of the labial frenulum is typically at the gingival margin or on to the palate, comprising more than 93% of all normal labial frenula.<sup>22</sup> This current study demonstrated that 97% of babies had a low insertion of the labial frenulum, comparable to that reported by Flinck et al.<sup>22</sup> The criteria used to determine if the lip was tethered, therefore, is not the insertion point of the frenulum but rather if there is evidence of local restriction such as blanching of the frenulum with elevation, bony remodeling of the alveolar ridge, lip dimpling, and observed failure of lip flanging during nursing.

As has been demonstrated in other studies, nipple pain is a major indicator of ankyloglossia and is often the driving force behind premature weaning.<sup>2</sup> This study demonstrates nipple pain resolution following surgical release of ankyloglossia. Nipple pain was a common initial complaint, and treatment demonstrated improvement at the 1 week and 1 month time points across all age categories.

The other major symptom often focused on by lactation consultants and medical providers is poor infant weight gain. The data in this study demonstrate a significant increase in milk transfer rate (~155% improvement). With

improved mobility of the midtongue toward the palate, infants can improve seal and vacuum production, leading to more efficient milk transfer.<sup>23</sup> Furthermore, the authors have noticed improved stamina on the breast; when the tongue motion drives milk extraction rather than compensatory muscle movements, the baby does not fatigue.

Maternal self-confidence and self-efficacy are intimately intertwined with breastfeeding success.<sup>2</sup> The BSES-SF is highly reproducible, easy to use, and can identify mothers at high risk for breastfeeding cessation. Furthermore, it can serve as a tool to evaluate the efficacy of interventions. Dennis identified numerous factors that predicted higher maternal self-efficacy scores.<sup>24</sup> Other studies demonstrate the clear connection between disrupted lactation and postpartum depression.<sup>25,26</sup> We have demonstrated a significant increase in maternal self-efficacy at 1 week and 1 month postprocedure. Nanishi and colleagues indicated that a BSES-SF score below 50 was predictive of breastfeeding cessation<sup>27</sup>; the preoperative mean score in this study of 43.9 increased to a score of 56.5 at 1 month postprocedure. This improvement indicates a perception that the problems associated with disrupted lactation were surmountable and predicts improved longevity of breastfeeding.

Signs and symptoms attributed to gastrointestinal reflux are common in infancy. They are distressing to infants and families, and often result in use of medication.<sup>28</sup> Using a validated, patient-based instrument we were able to demonstrate a reduction in GERD symptoms scores after frenotomy, suggesting that lingual restriction may be associated with infant reflux symptoms, and that correction of latch abnormalities attributed to ankyloglossia significantly improves reflux scores at 1 week and 1 month postprocedure. This is the first study that has measured reflux symptomatology before and after frenotomy. It has been suggested that the mechanism that explains the improvement of the reflux scores is a resolution of aerophagia, although no direct confirmation has been obtained. Whereas infant reflux is multifactorial in nature, the reflux improvement seen in the cohort soon after the procedure points more to a decrease in aerophagia from a poor latch than it does spontaneous resolution of other factors contributing to reflux.

There are a number of caveats to consider when interpreting these study results. The study design did not incorporate a control group due to the difficulty of obtaining meaningful follow-up, because parents nearly universally opted for frenotomy. Given the low risk of frenotomy and the high risk of suboptimal breastfeeding, many experts do not feel it ethical to offer an untreated control study arm. This study, in response, evaluated symptom severity early on, which reduces the likelihood of reporting naturally progressive symptom improvement. We found improvement in symptom severity by 7 days postprocedure when patients were reassessed in the office, but it is important to note that patients were not routinely reassessed at the 1 month time point unless symptoms persisted (the 1 month postprocedure data were obtained remotely). We assessed relative change for each participant, which provides an indicator of improvement while considering individual variation in preoperative health status. Finally, although not

reported here, the principal investigator (B.A.G) has treated a large population of older children (>12 weeks) who have ongoing breastfeeding difficulties, suggesting that spontaneous resolution cannot be counted on.

The study was conducted using only a 1,064-nm diode laser, which is the principal investigator's (B.A.G) preferred interventional tool when performing these procedures. The surgeon was routinely performing the same procedure using tenotomy scissors prior to the adoption of, and transition to, laser frenotomy. The surgeon noticed no change in the success of the procedure during that transition period. This study investigated patient outcomes using the surgeon's current preferred tool, but the authors feel that surgical technique and achieving a full release of the tethered tissue is the key to success of the procedure. Additionally, it is important to recognize that this study focused only on the impact of ankyloglossia and tethered maxillary labial frenula on breastfeeding. This focus on the frenula is only a portion of the clinical picture surrounding the difficulty some infants have with breastfeeding. As part of the decision-making process for proceeding with frenulum release, the authors emphasize the importance of a comprehensive head and neck evaluation. Factors such as retrognathia and palatal abnormalities must be considered prior to proceeding with frenotomy.

This prospective study demonstrates significant improvement in breastfeeding outcomes that impact dyad quality of life, and therefore are likely to improve breastfeeding quality and duration. Maternal self-efficacy, nipple pain, infant reflux symptoms, and the rate of milk transfer all significantly improved with lingual frenotomy with or without maxillary labial frenectomy, indicating a strong consistency of treatment effect. Infants with posterior tongue-tie showed the same improvement as infants with more classical tongue-tie anatomy.

## CONCLUSION

Surgical release of tongue-tie/lip-tie results in significant average improvement in maternal and infant breastfeeding outcome measures. Improvements occur early (1 week postoperatively) and continue to improve 1 month postoperatively. Improvements were demonstrated in both infants with classic anterior tongue-tie and less obvious posterior tongue-tie. Based on this finding, clinicians should identify posterior tongue-tie as a potential etiology of infant latch problems and reduced breastfeeding quality. This study identifies a previously under-recognized patient population that may benefit from surgical intervention if abnormal breastfeeding symptoms exist.

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