

## **Making sense of studies which claim benefits of frenotomy in the absence of classic tongue-tie**

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### **Conflict of interest**

Dr Pamela Douglas is Medical Director of a non-profit and charitable organisation, The Possums Clinic (Possums for Mothers and Babies Ltd). This organisation sells two online products, the [Gestalt Breastfeeding Online Program](#), and the [Possums Sleep Film](#) [www.possumsonline.com](http://www.possumsonline.com). All revenue goes towards further development of evidence-based education programs for parents and health professionals.

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## **Abstract**

By performing an in-depth analysis of one high profile example, this article aims to help breastfeeding support professionals understand the methodological flaws that characterise recent studies claiming to show the efficacy of frenotomy for the diagnoses of posterior tongue-tie and upper lip-tie. The example study, by Ghaheri et al. (2016), does not address definitional confusion, or control for the effects of the passage of time. It does not consider the effects of caring attention, validation and lactation consultant support. It also does not consider the extensive research over the past three decades which has established that reflux in the first six months of life is benign, even though increased reflux frequency may correlate with unsettled infant behaviour. Ghaheri et al. (2016) rely upon the hypothesis that reflux is caused by excessive air swallowing in infants with poor latch due to posterior tongue-tie and upper lip-tie, which lacks credible physiological mechanisms or supporting evidence. The authors' claim that conducting a randomized controlled trial to investigate the efficacy of frenotomy would be unethical contradicts the basic principles of good science. This article argues that our breastfeeding women and their babies deserve the most rigorous scientific methods available, and acknowledgement of the biases inherent in less rigorous research, if we are to make appropriate decisions concerning intervention with frenotomy, and to prevent unnecessary oral surgery.

## **Key messages**

- The incidence of frenotomy for diagnoses of ankyloglossia and upper-lip tie in infants has increased exponentially in high income countries in the past decade
- In-depth analysis of one high-profile study which claims to demonstrate breastfeeding improvement after laser surgery for tongue-tie and lip-tie demonstrates serious methodological weaknesses
- The authors' claim that many experts consider it unethical to conduct a randomized controlled trial to investigate the efficacy of laser frenotomy because of the risks to mothers and babies of withholding laser surgery contradicts the basic principles of good science

## **Introduction**

In early epidemiological data, and anecdotally, the numbers of frenotomies performed on breastfeeding infants has increased exponentially in the past decade in high income countries (Joseph et al., 2016; Walsh, Links, Boss, & Tunkel, 2017). After decades of neglect of the impact of classic (or anterior) tongue-tie on breastfeeding, research prior to 2005 began to demonstrate the efficacy of frenotomy for breastfeeding problems in babies with classic tongue-tie (Hall & Renfrew, 2005). Most clinicians agree that prompt scissors frenotomy for a classic tongue-tie is often required, particularly if there are breastfeeding problems.

In our specialised breastfeeding clinic, parents often present after consulting with multiple breastfeeding support professionals (BSPs). We have observed that normal, though anatomically diverse, lingual and maxillary labial frenula are commonly diagnosed as posterior tongue-tie (PTT) and upper lip-tie (ULT) and referred for frenotomy, although underlying problems of fit and hold (latch and positioning) remain evident and respond well

to clinical intervention (Douglas, 2016a, 2016b; Wattis, Kam, & Douglas, 2017). For example, in our experience, approaches to fit and hold that have been demonstrated to increase the risk of nipple pain more than fourfold continue to be applied by many BSPs, who then recommend frenotomy for PTT and ULT if problems persist (Thompson et al., 2016).

Overall, studies into the efficacy of frenotomy are of poor quality, and characterised by author bias. Since 2005, the poorly defined concept of PTT has been conflated with classic tongue-tie, which confuses the research (Coryllos, Watson Genna, & Salloum, 2004 Summer). Systematic reviews show only low-level evidence that frenotomy is helpful for breastfeeding problems, and there is no reliable evidence that the diagnoses of PTT and ULT are meaningful or useful for breastfeeding pairs (Francis, Krishnaswami, & McPheeters, 2015; O'Shea et al., 2017; Power & Murphy, 2015).

Although providers of oral surgery claim that pre-post surveys and chart reviews demonstrate the efficacy of the diagnosis and surgical treatment of PTT and ULT (Benoiton, Morgan, & Bauley, 2016; Ghaheri, Cole, Fausel, Chuop, & Mace, 2016; L. A. Kotlow, 2016; O'Callahan, Macary, & Clemente, 2013; Pransky, Lago, & Hong, 2015; Siegel, 2016), these are notoriously biased research methodologies (Vassar & Holzmann, 2013).

**A high profile study which claims efficacy of laser frenotomy for posterior tongue-tie and upper lip-tie does not control for multiple confounders**

In order to help BSPs who are making decisions about the potential benefits of frenotomy for a mother-baby pair, this article performs an in-depth analysis of one recent high profile study, by Ghaheri et al. (2016), which claims to demonstrate the efficacy of laser frenotomy for infants diagnosed with oral ties in the context of breastfeeding problems.

In this study, 237 mothers self-reported significant improvements one week and one month after surgery on three scales: the Breastfeeding Self-Efficacy Scale-Short Form

(BSES-SF); a visual analog scale (VAS) for breastfeeding pain severity; and the revised Infant Gastroesophageal Reflux Questionnaire (I-GERQ-R).

This analysis is concerned with the 179 infants who were diagnosed with and treated for upper lip-tie (ULT) in the study, and the 184 who were diagnosed with posterior tongue-tie (PTT). The authors do not reliably demonstrate benefits of laser surgery for these infants, but confuse association with causation, in the context of failure to control for multiple potential confounders. The following examples are offered to illustrate how interpretive bias may have affected the reporting of their data (Kaptchuk, 2003).

### **Effects of expectation**

Ghaheri et al.'s parent-reported improvements may be due to the effects of both the lactation consultant's and Dr Ghaheri's communicated expectations, not oral surgery (2016). Expectation has a proven neurobiological effect on both health professional and parental experience (Brody & Miller, 2011; Colloca, Jonas, Killen, Miller, & Shurtleff, 2014; Meissner, Bingel, & Colloca, 2011). For example, placebo has been found to decrease parent reported unsettled infant behaviour by 40% or more (Harb, Matsuyama, David, & Hill, 2016; Jordan, Heine, Meehan, Catto-Smith, & Lubitz, 2006; Partty, Lehtonen, & Kalliomaki, 2015).

### **Effects of time**

#### 1. Breastfeeding self-efficacy increases over time without intervention

BSES-SF measures a woman's self-perceived ability to breastfeed her child. Her psychological confidence, as measured by the BSES-SF, is affected by multiple factors and does not always correlate with longer periods of exclusive breastfeeding (Souza & Fernandes, 2014). BSES-SF scores increased by eight points over the first four weeks postpartum in a randomised controlled trial of 781 women, regardless of whether or not a breastfeeding intervention was applied (Otsuka et al., 2014). In Ghaheri et al.'s (2016) study, 59% of the babies were under 4 weeks of age.

## 2. Nipple pain decreases over time without intervention

Nipple pain is a spectrum condition, commonly resulting from suboptimal fit and hold (Rennie, Cowie, Hindin, & Jewell, 2009; Thompson et al., 2016). Prevention where possible, and intervention from the first signs of nipple discomfort, damage or pain, is required in order to protect breastfeeding. However, nipple pain reduces in the first 7-10 days postpartum whether or not women receive intervention (Dennis, Jackson, & Watson, 2014; Jackson & Dennis, 2016). In the absence of classic tongue-tie, the improvement in nipple pain observed by Ghaheri et al. (2016) may be explained not only by the effects of lactation consultant support and the neurobiological effects of expectation, but also by the passage of time.

## 3. Milk transfer improves over time without intervention

Pre- and post-feeding weighs are a marker of breastmilk intake over time. Ghaheri et al. (2016) assessed milk transfer in a subset of 60 pairs, whose oral connective tissue anatomic classifications and ages are not defined, though this subset is elsewhere stated to be ‘a mixed age population (almost all older than 3 days)’ (Ghaheri & Cole, 2017). This poorly defined group showed improved milk transfer by weighing relative to time at the breast, at an unspecified point of time in the week prior and the week after the intervention, potentially spanning up to a fortnight. However, we would expect milk transfer to increase over time without intervention for the 59% of the Ghaheri et al. (2016) study who were less than 4 weeks of age (Sakalidis et al., 2013). We might also have expected to see improvement in milk transfer in those with classic tongue-tie who received frenotomy, if the anatomic classifications of this subgroup had been defined.

### **Effects of caring attention, validation, and lactation consultant support**

Non-surgical breastfeeding interventions have demonstrated an increase in the BSES-SF comparable to the increases observed in Ghaheri et al.’s (2016) study (Yi, Yim, & Chow, 2016). Ghaheri et al. (2016) do not define the nature of the lactation consultant interventions

mothers received in addition to the referral to Dr Ghaheri for oral surgery. The women's improved BSES-SF scores may be caused by the psychological effects of the caring attention, validation, and professional support offered by the lactation consultant, Dr Ghaheri, and his staff. Clinical support may also have been offered in the subsequent month but is not investigated.

### **Reflux occurs more frequently with higher levels of sympathetic nervous system arousal but is a benign marker**

The concept of Aerophagia Induced Reflux (AIR), caused by oral ties, has been proposed to explain the observed link between breastfeeding difficulty, and the cluster of signs often attributed to gastro-oesophageal reflux disease (GORD) (back-arching, increased frequency of reflux episodes, crying and not going to sleep when laid down, crying and fussing) (Kotlow, 2011; Kotlow, 2016; Siegel, 2016). It is hypothesised that infants with a tongue-tie or ULT swallow more air when breastfeeding, causing gastric distention, colic and reflux. In 2016, Siegel published a retrospective analysis of 1000 breastfeeding mother-baby pairs showing reduced parent-reported GORD signs in 71% of infants after he applied oral laser surgery and Kotlow also published surveys of 340 mother-baby pairs before, and 2 days and 2 weeks after, he applied laser surgery, showing a 93% reduction in signs of GORD.

However, both these studies are methodologically weak, demonstrating interpretive bias (Kaptchuk, 2003; Vassar & Holzmann, 2013).

An extensive body of research over the past three decades has carefully elucidated the physiological mechanisms of infant reflux (Douglas & Hill, 2011a; Douglas & Hill, 2011b; Douglas, Hill, & Brodribb, 2011). There is no evidence in barium X-ray, intra-oesophageal pH monitoring, or manometry studies to suggest that babies who have fussiness at the breast swallow more air than others; there is no evidence to suggest that air in the stomach is a cause of increased frequency or noxiousness of refluxate, or of oesophageal pain (Sherman et

al.,2009; Vandenplas et al., 2009) There is no evidence of air being swallowed during ultrasound assessments of successful breastfeeding, of breastfeeding with tongue-tie, or of breastfeeding with nipple pain (Garbin et al., 2013; D. Geddes, 2010; D. T. Geddes et al., 2008; McClellan, Kent, Hepworth, Hartmann, & Geddes, 2015). Large volumes of air are not normally observed in the stomachs of breastfeeding infants (Gridneva et al., 2017).

The AIR hypothesis acknowledges the link between breastfeeding difficulty and a cluster of symptoms that have been previously labelled as GOR or GORD, but does not consider the neurobiological model of unsettled infant behaviour (Douglas & Hill, 2013). This model is the first to acknowledge that breastfeeding/infant feeding difficulty have a significant role to play in cry-fuss problems and frequency of reflux. It proposes that breastfeeding difficulty and associated poor satiety result in hyperarousal of the infant's sympathetic nervous system (SNS) and hypothalamic-pituitary-adrenal (HPA) axis. Elevated SNS activity increases the frequency of reflux through known effects on gut motility, and on gastric contraction in particular (Douglas, 2013; Douglas, 2005).

The I-GERQ-R is designed to evaluate the severity of GOR symptomatology in infants by parent report (Kleinman et al., 2006). However, the I-GERQ-R score does not correlate with oesophageal discomfort or pain in breastfeeding infants, because the assumption that frequency of reflux, back-arching or unsettled behaviour correlates with gastro-oesophageal problems in this population has been disproven (Gieruszczak-Bialek, Konarska, Skorka, Vandenplas, & Szajewska, 2015; Sherman et al., 2009; Vandenplas et al., 2009). Refluxate is close to pH neutral for two hours after feeds, and does not cause acidic discomfort. Infant reflux is a normal physiological event, modulated by a range of factors including elevated SNS arousal. Babies cry when laid supine due to sensory need, not due to oesophageal pain or discomfort or aerophagia (Douglas & Hill, 2011a). Labelling reflux as a



medical condition increases parents desire for medical intervention, even when they are told that the treatment will not be effective (Scherer, Zikmund-Fisher, Fagerlin, & Tarini, 2013).

The change in the I-GERZ-R observed in Ghaheri et al.'s (2016) study may reflect downregulation of the infant SNS-HPA axis due to the neurobiological effects of parental expectation and lactation consultant support. These changes could also be due to the passage of time, since infant crying and fussing decreases between 6-16 weeks of life. It is important to note that placebo may reduce parental report of unsettled infant behaviour by at least 40% (Jordan et al., 2006).

### **Multiple other unproven assumptions**

Ghaheri et al. (2016) state that their 'study design did not incorporate a control group ... because ... many experts do not feel it ethical to offer an untreated control study arm.' Yet the risk of unintended outcomes for frenotomy for PTT and ULT (including oral aversion, scarring, haemorrhage and wound infection) has not been established; nor has it been established that surgical intervention (other than for classic tongue-tie) improves breastfeeding outcomes (Francis et al., 2015; O'Shea et al., 2017; Power & Murphy, 2015). The Assessment Tool for Lingual Frenulum Function has been demonstrated to be unreliable as a method of selecting those who will benefit from frenotomy, despite adequate inter-observer reliability (Amir, James, & Donath, 2006; Madlon-Kay, Ricke, Baker, & DeFor, 2008; Ricke, Baker, & Madlon-Kay, 2005). The list of problems that the mothers bring to Dr Ghaheri are common presentations in breastfeeding babies, with multiple causes other than oral ties. The Ghaheri et al. (2016) study is based upon multiple unproven assumptions concerning the validity of the diagnoses of PTT and ULT, the reliability of the assessment tools used, and the cause of measured outcomes.

### **Conclusion**

Given the exponential increase in prevalence of frenotomies for the diagnoses of PTT and ULT, a randomised controlled trial comparing surgical intervention with a standardised breastfeeding fit and hold intervention would address these methodological problems, and is urgently needed.

In the meantime, BSPs who make decisions throughout their working day concerning the potential benefits of frenotomy in infants with breastfeeding problems need to be aware of methodological weaknesses and interpretive biases in provider studies. Overtreatment is a serious problem in the provision of healthcare in high income countries (Brownlee et al., 2017). Breastfeeding families deserve the best possible science so that infants do not receive unnecessary surgical interventions when problems arise.

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