

Systematic Review

# The effect of frenotomy in infants with ankyloglossia on maternal nipple pain – a systematic review

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Dan Med J 2025;72(1):A06240378. doi: 10.61409/A06240378

## ABSTRACT

**INTRODUCTION.** Ankyloglossia in breastfeeding infants has been proposed to cause maternal nipple pain. Lingual frenotomy has been cited to reduce maternal nipple pain. The aim of this systematic review was to investigate if frenotomy in infants with ankyloglossia and breastfeeding problems reduces maternal nipple pain.

**METHODS.** We conducted a systematic literature search for RCTs comparing frenotomy to a sham procedure or usual care in mother-infant dyads with ankyloglossia and maternal nipple pain. Maternal nipple pain was registered as the main outcome. We conducted a meta-analysis and assessed the risk of bias using Rob 2.0 and the quality of evidence, adopting the GRADE approach.

**RESULTS.** Five RCTs were included in the review. Three RCTs were used for the meta-analysis. The meta-analysis showed a significant pre-post intervention reduction in maternal nipple pain in the frenotomy group compared with the comparison group: mean difference = -1.23; 95% confidence interval: -1.88 to -0.57. The overall bias was assessed to range from “some concerns” to “high”. The quality of evidence for the assessed outcome, maternal nipple pain, was classified as “low” to “very low”.

**CONCLUSIONS.** We found that frenotomy reduced maternal nipple pain in the short term. Despite being statistically significant, the clinical relevance of a 1.2-point reduction on a ten-point VAS must be questioned. Due to a considerable risk of bias along with a low study quality, the definitive benefit of frenotomy on maternal nipple pain remains unproven. Hence, quality large-scale RCTs are warranted.

## KEY POINTS

- This study reported a small, yet statistically significant, reduction in maternal nipple pain following infant frenotomy. The clinical relevance of this small reduction is questionable.
- The overall risk of bias ranged from “some concerns” to “high”. The quality of evidence was “low” to “very low”.
- The definitive benefit of frenotomy on maternal nipple pain remains unproven.
- Quality large-scale RCTs are warranted.

Ankyloglossia is a common congenital condition. The prevalence of ankyloglossia is reported to fall in the 4-11% range among newborns [1, 2]. This variability reflects the absence of internationally accepted diagnostic criteria. Clinicians describe ankyloglossia as an unusually short, thick and tight lingual frenulum, possibly resulting in restricted tongue movement.

Several diagnostic classification systems exist. Among the most commonly used is the Corryllos Classification System, which is a method based solely on the anatomical appearance [3]. In contrast, the Hazelbaker Assessment Tool for Lingual Frenulum Function (ATLFF) and the Tongue-tie and Breastfed Baby (TABBY) assessment tool assess both the tongue functionality and the appearance of the frenulum [4-6].

Ankyloglossia can be treated with frenotomy; a minor surgical procedure whereby the tongue-tie is cut and released. This can be easily performed using surgical scissors, a scalpel or a laser.

Over the past few decades, the incidence of ankyloglossia and the frenotomy rate have been increasing. A Danish study exploring the 1996-2015 period reported a more than quadrupling of the incidence of children diagnosed with ankyloglossia and more than a sevenfold increase in frenotomy [7]. One US study, covering the 1997-2012 period, reported an almost tenfold increase in the diagnosis of ankyloglossia and an 866% increase in frenotomy [8]. Another recent study reported a dramatic increase in publications discussing ankyloglossia and its impact on breastfeeding outcomes in the 1987-2022 period [9]. This reflects an overall increased clinical concern over ankyloglossia.

Ankyloglossia is one of several factors that may contribute to breastfeeding problems. A recent systematic review found the total prevalence of breastfeeding difficulties among infants with ankyloglossia to be 49%. The authors reported the most common symptoms associated with ankyloglossia to be maternal nipple pain and poor latch, with a prevalence of 29.9% and 28.6%, respectively. Furthermore, before intervention, early undesired weaning occurred in 20% of infants with ankyloglossia [10]. Similarly, a review stated that sucking/latching and maternal nipple pain were considered to be the main reasons for abandoning breast-feeding [11].

Early undesired weaning is far from ideal as breastfeeding has health-promoting effects for both mother and child [12]. The WHO recommends exclusive breastfeeding for infants under six months of age [13]. Among infants born in the US in 2019, 83% started out receiving some breast milk. At six months, only 24.9% were exclusively breastfed [14]. Among infants born in Denmark in 2022, 85.8% and 13.7% were exclusively breastfed at two weeks and six months, respectively [15]. This underlines the importance of investigating the effect of frenotomy on nipple pain and poor latch.

One of the most comprehensive and thorough reviews on the subject is a systematic Cochrane review from 2017. The authors did not find frenotomy to have a consistent positive effect on infant breastfeeding. However, they found that frenotomy reduced breastfeeding mothers' nipple pain in the short term [16]. Nevertheless, there may be some serious concerns regarding the latter analysis as it was based on group differences in post-intervention maternal nipple pain between frenotomy and controls and was not a comparison of the differences in individual pre- and post-frenotomy pain scores. Additionally, more randomised controlled trials (RCTs) on the subject have been published after the Cochrane review. Overall, a new meta-analysis is warranted.

Therefore, the present study aimed to conduct a systematic review and meta-analysis investigating if frenotomy in children younger than four months of age with ankyloglossia and breastfeeding problems decreases self-reported maternal nipple pain.

## Methods

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines [17]. The protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO; CRD42024510960) and is publicly available.

Under Danish law, this systematic review and meta-analysis of aggregated published data did not require

approval from the institutional review board or the ethical committee as it employed deidentified patient data.

The review was structured by the Population, Intervention, Comparison and Outcome (PICO) framework [18]. The population of interest was mother-infant dyads in which the infant had ankyloglossia and the mother experienced breastfeeding problems, specifically maternal nipple pain. The intervention group underwent a lingual frenotomy. This group was compared with infants who underwent a sham procedure or were managed conservatively. The outcome was self-reported maternal nipple pain.

This review aimed to answer the following question: Does frenotomy in infants younger than four months with ankyloglossia and breastfeeding problems reduce maternal nipple pain?

## **Study inclusion**

The study selection was guided by the PICO criteria. Studies were eligible if they reported on 1) mature infants under four months of age with ankyloglossia and breastfeeding problems; 2) pre- and post-intervention maternal nipple pain scores on a validated pain scale; and adopted 3) a randomised controlled study design. Studies including children with major comorbidity and studies with a high cross-over (more than 20%) before the first follow-up were excluded.

## **Literature search and selection**

The search strategy was developed with assistance from a professional research librarian. PubMed, Embase, CINAHL, PsycInfo, Web of Science and the Cochrane Library were searched. Database searches were conducted on 14 and 15 December 2023, and follow-up searches were conducted on 1 and 8 May 2024. Searches consisted of terms related to ankyloglossia, frenotomy, infants, pain and breastfeeding. The language was restricted to English, Danish, Swedish and Norwegian (for the detailed search strategy, see [Supplementary Table 1](#)). We searched previous reviews, including cross references. Search results were uploaded to EndNote (Clarivate Analytics, London, UK), and duplicates were removed.

The eligibility of the studies was initially assessed based on titles and abstracts followed by full-text evaluation. The screening and assessment of study eligibility were performed independently by two reviewers (LA and TO). Any disagreements were resolved through discussion.

## **Data extraction**

The extracted data included study characteristics, demographics, ankyloglossia assessment, time to follow-up and validated scores of maternal nipple pain before and after the intervention. When necessary, the authors of the included studies were contacted for further information. Data were recorded in Microsoft Word.

## **Risk of bias and quality of evidence**

Two reviewers (LA and TO) independently assessed the included RCTs for bias using the modified RoB 2.0, which allows an assessment of the overall risk of bias [19]. Any discrepancies were resolved through discussion.

We used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to assess the quality of the evidence for frenotomy in terms of maternal nipple pain [20]. The GRADE approach included four possible ratings: very low, low, moderate and high level of quality. By default, RCTs were considered high quality but downgraded one or two levels for serious or very serious limitations, respectively. Downgrading was based on the degree of risk of bias, consistency across studies, directness of the evidence, precision of estimates and presence of publication bias.

## **Data synthesis and meta-analysis**

If studies offered frenotomy to the comparison group after the first follow-up, we included outcome data only

from the first follow-up. In the meta-analysis, we compared the pre- and post-frenotomy nipple pain differences in the intervention group with similar changes in the control group, consisting of a sham operation or conservative care.

## Statistics

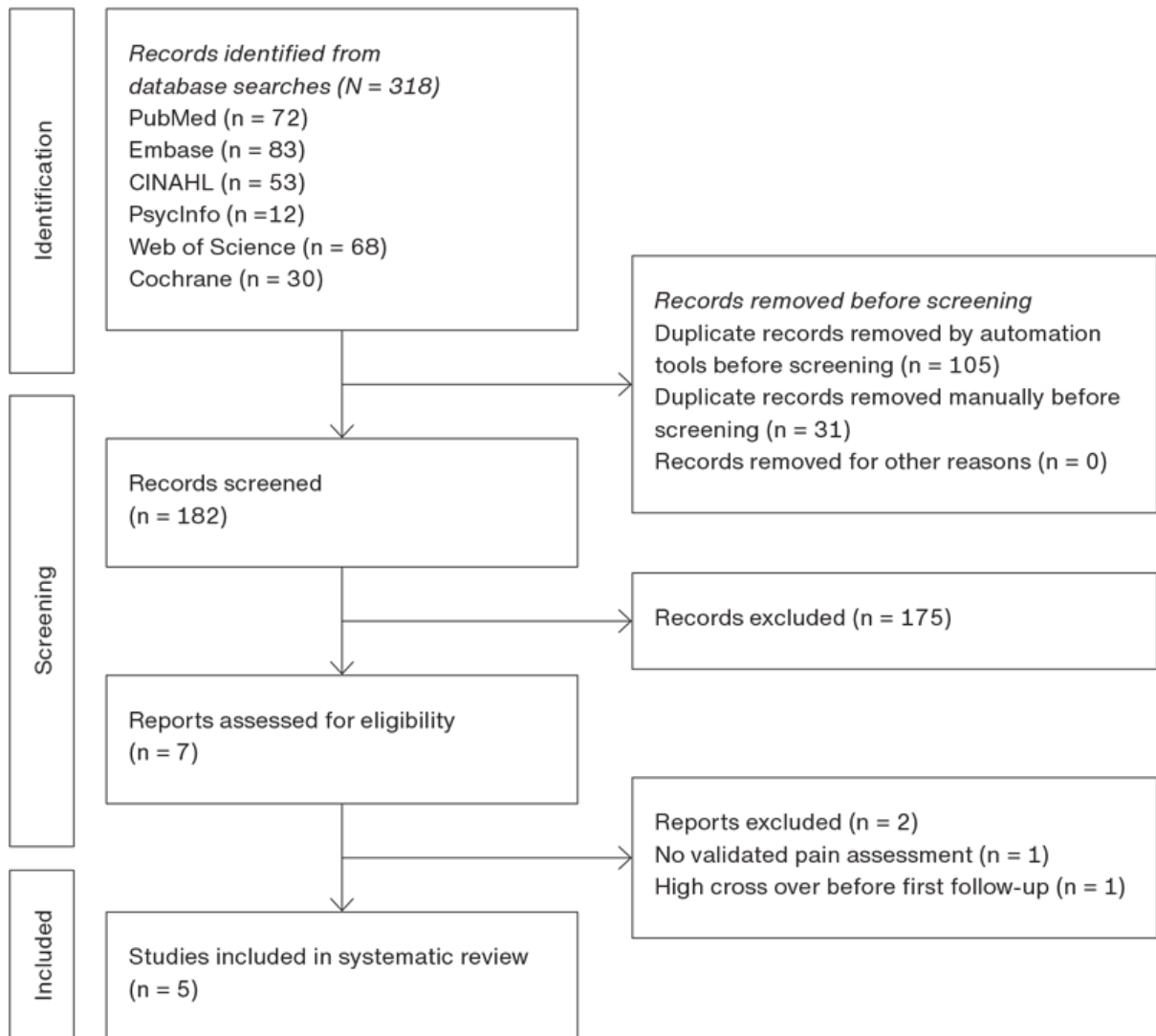
The meta-analysis was conducted using the “meta” suite of commands in STATA 18.0. Quantitative outcomes captured in multiple studies were eligible for meta-analysis. The overall mean difference (unstandardised) and 95% confidence interval (CI) were determined by the fixed effect model, employing the inverse-variance weighting method. A p-value below 5% was considered statistically significant. Heterogeneity measures  $H^2$  and  $I^2$  were calculated, and heterogeneity testing was reported.

## Results

### Results of the literature search

The database searches identified 318 articles. After duplicate removal, 182 articles were screened, and five studies were included in the final systematic review (**Figure 1**) [21-25]. In total, the five studies encompassed 263 mother-infant dyads, within which 134 infants underwent frenotomy. Three studies, totaling 180 mother-infant dyads were used for the meta-analysis [21-23]. One study was excluded from the review due to lack of a validated pain scale [2]. Another study was excluded due to high cross-over before the first follow-up [26]. The study by Emond et al. had 17% cross-over before the first follow-up. This was considered low, and the study was therefore included [22]. We encountered no disagreements between assessors (LA and TO) in relation to the inclusion or exclusion of studies. The main characteristics of the five included studies are presented in **Table 1**.

**FIGURE 1** Study inclusion and exclusion flow diagram.  
Primary and follow-up search totals were summed.



**TABLE 1** Characteristics of included studies.

Reference	Infants (frenotomy/controls), n	Age, days		Tongue-tie assesment	Ankyloglossia severity, type, median (IQR) or mean $\pm$ SD	Follow-up, days	Pain scale
		range	median				
Ghaheri et al., USA, 2022 [21]	47 (23/24)	21-122	39	Coryllos	Posterior tongue-tie Type III (n = 35) Type IV (n = 12)	10	VAS
Emond et al., UK, 2014 [22]	105 (53/52)	< 14	Intervention group: 6 Comparison group: 9	HATLFF-short form	Mild-moderate degree of tongue-tie Nonsurgical arm, total: 8 (7-11) Surgical arm, total: 13.5 (11-16)	5	VAS
Berry et al., UK, 2012 [23]	28 (14/14)	6-115	23	-	-	Immediate	VAS
Buryk et al., USA, 2011 [24]	58 (30/28)	1-35	6 <sup>a</sup>	HATLFF	Significant tongue-tie <sup>b</sup> Nonsurgical arm: Function: 8.4 $\pm$ 2 Appearance: 5.7 $\pm$ 2.2 Surgical arm: Function: 9.4 $\pm$ 2.6 Appearance: 6.0 $\pm$ 1.6	Immediate	SF-MPQ
Dollberg et al., Israel, 2006 [25]	25 (14/11)	1-21	-	- <sup>c</sup>	-	Immediate	VAS

HATLFF = The Hazelbaker Assesment Tool for Lingual Frenulum Function; IQR = interquartile range; SD = standard deviation; SF-MPQ = Short-Form McGill Pain Questionnaire; VAS = visual analogue scale (0-10).

a) Mean.

b) Defined as HATLFF scores: function scores > 11 or appearance score < 8.

c) Ankyloglossia was defined as "the inability of the infant to protrude the tip of the tongue over the lower gum line while the tip was tied to the floor of the mouth by a tight cord of a frenulum, and the tongue became heart-shaped when lifted up".

## Maternal nipple pain

Three of the five included studies showed a significant pre-post intervention reduction in maternal nipple pain in the frenotomy group compared with the pre-post intervention reduction in maternal nipple pain in the comparison group (Table 2).

**TABLE 2** Summary of findings.

Reference	n	Follow-up, days	Pain scale	Ankyloglossia severity	Effect of frenotomy, +/- <sup>a</sup>	Overall bias <sup>b</sup>	Quality <sup>c</sup>
Ghaheri et al., 2022 [21]	47	10	VAS	Posterior tongue-tie	+	High	Low-Very low
Emond et al., 2014 [22]	105	5	VAS	Mild-moderate	-	High	
Berry et al., 2012 [23]	28	Immediate	VAS	-	-	Some concerns	
Buryk et al., 2011 [24]	58	Immediate	SF-MPQ	Significant tongue-tie	+	Some concerns	
Dollberg et al., 2006 [25]	25	Immediate	VAS	-	+	High	

SF-MPQ = Short-Form McGill Pain Questionnaire; VAS = visual analogue scale (0-10).

a) +: the study showed a significant reduction in maternal nipple pain from pre- to post-intervention in the frenotomy group compared with the reduction in the comparison group; -: the study did not show a significant reduction in maternal nipple pain from pre- to post-intervention in the frenotomy group compared with the comparison group.

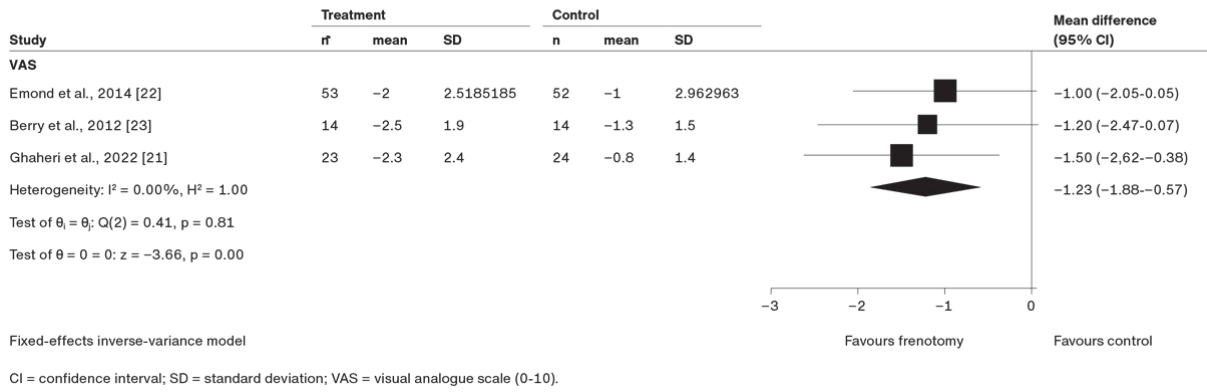
b) Quality assessment of randomised controlled trials assessing the effect of frenotomy on maternal nipple pain using the Cochrane Risk of Bias Assessment Tool (RoB 2.0).

c) The quality of evidence for the assessed outcome; maternal nipple pain.

None of the five included studies reported any adverse effects following frenotomy.

The meta-analysis showed a significant reduction in maternal nipple pain from pre- to post-intervention in the frenotomy group compared with the reduction observed in the comparison group: mean difference = -1.23; 95% CI: -1.88 to -0.57 (heterogeneity:  $I^2 = 0\%$ ,  $H^2 = 1.00$ ) (Figure 2). One study was excluded from the meta-analysis as pre- and post-intervention maternal nipple pain was not reported separately and numerically for the frenotomy and comparison group. Of note, the authors stated that a significant pain score decrease was recorded after frenotomy compared to sham ( $p = 0.001$ ) [25]. We did not combine visual analogue scale (VAS) and Short-Form McGill Pain Questionnaire (SF-MPQ) scores for the meta-analysis due to their different measurement units. Consequently, another study was excluded from the meta-analysis. This study found that SF-MPQ scores decreased from 16.77 (standard deviation (SD):  $\pm 1.88$ ) to 4.9 (SD:  $\pm 1.46$ ) in the frenotomy group and from 19.25 (SD:  $\pm 1.9$ ) to 13.5 (SD:  $\pm 1.5$ ) in the sham groups, from before to immediately after the procedure, respectively, yielding an effect size of 0.38. The frenotomy group improved significantly more than the sham group ( $p < 0.001$ ) [24].

**FIGURE 2** Meta-analysis: the effect of frenotomy on maternal nipple pain. The meta-analysis showed pre-post intervention reduction in maternal nipple pain in the frenotomy group compared with the pre-post intervention reduction in maternal nipple pain in the comparison group.



## Risk of bias assessment and quality of evidence

The overall bias for the five included studies was assessed and ranged from “some concerns” to “high” (Table 2 and [Supplementary Table 2](#)).

The quality of evidence for the assessed outcome, maternal nipple pain, was classified as “low” to “very low” due to the high risk of bias, inconsistent blinding and small study populations (Table 2).

Despite the inclusion of only five studies, we observed considerable heterogeneity between studies in terms of variation in follow-up, different tools used for assessing ankyloglossia, variation in the grade of severity of ankyloglossia among included participants, and the use of various scales to determine maternal nipple pain.

Furthermore, all studies offered frenotomy to participants initially allocated to the comparison group, which the majority accepted, resulting in a very short follow-up period before cross-over.

## Discussion

### Summary of main results and quality of evidence

The objective of this systematic review was to investigate if frenotomy in children younger than four months of age with ankyloglossia and breastfeeding problems decreases maternal nipple pain. After conducting a systematic literature search, we identified five RCTs meeting the inclusion criteria. The meta-analysis ( $n = 180$ ) showed a statistically significant pre-post intervention reduction in maternal nipple pain in the frenotomy group compared with the comparison group: a difference in mean change in maternal nipple pain of  $-1.23$  point on a ten-point scale. The clinical relevance of this may be questioned. The quality of evidence for the assessed outcome, maternal nipple pain, was classified as “low” to “very low”. This was due to a high risk of bias, inconsistent blinding and small study populations. In addition, we assessed the risk of bias to fall in the range from “some concerns” to “high”; hence, the results should be interpreted with some caution.

### Comparison with existing literature

In line with prior systematic reviews and meta-analyses, we found that maternal nipple pain decreased significantly after frenectomy [16, 27, 28]. Similar to our review, two systematic reviews reported concerns about the quality of the evidence [16, 28].

A systematic review including 20 original research articles reported on maternal nipple pain before and after frenotomy in children with ankyloglossia under one year. Four of the 20 studies were RCTs and two of these were

included in our review. In 19 of the 20 studies, the authors found a decrease in maternal nipple pain after frenotomy. The improvement was reported to occur immediately after frenotomy and until two weeks after the procedure. As mentioned by the authors, the included studies had several methodological limitations [29]. Furthermore, the authors did not assess the quality of evidence.

A systematic review from 2015 included 29 studies: five RCTs (four of which were also included in our review), one retrospective cohort and 23 case series. The authors concluded that *“a small body of evidence suggests that frenotomy may be associated with mother-reported improvements in breastfeeding, and potentially in nipple pain, but with small, short-term studies with inconsistent methodology, the strength of the evidence is low to insufficient”* [30].

Some studies found the evidence sufficient to recommend frenotomy in infants with ankyloglossia and breastfeeding problems in terms of maternal nipple pain [11, 27].

While no serious complications were reported among the 263 infants in the five trials included in this review, other reports described complications following frenotomy. The New Zealand Pediatric Surveillance Unit prospectively surveyed infants aged less than one year in New Zealand for a two-year period. They identified 23 serious complications following frenotomy, yielding a rate of moderate to severe complications in 1% of infants undergoing frenotomy. The total annual incidence of complications after frenotomy was 13.9 per 100,000 infants. Among these, 75% required admission to hospital [31]. A recent systematic review investigated major complications from tongue-tie release in pediatric patients. They found 47 major complications reported in 34 patients, including poor feeding, hypovolemic shock, apnoea, acute airway obstruction and Ludwig angina. They concluded that reporting of complications after frenotomy is lacking [32].

A variety of consequences have been proposed to be associated with ankyloglossia. Poor latch/breastfeeding, along with maternal nipple pain, is reported to be one of the symptoms most commonly associated with ankyloglossia [10]. As mentioned in the introduction, a Cochrane review did not find frenotomy to have a consistent positive effect on infant breastfeeding [16]. This was based on four of the five RCTs also included in the present study. The fifth RCT was not included in the Cochrane review due to later publication. This RCT concluded that the release of posterior tongue-tie statistically significantly improved objective infant feeding parameters [21].

A cohort study from 2024 found no significant difference in the prevalence of exclusive and total breastfeeding at one, four and six months between children with defined/suspected ankyloglossia and those without ankyloglossia [33].

Importantly, not all infants with ankyloglossia have breastfeeding problems [10, 34].

## **Strengths and limitations**

A strength of our systematic review was the stringent inclusion criteria adopted, ensuring the inclusion of only the highest quality research articles available.

We assume that the pre-post intervention reduction in pain has greater clinical relevance than just the post-intervention nipple pain value. Therefore, we believe a strength of this study is that we compared the pre-post-intervention reduction in maternal nipple pain in the intervention group with the pre-post-intervention reduction in the comparison group. This contrasts with a Cochrane review that simply compared the post-intervention nipple pain in the intervention group with the same in the comparison group [16]. Nonetheless, we essentially reached similar results and conclusions.

A limitation of this study was the inability to include all studies using VAS as pain assessment in the meta-analysis. This was due to one RCT not reporting VAS separately and numerically for the frenotomy and



comparison group. We contacted the author to obtain this information but unsuccessfully [25].

A consequence of only assessing the outcome before cross-over was a short follow-up period, ranging from immediately to a maximum of ten days. This limited our study to only assess the short-term effects of frenotomy.

### Association with clinical practice

Our systematic review supports that frenotomy is associated with a statistically significant reduction in maternal nipple pain. However, we question the clinical relevance of the observed difference in mean change in maternal nipple pain of -1.23 points on a ten-point scale. We find the clinical relevance of the magnitude of the effect doubtful. In addition, the long-term outcome of maternal nipple pain, such as the duration and exclusiveness of breastfeeding, cannot be inferred from the present study. Furthermore, owing to the risk of bias ranging from “some concerns” to “high” and the quality of evidence being assessed as “low” to “very low”, we infer that the definitive positive effect of frenotomy on maternal nipple pain has yet to be proven.

Accepting the absence of quality evidence, we recommend that health professionals advise and treat their patients according to their national guidelines or consensus statements. For instance, health professionals in Denmark should use the Danish National Clinical Guideline [35]. New clinical guidelines/consensus statements should be prepared jointly by health professionals from various relevant and related fields to provide patients with more consistent evidence-based advice and treatment.

### Implications for future research

This research area would benefit from quality RCTs with large populations, correct blinding, utilisation of validated ankyloglossia assessment tools and pain scales, and both short and long-term follow-up.

### Conclusions

We found that frenotomy reduces maternal nipple pain in the short term. Despite being statistically significant, the clinical relevance of a 1.2 point reduction on a ten-point VAS must be questioned. Furthermore, the overall risk of bias varied from “some concerns” to “high”, and the quality of evidence was “low” to “very low”. Hence, the definitive benefit of frenotomy on maternal nipple pain remains unproven.

To determine the effects of frenotomy on maternal nipple pain, high-quality, large-scale RCTs are warranted.

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**Accepted** 5 November 2024

**Published** 12 December 2024

**Conflicts of interest** Potential conflicts of interest have been declared. Disclosure forms provided by the authors are available with the article at [ugeskriftet.dk/dmj](https://ugeskriftet.dk/dmj)

**References** can be found with the article at [ugeskriftet.dk/dmj](https://ugeskriftet.dk/dmj)

**Cite this as** Dan Med J 2025;72(1):A06240378

doi 10.61409/A06240378

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<https://content.ugeskriftet.dk/sites/default/files/2024-11/a06240378-supplementary.pdf>

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