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Evaluation of the effects of high-level laser and electrocautery in lingual frenectomy surgeries in infants: protocol for a blinded randomised controlled clinical trial

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ABSTRACT

Introduction Ankyloglossia (tongue-tie) is an anomaly characterised by an abnormally short, thick or small lingual frenulum that restricts tongue movements. This condition is considered one of the factors that can interfere with breast feeding by diminishing the ability of the newborn to latch adequately. According to the Brazilian Health Ministry, the prevalence of this anomaly among newborns is 3%–16%. Frenectomy is the most suitable surgical procedure for the treatment of ankyloglossia. The aim of this study is to compare the performance of electrocautery and high-power diode laser as forms of frenectomy.

Methods and analysis The proposed study will be a randomised, controlled, blind clinical trial involving the participation of healthy infants 0–3 months of age with breastfeeding difficulty and a diagnosis of tongue-tie with an indication for lingual frenectomy. The guardians will receive clarifications regarding the procedures and will authorise the participation of the infants by signing a statement of informed consent. A non-blinded researcher will perform the screening and procedures and a blinded researcher will perform the postoperative evaluations. Fifty-six infants will be randomly allocated into two groups (n=28): the electrocautery group or the high-power laser group. The preparation of the patients, asepsis and infection control procedures will rigorously follow biosafety norms. For both groups, patient histories will be taken, clinical evaluations will be performed and a standardised photograph of the lingual frenulum will be taken before surgery. The Bristol Tongue Assessment Tool will be used. We will evaluate pain in the mother during breast feeding before, immediately after, and 15 days after surgery.

Ethics and dissemination This protocol was submitted to the Research Ethics Committee of Nove de Julho University, having been given a favourable opinion (Number: 4387769). Results will be submitted to international peer-reviewed journals and presented at international conferences.

Trial registration number NCT04487418.

Strengths and limitations of this study

- The study will compare a more conventional treatment (electrocautery) to a more current therapy (high-power diode laser), giving an aspect of innovation to the research.
- The evaluation of the lingual frenum in infants and determination of its association with breast feeding.
- Difficulty in handling and containing the infants during surgery.
- Difficulty in evaluating the surgical wound is a limitation.
- The best postoperative result is observed in infants who are exclusively breast feeding when compared with babies who are bottle-fed.

INTRODUCTION

Ankyloglossia (tongue-tie) is a congenital oral anomaly characterised by a short, tight lingual frenulum that affects the movements and functions of the tongue, such as sucking, speech and eating.[1] This condition can be found in newborns and children as well as adolescents and adults.[2]

Tongue-tie in infants is related to difficulty breast feeding, choking or spitting up, delayed speech development or deterioration in speech and behavioural problems.[3 4] Lingual frenectomy (lingual frenulum reposition) is a less invasive technique and is therefore more recommended for infants. The surgery is performed conventionally with a scalpel or surgical scissors or with thermal techniques, such as electrocautery or high-power laser.[2 5–7] The prognosis of lingual frenectomy is favourable when early diagnosis and intervention are performed.[5]

Frenectomy improves tongue posture and movements, oral functions, lip posture and oral communication.[8 9] Multidisciplinary follow-up with a paediatrician, speech therapist and paediatric dentist is fundamental to the proper diagnosis and indication for surgery.

Labial and lingual frenectomies may be performed for different orthodontic, periodontal and functional reasons. The prevalence of tongue-tie in newborns ranges from 4% to 16% and this condition occurs more often in males, with a male-to-female proportion of 2.5:1.[8]

The use of an appropriate protocol for the evaluation of the lingual frenulum could be helpful in determining the indication for speech therapy or surgery. The evaluation of all patients before and after frenectomy and speech therapy is crucial to providing scientific evidence for decision making, which is better for the patient.[9]

The Bristol Tongue Assessment Tool (BTAT) was developed based on clinical practice and the Hazelbaker Assessment Tool for Lingual Frenulum Function. This is an objective measure that is easy to administer for the determination of the severity of tongue-tie, the selection of infants that may benefit from surgical intervention (frenotomy or frenectomy), and the monitoring of the effect of the procedure. The BTAT components are (1) appearance of the tongue tip, (2) attachment of the frenulum to the lower gum edge, (3) lift of the tongue and (4) protrusion of the tongue. The scores obtained for the four components are summed, with the total ranging from 0 to 8 points. A score of 0–3 points indicates a potential serious abnormality of tongue function.[10 11]

In infants with tongue-tie, one should always consider whether this condition interferes with breast feeding. Healthcare providers who work with nursing mothers and newborns must perform a routine breastfeeding assessment. For such, the diagnosis is complemented with the use of the Breastfeeding Assessment Protocol proposed by the United Nations International Children's Emergency Fund (UNICEF).[12]

In 1995, the US Food and Drug Administration approved the use of lasers in dental procedures involving soft tissues, gums, periodontal ligaments and fibres, tongue support tissues, mucositis, hyperplasia, tumours and lesions.[3 13 14] Some studies suggest that frenulum surgery with a high-power laser is a good alternative to surgery with a conventional or electric scalpel. Patients report higher levels of satisfaction, with fewer complications that affect speech and chewing and a less painful postoperative period, minimising the need for analgesics or anti-inflammatory agents.[7 13]

Lasers are classified by emission power (low or high).[6 15] The decision for which power to use is based on the biological characteristics and optical properties of the target tissue, the chromophores present, the emission mode, irradiation technique, exposure time and intensity (power density or irradiance). Lasers have different photothermal effects on soft tissues, such as coagulation, surface vaporisation, incision and even carbonisation.

High-power laser (diode, argon, neodymium: YAG, erbium: YAG, erbium, chromium: YSGG and carbon dioxide) is an effective modality in surgical procedures involving soft tissues. The effects of a high-power laser include increased haemostasis and the sealing of microvessels, minimal or no bleeding, a precise cut and better viewing of the surgical field. Other benefits include reductions in postoperative pain and inflammation, accelerated tissue repair, a reduction in the formation of keloids, a lower occurrence of complications related to speech and chewing, satisfaction on the part of patients and parents, and immediate access to functions such as nutritive sucking, breast feeding, phonetics and swallowing.[6 7 16]

According to some studies, thermal damage is three to five times deeper after electrocautery than surgical laser.[17 18] The surgical technique consists of the administration of a small quantity of anaesthetic (topical anaesthesia is sometimes sufficient) and following the vertical axis of the frenulum until the wound presents a linear shape; the laser is then administered transversely until the wound takes on a rhomboidal shape.[13]

Methods

The aim of the proposed blinded, randomised, controlled clinical trial is to analyse the beneficial effects of a high-power laser application in frenectomy and the postoperative period in comparison to the conventional procedure with electrocautery.

This protocol follows the Standard Protocol Items for Randomised Trials recommendations, as displayed in table 1.

The study began in September 2020 with the recruitment of patients and its completion is planned for December 2021.

Participants

Inclusion criteria

Healthy infants 0–3 months of age with a diagnosis of tongue-tie scored 0–3 points on the BTAT determined by a speech therapist, dentist or paediatrician and difficulty breast feeding.

Exclusion criteria

Infants with congenital or systemic abnormalities, such as blood dyscrasia, haemophilia, diabetes, nutritional deficiencies, immunodeficiency, those with abnormalities of the oral cavity, those under medical treatment and using medication, and those not well on the day of the surgical procedure will be excluded from the study.

Patient and public involvement

The guardians of the patients were not involved in the design of this study. After the data analysis, the guardians will be given the opportunity to participate in a result-sharing meeting if they so desire. The consent form for the surgery signed by guardians of the participants explains that the storage of data for each participant and family member is within the terms of confidentiality.

Table 1 Schedule of enrolment, interventions and assessments of study

	Study period			
	Allocation			Close-out
	Enrolment	Postallocation		
		0*	t_1	t_2
Enrolment				
Eligibility screening	X			
Informed consent	X			
(List other procedures)	X			
Allocation	X			
Interventions				
(Intervention A)		X	X	X
(Intervention B)		X	X	X
Assessments				
Bristol Tong Assessment tool		X	X	X
Standardised Photograph		X	X	X
Breastfeeding assessment (VAS scale)		X	X	X
Surgery/lingual frenectomy		X		

*0=baseline, t_1=immediately after treatment, t_2=15 days after the treatment.
VAS, Visual Analogue Scale.

Sample calculation

Due to the lack of previous studies on the results of infants submitted to frenectomy, it was not possible to calculate the sample size using known data. Thus, the sample was calculated using an estimate of the effect size, considering 0.25 as the minimum clinically relevant different between groups. The sample size was calculated based on the study entitled 'A flexible statistical power analysis programme for the social, behavioural and biomedical sciences. Behaviour Research Methods' (2007)[19] and using repeated-measures analysis of variance (ANOVA) with the aid of the G*Power program. Fifty-six infants will participate in the study.

Randomisation

The participants will be randomly allocated to two groups using a randomisation site (randomisation.com):

G1-surgery with electrocautery (n=28).

G2-surgery with high-power diode laser (n=28).

Blinding

A non-blinded researcher will conduct the treatments and a blinded researcher will perform the postsurgery evaluations.

Interventions

Proper care will be taken during the surgery with laser. All individuals in the surgery room will be obligated to wear specific protective eyewear. Preanaesthesia will be performed with a topical benzocaine pomade and anaesthesia will be performed with either topical benzocaine or tetracaine drops or a local injection of 2% lidocaine (1:100 000 with epinephrine), injecting a small amount (calculated based on the patient's weight) with a short needle slowly and carefully in the region of the lingual frenulum and base of the tongue, depending the patient's age and conditions of the lingual frenulum. The oral surgeon will make these decisions independently for each case.

The tongue will be pushed in the posterior direction using forceps supported on the floor of the mouth. An analgesic will be prescribed and administered. For both techniques, the infant will be placed in the supine position on the chest of an adult caregiver, who will be lying on the dental chair. In some situations, the knee-to-knee position may be used. The oral surgeon will make this decision on an individual basis depending on the best way to perform the protective stabilisation of the patient. Asepsis and infection control will rigorously follow biosafety norms.

The incision in both surgeries will occur in the same way with a pendular movement and the surgical procedure will last around 30–40 s.

Surgery with electrocautery: G1

Surgical incisions performed with electrocautery have low blood loss and rapid tissue separation without loss of fluid. The fine nickel-chromium tip reaches a temperature of up to 1200°C and is suitable for incisions and sections of small areas.

The incision will be made in the lingual frenulum by cutting and releasing the fibres of the frenulum that are preventing or limiting tongue movements. With the

Table 2 High Power diode laser

Parameters	High power diode laser group
Wavelength	980 nm ±20 nm
Medium	InGaAsP semiconductor diode
Delivering system	Optical fibre
Optical fibre diameter	400 µm
Optical fibre area	0.01 cm^2
Irradiation mode	Contact, scanning
Radiant power 0.5 W–5 W (±20%)	1.0W, 1.5 W or 2W
Emission mode	Continuous or pulse modulation (repeated pulse)
Pulse width 0.1–99.0 ms	Continuous mode: 1.0–99 ms (continuous exposure) Pulse modulation mode: 0.1–99 ms (repeated exposure)
Repetition rate 10–100 Hz	10–50 Hz
Duty cycle (1%–99%)	50%–99%

removal of the fibres from the free anteroventral portion to the base of the tongue, the tongue will be released, enabling proper movements. When the anterior third of the tongue is free, the lingual frenulum will be positioned in this region. No suture will be performed. The guardians will receive clarifications regarding the formation of a membranous pseudoplaque for second-intention healing. This membrane will form between the first and third day after surgery.

High-power diode laser surgery: G2

High-power diode laser surgery (DMC, São Carlos, Brazil) will be performed at a wavelength in the infrared region (980 nm) in either continuous or intermittent mode. The beam will be delivered by an optical fibre (300 nm) in contact with the target tissue, using pendulum or brushing movements scanning the surface of the soft tissue (table 2). During the surgical procedure, the optical fibre will be cleaved using a carbide or diamond tip pen, always observing the proper cleaving technique and adequate beam.

The surgical procedure will be performed choosing a safe, effective power that causes minimal thermal damage (controlled heating) to achieve coagulation, incision and vaporisation of the soft tissue and fibres of the lingual frenulum. A power of 1.5 W to a maximum of 2 W will be used, with the discerning evaluation of the histological characteristics of the target tissue and careful observance of signs of excessive heating and carbonisation. Thus, the choice of parameters is dynamic and depends greatly on the experience, skill, and caution of the operator. Photothermal effects will be obtained with the possibility of secondary photobiomodulation effects and minimal risk of harm to the adjacent tissues and deep structures. No suture will be performed. The guardian will receive clarifications regarding the formation of a membranous pseudo-plaque for second-intention healing. This membrane will form between the first and third day after surgery.

Postoperative care

After both surgeries, the guardians will be instructed not to allow the child to place objects in the mouth and will receive the following information: slight bleeding may occur at the surgical site after surgery, but will be temporary; a whitish plaque will form where the frenulum was cut (plaque resulting from the second-intention repair (tissue healing) process), which must not be removed with any product or by accident due to contact with any object placed in the mouth, as this plaque will serve as a 'bandage' protecting the surgical wound and will disappear in a few days.

Evaluations

Evaluations will involve standardised photographs of the region of the lingual frenulum and the administration of both the Bristol protocol and Visual Analogue Scale (VAS) to the nursing mother before and immediately after the surgical procedure as well as 15 days after surgery.

The primary outcome of this study is the release and repositioning of the lingual frenulum in nursing participants. The secondary outcome is improved scar repair and decreased maternal breast pain during breast feeding after lingual frenectomy. The method of evaluation scare repair will be through standardised photographs in which it will be possible to record the clinical aspect of the surgical wound, healing and lingual mobility according to the Bristol Protocol. The photographs will be evaluated by trained researchers, experienced in the field, calibrated and blind.

Photography of lingual frenulum

Postoperative tissue repair will be assessed through standardised photographs taken immediately and 15 days after the surgical procedure. The photographs will be taken by a calibrated evaluator, as follows: frontal and intraoral photograph with the median sagittal plane of the patient parallel to the vertical edges of the image (corner of lips) and the occlusal plane parallel to the horizontal edges of the image (upper and lower lip line) focused on the region of the lingual frenulum.

Bristol protocol

The Bristol Tongue Assessment will be used to evaluate the lingual frenulum. This protocol addresses the appearance of the tongue tip, attachment of the frenulum to the lower gum edge, lift of the tongue and protrusion of the tongue. The scores obtained for the four items are summed, with the total ranging from 0 to 8 points (table 3). A score of 0–3 points indicates a potential serious abnormality of tongue function.[10 11]

Table 3 Bristol Tongue Assessment Tool (BTAT)

BTAT			
Elements	**0**	**1**	**2**
Tongue tip appearance	Heart shaped	Slight cleft/ notched	Rounded
Attachment of frenulum to lower gum ridge	Attached at top of gum ridge	Attached to inner aspect of gum	Attached to floor of mouth
Lift of tongue with mouth wide (crying)	Minimal tongue lift	Edges only to mid-mouth	Full tongue lift to mid-mouth
Protrusion of tongue	Tip stays behind gum	Tip over gum	Tip can ascend over lower lip

Pain assessment: VAS

The VAS will be administered to the nursing mothers before, immediately after and 15 days after the surgical procedure. During breast feeding, the mother will be asked about pain in the breasts while looking at the scale and choosing a score of 0–10 that corresponds to the pain intensity experienced.[20 21]

Statistical analysis

The data will be tabulated and treated using GraphPad PRISM V.7.0. The Kolmogorov-Smirnov test will be used to determine the normality of the data. Variables that fit the Gaussian curve will be expressed as mean and SD. Two-way ANOVA will be used for comparisons between the groups, with the significance level set to 5% ($p<0.05$) by one of the authors (PMC, Applied Statistics Specialist).

Ethics and dissemination

This study was designed following the Consolidated Standards of Reporting Trials statement. Results will be submitted to international peer-reviewed journals and presented at international conferences.

The study will be conducted in accordance with the norms governing research involving human subjects stipulated in Resolution no 466/12 and 510/2016 of the Brazilian National Board of Health and has received approval from the Human Research Ethics Committee of Nove de Julho University (certificate number: 4387769). The guardians of the children will agree to participate by signing a statement of informed consent.

DISCUSSION

Ankyloglossia or tongue-tie is a condition in which the lingual frenulum attaches near the tip of the tongue and may be short, tight and thick. This condition has been cited as a cause of poor breast feeding and maternal nipple pain. Frenectomy is commonly performed to correct the restriction to tongue movements and enable more effective breast feeding with less maternal nipple pain.[22] The techniques used for frenectomy have differences in terms of execution, healing and the postoperative period. Frenectomy can be performed in the conventional way (use of scalpel, surgical scissors and/or electrocautery) or in an innovative way, with the use of high-power laser.[23]

Based on the evidence available from recent studies, infants with tongue-tie have a lower likelihood of being breastfed in the first weeks of life and a greater risk of using a bottle for feeding. Problems with breast feeding (pain and latching difficulty) are more prevalent and persistent among mothers whose infants have tongue-tie. Lingual frenectomy is recommended for the repositioning of the lingual frenulum.

Electrocautery, like laser, favours a surgical cut with little or no bleeding. Electrocautery is recommended for performing frenectomy due to its effectiveness and safety. It is a procedure that causes light bleeding and does not have postoperative complications. The use of electrocautery in frenectomy provides a reduction in work time as well as greater comfort and safety for the infant and surgeon.[24] Clinical studies report that laser and electrocautery used for frenectomy provide better patient perception in terms of postoperative pain and function than that achieved using the scalpel technique.

The use of high-power laser in soft tissue surgeries has achieved favourable results and considerable acceptance due to the improvement in the tissue repair process, the reduction in the risk of infection of the surgical wound due to the thermal effect (sealing of vessels), less contraction of the healed tissue and the ease of use with aseptic optical fibre. The effects of laser (vaporisation, coagulation and incision capacity) facilitate the surgical technique and ensure greater predictability regarding the clinical response. Some studies suggest that the use of the high-power laser for lingual frenectomy in newborns favours postsurgery tissue healing and offers greater comfort to both the nursing mother and infant, thereby favouring breast feeding.

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