Content validation of an orofacial myofunctional assessment protocol for infants

Validação do conteúdo de um protocolo de avaliação da motricidade orofacial em lactentes

Validación del contenido de un protocolo para la evaluación de la motricidad orofacial en bebés

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Abstract

Introduction: The instruments for evaluating the structures and functions of the stomatognathic system in babies have been lacking in studies. Objective: To validate the content of a speech-language instrument to assess orofacial motricity for babies aged between one month and two years old. **Methodology:** The instrument for "speech-language assessment of the orofacial motricity of babies from one month to two years old" was created based on the data obtained by the integrative review. The instrument's content was validated through the evaluation of four judges. The judges classified each item according to clarity, based on a four-point Likert scale, as follows: (4) very clear, (3) clear, (2) lightly clear, (1) unclear, to perform content validation by applying the Content Validation Index (CVI) equation. **Results:** The developed protocol has eight items and a brief anamnesis: Oral Habits; Structural Assessment; Breathing; Voice; Functional Assessment; Feeding and Swallowing - liquids and food in pieces; and Speech-Language Diagnosis. The next step included the analysis of the representativeness of

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the protocol items by the judges. After the second analysis, the validation of the content resulted in the permanence of the eight items with a total Content Validity Index of 100%. **Conclusion**: The content of the protocol was considered valid for use in the evaluation of the target audience, proven by people with experience in the area. The final version of the Protocol for the Speech-Language Pathology Assessment of Orofacial Motricity in Babies was completed with eight assessment items.

Keywords: Stomatognathic System; Infant; Feeding behavior; Clinical Protocols.

Resumo

Introdução: Muitos estudos têm se dedicado a compreender melhor a dinâmica da avaliação das estruturas e funções estomatognáticas de lactentes; até a presente pesquisa não foram encontrados estudos específicos para essa faixa etária, até recentemente. **Objetivo:** Validar o conteúdo de um instrumento fonoaudiológico de avaliação da motricidade orofacial para lactentes na faixa etária de um mês a dois anos. **Metodologia**: Foi elaborado o instrumento para "avaliação fonoaudiológica da motricidade orofacial de lactentes de um mês a dois anos" a partir dos dados obtidos na literatura. A validação do conteúdo do instrumento se deu por meio da avaliação de quatro juízes para clareza dos itens propostos no protocolo e da representatividade dos mesmos no processo de validação do conteúdo. Os juízes classificaram cada item quanto à clareza, a partir de uma escala tipo *Likert* de quatro pontos, sendo: (4) muito claro, (3) claro, (2) pouco claro, (1) sem clareza, com o propósito de realizar a validação do conteúdo por meio da aplicação da equação do Índice de Validação do Conteúdo (IVC). **Resultados:** O protocolo desenvolvido possui 8 itens e uma breve anamnese: Hábitos Orais; Avaliação Estrutural; Respiração; Voz; Avaliação Funcional; Alimentação e Deglutição - líquidos e alimentos em pedaços; Diagnóstico Fonoaudiológico. A etapa seguinte contou com a análise da representatividade e para clareza dos itens do protocolo pelos juízes, e após a segunda análise, a validação do conteúdo resultou na permanência dos 8 itens com Índice de Validade de Conteúdo total de 100%. **Conclusão:** O conteúdo do protocolo foi considerado válido para uso na avaliação do público-alvo, comprovado por profissionais com experiência na área. A versão final do Protocolo de avaliação fonoaudiológica da motricidade orofacial de bebês foi finalizada com 8 itens de avaliação.

Palavras-chave: Sistema estomatognático; Lactente; Comportamento alimentar; Protocolos Clínicos

Resumen

Introducción: Los instrumentos para la evaluación de las estructuras y funciones del sistema estomatognático en los bebés han mostrado falta de estudios. **Objetivo**: Validar el contenido de un instrumento de fonoaudiología para la evaluación de la motricidad orofacial en bebés de un mes a dos años de edad. **Metodología**: Inicialmente, se llevó a cabo la elaboración del instrumento para la "evaluación logopédica de la motricidad orofacial de bebés de un mes a dos años de edad" propiamente dicho, a partir de los datos obtenidos por la revisión integradora. La validación del contenido del instrumento se realizó a través de la evaluación de cuatro jueces. Los jueces calificaron cada ítem en términos de claridad, utilizando una escala de Likert de cuatro puntos, de la siguiente manera: (4) muy claro, (3) claro, (2) poco claro, (1) poco claro, con el propósito de realizar la validación de contenido a través de la aplicación de la ecuación del Índice de Validación de Contenido (CVI). Resultados: después de la lectura y discusión de los artículos, fue posible desarrollar el protocolo que contiene 8 ítems y una breve anamnesis, que son: Hábitos Orales; Evaluación Estructural; Respiración; Voz; Evaluación Funcional; Alimentación y deglución: líquidos y alimentos en trozos; y; Diagnóstico de Patología del Habla-Lenguaje. El siguiente paso fue el análisis de la representatividad de los ítems del protocolo por parte de los jueces, y luego del segundo análisis, la validación de contenido resultó en la permanencia de 8 ítems con un Índice de Validez de Contenido total del 100%. **Conclusión**: El contenido del protocolo se consideró válido para su uso en la evaluación del público objetivo, confirmado por personas con experiencia en el área. La versión final del Protocolo de evaluación de la patología del habla y el lenguaje para la motricidad orofacial en bebés se completó con 8 ítems de evaluación.

Palabras clave: Sistema estomatognático; Latente; Comportamiento alimentario; Protocolos Clínicos

Introduction

Some studies address the evaluation and speech-language pathology assessment protocols for newborns, especially before hospital discharge[1-2]. However, the literature is scarce on longitudinal follow-up approaches or speech-language pathology assessment of infants over one month to verify the adherence to speech-language recommendations or the presence of muscle changes and harmful oral habits, which, if left untreated, can lead to serious impairments in the stomatognathic system. The importance of creating an assessment tool for the structures and functions of the stomatognathic system focused on evaluating infants arises from the lack of studies with this focus. Despite the extensive work of speech-language pathologists with postpartum women and newborns, there is a scarcity of follow-up/assessment in the following months regarding aspects related to the orofacial myofunctional skills of infants[3].

An assessment protocol can support the work of speech-language pathologists with the infant population, whether in private or public practice, in children's hospitals or private clinics, facilitating speech pathology diagnoses and decision-making regarding interventions, and monitoring the progress of speech therapy. It is important to note that at the time of developing the research project that led to this work, no published assessment protocols for orofacial motor skills were found specifically designed for the age range of 1 month to 24 months. Recently, Medeiros et al.[3] published a protocol designed for orofacial motor skills assessment for infants aged 6 to 24 months and another for the assessment of infants and preschoolers aged 6 months to 71 months (Medeiros et al)[5]. These instruments represent a significant advancement in an attempt to standardize assessment data.

The study of standardization, along with further research and the consolidation of investigation protocols for specific age groups, can promote standardization in speech-language pathology assessment of individuals, facilitating the comparison of results both within and between subjects. This, in turn, can increase productivity in assessments and help organize collected information regardless of the assessment location[2]. Therefore, the objective of this study was to validate the content of a speech-language pathology assessment instrument for orofacial myofunctional skills in infants.

Methodology

This is a descriptive documentary research carried out with the approval of the Institutional Review Board (#3949708 by April 2020). This study presents the stages of construction and content validation of an orofacial myofunctional skills assessment in infants aged between one month and two years old. The protocol was developed based on research produced by the authors[5].

The content validation of the instrument was carried out through the assessment of four judges with experience in the field. The selection criteria for the judges included a professional background in Speech-Language Pathology (SLP), expertise in orofacial myofunctional therapy, authorship of scientific publications, a Master's degree in the field, and the signing of an informed consent form (ICF) agreeing to participate in the study as evaluators. Exclusion criteria for the judges were the failure to submit the questionnaires within the pre-established timeframe or failure to complete the validation instrument. In addition to the ICF, each judge received a confidentiality agreement in which they agreed not to use any provided materials, make copies or recordings of the content, or disclose confidential knowledge or information until the data is published.
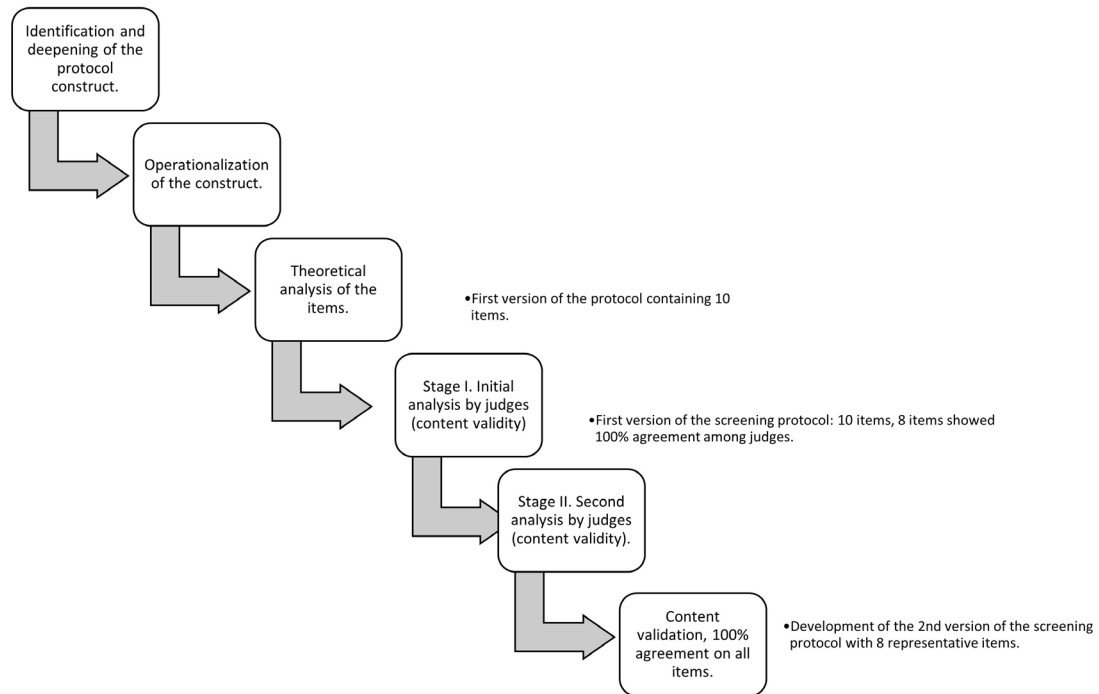
Figure 1. Graphic representation of the validation steps of the protocol.

To evaluate the content of the protocol, the judges received the instrument through digital platforms for evaluation, along with a cover letter from the researchers' containing instructions on how to proceed with the assessment. They were first instructed to evaluate the instrument, determining its comprehensiveness, including whether each domain or concept was adequately covered by the set of items and whether all dimensions were incorporated. At this stage, they could suggest the inclusion or elimination of items. They were also asked to analyze the items individually, assessing their clarity and representativeness. In terms of clarity, they were to evaluate the wording of the items, whether they were written in a way that made the concept understandable and whether they adequately expressed what was expected to be measured[6].

After the analysis of the first version of the instrument, the judges rated each item for clarity using a four-point Likert scale, where four represented 'very clear,' three 'clear,' two 'slightly clear,' and one 'unclear.' The purpose was to carry out content validation through the application of the Content Validation Index (CVI) equation. The Likert scale is used to measure the opinions, beliefs, or attitudes of questionnaire or instrument respondents through a sequence of statements that allow different degrees of agreement. Depending on the research phenomenon and the investigator's objectives, the number of odd or even response options may accompany each statement[7]. If the judges marked options 1, 2, or 3, they could suggest modifications to the proposed content, and the items would be rewritten. After the adjustments were made to the protocol, the judges conducted a second assessment based on the same four-point scale mentioned earlier. The response was to be given within a maximum period of fifteen days[6].

At the end of this second assessment of the protocol, the data was processed and analyzed using the CVI, which measures the proportion or percentage of agreement among experts on certain items of an instrument[6]. In this study, for the calculation of the CVI, the highest scores were used, meaning responses of 'very clear' and 'clear' for each item, divided by the total number of experts, with items that obtained values of one and two being excluded. The acceptable agreement rate for this proportion was defined as 90% or higher[8]. Modifications were made to questions that did not achieve this rate based on the suggestions of the experts, and a new round of assessment was conducted, when necessary.

Results

The protocol was constructed based on the literature cited in the study by Chitz and his colleagues[5]. Eight assessment items and a brief client case history were established. The client case history aims to understand the infant's clinical history. The assessment items were as follows: Oral Habits, Structural Evaluation, Respiration, Voice, Functional Assessment, Feeding and Swallowing - liquids and solid foods, and, finally, Speech Pathology Diagnosis.

Chart 1. Judge panel characterization

Variables	Judge 1	Judge 2	Judge 3	Judge 4
Gender	Female	Female	Female	Female
Educational level	Doctorate	Master's	Doctorate	Post doctorate
Years of Education	25 years	22 years	18 years	12 years
Publications in the Area	yes	yes	yes	yes
Years of Experience in the Field	25 years	22 years	18 years	12 years

Chart 2. Content validity index (CVI) of the protocol for assessment orofacial motor skills in infants one month to two years old

Items of the validation instrument and instructional guide	Frequency of agreement among judges (n = 4)	Representative/ Non-representative
CHILDREN /CASE HISTORY DATE	4	Representative
1.ORAL HABITS	4	Representative
2.STRUCTURAL EVALUATION	4	Representative
2.1 Cheeks	4	Representative
2.2 Lips	4	Representative
2.3 Tongue	4	Representative
2.4 Palate	4	Representative
2.5 Dentition	4	Representative
2.6 Nose	4	Representative
2.7 Jaw	4	Representative
3 BREATHING	4	Representative
4 VOICE	4	Representative
5 FUNCTIONAL ASSESSMENT	4	Representative
5.1 Non-nutritive Sucking	4	Representative
5.2 Nutritive Sucking during Breastfeeding	4	Representative
6 FEEDING AND SWALLOWING- LIQUIDS	4	Representative
7 FEEDING AND SWALLOWING- SOLID FOODS	4	Representative
8 SPEECH - LANGUAGE PATHOLOGY DIAGNOSIS	4	Representative
9 ORAL REFLEXES	3	No-representative
10 SENSITIVITY	3	No-representative

*CVI should be equal to or greater than 90%

The panel of experts consisted of four judges, and all had to agree at a rate of at least 90% for the item analyzed to be considered representative. Of the 10 items, eight items achieved agreement rates of over 90%, while the remaining two items that did not reach this percentage were excluded. The excluded items were "*Sensitivity*", which was removed because two judges rated it as clear (3) instead of very clear (4) due to difficulties in recognizing normal or altered conditions solely based on the baby's facial expression during the assessment. The item *"Oral Reflexes"* was also rated as clear (3) by the evaluators, so it was removed because of the broad age range covered by the protocol. As the child grows older, the expectations for normal oral reflexes change, making it difficult to mark the item in the protocol as either 'present' or 'absent'.

Chart 3. Evaluation protocol of orofacial motor skills infants from one month to two years of age

INFANTS DATA HISTORY	
CASE HISTORY	
Accompanying caregiver:	
Patient's name:	
Evaluation date:	
Date of birth:	Current age:
Who referred to Speech Therapy?	
Main complaint:	
Complications during birth/pregnancy:	
Did the baby require any type of feeding tube since birth:: _____ Usage time:_____	
Gestational age at birth:	
Corrected gestational age (current):	
Type of delivery:	Apgar: 1st 5th
Birth weight:	Current weight:
Was the tongue tie test performed: ( ) yes. Result: _____ ( ) no	
Exclusive breastfeeding: ( ) yes, until ____ months ( )yes, up to the current moment ( ) no	
Used infant formula	( ) no ( ) yes, up to ____ months ( ) yes, still does. Currently consumes _____ ml per day (including nighttime intake, if applicable). Type of formula:_____ What utensil (in case of bottle, provide details in the following item:_____
Bottle	(0) no (1) yes Nipple type:_____ Nipple material: _____ How is the nipple hole? ( ) unchanged ( ) increased to increase milk flow _____ Frequency of use: _____ Started complementary feeding? ( ) yes, at _____ months ( ) no
Has solid food introduction started?	( ) yes, at _____ months ( ) no
What types of foods is the baby currently consuming?	_____
Presence of food allergy	( ) yes. Specify: _____ ( ) no
What utensil/method is used for feeding?	( ) small cup. Type:_____ ( ) spoon. Type:_____ ( ) hand
hand Is there any feeding difficulty?	(0) no (1) yes Specify: _____
Is there food refusal?	(0) no (1) yes
What is the method of complementary feeding?	( ) BLW *Baby-led Weaning ( ) participative (combining BLW and traditional) ( ) traditional: ( ) mashed foods with a fork ( ) pureed foods ( ) strained foods
Respiratory problems	(0) no (1) yes. Specify:_____
Use of medications for respiratory problems	(0) no (1) yes. Which:_____
Craniofacial malformations	(0) no (1) yes. Specify: _____
Brief overview of neuropsychomotor development:	
Child's general health:	

1. Oral Habits	
1.1 Used intermediate silicone pacifier	(0) no (1) yes. Until _____ months (2) Yes, still using currently. Frequency: _____
1.2 Digital sucking	(0) absent (1) present Until _____ months (2) Yes. Present up to the current time. Frequency: _____
1.3 Pacifier	(0) absent (1) present. Until _____ months (2) Yes. Present up to the current time. Nipple type: _____ Nipple material: _____ Frequency of use: _____
1.4. Other habits (e.g., sucking on items, chewing cheeks, tongue or lip sucking, etc.)	Specify:

2. Structural Evaluation	
2.1 Cheeks	
2.1.1 Tension	(0) normal (1) hypertonic (1) hypotonic
2.1.2 Mucosa	(0) normal (1) injured
2.1.3 Facial analysis/posture	(0) symmetrical (1) asymmetrical
2.2 Lips	
2.2.1 Resting presentation	(0) occluded (1) open without lip eversion (2) open with lower lip eversion
2.2.2 Tension	(0) normal (1) hypertonic (1) hypotonic
2.2.3 Upper lip	(0) symmetrical (1) asymmetrical Specify:_____
2.2.4 Lower lip	(0) symmetrical (1) asymmetrical Specify:_____
2.2.5 Labial Commissures	( ) same height ( ) right higher ( ) left higher
2.2.6 Lip posture at rest	(0) sealed (1) slightly open (2) wide open
2.2.7 Mucosa	(0) normal (1) injured. Specify:_____
2.2.8 Upper lip frenulum	((0) normal (1) altered. Specify:_____
2.2.9 Lower lip frenulum	(0) normal (1) altered. Specify:_____
2.3 Tongue	
2.3.1 Tongue Posture	(0) elevated (1) flat (1) retracted (2) protruded ( ) not possible to observe
2.3.2 Appearance	(0) normal (1) macroglossia (1) cleft (1) geographical ( ) not possible to observe
2.3.3 Tongue Tension	(0) normal (1) hypertonic (1) hypotonic ( ) not possible to assess
2.3.4 Lingual frenulum evaluation	(0) normal (1) anterior (1) short (*the frenulum is considered normal when it attaches at the midpoint of the sublingual face and the floor of the mouth).
2.3.5 Tongue tip during elevation	( ) rounded (1) slight cleft at the apex (2) heart-shaped
2.3.6 Thickness of the lingual frenulum	(0) thin (1) thick
2.3.7 Frenulum attachment on the sublingual face of the tongue	(0) in the middle plane (1) between the middle plane and the apex (2) at the apex
2.3.8 Frenulum attachment on the floor of the mouth	(0) visible only from the sublingual caruncles (1) visible starting from the inferior alveolar crest
2.4 Palate	
2.4.1 Hard palate	(0) normal (1) altered. Specify:_____ (1) presence of congenital anomaly type:_____
2.4.2 Soft Palate	(0) normal (1) cleft uvula (1) sulcus (1) deviated
2.4.3 Soft Palate Mobility	(0) adequate (1) inadequate
2.5 Dentition	
2.5.1 Number of teeth	_____
2.5.2 General dental health:	
2.5.3 Which teeth A) Upper central incisor B) Upper lateral incisor C) Upper canine D) Upper 1st molar E) Upper 2nd molar F) 2nd molar G) Lower 1st molar H) Lower canine I) Lower lateral incisor J) Lower central incisor	( ) lower central incisors ( ) right ( ) left Note: eruption is expected at 6 months. ( ) upper central incisors ( ) right ( ) left Note: eruption is expected starting at 6.5 months. ( ) lower central incisors ( ) right ( ) left Note: eruption is expected at 7 months. ( ) upper lateral incisors ( ) right ( ) left Note: eruption is expected at 8 months. ( ) premolars ( ) right ( ) left Note: eruption is expected between 12 months. ( ) canines ( ) right ( ) left Note: eruption is expected between 18 months.
2.5.4 Any occlusal abnormalities	(0) no (1) yes. Specify:_____
2.6 Nose	
2.6.1 Nasal wings	(0) symmetrical (1) asymmetrical. Specify:
2.6.2 Nasolabial angle	(0) 90º (1) greater than 90º (1) less than 90º
2.6.3 Philtrum	(0) normal (1) small (1) large
2.7 Mandible	
2.7.1 Posture	(0) normal (1) semi-lowered (2) lowered
2.7.2 Presence of dysfunctions	(0) normal (1) prognathism (1) retrognathism

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3. Respiration	
3.1 Respiratory mode	(0) nasal (1) oronasal (2) oral

4. Voice	
4.1 Shows signs of pediatric dysphonia	(0) no (1) yes. Specify:_____
4.2 Voice type-related changes (e.g., hoarseness, breathiness, harshness...)	(0) no (1) yes. Specify:_____
4.3 Resonance changes	(0) no (1) yes which: _____
4.4 History of aphonia	(0) no (1) yes. which: _____

5. Functional Evaluation	
5.1 Non-Nutritive Sucking (digital sucking on the evaluator's gloved finger) - (performed on babies up to 3 months)	
5.1.1 Suction elicited easily	(0) yes (1) no
5.1.2 Tongue movement	(0) adequate (1) altered (2) absent
5.1.3 Tongue canalization	(0) present (1) absent
5.1.4 Jaw movement	(0) adequate (1) altered (2) absent
5.1.5 Suction strength	(0) strong (1) weak (2) absent
5.1.6 Suction pattern	(0) several suctions with short pauses (1) Few suctions with long pauses Note: For babies up to 3 months, 6 to 8 suctions with short pauses are expected. Average suctions per block: _____
5.1.7 Rhythm maintenance	(0) satisfactory (1) slow () fast (or without pauses) (1) absent
5.1.8 Lip sealing during suction	(0) adequate (1) altered
5.2 Nutritive Sucking at Breastfeeding (observe the baby breastfeeding for 3 minutes)	
5.2.1 Behavioral state	( ) alert ( ) sleepy ( ) agitation ( ) crying
5.2.2 Nipple latch	(0) adequate (1) inadequate
5.2.3 Baby's posture during feeding	(0) sitting (0) lying with the trunk inclined at 30° or more (1) lying in a completely horizontal position
5.2.4 Suction rhythm	(0) several suctions with short pauses (1) Few suctions with long pauses
5.2.5 Bites the areola/nipple	(0) no (1) yes
5.2.6 Tongue clicks during breastfeeding	(0) no (1) yes
5.2.7 Coordination of suction-breathing-swallowing	(0) yes (1) no. Specify what was observed:_____
5.2.8 Escape through the labial commissure	(0) no (1) yes
5.2.9 Presence of choking or coughing	(0) no (1) yes
5.2.10 Vocal Quality	0) no modifications after breastfeeding (1) with modifications after breastfeeding. Specify:_____
5.2.11 Signs of stress	(0) not present (1) hiccups (1) crying (1) tongue tremors (1) skin color variations (1) others, Specify: _____

6. Feeding and Deglutition - Liquids	
6.1 Utensil used for evaluation	( ) bottle, type of nipple:_____ Note: Check if the bottle hole is suitable or increased. ( ) cup, type:_____ ( ) dosing spoon ( ) others, Specify: _____
6.2 Posture during feeding	( ) sitting ( ) lying with the trunk inclined at 30° or more ( ) lying in a completely horizontal position
6.3 Use of a straw	( ) yes ( ) no
6.4 Bites the nipple	(0) no (1) yes
6.5 Tongue clicks during feeding	(0) no (1) yes
6.6 Coordination of suction-breathing-swallowing	(0) yes (1) no. Specify what was observed:_____
6.7 Escape through the labial commissure	(0) no (1) yes
6.8 Presence of choking or coughing	(0) no (1) yes
6.9 Volume of liquid ingested:	_____ ml
6.10 Ingestion time:	___ min
6.11 Vocal Quality	(0) no modifications after ingestion (1) with modifications after ingestion. Specify:_____

7. Feeding and Deglutition - Solid Foods (for those over 6 months)	
7.1 Posture during feeding	(0) sitting with plantar support (1) sitting without plantar support
7.2 Feeding method	( ) with utensils. Which:_____ ( ) with hands
7.3 Amount offered	( ) adequate ( ) inadequate
7.4 Texture preference	( ) liquid ( ) thickened liquid ( ) pasty ( ) semi-solid ( ) solid ( ) none
7.5 Food used	( ) pasty: food _____ ( ) solid: food _____
7.6 Bolus capture (when using utensils)	(0) adequate (1) inadequate
7.7 Labial sealing	(0) yes (1) no
7.8 Jaw movement during chewing	(0) adequate (1) inadequate Note: Between 5 and 6 months, vertical jaw crushing movement with a "kneading" pattern is expected. After 7 months, lateral jaw movement is expected. After 1 year, the child is already able to perform jaw rotation movements.
7.9 Tongue movement during chewing	( ) kneading ( ) anteroposterior ( ) posteroanterior ( ) not possible to observe
7.10 Anterior oral escape	(0) no (1) yes
7.11 Coughing	(0) no (1) yes
7.12 Nasal reflux	(0) no (1) yes
7.13 Drooling	(0) no (1) yes
7.14 Swallow rhythm	(0) one swallow (1) two swallows (2) multiple swallows
7.15 Residue in the oral cavity after swallowing	(0) no (1) yes
7.16 Vocal Quality	(0) no modifications after eating (1) with modifications after eating. Specify:_____

8. Speech-Language Pathology Diagnosis	
8.1 Possible diagnosis	( ) Dysphagia ( ) Velopharyngeal Dysfunction ( ) Orofacial and/or cervical Myofunctional Disorder ( ) Altered Tongue Frenulum ( ) Harmful oral habits ( ) others, specify:_____
8.2 Referrals	( ) Nutritionist ( ) Otorhinolaryngologist ( ) Orthodontist ( ) others, specify:_____

Discussion

Chart 1 presents the characterization of the judges, confirming that the judges had the technical competence to perform the proposed task, as in the validation processes of other existing protocols in the literature[2,9]. After the judges' first evaluation of the protocol, the responses were analyzed individually, and the instrument was revised based on suggested content. Thus, after the judges' second evaluation, the protocol that initially contained ten assessment items was reduced to eight items (Figure 1).

The first of the remaining items in the final version of the protocol is the client case history, which seeks to investigate the clinical history of the infant. This item encompasses relevant information about the individual's pre- and postnatal history[10]. Client case history is the first phase of any assessment process, with its importance lying in the identification of problems, guiding clinical reasoning toward possible diagnoses, planning, and implementing the rehabilitation process[10]. Throughout the data validation process, information related to gestation,

delivery, and motor development were added to this item. Among the studies found in the literature, only one (Medeiros et al. 2002) includes a client case history that covers all aspects of development. This recent study validated its content and, along with the clinical examination, presents a protocol for use in clinical and research settings with infants and preschoolers up to 5 years and 11 months of age.

The second item addresses questions related to oral habits of the child. This is necessary because the presence of oral habits directly affects oral motor and craniofacial development, bone growth, and can negatively impact breastfeeding, potentially leading to early weaning[11,14-16]. A shorter duration of breastfeeding increases the possibility of developing detrimental oral habits[15], justifying the need to include this item in the protocol. Detrimental oral habits are also associated with other alterations in orofacial functions such as breathing, swallowing, chewing, and speech, as well as alterations in facial bone growth and malocclusion[15].

The section that initiates the structural evaluation of the infant includes the assessment of cheek, lip, and tongue tension, as well as the observation of the posture of orofacial structures such as cheeks,

nose, tongue, teeth, palate, jaw, and lips[8]. In addition, as explored in the literature[3,11,12,17], the evaluation of the lingual frenulum is included. One of the references found in the literature is a validated instrument for the evaluation of the lingual frenulum in all dimensions, myofunctional assessment, functions, position, and movement of the tongue at rest and during nutritive and non-nutritive suction and swallowing[11]. In infants, tongue movements are essential for proper breastfeeding, weight gain, and are directly related to suction and swallowing functions coordinated with breathing[12]. In this protocol, the parameters for evaluating the lingual frenulum are summarized, suggesting that, in case of indications of alteration, a specific lingual frenulum assessment protocol should also be applied.

Within the age range covered by this protocol, the eruption of baby teeth occurs, typically around the sixth month of life, following the sequence of central incisors, lateral incisors, first molars, and canines. This phase marks the introduction of complementary foods[18]. In the item that covers this aspect, an image was added, according to the suggestion of one of the judges, to facilitate the evaluator's marking regarding the teeth already present.

Breathing is also addressed in this protocol, as the correct breathing pattern is essential for the harmonious growth of orofacial structures[19]. Breathing disorders can be of physiological, emotional, or learned origin, and their effects will be determined by the frequency, intensity, duration of the habit used, as well as the patient's age and the time of onset[20]. Few protocols found in the literature include breathing evaluation[3,4,20].

The item related to the assessment of the infant's voice was included because the literature shows existing relationships between voice changes and orofacial motor skills[21]. Additionally, some infants requiring speech therapy follow-up have a history of orotracheal intubation and extended periods in the Intensive Care Unit (ICU), with history of dysphagia, tracheomalacia, and previous organic dysphonias[21]. It's important to note that this item serves as a screening function, and when a vocal alteration is identified, a complete vocal evaluation is suggested, with a specific protocol.

Functional evaluation is divided by age group. For infants up to three months, the protocol suggests non-nutritive sucking with a gloved little finger touching the anterior part of the palate (palatal papilla) to trigger the sucking reflex[22]. The item also includes parameters for evaluating nutritive sucking, which applies to any age within the protocol's age range, as long as the infant is still breastfeeding. The evaluation of liquid swallowing, an item proposed according to the literature[11,14], can be done using a cup with a straw or a bottle.

For infants over six months, who have already started complementary feeding, the protocol also proposes the evaluation of an infant's ability to consume solid foods. For this test, it is suggested to offer a food that the baby is used to eating and that matches their level of development and age. If necessary, soft food can be used, and this should be duly marked in the protocol.

It's important to note that for a baby's feeding and swallowing to be efficient, adequate development of the entire stomatognathic system and body coordination are necessary. Supporting the head and trunk is essential for controlling the head and neck musculature, avoiding other functional difficulties[23]. In this regard, validated instruments in the literature address aspects related to body posture and its relationship with the stomatognathic system. For this reason, this aspect is not included in the present protocol. Future studies may provide greater clarity on this relationship.

The eighth item allows for the selection of a possible diagnosis and the necessary referrals after the entire assessment has been completed. From the protocols found in the literature, only two[4,11,12] include a section for describing a possible diagnosis based on the assessment. Some mentioned diagnoses, such as dysphagia, velopharyngeal dysfunction, or the presence of an altered lingual frenulum, which pointed to the need for a specific assessment. Regarding dysphagia, for example, a total of 21 items in this protocol are similar and/or identical to items in pediatric dysphagia screening instruments[24]. However, considering the specificity required to identify children suspected of having dysphagia, this protocol also serves as a referral alert for screening and/or specific assessments in these areas, avoiding negative consequences for the child's development.

Throughout the protocol, numerical scores are present, with zero indicating normal results and one or two indicating altered results. It should be emphasized that the total value could be used in the future to assess the degree of orofacial motor skill alteration in infants and then compare the assessment and reassessment of infants in speech

therapy, providing objective data for the family and demonstrating the effectiveness of speech therapy intervention. Future studies applying the protocol could provide further clarity on this aspect, including standardizing the degree of alteration based on the values found.

The content validation of the protocol for assessing orofacial motor skills in infants aged one month to two years (chart 3) may help identify the difficulties faced by many mothers during the period of exclusive breastfeeding, influencing appropriate guidance throughout this process and contributing to a reduction in early weaning rates. Additionally, it is known that the use of protocols promotes standardization in subject assessment, facilitates result comparison, increases productivity in patient care, and centralizes the collected information regardless of the data collection location[17][15]. Future studies are suggested to evaluate the applicability and validity of this protocol and make any necessary adjustments, considering new publications.

Regarding the study's limitations, it is noted that the protocol does not include the addition of photos and videos, as these can be obtained for comparison purposes at the discretion of the speech therapist. It is important to emphasize that the absence of such content does not compromise the assessment. Subsequent research is suggested to analyze the applicability and validity of this protocol, making any necessary adjustments while also considering new publications[4].

Conclusion

The final version of the Orofacial Myofunctional Assessment Protocol For in infants has been considered valid for use in assessing the target audience, as confirmed by individuals with experience in the field. The final protocol version consists of a case history and eight assessment items: Oral Habits; Structural Assessment; Breathing; Voice; Functional Assessment; Feeding and Swallowing - liquids and solid foods; and finally, Speech-Language Pathology Diagnosis.

Studies like this can guide evidence-based speech-language pathology practice. The second phase of this work, the application of the protocol, is to be carried out in a subsequent project by the researchers.

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