

Orofacial myofunctional assessment protocols for cleft lip and palate: systematic review

Protocolos para Avaliação Miofuncional Orofacial para Fissura Labiopalatina: revisão sistemática

Protocolos de evaluación miofuncional orofacial para labio y paladar hendido: revisión sistemática

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Abstract

Introduction: Cleft Lip and Palate are congenital malformations that affect the lips and/or palate and compromise other orofacial structures and functions. The orofacial myofunctional alterations caused by clefts are specific to the malformation and require a comprehensive and specific evaluation of the stomatognathic system. **Objective:** The objective of this systematic review is to identify the orofacial myofunctional assessment protocols for cleft lip and palate and to verify the specific variables for the assessment of this malformation. **Methods:** This systematic review followed the recommendations of the “Preferred Reporting Items for Systematic Reviews and Meta-Analyses”, approved by the COMPESQ of the educational institution and registered in PROSPERO. The search strategy for the review was guided by the “PICO” strategy. Searches were conducted in the following databases (between 2010 and May 2020): MEDLINE (PubMed), LILACS, Web of Science, EMBASE, CINAHL, and Scielo. Cross-sectional observational studies, cohort studies, case-control studies, and clinical trials were included, with instruments for orofacial myofunctional evaluation for cleft lip and palate in English, Spanish, and Portuguese languages. The “Study Quality Assessment Tools” were used to assess the quality of

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Authors' contributions:

AFDR: research design, writing, database search, data collection, data analysis, interpretation, writing of the manuscript.

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observational studies. **Results:** Three articles with protocols for orofacial myofunctional evaluation among the population with cleft lip and palate were included. The variables considered specific in the comparison of protocols were lips, tongue, teeth, cheeks, hard palate, labial, and lingual mobility. **Conclusion:** This systematic review identified three orofacial myofunctional assessment protocols for individuals with cleft lip and palate, focusing on the evaluation of the structures of the lips, tongue, soft and hard palate, cheeks, teeth, and labial and lingual mobility. The comparison of frequent items with the AMIOFE-A protocol indicated the absence of essential variables such as: FLP classification, scar characteristics, evaluation of the lingual frenulum, number of teeth, presence and appearance of the uvula and palatine tonsils, mobility of the soft palate and pharynx, as well as specific aspects of speech and velopharyngeal function. It is recommended to create a comprehensive instrument that assesses orofacial functions, structures, mobility, tonicity, and sensitivity. This would aid in the development of precise therapeutic plans and improve the quality of research. Furthermore, future studies should standardize the age ranges of samples to allow for more accurate comparisons and widely applicable protocols.

Keywords: Cleft Lip; Cleft Palate; Stomatognathic System; Stomatognathic System Abnormalities; Speech, Language and Hearing Sciences.

Resumo

Introdução: Fissuras Labiopalatinas são malformações congênitas que acometem os lábios e/ou o palato e, comprometem outras estruturas e funções orofaciais. As alterações miofuncionais orofaciais causadas pelas fissuras são particulares da malformação e requerem uma avaliação completa e específica do sistema estomatognático. **Objetivo:** verificar protocolos utilizados para avaliação miofuncional orofacial nas fissuras labiopalatinas e averiguar as variáveis específicas para avaliação junto a esta malformação. **Métodos:** Esta revisão sistemática seguiu as recomendações do “*Preferred Reporting Items for Systematic Reviews and Meta-Analyses*”, aprovada pela COMPESQ da instituição de ensino e registrada na PROSPERO. A estratégia de busca da revisão foi guiada pela estratégia “PICO”. As pesquisas foram realizadas nas seguintes bases de dados (entre 2010 e maio de 2020): MEDLINE (PubMed), LILACS, Web of Science, EMBASE, CINAHL e Scielo. Foram incluídos estudos observacionais transversais, estudos de coorte, de controle de casos e ensaios clínicos, com instrumentos para avaliação miofuncional orofacial para Fissuras Labiopalatinas e nos idiomas inglês, espanhol e português. Para avaliação da qualidade dos estudos observacionais foi utilizado o “*Study Quality Assessment Tools*”. **Resultados:** Foram incluídos três artigos com protocolos de avaliação miofuncional orofacial junto à população com fissuras labiopalatinas. As variáveis consideradas como específicas na comparação dos protocolos, foram: os lábios, língua, dentes, bochechas, palato duro, mobilidade labial e lingual. **Conclusão:** Esta revisão sistemática identificou três protocolos de avaliação da Motricidade Orofacial para indivíduos com fissura labiopalatina, que focaram na avaliação das estruturas dos lábios, língua, palato mole e duro, bochechas, dentes, e na mobilidade labial e lingual. A comparação dos itens frequentes com o protocolo AMIOFE-A, indicou a ausência de variáveis essenciais, como: a classificação da FLP, características das cicatrizes, avaliação do frênulo lingual, quantidade de dentes, presença e aspecto da úvula e das tonsilas palatinas, mobilidade do palato mole e da faringe, além de aspectos específicos da fala e da função velofaríngea. Recomenda-se a criação de um instrumento abrangente que avalie funções, estruturas, mobilidade, tonicidade e sensibilidade orofacial. Isso auxiliaria na elaboração de planejamentos terapêuticos precisos e na melhoria da qualidade das pesquisas. Além disso, futuros estudos devem padronizar as faixas etárias das amostras para permitir comparações mais precisas e protocolos amplamente aplicáveis.

Palavras-chave: Fenda Labial; Fissura Palatina; Sistema Estomatognático; Anormalidades do Sistema Estomatognático; Fonoaudiologia.

Resumen

Introducción: La fisura labiopalatina es una malformación congénita que afecta a los labios y/o paladar y compromete otras estructuras y funciones orofaciales. Las alteraciones miofuncionales orofaciales causadas por las fisuras son específicas de la malformación y requieren una evaluación

integral y específica del sistema estomatognático. **Objetivo:** Examinar los protocolos utilizados para la evaluación miofuncional orofacial en la fisura labiopalatina e investigar variables específicas para la evaluación en esta malformación. **Métodos:** Esta revisión sistemática siguió las recomendaciones de los “Preferred Reporting Items for Systematic Reviews and Meta-Analyses”, aprobadas por el COMPESQ de la institución educativa y registradas en PROSPERO. La estrategia de búsqueda para la revisión fue guiada por la estrategia “PICO”. Las búsquedas se realizaron en las siguientes bases de datos (entre 2010 y mayo de 2020): MEDLINE (PubMed), LILACS, Web of Science, EMBASE, CINAHL y Scielo. Se incluyeron estudios observacionales transversales, estudios de cohortes, estudios de casos y controles, y ensayos clínicos, con instrumentos para la evaluación miofuncional orofacial para la fisura labiopalatina en inglés, español y portugués. Se utilizaron las “Herramientas de Evaluación de la Calidad del Estudio” para evaluar la calidad de los estudios observacionales. **Resultados:** Se incluyeron tres artículos con protocolos para la evaluación miofuncional orofacial entre la población con fisura labiopalatina. Las variables consideradas específicas en la comparación de los protocolos fueron: labios, lengua, dientes, mejillas, paladar duro, movilidad labial y lingual. **Conclusión:** Esta revisión sistemática identificó tres protocolos de evaluación miofuncional orofacial para individuos con fisura labiopalatina, que se centraron en la evaluación de las estructuras de los labios, la lengua, el paladar blando y duro, las mejillas, los dientes y la movilidad labial y lingual. La comparación de los ítems frecuentes con el protocolo AMIOFE-A indicó la ausencia de variables esenciales, tales como: clasificación de FLP, características de las cicatrices, evaluación del frenillo lingual, cantidad de dientes, presencia y aspecto de la úvula y las amígdalas palatinas, movilidad del paladar blando y la faringe, además de aspectos específicos del habla y de la función velofaríngea. Se recomienda la creación de un instrumento integral que evalúe funciones orofaciales, estructuras, movilidad, tonicidad y sensibilidad. Esto ayudaría en la elaboración de planes terapéuticos precisos y en la mejora de la calidad de la investigación. Además, los estudios futuros deben estandarizar los rangos de edad de las muestras para permitir comparaciones más precisas y protocolos ampliamente aplicables.

Palabras clave: Labio Hendido; Paladar Hendido; Sistema Estomatognático; Anomalías del Sistema Estomatognático; Fonoaudiología.

Introduction

The Stomatognathic System (SS) is responsible for extremely important functions of the human body, such as breathing, chewing, swallowing, and speech. For these functions to occur in harmony, the integrity of its structures, which include bones, teeth, the temporomandibular joint, muscles, the vascular system, and nerves, is essential¹. When there are structural or functional disturbances in this system, interdisciplinary or multidisciplinary intervention is crucial for evaluation and treatment. Health professionals who should evaluate and, when necessary, rehabilitate the system include Otorhinolaryngologists, Oral and Maxillofacial Surgeons, Orthodontists, Speech Therapy, among others¹.

In Brazil, the speech therapy is responsible for identifying orofacial myofunctional disorders. Protocols such as MBGR² (Marchesan, Berrentin-Felix, Genaro, Rehder) and AMIOFE (Orofacial Myofunctional Evaluation with Scores)^{3,4,5}, have

been validated for assessing Orofacial Motricity (OM) in both children⁴ and adults^{2, 5}. The use of validated protocols for OM evaluation enhances the quality and efficacy of scientific research as they propose standardized assessments through scores, allowing for the grading of individuals' orofacial myofunctional difficulties and their improvements with speech-language intervention^{2,3,6}.

The OM evaluation of individuals with Cleft Lip and Palate (CLP) provides insight into the anatomical and functional conditions of the SS, which aids in diagnosis and therapy when needed.

Craniofacial malformations can affect the development of SS structures and functions, as is the case with CLP. CLP is one of the most common congenital orofacial malformations worldwide⁷. In Brazil, the average prevalence rate is 0.51 per thousand live births, with the highest rates found in the South (0.72 per thousand live births) and Southeast (0.54 per thousand live births)⁸.

CLP occurs due to the failure of branchial and/or pharyngeal processes to fuse between the 4th

and 9th week of gestation, preventing the closure of the lips and/or palate and leading to orofacial myofunctional alterations⁷.

In individuals with CLP, the most common OM alterations affect the lips, palate, velopharyngeal sphincter, uvula, and, consequently, stomatognathic functions⁹. A study demonstrated that children with CLP have more orofacial dysfunctions and greater negative impacts on social well-being than children without CLP¹⁰. For this reason, detailed anamnesis, follow-up with a multidisciplinary team, and OM evaluation are crucial for the treatment of cleft patients, even when lip and/or palate corrective surgeries have been performed⁹.

Given the specificity of craniofacial malformations, particularly CLP, this systematic review aimed to identify protocols used for OM evaluation in CLP and to examine the specific variables for evaluating this malformation. The results obtained are expected to aid researchers in standardizing data collection and facilitating the comparison of findings across different studies focused on individuals with CLP.

Methods

Protocol and Registration

This systematic review was approved by the Research Committee - COMPEAQ of the educational institution under number 023/2020 and registered with the International Prospective Register of Systematic Reviews - PROSPERO under protocol number CRD42020181208. It followed the guidelines proposed by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) instrument¹¹.

Search Strategy

This systematic review followed the PICO search strategy, where “P” refers to the “popula-

tion”; “I” refers to the “intervention,” which corresponds to the action or treatment being investigated or applied to resolve a specific health problem and can be adapted to describe different evaluations or diagnostic methods used in the included studies; “C” refers to “control or comparator”; and “O” refers to “Outcomes” or measured results. This approach is essential for structuring research questions clearly and objectively, allowing for a thorough analysis of available evidence and facilitating comparisons between different studies. Therefore, the strategy was structured as follows:

- Population: individuals with cleft lip and/or palate.
- Intervention: protocols for evaluating orofacial motricity specific to individuals with CLP.
- Comparison: no comparator.
- Outcome: identification of specific protocols for orofacial myofunctional evaluation in individuals with CLP.

The questions that guided this systematic review were: “Is there a validated protocol specific to individuals with CLP? What variables would be specific to CLP when comparing eligible protocols with a general population protocol?”

Searches were conducted in the following databases (in May 2020): MEDLINE (access via PubMed), LILACS, Web of Science, EMBASE, CINAHL, and Scielo. The search terms, used according to MESH entry terms and combined with Boolean operators, were: Cleft lip OR cleft palate AND Speech Therapy OR Myofunctional therapy OR Evaluation Study OR Speech-Language Pathology AND Stomatognathic System. Filters applied were: articles published between 2010 and 2020 and in English, Portuguese, and Spanish. Although this review aims to identify assessment protocols, the term “Myofunctional therapy” was included to encompass and analyze which assessment protocols were used in intervention studies.

Eligibility Criteria

Included were cross-sectional observational studies, cohort studies, case-control studies, and clinical trials that featured instruments for orofacial myofunctional evaluation for cleft lip and palate (CLP).

Studies that did not address orofacial myofunctional evaluation for cleft lip and palate, those without full-text availability, duplicate articles, systematic reviews, case reports, comments, monographs, theses, dissertations, editorials, or letters, and studies published before 2010 were excluded.

Data Collection Process

The first and second reviewers independently selected the titles and abstracts of all identified works from the digital search in the research databases. Both reviewers selected abstracts, and those articles that did not meet the eligibility criteria were excluded from full-text evaluation. Discrepancies between the two reviewers regarding the selection of articles for full reading were resolved by the third reviewer.

The first and second reviewers independently performed a full reading of the selected articles. Differences between the reviewers were resolved by the third reviewer, who made the final decision.

From the selected studies, using the eligibility criteria, the following data were extracted: methodological design, number of subjects, age of subjects, assessment protocol, items specific to CLP, statistical analysis regarding specificity and sensitivity, as well as the main results found. Disagreements in data extraction were resolved through discussion and the decision of the third reviewer.

Analysis and Comparison of Results

Data from the included studies were extracted and transferred to a Microsoft Excel spreadsheet, which allowed for comparison of the variables of each orofacial myofunctional assessment protocol in tables. The items were categorized according to the type of evaluation: orofacial functions, structures, mobility, tone, sensitivity, and additional data from each protocol. The items were classified as very frequent (present in 100% of the protocols), frequent (present in at least 50% of the protocols), and infrequent (present in less than 50% of the protocols). This classification helped identify the most frequent and essential data in an orofacial myofunctional protocol for the CLP population.

To verify the variables specific to CLP, those identified as “very frequent” and “frequent” were transferred to another Microsoft Excel spreadsheet to compare them with the AMIOFE Expanded Protocol (AMIOFE-A)³. AMIOFE-A was used as it is a quantitative instrument, providing standardized evaluation with objectivity and consistency, validated and used in various orofacial myofunctional conditions.

Quality Assessment

The quality of the observational studies was assessed using the “*Study Quality Assessment Tools*” from the National Heart, Lung, and Blood Institute, National Institutes of Health (NIH-NHLBI)¹³.

Results

A total of 1617 articles were found, of which three studies¹⁴⁻¹⁶ were considered potentially relevant based on the eligibility criteria. Figure 1 shows the flowchart of the studies included in this review.

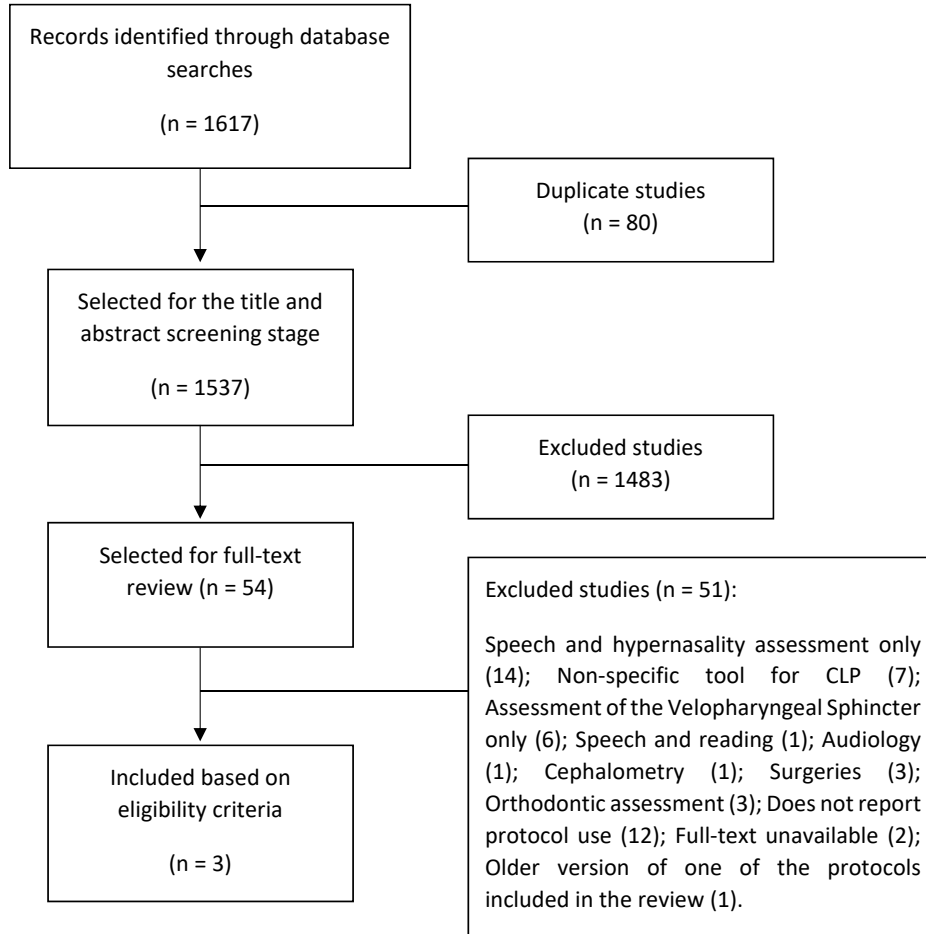


Figure 1. Flowchart of the included studies

Table 1 shows the characteristics of the included studies. It can be observed that the protocol by Graziani et al. (2019)¹⁴ had a specific title regarding CLP and detailed the validation process. The ages of the research participants varied across the analyzed studies. One study¹⁵ considered the

age range from zero to nine years, while another included patients over six years old, and another was conducted with young adults. Table 1 provides a comparative overview of the studies, allowing a well-founded analysis of the methodologies, objectives of each article, and the findings presented.

Table 1. Characteristics of the included studies

First author	Year	Objective	Sample	Study type	Assessment protocol
Campillay ¹⁵	2010	Evaluate the feeding of children with clefts and describe their characteristics	23 patients with CLP, 14 male and 9 female. Selected by convenience sampling. Ages ranged from zero to nine years.	Cross-sectional	Assessment protocol of the stomatognathic system adapted by the study authors, based on the protocols suggested by Altmann (1997) and Watson, Sell, and Grunwell (2005).
Meneguetti ¹⁶	2017	Characterize the profile and speech of patients undergoing primary palatoplasty	97 individuals with a diagnosis of non-syndromic palatine cleft, with or without associated cleft lip. Minimum age of six years, with no maximum age restriction.	Cross-sectional	Assessment of the stomatognathic system using the institution's own instrument.
Graziani ¹⁴	2019	Expand, validate content and criteria, and develop a myofunctional orofacial assessment protocol for individuals with cleft lip and palate, and define evaluation parameters for the use of the instrument.	11 evaluators 30 young adults (mean age = 23.8 years) with repaired unilateral cleft lip and palate.	Cross-sectional	"PROTIFI" abbreviation for "Protocolo de Avaliação Miofuncional Orofacial para Indivíduos com Fissura Labiopalatina."

The evaluation of orofacial functions—breathing, swallowing, chewing, speech, and voice—was frequent, being present in two protocols^{15,16}, while

the ability to suckle was assessed in only one study¹⁵. The variables can be analyzed in Table 2.

Table 2. Comparison of specific evaluation variables for Cleft Lip and Palate

Function	Campillay et al., 2010	Meneguetti et al., 2017	Graziani et al., 2019	%	Conclusion
Breathing	No	Yes	Yes	66%	Frequent
Sucking	Yes	No	No	33%	Low frequent
Deglutition	Yes	Yes	No	66%	Frequent
Chewing	No	Yes	No	33%	Low frequent
Speech	No	Yes	Yes	66%	Frequent
Voice	No	Yes	Yes	66%	Frequent
Structures					
Lip	Yes	Yes	Yes	100%	Very frequent
Tongue	Yes	Yes	Yes	100%	Very frequent
Cheeks	Yes	Yes	Yes	100%	Very Frequent
Hard Palate	Yes	Yes	Yes	100%	Very frequent
Palatine tonsils	No	Yes	Yes	66%	Frequent
Soft palate	No	Yes	Yes	66%	Frequent
Uvula	No	Yes	Yes	66%	Frequent
Teeth	Yes	Yes	Yes	100%	Very frequent
Mobility					
Lip	Yes	Yes	Yes	100%	Very frequent
Tongue	Yes	Yes	Yes	100%	Very frequent
Soft palate	No	yes	Yes	66%	Frequent
Pharynx	No	Yes	Yes	66%	Frequent
Tonicity					
Lip	Yes	No	Yes	66%	Frequent
Cheeks	Yes	No	Yes	66%	Frequent
Tongue	Yes	No	Yes	66%	Frequent
Mentalis muscle	No	No	Yes	33%	Low frequent
Sensibility					
Pain in facial, cervical and temporomandibular joint muscles	No	No	Yes	33%	Low frequent
Tactile sensitivity in the mentalis muscle, lips, tongue, incisive papilla and cheeks	No	No	Yes	33%	Low frequent
Types of surgery performed	No	Yes	No	33%	Low frequent
Language					
Expressive	No	Yes	No	33%	Low frequent
Receptive	No	Yes	No	33%	Low frequent

The orofacial structures commonly evaluated by the protocols were lips, tongue, cheeks, hard and soft palate, palatine tonsils, uvula, and teeth. In Table 2, it can be seen that lips, hard palate, cheeks, and teeth were very frequent. Additionally, the presence of fibrosis in the lip scar, the lingual frenulum, and the presence of fistula and/or fibrosis in the palate were observed in all instruments.

Regarding mobility, tone, and sensitivity of orofacial structures, the results can be seen in Table 2. Data on reconstructive surgeries and

expressive and receptive language were evaluated only in the instrument by Meneguetti et al. (2017)¹⁶.

The aspects of speech and velopharyngeal function to be evaluated in detail in the included instruments can be seen in Table 3. Both functions have complex aspects that require distinct evaluation criteria from other orofacial items. Separating these data allowed for a more precise and focused analysis, facilitating the identification of patterns and understanding the peculiarities associated with these specific functions.

Table 3. Comparison of variables related to the specific assessment of speech and velopharyngeal function for Cleft Lip and Palate

Speech and velopharyngeal function	Campillay et al., 2010	Meneguetti et al., 2017	Graziani et al., 2019	%
Mirror test (Blow; words and phrases with plosives and fricatives)	No	Yes	Yes	66%
Vocal Resonance (Hyponasality or Hypernasality)	No	Yes	Yes	66%
Phonological Disorder	No	Yes	Yes	66%
Compensatory Disorders	No	Yes	Yes	66%
Obligatory disorders (Hypernasality; nasal air emission; low intraoral pressure; nasal snoring; facial mimicry)	No	Yes	Yes	66%
Functional adaptation	No	Yes	Yes	66%
Acoustic Distortion	No	No	Yes	33%
Speed	No	Yes	Yes	66%
Mouth Opening	No	No	Yes	33%
Lip movement	No	No	Yes	33%
Jaw movement	No	No	Yes	33%
Spittle	No	No	Yes	33%
Pneumophonoarticulatory Coordination	No	No	Yes	33%
Intelligibility	No	Yes	Yes	66%
Articulatory Precision	No	Yes	Yes	66%

The comparison of the variables categorized as “very frequent” and “frequent” in this systematic review for individuals with CLP with the AMIOFE

protocol—used for the general population—can be seen in Table 4.

Table 4. Comparison of the variables categorized as “very frequent” and “frequent” with the AMIOFE Expanded protocol

Very frequent” and “frequent” with the CLP protocol.	AMIOFE-A
Classification of Cleft Type	Does not include
Lip Aspect - Presence of scar, scar appearance, presence of fibrosis, and mucosa.	Evaluates the lips but does not include observations about fissures and scars.
Lingual frenulum	Does not include
Hard palate - Presence of surgeries, scar characteristics, presence of fistula, fibrosis, or dehiscence.	Evaluates the hard palate but does not include observations about fissures and scars.
Teeth: quantity, type of dentition, dental occlusion. Evaluates dental occlusion but not the quantity of teeth.	Evaluates dental occlusion, but not the number of teeth.
Uvula and palatine tonsils	Does not include
Cheeks	Evaluate
Mobility of the soft palate and pharynx	Does not include
Breathing - Type and mode of breathing	Does not include the assessment of the type of breathing.
Swallowing of soft foods	Evaluate only solids and liquids
Speech, phonation, and velopharyngeal function	Does not include

The result of the quality assessment of the studies using the “Study Quality *Assessment Tools* - *NIH/NHBLI*”¹³ showed that the study by Graziani

et al.¹⁴ had the highest methodological quality, as seen in Table 5.

Table 5. Quality assessment of included studies

NIH/NHBLI Criteria	Campillay, 2010		Meneguetti, 2017		Graziani, 2019	
	Yes	No	Yes	No	Yes	No
1. Was the research question or objective in this paper clearly stated?	X		X		X	
2. Was the study population clearly specified and defined?	X		X		X	
3. Was the participation rate of eligible persons at least 50%?		X		X	X	
4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study prespecified and applied uniformly to all participants?	X		X		X	
5. Was a sample size justification, power description, or variance and effect estimates provided?	X		X		X	
6. For the analyses in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?		X		X		X
7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?		X		X		X
8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?		X	X		X	
9. Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	X			X	X	
10. Was the exposure(s) assessed more than once over time?		X	X		X	
11. Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	X		X		X	
12. Were the outcome assessors blinded to the exposure status of participants?		X	X		X	
13. Was loss to follow-up after baseline 20% or less?	X		X		X	
14. Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?	X		X		X	
Quality Rating (Good, Fair, or Poor)	Fair		Fair		Good	

Discussion

In this systematic review, the included instruments were specific for myofunctional assessment of individuals with CLP, and one protocol, named PROTIFI14, was validated.

The evaluation of orofacial structures was present in the included protocols, being these: lips, tongue, cheeks, hard palate, and teeth¹⁴⁻¹⁶. All se-

lected studies¹⁴⁻¹⁶ highlighted attention to the aspect of the lips: whether operated or not, the presence of fibrosis, and the aspect of the scar. Complications observed after cheiloplasty include hypertrophic scars, lip retraction, asymmetries in the lip region, and fibrosis. Such complications can affect both the appearance and function of the lips^{9,17}.

Regarding the tongue structure, the analyzed protocols agreed on checking its posture within the oral cavity, mucosa, and fixation of the lingual

frenulum^{14,16}. It should be noted that frenulum evaluation should be considered, as the occurrence of ankyloglossia and CLP is associated with mutations in the expression of the TBX22 gene during the fusion of the palatine processes^{18,19} and, therefore, may be present in CLP cases with associated syndromes¹⁹.

In the palate, the evaluation of its shape (depth and width), the occurrence of closure surgery, the presence of fibrosis and fistula, as well as its overall aspect are the suggestions found^{14,16}. Fibrosis is a pathological process of muscle tissue repair. It occurs due to the loss of a large volume of muscle tissue, leading to reduced or impaired function²⁰. In CLP, fibrosis usually occurs when palate surgery is performed early. The fibrotic tissue limits the formation of new myofibrils in the scar area and has consequences for velopharyngeal sphincter function and speech sound production²⁰.

Lip and tongue mobility, evaluated as “very frequent,” were present in the analyzed protocols. The lip movements suggested in the PROTIFI¹⁴ protocol were: protrude, retract, and click. The tongue movements were suction on the palate, click, vibrate, touch the apex, labial commissures, incisive papilla, right cheek, and left cheek. Campillay et al.¹⁵ analyzed the mobility of these structures during sucking and swallowing functions. Meneguetti et al.¹⁶ evaluated lip mobility in protrusion and smiling and tongue mobility during swallowing (whether the movement was towards the palatine papilla or protrusion between the teeth).

Lingual posture and mobility may be altered when some individuals with CLP perform compensations for the performance of orofacial functions⁹. Furthermore, in cases where maxillary growth is deficient relative to the mandible, this disproportion alters the habitual posture of the tongue and its mobility¹⁴.

Regarding teeth, the protocols observed oral health, type of dentition (deciduous, mixed, or permanent)^{14,15}, and dental occlusion^{14,16}. Dental occlusion in individuals with CLP may suffer changes due to the absence of labial and/or palatal structure. These potential changes were noted by the authors of the instruments, classifying them as: anterior crossbite, posterior crossbite, edge-to-edge bite, or open bite^{14,16}.

Concerning orofacial functions, breathing was analyzed in terms of type and mode^{14,16}. CLP can cause a reduction in the dimensions of the nasal

cavity, leading to oral breathing¹⁴, making this function important to assess in these individuals. Two protocols presented nasal airflow evaluation to check for obstruction, using the millimeter mirror²¹. The authors of PROTIFI suggest that airflow should be analyzed before and after cleaning the nostrils.

Swallowing assessment was considered in the instruments by Campillay et al.¹⁵ and Meneguetti et al.¹⁶, which both paid attention to the presence of “nasal reflux.” This is a symptom of swallowing disorder commonly found in individuals with CLP¹⁵, occurring more frequently before palatal reconstruction surgeries¹⁶, although it can also be observed after surgeries¹⁶ in the presence of fistulas and velopharyngeal dysfunction^{14,22}.

Speech aspects were present in two protocols^{14,16}, with the evaluation based on the difficulties that generally occur in patients with CLP, such as compensatory and obligatory articulation disorders. Compensatory disorders are deviations in speech sound production, making the speech of these individuals unintelligible. Examples used in the protocols were: glottal stop, pharyngeal plosive, mid-dorsum palatal plosive, pharyngeal fricative, velar fricative, and posterior nasal fricative¹⁴. Obligatory disorders are direct or primary consequences of the cleft palate and/or velopharyngeal dysfunction, described in the instruments as: hypernasality, nasal air escape, and weak intraoral air pressure^{14,16,23,24}.

Vocal resonance evaluation was presented in two protocols^{14,16}, using the Glatzel mirror²¹ to visualize and measure nasal air escape during the production of blowing, the vowels “a,” “u,” “i,” and the phonemes [f], [s], [j], as well as sentences with plosive and fricative phonemes¹⁴. The presence of hypernasality was evaluated by the Meneguetti et al.¹⁶ instrument using the “cul-de-sac” technique.

The examination of the palatine tonsils and uvula was also classified as “frequent”^{14,16}, and in the protocols, the item descriptions included whether these structures were present or not. When present, the uvula can be bifid, a common alteration in cases of submucous cleft palate, being one of the clinical signs for this type of cleft²⁵.

The structure and mobility of the soft palate and pharynx should also be evaluated in patients with CLP^{14,16}. The instruments considered the presence of dehiscence, the appearance of the scar, and the integrity of the palate. Oroscopy at this stage is essential, given the malformation in the lips and/or

palate region²⁵. The mobility of these structures can be evaluated by the emission of the vowel /a/^{14,16}.

Chewing and sucking, although classified as “infrequent” in this systematic review, can be limited in patients with CLP, as clefts favor the appearance of dentofacial alterations, consequently affecting the chewing function. Some studies reported that individuals with CLP have difficulty chewing solids and prefer soft foods^{15,26}.

According to the instrument used by one of the included studies¹⁵, the data to be evaluated in the sucking of infants with CLP are: lip posture, tongue movement, coordination between sucking, breathing, and swallowing. The authors of this study¹⁵ reported that the sucking performance in infants with CLP depends on the type and extent of the cleft. The lack of labial and palatal structures can affect the negative pressure needed for efficient milk ejection^{15,27,28}.

The tone of the lips, tongue, and cheeks was evaluated in two instruments^{14,16}, and of the mentalis muscle in the PROTIFI¹⁴. The musculature was classified as “normal” in an adequate state of contraction when at rest, “decreased” or “hypotonic,” and “increased” or “hypertonic”^{14,16}.

The protocol by Graziani et al.¹⁴ was the only one that evaluated orofacial sensitivity, related to the verification of pain upon palpation, as well as the tactile sensitivity of the lips, incisive papilla, tongue, cheeks, and mentalis. In this included study, tactile sensitivity was verified using an esthesiometer, an instrument composed of a group of six colored nylon monofilaments with different diameters, used to touch the region to be tested. The authors mentioned that they included these assessments because all aspects contribute to the understanding of orofacial dysfunctions and favor the determination of therapeutic planning¹⁴.

Comparing the variables considered as “frequent” and “very frequent” for the orofacial myofunctional assessment protocols for CLP with the AMIOFE-A instrument³, it can be observed that a specific protocol for the myofunctional assessment of the cleft population is indeed necessary, as some variables were not present in the AMIOFE-A protocol, as shown in Table 4.

Scientific studies on assessment protocols in the field of Orofacial Myofunctional Therapy are still scarce, which represents one of the main limitations of this systematic review, reflected in the reduced number of studies included. The

characteristics of the analyzed articles varied, including the objective of the studies and the age range of the patients evaluated. This age variation is particularly relevant as it can directly influence the results obtained and the applicability of the protocols in different age groups. The diversity in sample ages is a crucial factor since orofacial development and motor skills can differ widely between children, adolescents, and adults. These differences impact the validity and effectiveness of assessment protocols when applied to heterogeneous populations. For this reason, the variation in age ranges hindered the robust and comparative meta-analysis, limiting the ability to generalize the findings comprehensively.

Another observed limitation is that studies from other world regions were not included, only Brazilian ones. According to some studies, regions like India, Asia, and Africa have high rates of CLP occurrence, approximately 1.09 per 1000 live births in India, 1.30 in China, 1.34 in Japan, and 0.7 in Africa^{29, 30}. However, cultural, religious, and demographic differences influence CLP treatment in each world region, possibly affecting the search strategy and results of this systematic review. Furthermore, the inclusion of studies only in English, Spanish, and Portuguese may have limited the scope of the data, excluding relevant research in other languages.

Conclusion

This systematic review identified three orofacial myofunctional assessment protocols for individuals with CLP: the Stomatognathic System Assessment protocol adapted by the researchers in the Campillay et al. study¹⁵, the Speech-Language Pathology Assessment – CLP (specific to the research institution in Meneguetti et al.)¹⁶, and the PROTIFI¹⁴ by Graziani et al. The variables commonly evaluated by the protocols were: the structure of the lips, tongue, soft and hard palate, cheeks, teeth, and lip and tongue mobility.

The comparison of the frequent variables between the CLP protocols and the AMIOFE-A highlighted the absence of essential items, such as: the classification of the type of CLP, the observation of cleft scars, the evaluation of the lingual frenulum, the number of teeth, the presence and appearance of the uvula and palatine tonsils, the mobility of the

soft palate and pharynx, as well as specific aspects of speech and velopharyngeal function.

Based on the data analyzed in this review, it is suggested that a comprehensive instrument, including the assessment of functions, structures, mobility, tone, and orofacial sensitivity, would assist professionals working with the CLP population in establishing reliable therapeutic plans for orofacial dysfunctions and would improve scientific research evaluating the MO of these individuals, providing quality and effectiveness in study outcomes. Additionally, it is imperative that future studies consider the standardization of age ranges in samples to allow for more accurate comparisons and the development of assessment protocols that are broadly applicable across different age groups.

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