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Original Article

Artigo Original

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Proposal and content validation of an orofacial myofunctional assessment protocol for individuals with cleft lip and palate

Proposta e validação do conteúdo de um protocolo de avaliação miofuncional orofacial para indivíduos com fissura labiopalatina

Keywords

Cleft Palate
Stomatognathic System
Validation Studies
Speech, Language and Hearing Sciences
Evaluation

ABSTRACT

Purpose: To create and validate the content of an orofacial myofunctional assessment protocol for individuals with cleft lip and palate. **Methods:** The first version of an orofacial myofunctional assessment protocol for individuals with cleft lip and palate was created by two speech-language pathologists, who contemplated the structural and functional aspects of the stomatognathic system. This version was analyzed by other two speech-language pathologists experienced in cleft lip and palate assessment, who suggested changes that led to the second version of the protocol. Dynamic and static images necessary for performing the orofacial myofunctional examination were recorded from three individuals with cleft lip and palate, who represented three life stages: childhood, adolescence, and adulthood. Five examiners evaluated the images, applied the proposed protocol, and judged each item regarding its clarity to validate the content, from Content Validity Index. **Results:** The assessment protocol was finalized with 13 items, ten related to structural aspects and three related to functional aspects, with their corresponding sub-items. The general agreement in the validation of its content was 100%, so that only one stage was required. **Conclusion:** A protocol to evaluate the orofacial myofunctional aspects of individuals with cleft lip and palate was created with 13 items, as well as their corresponding sub-items, and its content was validated.

Descritores

Fissura Palatina
Sistema Estomatognático
Estudos de Validação
Fonoaudiologia
Avaliação

RESUMO

Objetivo: Elaborar e validar o conteúdo de uma proposta de protocolo de avaliação miofuncional orofacial para indivíduos com fissura labiopalatina. **Métodos:** Uma primeira versão do protocolo de avaliação miofuncional orofacial para indivíduos com fissura labiopalatina foi elaborada por duas fonoaudiólogas e contemplaram-se os aspectos estruturais e funcionais do sistema estomatognático. Essa versão foi analisada por outras duas fonoaudiólogas com experiência em avaliação de indivíduos com fissura labiopalatina, as quais apresentaram sugestões, e foi obtida a segunda versão. Foram registradas imagens dinâmicas e estáticas, necessárias à realização do exame miofuncional orofacial, de três indivíduos com fissura labiopalatina, representantes das três fases da vida: infância, adolescência e adulta. Cinco examinadores as analisaram e aplicaram o protocolo proposto; além disso, julgaram cada item quanto à clareza para a validação do conteúdo, a partir da aplicação do Índice de Validação do Conteúdo. **Resultados:** O instrumento foi finalizado em 13 itens, dez referentes aos aspectos estruturais e três funcionais, com seus respectivos subitens. Houve 100% de concordância na validação do seu conteúdo e, assim, foi necessária uma única etapa. **Conclusão:** Um protocolo para avaliação miofuncional orofacial de indivíduos com fissura labiopalatina foi elaborado com 13 itens, e os respectivos subitens, e teve seu conteúdo validado.

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INTRODUCTION

Cleft lip and palate can affect the lip, the palate, or both, and can be associated with other more complex malformations[1]. In such cases, a number of stomatognathic system structures are affected, which requires us to understand the alterations presented. Thus, the use of a protocol to perform the orofacial myofunctional assessment facilitates establishing the diagnosis, defining the conduct and treatment planning, and carrying out all relevant referrals.

It is recommended[2] that the evaluation be performed at least twice in the first year and once in a year until adolescence, the period when the pharyngeal tonsil undergoes the process of involution; and after this phase, it should be conducted every 2 years until the completion of dental-skeletal development. Furthermore, it should also be performed before and after the interventions. This assessment shall include aspects such as anatomy and physiology, language, speech, and voice, as well as investigate the velopharyngeal function by instrumental methods[3].

The use of a standardized assessment tool facilitates the comparison of pre- and post-treatment results and leads to the discussion among professionals from different study fields[4-6]. In several areas of health, the validation of assessment tools has been performed to obtain more accurate and reliable results[7-9]. In Speech-Language Pathology and Audiology, some studies validated assessment protocols for diverse populations[10-14].

Specifically for individuals with cleft lip and palate, the literature presents some validated instruments[14,15], which cover aspects related to speech. In Brazil, professionals who assist individuals with cleft lip and palate use their own forms of evaluation, which require standardization and validation to facilitate the comparison of results and the development of research. This paper aims to contribute to the development and validation of the contents of a specific orofacial myofunctional assessment tool for individuals with cleft lip and palate, which favors the scientific improvement[16] in this field and supports the proposal of the Orofacial Motricity Committee of the Brazilian Society of Speech-Language Pathology and Audiology.

METHODS

The study was approved by the Research Ethics Committee of the Hospital for Rehabilitation of Craniofacial Anomalies of University of São Paulo (USP), under protocol no. 200.397, and all participants signed an informed consent.

For the development of the first version of the orofacial myofunctional assessment protocol, literature was consulted and, based on the clinical experience of two experts in orofacial motricity, particularly in cleft lip and palate patients, items and subitems were proposed on aspects related to the stomatognathic system and the performance of orofacial functions, in addition to possible answers for each item.

This version was presented to two other guest speech-language pathologists, with broad experience in the assessment of individuals with cleft lip and palate, who analyzed the protocol with respect to the items, subitems, and possible responses, and thus the second version was obtained after adjustments.

Static and dynamic images of three operated unilateral cleft lip and palate individuals at ages 7, 14, and 20 years, representing three stages of life: childhood, adolescence, and adulthood, were selected. Such individuals, randomly selected, were taken from a sample of 75 individuals from another study, and individuals with neurological or motor problems, hearing loss, syndrome or other associated malformations were not included.

For image capturing, subjects sat on a chair with a back support and feet flat on the floor. The images obtained with a digital camera (Sony DSC-HX1 model) helped in the assessment of each item and subitem of the proposed protocol, and an endoscopic camera (CCC Waterproof USB Endoscope, 10 mm), specifically for capturing oropharyngeal images, was used as well. The camera was attached to a tripod and positioned in front of the participants. The lenses were 1 m away from them, to frame the shoulders, neck and face. To have a better visualization of lips, tongue, hard palate, and soft palate, the camera was approximated. A single professional was responsible for capturing the images, which were stored in a computer and transferred to a mobile device (flash drive) to be subsequently analyzed.

Five new examiners with clinical experience ranging from 6 to 20 years in the care of individuals with cleft lip and palate analyzed the images from the proposed protocol. They received previous verbal and written guidance as to the completion of the protocol. After assessment, the examiners rated each item on its clarity in a four-point scale: 1 = no clarity; 2 = unclear; 3 = clear and 4 = very clear, to perform content validation by applying the equation of the Content Validation Index (CVI)[17]. If the examiners marked options 1 or 2, the items had to be reformulated[18].

RESULTS

The orofacial myofunctional assessment protocol specific for individuals with cleft lip and palate was elaborated after analysis by four speech-language pathologists. It contains 13 items, 10 related to structural aspects and 3 related to functional aspects, with their corresponding subitems (Appendix 1). The items included referenes to the lips, tongue, cheeks, teeth and occlusion, palatine tonsils, hard palate, soft palate, and uvula and pharyngeal walls, as well as breathing, speech, and velopharyngeal functions.

In content validation, the investigators examined the items on the basis of their clarity for the calculation of the CVI (Tables 1 and 3); 75% of the examiners classified the items as "very clear" and 25% as "clear", with 100% agreement.

DISCUSSION

The purpose of this study was to develop and validate the content of a specific instrument for orofacial myofunctional assessment for individuals with cleft lip and palate. Some

Table 1. Distribution of the frequency of the content validity index regarding the assessment of aspects of the lips, tongue, cheeks, palatine tonsils, teeth, occlusion, and hard palate

Aspects and Description	Very clear (%)	Clear (%)
Lips		
Habitual position	60	40
Upper lip appearance	60	40
Lower lip appearance	20	80
External mucosa	80	20
Internal mucosa	20	80
Upper mouth vestibule	60	40
Length of the upper lip	60	40
Tongue		
Habitual position	40	60
Width	60	40
Height	40	60
Mucosa	80	20
Extension of the frenulum	80	20
Fixation of the frenulum on the tongue	40	60
Fixation of the frenulum on floor	80	20
Function limitation	100	0
Cheeks		
Mucosa	100	0
Palatine tonsils		
Presence	80	20
Size	60	40
Teeth		
Dentition	100	0
Number of teeth	100	0
Missing teeth	80	20
Teeth health	80	20
Gum health	80	20
Use of orthodontic appliances	100	0
Dental prosthesis	80	20
Occlusion		
Horizontal relationship	80	20
Vertical relationship	80	20
Transverse relationship	80	20
Hard palate		
Aspect	80	20
Depth	60	40
Width	60	40
Fistula	80	20

aspects concerning the general orofacial myofunctional assessment, such as mobility, muscular tonus, chewing and swallowing, were not anticipated, as it is believed that such assessments do not differ from those applied in other cases and thus other available assessment tools[5,6] can be used.

The elaboration of the items contemplated in the proposal was based on professional experience and in the literature on the field of orofacial motricity and related to cleft lip and palate[4,5,19-29].

In the first version proposed, the examiners who analyzed it suggested some adjustments related to possible answers, which helped clarify the proposal. According to

Table 2. Distribution of the frequency of the content validity index regarding the assessment of aspects of the soft palate, uvula, pharynx, and mirror test

Aspects and Description	Very clear (%)	Clear (%)
Soft palate		
Aspect	80	20
Diastasis	60	40
Symmetry	60	40
Extension	100	0
Fistula	60	40
Insertion of the levator muscle	100	0
Mobility	60	40
Uvula		
Aspect	100	0
Pharynx		
Lateral walls	60	40
Posterior wall	100	0
Mirror test		
Blowing	100	0
"/a/"	100	0
"/u/"	100	0
"/i/"	100	0
/f/	100	0
/s/	100	0
/ʃ/	100	0
Phrases /p/	100	0
Phrases /b/	100	0
Phrases /t/	100	0
Phrases /d/	100	0
Phrases /k/	100	0
Phrases /g/	100	0
Phrases /f/	100	0
Phrases /v/	100	0
Phrases /s/	100	0
Phrases /z/	100	0
Phrases /ʃ/	100	0
Phrases /ʒ/	100	0

Table 3. Distribution of the frequency of the content validity index regarding the assessment of aspects of speech, voice, and breathing

Aspects and Description	Very clear (%)	Clear (%)
Speech		
Hypernasality	100	0
Hyponasality	100	0
Phonological disorder	60	40
Compensatory articulation	60	40
Obligatory errors	60	40
Functional adjustment	60	40
Acoustic distortion	60	40
Speed	80	20
Mouth opening	80	20
Lip movement	80	20
Mandibler movement	100	0
Saliva	100	0
Coordination between breathing and speech	100	0
Intelligibility	100	0
Articulatory precision	60	40
Voice		
Pitch	100	0
Loudness	100	0
Voice quality	80	20
Breathing		
Mode	80	20

some authors, the assessment of the instrument by experienced and competent examiners in the specific area to be tested is essential and should be considered in the content validation process[8,13,29].

The content validation refers to the judgment from different examiners of an instrument, who must consider the items regarding content and the relevance of objectives to be measured, as well as make suggestions on how to remove, add, or modify items[7].On the basis of evaluation conducte by a group of experts, some authors performed content validation only by means of qualitative analysis[18,29], whereas other authors considered it highly relevant to perform a quantitative analysis[8,13].

In this study, for the content validation, performed through analysis from the examiners, images from individuals with complete unilateral cleft lip and palate were selected, due to its incidence and also because this type of cleft affects many aspects of the stomatognathic system. Thus, all items proposed in the protocol could be included. In addition, one individual at every stage of life (childhood, adolescence, and adulthood) was selected so that the instrument could be applied to different age groups.

In the content validation, the CVI was used to measure the percentage of agreement between the five examiners who assessed the second version. The 100% agreement was obtained, in which 75% examiners classified the items as "very clear" and 25% as "clear." According to some authors, as the examiners did not mark the "no clarity" and "unclear" options, there was no need to exclude or reformulate any item[18].

The proposal was adequate and the content of the instrument was validated in a single step, with a percentage of agreement above that established in the literature to be considered valid[13,17,18,29]. Thus, the content of the instrument proposed in this study was considered to be a valid and accurate measure for the 13 items evaluated, as well as their subitems.

This study did not aim to establish assessment criteria for the judgment of certain items, which will be conducted in a new study, as well as the continuity of the validation process of the instrument. In the course of this study, it was verified that the quality of images requires suitable equipment and techniques to facilitate the visualization of detailed structures for assessment.

CONCLUSION

A proposed protocol for the orofacial myofunctional assessment of individuals with cleft lip and palate, consisting of 13 items covering both structural and functional aspects, was developed and its content was validated.

**AFG participated in the study idealization, data collection, analysis and interpretation, and drafting of the article; APF participated in the idealization of the study, data analysis, and interpretation; KFG participated in the idealization of the study, data analysis and interpretation, and drafting of the article.*

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Appendix1. Myofunctional Assessment Protocol Developed

Orofacial Myofunctional Assessment – Cleft Lip and Palate

Name: _____Date of birth: ___/___/___ Age:_____

Registration number: _____ Date of examination: ___/___/___ Clinical Condition: _____

Type of Cleft: *[ ] Lip*: ☐ complete ☐ unilateral ☐ incomplete ☐ bilateral *[ ] Palate*: ☐ complete ☐ incomplete *[ ] Lip and Palate*: ☐ unilateral ☐ bilateral

Lips [ ] Sum all scores (best result = 0 and worst result = 11)

Habitual position:	(0) closed	(1) closed with tension	(1) Sometimes open, sometimes closed	(1) Half-open	(2) Open
Aspect: - *Upper*	(0) absence of cleft	(1) scar with little fibrosis	(1) scar with much fibrosis		(1) non-operated
- *Lower:*	(0) no alteration	(1) with eversion	(1) presence of pits (points of depression)		
Mucosa - *External:*	(0) normal	(1) dry	(1) injured		
- *Internal*:	(0) normal	(1) with teeth marks	(1) injured		
Upper mouth vestibule:	(0) normal	(1) partial lip adherence	(1) complete lip adherence		
Length of the upper lip:	(0) covers 2/3 of the incisors		(1) covers more than 2/3	(1) covers less than 2/3	

Notes: _____

Cheeks [ ]Sum all scores (best result = 0 and worst result = 6)

Mucosa: (0) normal	(1) teeth / braces marks R (1) teeth / braces marks L	(1) R alba (white) line (1) L alba (white) line	(1) injured R (1) injured L

Notes: _____

Tongue [ ]Sum all scores (best result = 0 and worst result = 14)

Habitual position:	(0) not visible	(1) on mouth floor	(2) protrude between the teeth		
Width:	(0) adequate	(1) increased			
Height:	(0) adequate	(1) increased			
Mucosa:	(0) normal (1) geographic	(1) cleft	(1) with teeth marks	(1) with braces marks	(1) injured
	Extension: (0) adequate	(1) short			
	Tongue fixation:	(0) middle section	(1) anterior to middle section	(2) at the apex	
Frenulum:	*Fixation on the floor of the mouth*:	(0) between caruncles	(1) between caruncles and the alveolar crest		(2) on alveolar crest
	Limitation of function:	(0) absent	(1) present		

Notes: _____

Palatine tonsils [ ]Sum all scores (best result = 0 and worst result = 1)

Presence:	☐ present	☐ not visible
Size:	(0) adequate	(1) hypertrophy (side) _____

Notes: _____

Teeth [ ] Sum all scores (best result = 0 and worst result = 8)

Dentition: ☐ deciduous		☐ mixed	☐ permanent		
Number of teeth: R upper _____		L upper _____	R lower _____	L lower _____	
Missing teeth: (0) absent		(1) present *(elements)*: _____			
Oral health:	*Teeth:* (0) good	(1) regular	(2) bad		
	Gum: (0) good	(1) regular	(2) bad		
Orthodontic appliance: (0) absent		(1) present	☐ retainer	☐ braces	
Dental prosthesis: (0) absent		(1) fixed	(1) removable	☐ partial	☐ total

Notes: _____

Occlusion [ ] Sum all scores (best result = 0 and worst result = 6)

Horizontal relationship:	(0) adequate	(1) bite on top	(2) overjet	(2) crossbite
Vertical relationship:	(0) adequate	(1) bite on top	(2) overbite	(2) open bite
Transverse relationship:	(0) adequate	(1) unilateral posterior crossbite _____		(2) bilateral posterior crossbite

Notes: _____

Hard palate [ ] Sum all scores (best result = 0 and worst result = 6)

Aspect: (0) intact	(1) operated, with little fibrosis		(1) operated, with much fibrosis		(1) dehiscent	(1) non-operated
Bony notch:(0) absent	(1) present					
Depth:(0) adequate	(1) increased					
Width:(0) adequate	(1) reduced					
	(0) absent	(1) present	(1) vestibular *(side)*: _____		(1) hard palate	
Fistula:	*Size:*	[ ] small	[ ] medium	[ ] large	[ ] other: _____	
	Shape:	[ ] circular	[ ] linear	[ ] irregular		

Note: _____

Soft palate[ ] Sum all scores (best result = 0 and worst result = 14)

Aspect:	(0) intact	(1) operated, with little fibrosis (1) operated, with much fibrosis	(1) dehiscent _____ (1) non-operated	(1) pharyngeal flap	
Diastasis:	(0) absent	(1) present			
Symmetry:	(0) present	(1) absent: _____			
Extension:	(0) long	(1) regular	(2) short	☐ pharyngeal flap	
	(0) absent		(1) transition	(1) soft palate	
Fistula:	*Size:*	[ ] small	[ ] medium	[ ] large	[ ] other: _____
	Shape:	[ ] circular	[ ] linear	[ ] irregular	
Insertion of the levator muscle:(0) posterior part			(1) middle part	(2) anterior part	☐ undefined ☐ pharyngeal flap
Mobility - *speaking "a" repeatedly:*		(0) good R	(1) regular R	(2)little R	(3) absent R ☐ pharyngeal flap
		(0) good L	(1) regular L	(2) little L	(3) absent L

Notes:_____

Uvula[ ]Sum all scores (best result = 0 and worst result = 1)

Aspect:	(0) normal	(1) altered	☐ hypotrophic ☐ operated	☐ grooved ☐ non-operated	☐ bifid ☐ pharyngeal flap	☐ dehiscent

Notes: _____

Pharynx [ ]Sum all scores (best result = 0 and worst result = 4)

Lateral walls - *speaking "a" repeatedly:*	Right: (0) good	(1) regular	(2) little	☐ unobservable
	Left: (0) good	(1) regular	(2) little	☐ unobservable
Posterior wall *(Passavant ridge):*	(0) present	☐ tentative	☐ unobservable	

Notes: _____

Breathing[ ]Sum all scores (best result = 0 and worst result = 5)

Type:	(0) medium/lower	(1) medium/high		
Mode:	(0) nasal	(1) oronasal	(2) oral ☐ functional	☐ organic: _____
Possibility of breathing through the nose	(0) 2 minutes or more	(1) between 1 and 2 minutes	(2) less than 1 minute	

Notes: _____

Nasal flux *(use mirror)*	Before blowing:	☐ similar between nostrils	☐ mildly asymmetry	☐ severely asymmetry
	After blowing in order to clean hygiene:	☐ similar between nostrils	☐ mildly asymmetry	☐ severely asymmetry

Notes: _____

Velopharyngeal function:

Mirror test [ ] Sum all scores (best result = 0 and worst result = 19)

(0) absent (1) present: [A] mild [B] moderate [C] intense

[ ] Blow		[ ] "a" "u"[ ]	[ ] "i" [ ] /f/	[ ] /s/ [ ] /ʃ/	
Phrases:	Plosives:	[ ] *Papai pediu pipoca*	[ ] *O tatu estava na toca*	[ ] *Cacá cortou o cabelo*	
		[ ] *A babá beijou o bebê*	[ ] *O dedo da Dada doeu*	[ ] *Gugu gosta do gato*	
	Fricatives:	[ ] *A fita da fada é de filó*	[ ] *O saci sabe assobiar*	[ ] *Chico chupa chupeta*	
		[ ] *Vovó viu o vestido*	[ ] *A casa da Zezé é azul*	[ ] *O jipe é do Juca*	

Notes: _____

Speech analysis[ ]Sum all scores (best result = 0 and worst result = 19)

Hyponasality:	(0) absent	(1) mild	(2) moderate	(3) severe		
Phonological disorder:	(0) absent	(1) present:	☐ omission	☐ substitution	☐ others *(describe):*_____	
Compensatory articulation:	(0) absent	(1) present:	☐ glottal stop	☐ pharyngeal plosive	☐ middorsum palatal stops	
		☐ pharyngeal fricative	☐ velar fricative	☐ posterior nasal fricative		
Obligatory errors:	(0) absent	(1) present: ☐ nasal air emission ☐ weak consonant ☐ nasal turbulence ☐ nasal grimacing	☐ hypernasality:[ ] mild [ ] moderate [ ] severe			
Functional adjustment:	(0) absent	(1) present:	☐ interdental tongue	☐ deviations from articulation place		
		☐ frontal lisp	☐ lateral lisp	☐ other _____		
Acoustic distortion:	(0) absent	(1) present *(describe):*_____				
Speed:	(0) adequate	(1) increased	(1) reduced			
Mouth opening:	(0) adequate	(1) reduced	(1) increased			
Lip movement:	(0) adequate	(1) reduced	(1) increased			
Mandible movement:	(0) adequate	(1) altered:	☐ reduced	☐ deviation R	☐ deviation L	☐ anteriorization
Saliva:	(0) swallowed	(1) at lip corners	(1) at lower lip	(1) splashes	(1) slobbers	
Coordination between breathing and speech:	(0) adequate	(1) altered *(describe):*_____				
Intelligibility:	(0) adequate	(1) altered:	☐ slightly	☐ highly	☐ unintelligible	
Articulatory precision:	(0) adequate	(1) altered*(describe)*: _____				

Notes: _____

Voice [ ] Sum all scores (best result = 0 and worst result = 3)

Pitch:	(0) adequate	(1) altered: *(describe)*: _____
Loudness:	(0) adequate	(1) altered: *(describe)*: _____
Voice quality:	(0) adequate	(1) altered: *(describe)*: _____

Note: _____

Speech- Samples for registration: - Spontaneous speech, Count from 1 to 20 and months of the year, Reading/repetition of phrases, Reading of texts

		Description	Therapeutic test			
			Isolated	*Syllable*	*Word*	*Phrases*
Bilabial	[p]					
	[b]					
	[m]					
Labiodental	[f]					
	[v]					
Interdental	[t]					
	[d]					
	[n]					
Alveolar	[s]					
	[z]					
	[l]					
	[r]					
	[l] group					
	[r] group					
Palatal	[ʃ]					
	[ʒ]					
	[ɳ]					
	[ʎ]					
Velar	[k]					
	[g]					
	[R]					
Archiphonemes	{R}					
	{S}					
Affricates	[tʃ]					
	[dʒ]					

Diagnostic conclusion: _____

_____

Conduct: _____

_____

Referral: ☐ no☐ yes _____

Guidance: ☐ no ☐ yes_____

Follow-up: ☐ no☐ yes _____

Responsible Speech-Language Pathologist (signature and stamp):_____