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Validity and reliability of a protocol of orofacial myofunctional evaluation for patients with obstructive sleep apnea

Gislaine A. Folha[1,2], Fabiana C. P. Valera[1,2], Cláudia M. de Felício[1,2]

[1]Department of Ophthalmology, Otorhinolaryngology and Head and Neck Surgery, School of Medicine of Ribeirão Preto, University of São Paulo, Ribeirão Preto; [2]Craniofacial Research Support Center, University of São Paulo, Ribeirão Preto, Brazil

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There is no standardized protocol for the clinical evaluation of orofacial components and functions in patients with obstructive sleep apnea. The aim of this study was to examine the validity, reliability, and psychometric properties of the Expanded Protocol of Orofacial Myofunctional Evaluation with Scores (OMES-expanded) in subjects with obstructive sleep apnea. Patients with obstructive sleep apnea and control subjects were evaluated, and the validity of OMES-expanded was tested by construct validity (i.e. the ability to discriminate orofacial status between apneic and control subjects) and criterion validity (i.e. correlation between OMES-expanded and a reference instrument). Construct validity was adequate; the apneic group showed significantly worse orofacial status than did control subjects. Criterion validity of OMES-expanded was good, as was its reliability. The OMES-expanded is valid and reliable for evaluating orofacial myofunctional disorders of patients with obstructive sleep apnea, with adequate psychometric properties. It may be useful to plan a therapeutic strategy and to determine whether the effects of therapy are related to improved muscle and orofacial functions.

Cláudia Maria de Felício, Department of Ophthalmology, Otorhinolaryngology, and Head and Neck Surgery, Faculty of Medicine of Ribeirão Preto, University of São Paulo, Av. dos Bandeirantes, 3900, 14049-900 Ribeirão Preto, SP, Brazil

E-mail: cfelicio@fmrp.usp.br

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The stomatognathic system performs feed functions and participates in breathing in a harmonious way owing due to the presence of a sophisticated sensorimotor system that is under the control of different cortical and subcortical regions (1). However, harmony may be disrupted, and alterations/dysfunctions of the appearance, posture, and/or mobility of the lips, tongue, mandible, and cheeks, as well as of respiration, swallowing, mastication, and speech, may occur. These changes are collectively termed orofacial myofunctional disorders (OMDs) and may occur in association with several oral diseases and their oral manifestations, such as malocclusion, and with temporomandibular disorders, mouth breathing, and genetic, congenital, acquired, or degenerative disorders (2–4). Hence, several health professionals, among them oral disease specialists, are involved in the management of patients with OMDs.

Researchers have also observed OMDs in patients (children and adults) with obstructive sleep apnea (OSA) (5–12). Obstructive sleep apnea is a complex sleep disorder, the pathogenesis of which is not yet fully understood; it is characterized by repetitive episodes of upper airway occlusion during sleep, and its typical symptoms include snoring during sleep and excessive daytime sleepiness (13). Treatments for adult patients with OSA include continuous positive airway pressure (CPAP), uvulopalatopharyngoplasty, mandibular advancement with an oral appliance, or surgery, along with lifestyle modifications; variable rates of success have been reported (10, 11, 14–16).

The potential of oropharyngeal exercises/orofacial myofunctional therapy (OMT) for improving upper airway function in OSA has also been investigated because possible factors explaining the airway collapse are neurophysiological changes in the control of the upper airway musculature (11), especially in the dilator muscles of the pharynx, such as the genioglossus and tensor palatine, as well as tongue volume and tongue position (8, 10–12, 17–20). Results have shown reduction of the apnea/hypopnea index (AHI) and an improvement of quality of life in adults after exercise-based therapy for oropharynx muscles and OMDs (8, 18). Despite these findings, there is no consensus on which exercises are most appropriate for the treatment of patients with OSA (20), with a lack of specificity regarding therapeutic targets and procedures.

The heterogeneity of oral and oropharyngeal exercises (20) may be explained, at least in part, by the lack of a standardized evaluation protocol of orofacial components and functions for the diagnosis of OMDs in patients with OSA (9). Such a protocol is necessary to establish the appropriate therapeutic strategy for the relief of conditions that contribute to OSA (19), and also for outcome analysis to determine whether the

effects of OMT, such as a reduction of AHI, are, in fact, related to improved muscle and orofacial functions.

We believe that, to fill this gap in the literature, the Expanded Protocol of Orofacial Myofunctional Evaluation with Scores (OMES-expanded), previously validated for children (21), may be useful for the diagnosis of OMDs in young and adult individuals with oral diseases or disorders, among them patients with OSA.

The OMES-expanded permits the assessment of appearance/posture and mobility of the stomatognathic system, and of functions such as breathing, swallowing, and mastication (21), using observations made on an ordinal level of measurement, as defined by the psychophysical principles of measurements (22), such as those of the OMES protocol previously validated for adults (23). However, OMES-expanded has the advantage of allowing a detailed assessment because it comprises more items to be evaluated and numerical scales with a greater amplitude than in the OMES protocol.

A detailed analysis of precision of movements and of orofacial functions, as proposed in OMES-expanded, may provide more accurate and relevant information about functional changes in patients with OSA. In addition, diagnostic precision can be improved with a greater number of items and with expanded assessment scales (24, 25).

A validated clinical evaluation could supplement the investigations of the morphophysiology of the upper airway by imaging analysis and electromyography (5, 7, 10, 15). However, it is first necessary to prove the validity of the instrument for young and adult people with OSA.

The validity of an instrument is an estimate of how well the instrument assesses what it intends to assess. The ability of the instrument to discriminate between groups with different degrees of severity of the disorder under study demonstrates its construct validity, whilst the convergent validity criterion is demonstrated by correlation between the instrument and other instruments previously validated for assessing the same disorder (26). In the current study, the disorder under investigation is the OMD. A validation study also requires reliability estimates, which can be defined as the degree of consistency across repeated intra- and inter-examiner measurements (21, 26, 27).

In view of the need for a valid instrument to evaluate OMDs in patients with OSA, and because OMES-expanded was tested only on children (21), the purpose of the current study was to determine the validity and the reliability of OMES-expanded for young and adult people with OSA. The psychometric properties of the instrument (i.e. sensitivity, specificity, positive predictive value and negative predictive value) were also examined.

Material and methods

The Institutional Review Board of the Ribeirão Preto School of Medicine, University of São Paulo (São Paulo, Brazil), approved the protocol, and all subjects gave written informed consent to participate.

Subjects

A total of 133 subjects [99 consecutive patients who sought treatment for OSA at the University Hospital, Ribeirão Preto School of Medicine (University of São Paulo, São Paulo, Brazil), and 34 individuals without complaints of OSA who volunteered for evaluation and who met the inclusion criteria (the control group)], participated in this study. The distribution, demographic data, body mass index (BMI), and AHI of the subjects are presented in Table 1.

Inclusion criteria for OSA patients were: daytime somnolence (as assessed using the Epworth Sleepiness Scale); snoring (according to the Stanford Snoring Scale); a sleep efficiency of more than 75%, and an AHI of more than five events per hour during sleep, as determined by polysomnography (PSG) performed according to the technical parameters of the American Academy of Sleep Medicine (13); and no previous or current treatment or use of any device for the reduction of signs and symptoms of OSA.

Inclusion criteria for controls (asymptomatic) were: adequate sleep hygiene habits; and no complaints of OSA or daytime somnolence (as assessed by the Epworth Sleepiness Scale), or of snoring (according to the Stanford Snoring Scale).

Exclusion criteria for both groups were: neurological or cognitive deficit; previous or current OMT; tumors or traumas in the head and neck region; and current use of analgesics, psychiatric drugs, or muscle relaxants.

Orofacial myofunctional evaluation

Evaluations using OMES-expanded and PSG were performed in the same week for patients with OSA. During evaluation, patients were mixed with controls to avoid identification according to group. All assessments were video recorded for further analysis, as explained below.

Evaluation using OMES-expanded: All subjects were individually evaluated by visual inspection during the session and this evaluation was later complemented with analysis of video-recorded images.

During the evaluation sessions, the subjects sat on a chair with a backrest, with their feet resting on the floor at a standardized distance (1 m) from the lens of the camera (Sony Handycam videocamera, Hi8/ccd-TRV 138; Sony Eletronics, San Diego, CA, USA), which stood on a tripod and was set at the level of the face, neck, and shoulders of the subject.

Table 1

Characteristics of subjects evaluated in the study

Study group	*n*	Age (yr)	BMI (kg m^{-2})	AHI (h^{-1})
OSA (total)	99	45.1 ± 9.1	32.1 ± 6.1	37.5 ± 34.5
Male	47	41.9 ± 7.9	31.0 ± 5.4	48.9 ± 38.7
Female	52	48.0 ± 9.1	33.1 ± 6.6	27.1 ± 27.5
Control (total)	34	29.1 ± 6.3	22.5 ± 2.9	–
Male	13	31.8 ± 7.6	23.1 ± 2.0	–
Female	21	27.5 ± 4.9	22.1 ± 3.5	–

AHI, apnea/hypopnea index; BMI, body mass index; OSA, obstructive sleep apnea.
Values are given as *n* or mean ± SD.

The OMES-expanded was applied according to a previously described methodology (21). Predetermined scores were attributed to the following items, with the highest scores indicating normal patterns without deviation:

Appearance/posture: face (symmetry, proportion between facial thirds and nasolabial sulcus), cheeks (volume and tension), mandible (vertical posture, anteroposterior position, and relation with the midline), lips (position, configuration, and appearance of labial commissures), and tongue (position in the oral cavity, appearance, and volume) were evaluated. The scores were attributed using a 4-point scale, with scores ranging from 1 (severe alteration) to 4 (normal).

Mobility: subjects were asked to perform separate movements of the lips, tongue, cheeks, and mandible. A 6-point scale, with scores ranging from 1 to 6, was used. Separate movements of each component, precise and without tremors, were considered to be normal and received a score of 6. When severe inability was observed, a score of 1 was assigned.

Functions: breathing, deglutition, and mastication were evaluated as described below.

(a) *Breathing mode*: the examiner determined whether the subject appeared to inspire and expire through the nostrils or the mouth, or though both pathways, and attributed scores on the following 4-point scale: score 4, the lips remained in occlusion without effort, mainly during situations of rest and mastication, with the tongue contained in the oral cavity (normal pattern); score 3, mild alteration, when the subject presented oronasal inspiration but was able to perform inspiration only through the nose without showing signs of fatigue and dyspnea; score 2, moderate alteration, when the condition was similar to mild alteration but the subject did not maintain a nasal pattern; and, score 1, severe alteration, when the subject, while trying to perform inspiration only through their nose, showed signs of fatigue and dyspnea and opened their mouth to inspire within a few seconds, a pattern observed both at rest and during mastication.

(b) *Deglutition*: this assessed separately with solid and liquid boluses, with the following observations:

(i) Labial behavior: when the lips were occluded without apparent contraction, the behavior was considered normal and a score of 4 was attributed; a score of 3 was attributed to medium lip contraction; a score of 2 to severe contraction; and a score of 1 to the absence of lip occlusion.

(ii) Tongue behavior: it was considered normal when the tongue was contained in the oral cavity and this received a score of 4. A score of 3 was attributed to tongue interposed between teeth in the limit of the incisal surfaces (or margins, in the absence of teeth), with a reduced vertical dimension of occlusion (VDO) in cases of overbite; a score of 2 was given to tongue on the limits of the incisal surfaces with normal VDO; and a score of 1 was given to tongue placed beyond the incisal surfaces. In order to observe tongue behavior, it was explained to the subject that they should proceed in their habitual manner, but that the examiner would place their index finger under the subject's chin and their thumb under the subject's lower lip (region of the mentalis muscle) and that the subject's lips would be separated after swallowing. Immediately after deglutition, the examiner separated the lips of the subject in order to visualize the teeth (or even the tongue, in the event of tongue interposition).

(iii) Other: other behaviors and signs of alteration (movement of the head or of other parts of the body, sliding of the mandible, tension of the facial musculature, food escape, choking, and noise) were observed, and a presence [1] or absence [2] scale was used for each sign.The efficiency of deglutition was assessed and a score of 3 was attributed when there was no more than one repetition of deglutition of the same bolus, a score of 2 when there were two to three repetitions, and a score of 1 when multiple swallows occurred.

(c) *Mastication*: subjects were instructed to chew a Bono chocolate-filled cookie (Nestle, São Paulo, Brazil) in their usual manner. Masticatory type was evaluated (using a 10-point scale) according to the percentage of chewing strokes on each side of the oral cavity, determined by observing the bolus localization (volume on cheeks) as well as the orofacial movements, especially jaw, lips, and cheek displacements (using video analysis), as follows: bilateral and alternate chewing (chewing strokes occurring on each side 50% of the time or on the same side from 40% to 60% of the time) was given a score of 10; simultaneously bilateral (chewing strokes occurring on both sides 95% of the time), was given a score of 8; unilateral preference grade 1 (chewing strokes occurring on the same side 61–77% of the time), was given a score of 6; unilateral preference grade 2 (chewing strokes occurring on the same side 78–94% of the time), was given a score of 4; chronic unilateral (chewing strokes occurring on the same side 95–100% of the times or masticatory strokes occurring in the region of the incisors and canines), was given a score of 2; and failure to chew was given a score of 1.

The bite was observed and the examiner attributed scores on a 4-point scale, with a score of 4 indicating biting with the incisors and a score of 1 given when the subject did not bite the food but broke it into pieces with their hands before bringing it to their mouth. Other behaviors and signs of alteration (movement and/or altered posture of the head and of other parts of the body, food escape, and uncoordinated jaw movements) were observed, and a presence [1] or absence [2] scale was used for each sign (21).

The final score is a sum of partial scores. An OMES-expanded score of 232 indicates the total absence of OMDs, and as lower the score, highest the degree of OMDs.

Reference protocol: The OMES protocol, a measure of orofacial myofunctional status validated for young and adult people (23), was used as the reference test. This protocol comprises the same categories, although with fewer items and lower scale amplitude, as in OMES-expanded.

An OMES score of 103 indicates the complete absence of OMDs. Recorded images were used for analysis.

Examiners

Two speech-language pathologists, previously trained and blinded regarding whether subjects were controls or OSA patients, participated in the study. Examiner 1 performed all evaluations in vivo applying OMES-expanded ($n = 133$) and also performed evaluations for criterion validity using the OMES protocol ($n = 50$). Video-recorded images were used during the OMES protocol and the subsequent evaluations, with no identification of the subjects (21, 23).

A randomly selected percentage of subjects (26%, $n = 13$) was re-evaluated by Examiner 1 and Examiner 2 using OMES-expanded. Examiner 2 was blind to the outcome of Examiner 1's evaluation. Evaluations performed by the same examiner were scheduled with an interval of at least 30 d to avoid memory effects. These data were used to determine intra- and inter-examiner reliability and agreement.

Data analysis

The subjects were grouped according to the aims of the analysis, as explained below.

Validity of OMES-expanded

Two types of validation were performed: construct validity and criterion validity.

Construct validity: The ability of OMES-expanded to discriminate subjects (construct validity) according to the degree of OMD was tested in two ways:

(a) comparisons of all patients with OSA ($n = 99$) and control subjects ($n = 34$) with the whole study group. The characteristics of the subjects are presented in Table 1.
(b) comparisons of 20 (11 male and nine female) patients with OSA and 20 (nine male and 11 female) control subjects, paired for age and sex, with risk factors for OSA. Subject characteristics are given in Table 2.

Criterion validity: To test whether OMES-expanded actually measured the orofacial myofunctional status of young and adult control subjects and patients with OSA (criterion validity), a correlation coefficient between its total score and a reference protocol total score was calculated for a subsample of 50 participants: 37 (20 male and 17 female) patients with OSA and 13 (eight male and five female) control subjects (see Table 3 for group characteristics).

To create this subsample with a similar proportion of OSA patients (74%) and control subjects (26%) relative to the whole sample, the 50 participants were selected from the groups using the function 'randomly selected a subset' of the GraphPad software (www.graphpad.com/quickcalcs).

Analysis of sensitivity, specificity, and positive and negative predictive values

Descriptive statistics of the reference protocol scores and the OMES-expanded scores were performed, and the 25th and 75th percentiles were obtained ($n = 50$; the same subjects as used in the criterion validity analysis). The 75th percentile was adopted as the cut-off point (i.e. 25% of the subjects who obtained lower scores than the remainder of the population were characterized as presenting relevant OMDs) (21). Thus, the cut-off scores adopted were 80 for the reference protocol and 152 for OMES-expanded. Based on these values, the diagnostic ability of OMES-expanded was quantified by calculating the sensitivity as the proportion of true positives that were correctly identified by the test (i.e. the number of subjects with an OMD diagnosis by both OMES-expanded and the OMES protocol/total number of subjects with an OMD diagnosis by OMES), and specificity was quantified as the proportion of true negatives correctly identified by the test (i.e. the number of subjects without an OMD diagnosis by both OMES-expanded and the OMES protocol/total number of subjects without an OMD diagnosis by OMES).

Also, the probability that the test would give the correct diagnosis was calculated by the positive predictive value (as the proportion of patients with positive test results who were correctly diagnosed by OMES-expanded) and the negative predictive value (as the proportion of patients with negative test results who were correctly diagnosed by OMES-expanded) (28, 29).

Statistical analysis

The correlation between OMES-expanded and the OMES protocol was calculated using Spearman's correlation coefficient. The patients with OSA were compared with the con-

Table 2

Construct validity: characteristics of subjects paired for age and sex

Study group	*n*	Age (yr)	BMI (kg m^{-2})	AHI (h^{-1})
OSA (total)	20	34.1 ± 5.6	31.6 ± 6.2*	41.8 ± 33.2
Male	11	34.1 ± 5.5	32.1 ± 6.9	55.9 ± 35.5
Female	9	34.1 ± 6.0	30.9 ± 5.4	24.6 ± 20.9
Control (total)	20	31.7 ± 6.5	21.9 ± 2.5	–
Male	9	34.3 ± 7.6	23.0 ± 2.0	–
Female	11	29.5 ± 4.8	21.1 ± 2.7	–

AHI, apnea/hypopnea index; BMI, body mass index; OSA, obstructive sleep apnea.
Values are given as *n* or mean ± SD.
*Significant difference at $P < 0.05$ (Mann–Whitney *U*-test). There was no significant difference in sex distribution ($P > 0.05$) according to Fisher's exact test.

Table 3

Criterion validity: characteristics of subjects

Study group	*n*	Age (yr)	BMI (kg m^{-2})	AHI (h^{-1})
OSA (total)	37	44.7 ± 7.5	32.8 ± 6.0	40.5 ± 39.2
Male	20	43.1 ± 6.4	32.3 ± 5.9	54.9 ± 46.1
Female	17	46.5 ± 8.6	33.3 ± 6.3	23.6 ± 18.9
Control (total)	13	31.3 ± 6.8	22.9 ± 2.2	–
Male	8	31.2 ± 8.3	22.7 ± 2.2	–
Female	5	31.4 ± 4.0	23.23 ± 2.5	–

AHI, apnea/hypopnea index; BMI, body mass index; OSA, obstructive sleep apnea.
Values are given as *n* or mean ± SD.

trols using the Mann–Whitney *U*-test. Sex distribution between the paired groups was compared using Fisher's exact test. Consistency and stability of the intra- and inter-examiner measurements (reliability coefficient) were determined using the Split-half method. The analyses were performed using STATISTICA software (StatSoft, Tulsa, OK, USA).

MEDCALC software (Mariakerke, Belgium, Version 11.0.1) was used to calculate the sensitivity, specificity, and positive and negative predictive values of OMES-expanded, and inter-examiner agreement was determined by the weighted Kappa coefficient (K'_w). The level of significance was set at 0.05.

Results

Validity of OMES-expanded

Construct validity: The ability of OMES-expanded to reflect normal and altered orofacial myofunctional status was demonstrated by the significant differences observed between patients with OSA and controls for the score of each category and for the total score ($P < 0.0001$) when all patients with OSA ($n = 99$) and controls were compared ($n = 34$) (Table 4), as well as when 20 patients with OSA were compared with 20 controls paired for age and sex (Table 5).

Criterion validity: There was a statistically significant correlation between the total scores generated by OMES-expanded and by the OMES protocol ($r = 0.88$, $P < 0.001$).

Sensitivity, specificity, and positive and negative predictive values

The OMES-expanded showed good sensitivity (67%), specificity (91%), positive predictive value (77%), and negative predictive value (86%).

Reliability and agreement

The reliability coefficients for the evaluations performed using OMES-expanded were 0.83 (intra-examiner, test and retest) and 0.82 (between examiners). The K'_w of 0.80 indicated very good inter-examiner agreement.

Discussion

This study was carried out in view of the need for a validated instrument to evaluate OMDs in patients with OSA. The results showed that OMES-expanded is valid for the assessment of young and adult patients with OSA because it was able to discriminate between this group and the control group and correlated significantly with the previously validated OMES protocol.

The construct validity of OMES-expanded was demonstrated by the identification of remarkable differences between control subjects and patients with OSA, observed both for comparisons with entire groups and with groups paired for age and sex. This second analysis was carried out because age and sex are risk factors for OSA (13), and there are no reports of the effects of these variables on OMDs. The results for both comparisons were quite similar; overall, patients with OSA showed lower scores compared with control subjects who, as expected, had mean values close to maximum scores (3, 23).

Based on these findings, the assumption can be made that the worse orofacial myofunctional status observed in the OSA group compared with the control group may be related to upper airway sensorimotor impairment (30). However, the role of these changes in the pathogenesis or progression of OSA still requires further clarification (31), as is also the case for other features (19).

Table 4

Construct validity of the Expanded Protocol of Orofacial Myofunctional Evaluation with Scores (OMES-expanded): comparison between obstructive sleep apnea (OSA) and control groups

Item and category sum	Maximum protocol scores	OSA group ($n = 99$)	Control group ($n = 34$)	*P*
Appearance/Posture	64	45.60 ± 6.17	58.76 ± 3.75	<0.001
Face	12	8.77 ± 1.50	10.76 ± 1.12	<0.001
Cheek	8	5.52 ± 1.43	7.61 ± 0.69	<0.001
Mandible	12	9.27 ± 1.71	11.35 ± 0.84	<0.001
Lips	16	11.26 ± 2.55	14.91 ± 1.65	<0.001
Palate	8	6.27 ± 1.80	7.41 ± 0.78	<0.001
Tongue	8	4.53 ± 1.33	6.70 ± 1.33	<0.001
Mobility	114	75.57 ± 16.53	99.64 ± 9.95	<0.001
Lips	24	17.71 ± 4.45	22.62 ± 2.35	<0.001
Tongue	36	19.72 ± 7.05	28.08 ± 7.25	<0.001
Mandible	30	19.27 ± 5.47	21.41 ± 3.94	<0.001
Cheek	24	18.85 ± 5.09	23.52 ± 0.92	<0.001
Functions	54	40.62 ± 4.87	48.79 ± 3.05	<0.001
Breathing	4	3.36 ± 0.89	3.97 ± 0.17	<0.001
Deglutition	28	22.97 ± 3.08	26.20 ± 2.08	<0.001
Mastication	22	14.28 ± 3.00	18.61 ± 2.08	<0.001
Total OMES-expanded	232	161.64 ± 22.38	203.23 ± 13.67	<0.001

Values are given as *n* or mean ± SD.
$P < 0.05$ indicates significance (Mann–Whitney *U*-test).

Table 5

Construct validity of the Expanded Protocol of Orofacial Myofunctional Evaluation with Scores (OMES-expanded): comparison between obstructive sleep apnea (OSA) and control groups paired for age and sex

Item and category sum	Maximum protocol scores	OSA group (n = 20)	Control group (n = 20)	P
Appearance/Posture	64	45.20 ± 7.51	59.75 ± 2.25	0.0001
Face	12	8.70 ± 1.70	10.95 ± 1.10	<0.001
Cheek	8	5.80 ± 1.54	7.60 ± 0.75	<0.001
Mandible	12	9.25 ± 1.80	11.40 ± 0.70	<0.001
Lips	16	11.40 ± 3.05	15.20 ± 0.83	<0.001
Palate	8	5.50 ± 2.23	7.50 ± 0.76	<0.001
Tongue	8	4.55 ± 1.15	7.10 ± 1.25	<0.001
Mobility	114	74.45 ± 17.24	103.4 ± 8.74	0.0001
Lips	24	18.30 ± 4.65	22.8 ± 2.21	<0.001
Tongue	36	19.15 ± 7.31	30.50 ± 6.60	<0.001
Mandible	30	19.00 ± 5.10	26.35 ± 3.88	<0.001
Cheek	24	18.00 ± 5.75	23.75 ± 0.64	<0.001
Functions	54	40.35 ± 4.74	49.00 ± 2.64	0.0001
Breathing	4	3.35 ± 1.00	4.00 ± 0.00	0.060
Deglutition	28	22.95 ± 2.50	26.55 ± 1.73	<0.001
Mastication	22	14.05 ± 2.93	18.45 ± 2.26	<0.001
Total OMES-expanded	232	160.0 ± 24.44	212.15 ± 11.4	0.0001

Values are given as n or mean ± SD.
$P < 0.05$ indicates significance (Mann–Whitney U-test).

Other studies have also reported OMDs in patients with OSA, such as facial asymmetry, an unfavorable maxillomandibular relationship, inadequate posture of the tongue (7), changes in masticatory pattern, and disorders of the oral phase of deglutition (8, 9), although previous evaluations of patients with OSA were performed without a validated scale-based instrument.

The findings confirm an interaction between orofacial function impairment and sleep breathing disorders that needs to be managed by an interdisciplinary clinical team with experience in oral health-related sleep disorders [e.g. sleep specialists and oral health specialists, such as a dentist, an orthodontist, an oral and maxillofacial surgeon (11), and a speech pathologist].

As mentioned earlier, age and sex are risk factors for OSA. The prevalence and severity of OSA is higher in men than in women, especially in women before menopause (11, 32, 33). A plausible explanation is the protective effect of estrogen in women during the reproductive period, in addition to body fat distribution and anatomy of the upper airways, among other differences between sexes (6, 32).

However, in the current study, the number of men and women with OSA was similar, probably because the study sample was selected from among patients who sought treatment for OSA, not from the general population. It was also observed that women were, on average, older than men, probably because in women the incidence of OSA increases during the menopausal and postmenopausal periods as a result of reduced estrogen secretion (33).

Obesity is another risk factor for OSA. However, in the present study, the sample size was too small to match controls and patients with OSA also for BMI. Furthermore, obese individuals without at least some symptoms of sleep apnea (especially men) are rare (6). In a future study, an increased number of volunteers will be necessary to assess the potential effect of increased BMI on orofacial myofunctional status, particularly for patients with OSA.

The strong correlation between OMES-expanded and the reference OMES protocol demonstrated the criterion validity. In the current study, the OMES protocol was the reference test owing to the absence of a valid measure of OMDs for patients with OSA. Moreover, it is the only instrument with an ordinal level of measurement that has been validated for orofacial myofunctional evaluation of young and adult subjects (23).

Compared with the OMES protocol, OMES-expanded has more items and wider scales, favoring a detailed analysis of components, movement precision, and orofacial functions by an examiner. It becomes possible to separate quantitatively more aspects, which may be clinically relevant for therapy planning and control. In addition to the advantages for clinical practice, because the instrument uses an ordinal level of measurement with at least four response options, and the categories (appearance/posture, mobility, or functions) can be analyzed by combining multiple items, these composite scores may be treated as continuous variables (34). This is useful for research because, with higher levels of measurement, more powerful statistical techniques (22) and options for analysis become available (35).

Therefore, the OMES-expanded may be more suitable for patients with OSA, delivering additional diagnostic and therapy-relevant information, as well as guiding intervention follow-up. This is warranted because of the limited evidence regarding the effects of exercises for OSA (19, 20).

Orofacial myofunctional disorders per se is not a problem involving a death risk; thus, the ideal would be for a diagnostic test to have a greater ability to identify subjects without (specificity) than with (sensitivity) OMDs, as verified here, to avoid the indication of a treatment for subjects who would not need it (21). Moreover, the predictive values indicate a high probability of correct diagnosis when the result is positive or negative.

Considering that the instrument's validity is based on subjective evaluation data, reliability estimates are required (26). In this study, the results showed very good intra-examiner (test–retest) and inter-examiner reliability, as well as very good inter-examiner agreement. These results show that the measurement of OMDs using OMES-expanded was reliable.

It is noteworthy that OMES-expanded is not an instrument for the diagnosis of OSA or for predicting its severity. For this purpose, the valid method is PSG (13, 36). Moreover, OMES-expanded does not permit the etiology of OSA to be defined. A limitation of the present study is that subjects in the control group were not analyzed using PSG. This was because the control subjects did not satisfy the minimum criteria for referral to PSG (36), such as complaints of snoring and excessive daytime somnolence (13) (i.e. the major manifestations of the disease), or obesity. However, and also considering other studies that did not evaluate control subjects using PSG (37, 38), it is necessary to recognize that the clinical impression or group categorization based on symptoms does not have the accuracy needed for the diagnosis of sleep disorders (36, 38).

The contribution of the current study to the investigations of OSA is presentation of the first validated instrument, based on a numerical scale at the ordinal level, to determine the presence and severity of OMDs, without determining the underlying etiology or the relationship with other variables. The rationale for this is that a method for measuring the real myofunctional status of patients with OSA had to be validated before other questions could be addressed. Additionally, OMES-expanded, previously validated for children, has shown validity for the evaluation of young and adult control subjects. The score values reported in the current study for both patients with OSA and controls, may be useful for future investigations and comparisons.

Studies that involve intervention for promoting orofacial function rehabilitation should use a validated scale-based instrument, such as OMES-expanded, for diagnosis and for the outcome measurement of the intervention.

In conclusion, the validity and reliability of OMES-expanded were demonstrated, ensuring credibility for the orofacial myofunctional evaluation of patients with OSA and of young and adult control subjects, within the limits of the parameters investigated.

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