

Validity of the ‘protocol of oro-facial myofunctional evaluation with scores’ for young and adult subjects

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SUMMARY The aims of this study were to analyse the validity, sensitivity and specificity of the protocol of oro-facial myofunctional evaluation with scores (OMES) for oro-facial myofunctional disorder (OMD) diagnosis in young and adult subjects. Eighty subjects were examined. The OMES was validated against the Nordic Orofacial Test-Screening (NOT-S) protocol (criterion validity) (Spearman correlation test). The construct validity was tested by analysis of the ability of the OMES (i) to differentiate healthy subjects ($n = 22$) from temporomandibular disorder (TMD) patients ($n = 22$), which frequently have OMD (Mann–Whitney test) and (ii) to measure the changes that occurred in a subgroup with TMD between the period before and after oro-facial myofunctional therapy (T group, $n = 15$) (Wilcoxon test). Two speech therapists trained with the OMES participated as examiners (E). There was a statistically significant correlation between the OMES and NOT-S protocols, which was negative because the two scales are

inverse ($r = -0.86$, $P < 0.01$). There was a significant difference between the healthy and TMD subjects regarding the oro-facial myofunctional status (OMES total score, $P = 0.003$). After therapy, the T group showed improvement in the oro-facial myofunctional status (OMES total score, $P = 0.001$). Inter- and intra-examiner agreement was moderate, and the reliability coefficients ranged from good to excellent. The OMES protocol presented mean sensitivity and specificity = 0.80, positive predictive value = 0.76 and negative predictive value = 0.84. **Conclusion:** The OMES protocol is valid and reliable for clinical evaluation of young and adult subjects, among them patients with TMD.

KEYWORDS: validation studies, myofunctional therapy, evaluation studies, mastication, deglutition, temporomandibular joint disorders, speech therapy

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Introduction

A relatively common problem of the stomatognathic system is the oro-facial myofunctional disorder (OMD), defined as ‘any pattern involving oral and/or oro-facial musculature that interferes with normal growth, development, or function of structures, or calls attention to itself’ (1). This collective label includes alterations/dysfunctions of the appearance, posture and/or mobility of the lips, tongue, mandible and cheeks and of the stomatognathic functions (2) (deglutition, mastication, respiration and speech) that possess vital and social characteristics (3, 4).

Oro-facial myofunctional disorder can occur at any age. Impaired oro-facial function is a common feature in dentofacial deformity (5), mouth breathing, temporomandibular disorders (TMDs) (3, 6–9), many genetic and congenital disorders, and anatomical abnormalities such as cleft lip and palate. It may also occur as a consequence of various acquired diseases (e.g. cerebrovascular accident, traumatic brain injury) and degenerative diseases (e.g. Parkinson’s disease, amyotrophic lateral sclerosis, multiple sclerosis) (10, 11). Because of the complexity of these functions, several health professionals are involved in the diagnosis of OMD (10).

Objective examinations such as surface electromyography and three-dimensional motion analysis have facilitated the diagnosis of problems affecting the stomatognathic system and its functions (7, 12, 13). However, oro-facial myofunctional evaluation continues to be considered essential for the diagnosis of OMD (4, 10, 14, 15).

The validation of the methods for assessment has been recommended for evidence-based practice (16). The validity of an instrument is an estimate of how well the instrument assesses what it proposes to assess, being an indicator of test veracity (17).

Protocols whose evaluation data can be expressed numerically are useful for subject comparison and to monitor the results of treatment. According to psychophysical principles, the level of measurement depends on pre-established conditions, so that the relations between attributes will be represented by the relations between numbers, which later will define the applicable statistical tests (18).

Three validated protocols of oro-facial myofunctional evaluation have been published thus far: the Nordic Orofacial Test-Screening (NOT-S) (10), based on a dichotomous judgment, that is, absence or presence of alteration; the protocol of oro-facial myofunctional evaluation with scores (OMES) (2) and the OMES-expanded (15).

The OMES protocol, validated for children, is an instrument for the evaluation of oro-facial structures and functions, which permits the examiner to express numerically on a categorical scale his perception of the characteristics and behaviours observed (2). This protocol has been used for the diagnosis and analysis of the evolution of treatment in young and adult subjects. Reports on patients with TMD have been published (3, 19), although the protocol was not validated for these age ranges or for this health problem.

TMDs encompass a group of musculoskeletal and neuromuscular conditions that involve the temporomandibular joints (TMJs), the masticatory muscles and all associated tissues. The signs and symptoms associated with these disorders are diverse and may include difficulties in chewing, speaking and other oro-facial functions, according to the American Association for Dental Research (20).

The main current questions about TMD concern the relation of this disorder with occlusion including the limits between normal and pathological occlusion, the dynamic interrelation of structures and functions, the consequences of the adaptive changes of TMD, and

the real effects and mechanisms of action of the therapeutic modalities (21, 22).

In view of the need for a valid instrument to evaluate OMD in young and adult subjects, among them TMD patients, the objectives of this study were to analyse the validity, sensitivity, specificity and predictive values of the OMES protocol for these age ranges, as well as the reliability and intra- and inter-examiner agreements.

Materials and methods

The project was approved by the Human Research Ethics Committee of the Dental School of Ribeirão Preto, University of São Paulo, Brazil, Protocol no. 2008.1.524.58.0 and all subjects gave written informed consent to participate.

Type of study: prospective and comparative.

Subjects

The study was conducted on 30 healthy volunteers (nine men and 21 women, mean age 28 ± 9.0 years) and 50 patients with TMD, with long-lasting pain (more than 6 months) (one man and 49 women, mean age 33 ± 11 years). The volunteers were invited to participate in the study and those with TMD were consecutive patients seeking treatment at the Dental School of Ribeirão Preto, University of São Paulo, who met the inclusion criteria.

The inclusion criterion for TMD subjects was to present TMD, with disk displacements (group II) and muscle diagnosis (group I), with or without arthralgia (group IIIa), according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) axis I (23), and permanent dentition, without dental pain or periodontal problems.

The inclusion criteria for healthy subjects were to present full natural permanent dentition (at least 28 teeth) and absence of periodontal problems, dentofacial deformities or TMD based on the RDC/TMD.

The exclusion criteria for both groups were: neurological or cognitive deficit, previous or current tumours or traumas in the head and neck region, current or previous orthodontic, oro-facial myofunctional or TMD treatment, and current use of analgesic, anti-inflammatory and psychiatric drugs.

All subjects were evaluated by the same experienced examiner, a PhD specialist in TMD and oro-facial pain accredited by the Federal Council of Dentistry.

The sample size was calculated to reject the null hypothesis (one-tailed test). Previously obtained descriptive statistics were used to estimate the minimum number of subjects required for a statistical analysis with 80% statistical power (type II error, beta) and with alpha (type I error) set at 5%. The number ranged from 5 to 18, depending on the variable analysed. Specifically for the OMES total score, the minimum number of subjects required was 13.

Data collection

Examiners

Two speech therapists specialised in oro-facial myofunctional therapy (OMT), accredited by the Federal Council of Speech Pathology and Therapy and trained in oro-facial myofunctional evaluation, performed the examination. The examiner 1 (E1) evaluated all the subjects enrolled in the study using the OMES and recorded the data on a printed chart and on video using a Panasonic M9000*. The second examiner (E2), with confirmed inter-examiner and intra-examiner reliability values of 0.94 and 0.92, respectively (15), and blind to the outcome of the other one, performed the evaluations based on video-recorded images using both the OMES and NOT-S protocols.

Oro-facial myofunctional evaluation with the OMES protocol

During the recording sessions, the individuals sat on a chair with a backrest with their feet resting on the floor at a standardised distance (1 m) from the lens of the camera, which stood on a tripod set at a height adjusted to focus on the face, neck and shoulders.

The OMES protocol was used for evaluation according to a previously described methodology (2, 15), as explained below.

Regarding the appearance and posture of the components of the stomatognathic system, scores were attributed using a 3-point scale: 3 = normal, 2 = mild alteration, 1 = severe alteration. The following items were evaluated:

- 1 Face: symmetry between the right and left sides;
- 2 Cheeks: volume, tension/configuration;
- 3 Lips: resting posture, lip volume and configuration;

- 4 Tongue: position at rest and volume.

The hard palate was not analysed because of the impossibility of doing so by means of the video-recorded images, but the item is part of the OMES protocol.

For the evaluation of mobility, the subjects were asked to perform separate movements of the lips, tongue, jaws and cheeks. The following movements were considered:

- 1 Lips: protrusion, stretching, lateroprotrusion to the right and to the left.
- 2 Tongue: protrusion, lateralisation to the right, lateralisation to the left, elevation, lowering and ability to keep the tongue stable in protrusion for 5 s.
- 3 Mandible: protrusion, lowering, elevation and lateralisation to the right and to the left.

In the analysis, separate movements of each component, precise and without tremors, were considered to be normal.

Dysfunction was considered to be present when lack of precision in the movement, tremor, associated movements of other components (e.g. lips accompanying the movements of the tongue) and inability to perform the movement were observed. Using the OMES protocol, the examiner attributed scores on a 3-point scale: 3 = normal, 2 = insufficient ability and tremors, 1 = severe inability.

Breathing was observed throughout the evaluation and was classified as nasal or oronasal. The examiner attributed scores on a 3-point scale: 3 = when the lips remained in occlusion without effort, mainly during situations of rest and mastication, with the tongue contained in the oral cavity (normal pattern); 2 = light dysfunction, when the subject presented oronasal inspiration but was able to perform inspiration only through the nose without showing signs of fatigue or dyspnoea, and 1 = severe alteration when the subject, while trying to perform nasal only inspiration, showed signs of fatigue and dyspnoea and opened his mouth to inspire, a pattern observed both at rest and during mastication.

During the video recording of the deglutition test, the subject was asked to bring a cup containing water at room temperature to his mouth and, after placing water in his mouth, to lower the cup so that his entire face could be visualised and to swallow in his habitual manner. A minimum of two and a maximum of four replicates were performed.

Next, it was explained to the subject that he should proceed as done in the previous test, but that the

*S-VHS movie camera; Panasonic of Brazil Limitada, São Paulo, SP, Brazil.

examiner would place her index finger under his chin and her thumb under his lower lip (region of the mentalis muscle) and that his lips would be separated after he had swallowed. Immediately after deglutition, the examiner separated the lips of the subject to visualise his teeth or even his tongue in case of the occurrence of tongue interposition.

For deglutition, assessed for both solid and liquid boluses, the pattern was considered to be normal when the subject presented the tongue contained in the oral cavity, contraction of elevator muscles and anterior sealing of the oral cavity without effort.

Regarding labial behaviour during deglutition, when the lips were occluded without apparent contraction, the behaviour was considered normal and a score of 4 was attributed to it. When the lips showed apparent light contraction, a score of 3 was attributed, a score of 2 was attributed to moderate contraction, and a score of 1 was attributed to the absence of lip occlusion.

Tongue behaviour during deglutition was considered normal when the tongue was contained in the oral cavity and received a score of 3. The remaining scores were assigned to the following behaviours: 2 = tongue interposed between teeth in the limit of the incisal surfaces (adaptation or dysfunction), and 1 = tongue placed beyond the incisal surfaces (excessive protrusion).

Other behaviours and signs of alteration such as 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. In the absence of each one of this signs, a score of 1 was attributed. If present, each sign received a score of 0.

The efficiency of deglutition, considered to be the ability to impel the bolus from the oral cavity to the oropharynx, was assessed for both solid and liquid boluses. A score of 3 was attributed for both consistencies 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 deglutitions occurred.

A chocolate-flavoured stuffed Bono[®] cookie[†] was used for the chewing test and the subject was instructed to chew it in his habitual manner. The total time spent to consume the food was measured with a digital chronometer (Casio – HS-60W-1DF, São Paulo, SP, Brazil) which was started after the food was placed in the oral cavity and stopped after the final deglutition of each portion.

[†]Nestlé, São Paulo, SP, Brazil.

Solid food ingestion was analysed starting from the bite and the following scores were attributed: 3 = biting with the incisors, 2 = biting with the canines and the premolars and molars, 1 = when the subject did not bite the food but broke it into pieces with his hands before bringing it to his mouth.

Mastication (trituration) was classified in terms of type and the following scores were attributed to it: 4 when it was bilateral and alternate, 3 = when simultaneously bilateral, 2 = with the masticatory strokes occurring on the same side of the oral cavity 66–94% of the times; 1 = chronic unilateral, when the masticatory strokes occurred on the same side 95–100% of the time, or anterior when the masticatory strokes occurred in the region of the incisors and canines; 1 = when the patient did not perform the function.

In addition, the presence of other behaviours and signs of alteration was analysed, such as movement and/or altered posture of the head and of other parts of the body, food escape and uncoordinated jaw movements. A score of 0 was attributed to the presence of each of these items, and a score of 1 to its absence.

Application of the NOT-S protocol

The NOT-S protocol (10), used as reference, contains 12 domains. For the purposes of the study, only the six domains for the clinical oro-facial examination were considered, while the six concerning anamnesis were excluded.

According to the methodology described by the authors of the NOT-S, E2 marked 'no' when the aspect observed was normal, that is, it did not present any alteration and attributed a score of 0 (zero) and marked 'yes' when impairments/impediments were observed in the domain, attributing a score of 1 (one). According to the items considered, a final score of 12 represented alteration in all items (10). The NOT-S protocol used here can be accessed online (<http://www.mun-h-center.se>), where it has been translated into 10 different languages.

After data collection, all subjects with a diagnosis of TMD received some type of treatment at the Dental School of Ribeirão Preto.

Analysis of criterion validity of the OMES protocol

To test the behaviour of the OMES protocol and to determine whether it really measured the parameters

for which it was proposed, concurrent validity was calculated. The examination part of the NOT-S protocol (10) was considered as the standard or reference test. All subjects evaluated by E2 ($n = 80$) and the total scores of both protocols were considered.

Analysis of construct validity of the OMES protocol

The construct validity of the OMES protocol was tested in two ways: a) By comparing 22 TMD patients (P group) (one man and 21 women, mean age 27.73 ± 9.9 years) to the 22 healthy subjects (C control group), paired by age and sex, to determine the ability of the OMES to differentiate subjects on the basis of the OMD degree; b) By the analysis of the ability of the OMES to measure the changes in oro-facial myofunctional status that occurred in TMD patients after they received OMT. For this purpose, the data for the evaluation of the diagnostic phase (DP) of the 15 subjects with TMD who adhered to treatment for the period of 120 days (T group, mean age = 34.8 ± 7.5) were compared with those of the final phase (FP) of evaluation, after OMT.

Briefly, OMT for the T group was planned by the speech pathologists on the basis of the following main objectives: favouring pain relief, mandibular mobility without deviations, symmetry, as well as equilibration of the stomatognathic functions in a manner compatible with occlusion. All patients were treated by the same speech pathologist. According to the treatment protocol, the patients participated in the OMT sessions, lasting 45 min each, at a weekly frequency during the first 30 days and every 2 weeks after this period, with no other additional therapeutic conducts (treatment duration = 120 days). A home exercises program was prescribed during each session. The OMT protocol for TMD therapy has been previously published (3).

Analysis of agreement and reliability

Agreement was calculated by the linear weighted Kappa index (Kw') proposed by Cohen (24), which measures the degree of concordance and permits the demonstration of the strength of relation existing between examiners and within the same examiner (test–retest). Reliability was calculated by the split-half method to determine the consistency and stability of the intra- and inter-examiner results.

For the analysis of inter-examiner agreement and reliability regarding the use and interpretation of the

OMES protocol, all the evaluations performed in all subjects ($n = 80$) by E1 and E2 were compared.

For the analysis of intra-examiner (E2) agreement and reliability, different subjects selected at random were reevaluated for each protocol (a sample percentage of more than 15%). The data used for the validation of the protocol (test) were considered and a new analysis of the images of the same subjects (retest) was performed after at least 15 days to avoid memory effects on the results.

Analysis of sensitivity, specificity, predictive values and prevalence

The sum of the NOT-S scores and the sum of the OMES scores were considered for the calculation of sensitivity, specificity, predictive values and prevalence. In the NOT-S protocol, a score of 12 indicates the highest degree of OMD and a score of zero indicates the absence of OMD, while in the OMES a score of 100 indicates the total absence of OMD and a score of zero indicates the highest degree of OMD. Thus, the NOT-S and OMES instruments have inverse scales.

After descriptive statistics and preliminary analysis, the median was adopted as the cut-off point. Thus, subjects who presented a NOT-S score higher than 2 and an OMES score lower than 86 were considered to have relevant OMD.

Statistical analysis

Correlation between the OMES and NOT-S protocols was calculated by the Spearman correlation coefficient. The P and C groups were compared by the Mann–Whitney test. The Wilcoxon test for paired data was used to compare the diagnosis and final phases of the T group. The intra- and inter-examiner reliabilities were calculated by the split-half test. The cut-off point for a diagnosis of OMD was determined using the descriptive analysis for median calculation. These calculations were made using the Statistica software[‡], with the level of significance set at 0.05.

To determine intra- and inter-examiner agreements, the linear weighted Kappa coefficient (Kw') was calculated. The strength of agreement of Kw' was classified as poor (<0.20), reasonable (0.21–0.40), moderate (0.41–0.60), good (0.61–0.80), and very good (0.81–1.00) (25).

[‡]StatSoft Inc., Tulsa, OK, USA.

Sensitivity, specificity, positive and negative predictive values, and the prevalence of OMD in the study population were also calculated, using the MedCalc software[§].

The technical error of measurement (random error) of the OMES protocol was also computed for 70% of sample as $[\Sigma (D^2)/2 \times n]^{0.5}$ (Dahlberg's formula), where *D* is the difference between the two repeated measurements, and *n* is the number of subjects.

Results

Criterion validity of the OMES protocol

There was a statistically significant correlation between the OMES protocol and NOT-S ($r = -0.86, P < 0.01$). Because the two scales are inverse, the correlation was negative.

Construct validity of the OMES protocol

- (a) The ability of the OMES to reflect normal and altered oro-facial myofunctional status was demonstrated by the significant differences observed between the C and P groups in the following items: appearance/posture of the mandible and face; mobility of the mandible; mastication and swallowing functions; and the total OMES score ($P < 0.01$). The results are listed in Table 1.
- (b) the ability of the OMES to measure the changes in oro-facial myofunctional status that occurred in TMD patients after they received OMT was demonstrated by the significant differences between the diagnostic evaluation and the evaluation after OMT in the following items: appearance/posture of the lips, cheek; mobility of tongue and mandible ($P < 0.05$); mastication and swallowing functions; and total OMES score ($P < 0.01$). There was a tendency to a significant difference in mandible posture ($P = 0.059$). The results are listed in Table 2.

Agreement and reliability

Inter-examiner (E1 × E2) and intra-examiner (E2) agreements (Kw') for the evaluations performed with the OMES protocol were moderate. The inter-examiner

Table 1. Oro-facial myofunctional evaluation in the control subjects (C) and TMD patients (P), mean and standard deviation (s.d.)

OMES	Maximum scores	C (n = 22)		P (n = 22)		P
		Mean	s.d.	Mean	s.d.	
Posture/appearance						
Lips	3	2.41	0.59	2.55	0.51	NS
Mandible	3	2.95	0.21	2.41	0.50	0.001
Cheek	3	2.86	0.35	2.68	0.48	NS
Face	3	2.36	0.49	2.00	0.00	0.001
Tongue	3	2.91	0.29	2.73	0.46	NS
Mobility						
Lips	12	11.50	0.80	11.23	1.31	NS
Tongue	18	14.91	2.51	14.45	2.87	NS
Mandible	15	13.73	1.24	12.73	1.20	0.00
Cheek	12	11.86	0.35	11.59	1.14	NS
Functions						
Breathing	3	2.73	0.46	2.77	0.43	NS
Deglutition	15	13.82	0.96	12.86	1.39	0.01
Mastication	10	9.27	1.16	7.64	1.68	0.001
Total score	100	91.32	5.44	85.64	6.51	0.01

OMES, oro-facial myofunctional evaluation with scores; *P*, probability of Mann–Whitney test for unpaired samples; NS, not significant ($P > 0.05$). Significant values for $P < 0.05$.

reliability coefficient was good (0.88) and the intra-examiner one was excellent (0.92).

The intra-examiner (E2) strength of agreement (Kw') for the evaluation with the NOT-S protocol was also moderate. The reliability for the application of the NOT-S, analysed by the test–retest method, was 0.89.

Sensitivity, specificity, predictive values and prevalence

The OMES applied to young and adult subjects presented good sensitivity (80.5%), specificity (80.0%), positive predictive value (76.0%) and negative predictive value (83.7%), and the prevalence was 46.2% for the OMES and 43.7% for the NOT-S.

Technical error of measurement

For all indices, the random error was very low, with values up to 0.21% for posture/appearance. Test–retest variability in the mobility ranged from 0.34% (lips) to 1.29% (tongue), in the functions it was 0.15% for breathing, 1.07% for deglutition and in the mastication

[§]Version 11.0.1; MedCalc Software, Mariakerke, Belgium.

Table 2 Comparison of the orofacial myofunctional scores of the T group in diagnosis phase (DP) and final phase (FP), after TMO. Mean and standard deviation (s.d.)

OMES	Maximum scores	DP		FP		P
		Mean	s.d.	Mean	s.d.	
<i>n</i> = 15						
Posture/appearance						
Lips	3	2.33	0.49	2.67	0.49	0.04
Mandible	3	2.40	0.51	2.80	0.41	NS
Cheek	3	2.27	0.46	2.60	0.51	0.04
Face	3	2.00	0.38	2.20	0.41	NS
Tongue	3	2.67	0.49	2.87	0.35	NS
Mobility						
Lips	12	11.20	1.32	11.73	0.59	NS
Tongue	18	13.33	3.15	16.93	1.39	0.001
Mandible	15	12.47	1.68	13.60	1.30	0.03
Cheek	12	11.27	1.44	11.80	0.56	NS
Functions						
Breathing	3	2.73	0.46	2.67	0.49	NS
Deglutition	15	11.47	2.70	14.07	1.03	0.001
Mastication	10	7.73	1.39	9.20	0.68	0.01
Total score	100	79.13	8.13	93.13	2.88	0.001

OMES, oro-facial myofunctional evaluation with scores; P, probability of Wilcoxon test for paired data; NS, not significant ($P > 0.05$). Significant values for $P < 0.05$.

it was lower than 1%. In all occasions, test–retest random error was lower than or close to the intra-group standard deviation, showing the good reproducibility of the indices.

Discussion

Oro-facial myofunctional evaluation is the fundamental step and the method most frequently used in clinical practice for the diagnosis of OMD, which is present in various health problems that affect the craniofacial complex and the stomatognathic functions (2, 4, 10, 11, 15), in part, because of the fact that the execution of certain exams may be impaired by technical complexity and by limited access to certain special materials (26).

This study was carried out in view of the need for a valid instrument based on a scale, at least at the categorical level, to evaluate OMD in young and adult subjects.

The validity of an instrument is associated with the reliability of the test used to make the diagnosis, with the training of the examiner that applies the test, and with the characteristics of the subjects for whom the test is proposed (27).

An instrument for diagnostic measurement must be analysed in terms of content, criterion and construct

validity. The content validity of the OMES, which involves the definition of the object of interest and the judgment of the relevance of each variable observed, has been determined in previous studies (2, 3).

Criterion validity is determined by comparing the instrument in question to another one taken as reference (17). The reference protocol adopted in this study was the NOT-S (10), which has been applied in other studies of OMDs (28, 29). The NOT-S and OMES protocols are not identical regarding the items evaluated clinically. For example, both instruments focus on the components of the stomatognathic system at rest and during functional movements, but while the NOT-S includes speech evaluation, the OMES includes the evaluation of swallowing and mastication. However, distinction among the items evaluated is an advantage because it avoids the circularity that would tend to inflate the estimates of validity.

According to the results obtained, the OMES is valid for the assessment of young and adult subjects because it showed a good correlation with the NOT-S.

An important difference between the OMES and NOT-S protocols is related to the level of measurement of their scales. The NOT-S employs a nominal scale in which the numbers only reflect whether the aspect observed is normal (score zero) or presents

impairments/impediments (score 1), thus involving dichotomous judgments. According to the authors, the NOT-S is an oro-facial screening that may disclose problems in an individual and identify the type and frequency of oro-facial disability in different syndromes and diseases (10). In contrast, the measurement scale of the OMES protocol also permits the grading of oro-facial myofunctional status (2) and the comparison of two distributions. This distinction represents an advantage for the clinical practice use of the OMES, as well as its use for research because the level of measurement defines the applicable statistical tests (18); the higher the level of measurement of a variable the more powerful are the statistical techniques that can be used to analyse it.

The construct validity of the OMES was demonstrated by the ability of this protocol to differentiate between control and TMD subjects. As found in this study, other investigations have demonstrated that subjects with TMD, the most prevalent clinical entity afflicting the masticatory apparatus (22), frequently have OMD. Among them, changes in appearance/posture and mobility of the oro-facial structures, disorders of the oral phase of deglutition (6, 9, 30) and disorders of mastication (3, 7, 19), which involves a greater risk of pain and more signs and symptoms of TMD (8). The choice of subjects with TMD was based on this previous knowledge, guaranteeing that OMD was present.

The relation between muscle pain and motor function, that is, muscle activity and movement, has been investigated (31, 32). The change in muscle recruitment may be a compensatory mechanism for pain relief or may precede the muscle pain symptoms in cases of TMD (9, 31).

Especially when long-standing, TMJ pain is associated with marked functional impairment (12). According to Cairns *et al.* (21), one testable hypothesis is that TMD causes irreversible degenerative alterations in the masticatory apparatus and, consequently, the system reacts with adaptive changes, in some cases also irreversible, in an attempt to regain the functional equilibrium.

In this study, OMT was the treatment chosen to analyse the ability of the OMES protocol to reflect changes in the oro-facial myofunctional status. Speech-Language pathologists are trained to evaluate and treat oral-motor function disorders (4).

The effects of exercise-based treatment of TMD have been analysed in several studies (33–35). Specifically,

OMT has been indicated for cases of TMD for many years (6) and has demonstrated positive effects on the reduction of OMDs and on the signs and symptoms of TMD (3, 19).

According to the results, after OMT, the patients presented a significant increase of OMES scores, indicating an improvement of the oro-facial myofunctional status.

Thus, the validity construct of the OMES protocol for young and adult subjects was confirmed according to the two prerequisites established in the literature, that is, the ability of the instrument to differentiate between symptomatic and asymptomatic subjects and to measure the changes occurring in symptomatic patients after treatment (36).

The validity of an instrument is an indicator of test veracity (17). As validity of the OMES was calculated considering the ratings of E2, in addition, it was also required to analyse the reliability of the examiner (E2).

Reliability was previously defined as the extent to which the result measured reflects the true result (17). Basically, it is possible to measure the percentage of agreement and the correlation of intra- and inter-examiner reliabilities. As a function of the type of scale of the NOT-S protocol, the strength of agreement was analysed by calculating the weighted Kappa coefficient (Kw'), which was indicated for the analysis of evaluations based on a dichotomous judgment, that is, absence or presence of disease (37). The inter- and intra-examiner Kw' value was moderate and the reliability coefficients ranged from good to excellent.

Inter-examiner agreement and reliability analyses were particularly important in view of the difference in the procedure of E1 (presence + analysis of video-recorded mastication data) and E2 (all items analysed only from video-recorded data).

The use of video-recorded images has proved to be useful in this type of study, because it permits the same examiner to repeat the evaluation (test–retest). Also the evaluation can be performed by different examiners at different times without provoking fatigue or other inconveniences for the subjects and without variations in their conditions (2, 15).

The results suggested the possibility of OMES application even though the examiner is not present during the recordings. However, the different conditions of evaluation between examiners may have prevented higher levels of agreement between them. The factors that contribute to possible differences between

face-to-face and video recording evaluation should be explored, among them the role of non-verbal language.

Despite the apparently easy use of the OMES protocol, it is essential for the examiner to be trained in its evaluation and in the ability to interpret it, which depends on the knowledge of the anatomy and physiology of the stomatognathic system, on the standards of normality of the functions, and the deviations and possible disorders. The same applies to the NOT-S, as pointed out by the authors (10).

In addition to being based on analyses of validity and reliability, the scientific rigour of a diagnostic test tends to be greater when its sensitivity, specificity and predictive values are determined (38), values that were found to be good in this study.

The median was adopted as the cut-off point because of the greater equilibrium observed between sensitivity and specificity. The obtained values indicated a good ability of the OMES to identify subjects with OMD when they really present the disorder and to identify subjects without OMD when they are actually free of this disorder, with a high probability of a subject to present OMD when the test is positive and not to present it when the test is negative.

Thus, the OMES may be useful for analysing the functional patterns in young and adult subjects, among them TMD patients.

When a diagnostic test is validated and has good sensitivity, good specificity and good predictive values for the alteration in question, the diagnosis becomes more precise and can favour the decision-making process regarding the treatment plan and patient follow-up during and after treatment (15).

However, it is important to point out that the OMES protocol is specific for the identification and grading of OMD, without determining the underlying aetiology.

Thus, it is one of many diagnostic tests that will be needed before treatment is begun on a patient. On this basis, according to the complaints and signs and symptoms of the patients, other clinical and/or instrumental examinations may be necessary to determine the underlying aetiology or the possible interrelations to be considered to prevent damage and promote health.

Conclusion

Based on the present results, the OMES protocol is valid for the assessment of oro-facial myofunctional status in young and adult subjects, permits the determination of

OMD degree before and after treatment, and can be used by different examiners or by a single examiner in multiple applications. By being based on a scale and by requiring no special equipment, it can be useful both in clinical practice and in research.

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Conflict of interest

The authors declare that they have no conflict of interest.

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