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Osteovox self-management concept study. Part 1: Focus on the population

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ABSTRACT

Objective: To analyze the prevalence of parafunctional behaviors in patients suffering from painful temporomandibular disorders (TMD) during the selection process of the study. **Methods**: This multidisciplinary study was based on seven selection criteria, of which the two main ones were parafunctions and symptomatology. The main clinical outcomes were (1) the type of TMD, (2) psychological symptoms, and (3) otological symptoms. From 409 consecutive examinations for TMD, 107 subjects met all criteria.

Results: During the selection process, among the 409 subjects, 81.9% were diagnosed with parafunctions. After the selection process, among the 107 parafunctional subjects, pain (71%) was more disabling than functional limitations (29%). Most patients (74%) exceeded the thresholds of psychometric scales. Otological symptoms were observed in 52% of the subjects.

Discussion: The study highlighted the importance of parafunctions and psychological factors in patients with painful TMD. Treatment should include all factors identified in this study (see Part 2).

KEYWORDS

Temporomandibular disorders (TMD); bruxism; epidemiology; psychology; otological symptoms; parafunctional behaviors; pain; risk factor

Introduction

The management of temporomandibular disorders (TMD) is varied and involves multiple health practitioners. A. Piron, an osteopath, and P. Dieudonné, a dentist specialized in TMD, have proposed a clinical protocol called the Osteovox self-management concept (OSMC), mainly for patients suffering from painful TMD. This approach is accessible to different types of therapists. The OSMC involves manual therapy, sensory-motor awakening, normalization of neuromuscular and biomechanical dysfunctions of the masticatory, lingual, and labial systems, and it facilitates the learning of self-normalizations. The OSMC is part of a self-management (SM) philosophy.

Even though the scientific data on the subject remains scanty, the recent literature is in agreement with SM programs [1,2]. However, the authors highlighted there is an important variety of SM programs. Therefore, it prevents drawing a definitive conclusion on which program should be favored. It also justifies the fact that more studies need to be undertaken on SM programs. Due to a lack of evidence from the scientific literature and thanks to a network of collaborators practicing the OSMC with satisfaction, the idea of a multicentric and prospective clinical study was born. Two major objectives were served: the evaluation of the efficiency of the OSMC and the collection of numerous clinical data, such as pain or functional limitation. The hypotheses of these clinical data were related to the efficacy of the OSMC. The study was split into two parts:

Part 1 concerns the observational aspect of the symptoms displayed by the population through the data collected in a prior evaluation (PE), and it analyzes the epidemiological and clinical data of the participants.

Part 2 concerns the therapeutic aspect via data collected from both an intermediate evaluation (IE) and a final evaluation (FE). It assesses the efficiency of the OSMC and its relationships with other epidemiological and clinical features studied in PE and developed in Part 1.

The OSMC is supposed to be used primarily by symptomatic patients who display bruxism both as an awakening and a sleep parafunction. Bruxism can be defined as a masticatory muscle activity during sleep and/or wakefulness. It is characterized by repetitive or

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sustained tooth contact and/or by bracing or thrusting of the mandible and is not a movement disorder in otherwise healthy individuals [3,4]. The authors' clinical experiences have led them to integrate the parafunctional behavior of the lingual and labial systems into the study. Indeed, most patients suffering from bruxism experience an excessive tension in the lips or in the tongue, regardless of its place in the mouth. This tension inescapably increases the tone of the other masticatory muscles (even without teeth contact). In this article, the terms "parafunctional behaviors" and "parafunctions" will be used instead of bruxism.

The first objective of this study was an epidemiological one: to analyze, through the selection process, the prevalence of parafunctional behaviors (whose authors make the hypothesis that it was high) in subjects suffering from painful TMD and then to assess the initial clinical characteristics of all the subjects included in the therapeutic part of the study after the selection process.

Materials and methods

The study was multicentered and multidisciplinary. It was carried out in private offices in Liège, Belgium; Nantes, France; and Brescia and Torino, Italy by eight practitioners: two dentists (SLh, AB), four osteopaths (AP, XT, CG, MS), and two speech therapists (SLi, BP). Before starting the clinical phase of the study, all the participants met over a period of two days in Liège (13th and 14th of October 2015) to standardize the modus operandi and to familiarize themselves with the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) 2014 [5]. The data covered in this article are only concerning the selection phase and the prior evaluation (PE). The selection took place between January 6 2016 and January 31 2017. The full protocol can be accessed at http://www.osteovox.org. The protocol was reviewed by the Ethics Committee of the University of Liege in Belgium (Secretariat Administratif du Comité d'Ethique Hospitalo-Facultaire de Liège). The study number was 2015-194. This was an overall registration that covered all participants in each center and country. The protocol was also registered on ClinicalTrials.gov prior to the beginning of the clinical phase (December 17 2015, under the number B707201525923). The study had no source of funding.

Participants

Eligibility

The five investigators responsible for the eligibility criteria (SLh, AP, CG, AB, MS) first selected all the patients who made an appointment because of a suspicion that they might have TMD. Seven filters were applied to select the desired population. The first five filters were the inclusion criteria; the sixth filter included the exclusion criteria, while the seventh filter referred to premature exits decided before the first intermediate evaluation (IE).

The seven filters that were chosen are described below.

- The first inclusion criterion was patients having TMD. The TMD had to be confirmed by the DC/ TMD [5].
- The second inclusion criterion was patients aged between 18 and 77 years.
- The third inclusion criterion was parafunctional behaviors in patients. Parafunctions had to be confirmed by the Oral Behaviors Checklist (OBC, see Appendix 2.3) [6,7]. The authors used a shortened version (10 items: 1, 3-11). Further, parafunctions were auto-evaluated by the patient through the Explanatory Model Scale (see Appendix 2.4) [8,9], which was a questionnaire in which the subject had to identify physical factors, behaviors, stress, and emotional upset as factors either causing or aggravating facial pain problems. The score went from 0 (not at all important) to maximum 4 (extremely important). The inclusion criterion was met if the total score on the Explanatory Model Scale of question A (causing factors) + Question B (aggravating factors) was equal to or greater than 3. To address potential sources of bias in patients included in the study, this self-assessment was confirmed after a 2-to-4-week observation period following an awareness session on the resting position of the masticatory system taught by the recruiting therapist.
- The fourth inclusion criterion was symptomatic patients. The symptomatology had to be confirmed either by the presence of facial pain in the last 30 days based on the Graded Chronic Pain Scale (GCPS v 2.0, see appendix 2.5) [10,11] or by a functional limitation in the last 30 days based on the Jaw Functional Limitation Scale (JFLS 20, see appendix 2.6) [12]. To be considered as symptomatic, the subjects had to get a positive score (different from zero) in at least one of the previous questionnaires.
- The fifth inclusion criterion was patients willing to conform to the requirements of the study, which were: coming regularly to the appointments and filling in the questionnaires. Informed consent had to be confirmed in writing after reading

a text approved by the Ethics Committee of Liège's University Hospital Center.

- The sixth filter included the exclusion criteria:
 - a significant medical history (serious or evolutionary pathology),
 - acute trauma of the temporomandibular joint (TMJ),
 - o pregnancy,
 - previous or associated treatments (treatment with antipsychotics, anxiolytics, hypnotics, musclerelaxants, or by an intraoral appliance),
 and addictions.
- The seventh filter involved only keeping patients who did not decide to withdraw from the study before the first IE and patients not showing up to all required appointments.

Sample

Table 1. Flow chart.

A few months after the beginning of the study, the statistician for the paper determined that the necessary sample was already obtained. He estimated this on the basis of a pre-analysis (statistical methods described further in the chapter) of the prior evaluation (PE) for 88 subjects. At that point, the relationship the authors wanted to investigate at PE was already significant. The authors created a flow diagram that encompassed the selection process in which the seven selected filters appeared (see Table 1).

Interventions and outcomes

As the article has been split into two parts, interventions were not developed in this part of the study, but in the second article.

The clinical study was conducted at three time points during five visits (V0, V1, V2, V3, and V4):

- (1) Diagnosis and inclusion (+ prior evaluation (PE)), in V0
- (2) Therapeutic sessions (+ intermediate evaluation (IE)), in V1/V2/V3
- (3) Closing session (+ final evaluation (FE)) in V4 (at the office or by mail or by phone).

Whether the sessions were organized in solo (osteopath alone) or in duo (dentist and osteopath or speech therapist), V0 and V1 were different:

- In solo: V0 and V1 were done in the same session (which lasted 1 h 30 min)
- In duo: V0 (45 min) and V1 (45 min) were done in two different sessions.

Primary outcome measure during the selection process

The main objective was to highlight the proportion of subjects with parafunctional behaviors who could later benefit from the OSMC therapy, in a general population

Flow chart							
All consecutive medical examinations for TMD in th	e office of 5 investigators	(dentist SLh; osteo	paths AP, CG, AB, MS)	N = 480			
In the selection			Out of selection				
1. Inclusion criteria: TMD confirmed	N = 436		Other diagnoses	N = 44			
2. Inclusion criteria: age from 18 to 77	N = 409 adult TMD		<18 N = 27; >77 N = 0	N = 27			
3. Inclusion criteria: parafunctional behaviors	N = 335 adult TMD w	vith parafunctions	Without parafunctions	N = 74			
4. Inclusion criteria: symptomatic	N = 260		Not symptomatic	N = 75			
5. Inclusion criteria: accept the study	N = 146		Disagree	N = 114			
6. Exclusion criteria (all)	None: N = 119		At least 1	N = 27			
 Exclusion as patient stopped before V2 (Stop at V1 or between V1 & V2) 	N = 12	Subjects in the Prior Evaluation	e study for n (PE) and treatment	N = 107 subjects with parafunctions			
V2 (+ V3 if necessary): continuation of treatment	Work in duo: V0: diagnosis & PE						
 → osteopaths AP = 9, XT = 14 & speech ther. Work in solo: V0 + V1: diagnosis & PE and beginning of the V2 (+ V3 if necessary): continuation of treatme → 4 osteopaths AP = 16, CG = 12, AB = 9, M 	treatment in the same s nt & IE	session		N = 43/107			

of patients with TMD. The method was described previously (see the third inclusion criterion for parafunctional behaviors).

Primary outcome after inclusion in the study

The main objective was to assess the patients' complaints (after inclusion in the study, all subjects were patients with both painful TMD and parafunctional behaviors) through the establishment of a total score, which was evaluated by a mathematical formula available in the supplemental appendix 1.1. The total score was based on two parameters: (1) pain, evaluated by four criteria: frequency, intensity, quality of life, and medication being used, and (2) functional limitation, evaluated on three criteria: mastication, mouth opening, and communication. To objectify these parameters, the questionnaires outlined below were used:

- (1) Pain/intensity (fixed parameter): The GCPS (see appendix 2.5) was used, and an average of the scores of the first three scales were recorded (items 2, 3, 4).
- (2) Pain/frequency (fixed parameter): A scale from 0 to 30 was used for the pain frequency over the last month of treatment (2015 questionnaire created by L'homme S, unreferenced, see Appendix 2.1).
- (3) Pain/quality of life (optional parameter): The GCPS (see appendix 2.5) was used to assess this by the average of the scores of the last three scales (items 6, 7, 8).
- (4) Pain/medication (optional parameter): the amount of analgesic consumed per week, chosen by the patient as the most suitable way to manage his or her pain. Medication was not scored per se but through the ratio between the amount of analgesic consumed after treatment and the amount of analgesic consumed before treatment (2015 questionnaire created by L'homme S, unreferenced, see Appendix 2.2).

Functional Limitation: The JFLS 20 (see appendix 2.6) was used for the following three criteria: mastication, mouth opening, and communication.

Finally, these two parameters (pain and functional limitation) were weighted by the patient via a visual analog scale (VAS, see supplemental appendix 1.2) from 0% to 100%. The patient had to assess the proportion of each parameter within the overall complaint. There were 11 possibilities: Pain 100%/Limitation 0% or Pain 90%/Limitation 10% or Pain 80%/Limitation 20% etc.

Secondary outcome measures

The practitioners conducted an evaluation of:

- (1) The patient's psychological state based on these two questionnaires, which were validated and tested for reliability for many years [13-15]: The Hospital Anxiety and Depression Scale (HAD, see supplemental appendix 2.8) [16] and the Symptom Checklist 90 Revised (SCL90, questionnaire not included in the appendix because there is no permission to reproduce it) [17]. The HAD is a 14-item scale that generates ordinal data. Seven of the items relate to anxiety and seven relate to depression. Absence of depression and/or anxiety can be correlated to a score from 0 to 7; uncertain situation to a score from 8 to 10; moderate anxiety from 11 to 14; and severe anxiety from 15 to 21. The SCL90 instrument helped evaluate a broad range of psychological problems and symptoms of psychopathology [17], among which include:
 - a. somatization (positive if the score was < 2 or > 14);
 - b. obsessive-compulsive (positive if the score was < 4 or > 16);
 - c. interpersonal sensitivity (positive if the score was < 2 or > 12);
 - d. depression (positive if the score was < 3 or > 17);
 - e. anxiety (positive if the score was < 0 or > 10);
 - f. hostility (positive if the score was < 1 or > 7);
 - g. phobic anxiety (positive if the score was < 0 or > 5);
 - h. paranoid ideation (positive if the score was < 0 or > 5);
 - i. psychoticism (positive if the score was < 0 or > 11);
 - j. a category of "additional items" (no cutoffs).
- (2) The patient's state of parafunctional behaviors via the OBC questionnaire (10 items: 1, 3–11). There were five levels of frequency for the sleep's activities (item 1) and for the 9 items related to waking hours activities (items 3–11), which gave a score from 0 to 4 by item. There were two scores: (1) the score for sleep's activities (ranging from 0 to 4 points) and (2) the score for waking hours' activities (ranging from 0 to 36 points).
- (3) The severity of TMD and its chronicity.

Severity. The subjects of the study were divided into three groups, according to the severity of the pain, ranging from mild situation to severe situation. This evaluation was based on the parameters used for the primary outcome measure related to pain:

- Mild situation, classified by two components of pain: frequency and intensity. Pain that did not affect the quality of life and did not require medication.
- Moderate situation, classified by three components of pain: frequency and intensity with either an impact on the quality of life or requiring medications.
- Severe situation, classified by four components of pain: frequency and intensity with both an impact on the quality of life and requiring medications.

Chronicity. This parameter was based upon the following three factors: (1) pain for at least three months, (2) pain impacting the quality of life (score > 0 for the items 6, 7, 8 of The GCPS), and (3) the presence of anxiety and/or depression (score \geq 11 for the HAD). These three parameters were evaluated thanks to questionnaires previously described. The subjects were divided into two groups suffering from either chronic pain or non-chronic pain:

- Chronic pain: a patient who suffered from all three clinical parameters at the same time.
- Non-chronic pain: a patient who did not experience all three clinical parameters simultaneously.

(4) Otological symptoms through a questionnaire developed by the authors (2015 questionnaire created by Piron A, unreferenced, see Appendix 2.7). This questionnaire is related to seven symptoms: a sensation of ear fullness (A), reduced hearing (B), hearing sounds too loud (C), hearing own breathing (D), hearing own heart (E), trembling in the ears (F), and dizziness (G).

Statistical methods

The software used for the statistics was R (3.4.0 version) (R Core Team, 2017). R is a language and environment for statistical computing created by the R Foundation for Statistical Computing, Vienna, Austria. Microsoft Excel was used for formatting the data, calculating the main lens, and for developing some graphics. Univariate and multivariate logistical and multinomial regressions were modeled to test the influence of certain parameters on binomial or polynomial variables (parafunctional behaviors and otological symptoms). The significance of the various tests was considered from a p-value of 0.05. The protocol respected the STROBE Guidelines [18].

Results

Participants

During the selection process, 409 adult subjects with TMD were screened to highlight the rate of parafunctional behaviors. After the selection process, 107 adult subjects (painful TMD with parafunctional behaviors) were screened to assess the main clinical outcomes: (1) the type of TMD, (2) psychological symptoms, and (3) otological symptoms before the beginning of the treatment. A flow diagram is presented in Table 1.

The characteristics related to DC/TMD Axis I and Axis II of the 107 painful TMD patients with parafunctional behaviors are presented in Table 2. Myalgia was the most predominant (84.1%) type of pain, followed by TMJ pain (63.6%), and headache (42.1%). A meniscal disorder was diagnosed in 72 subjects (67.3%), of which reducible dislocations (71.6%) were more abundant than irreducible dislocations (28.4%). Finally, a degenerative disorder was diagnosed in 11 subjects (10.3%) (Table 2).

Outcomes

Primary outcome measure during the selection process

Among the 409 patients aged between 18 and 77 years with a TMD, 335 subjects (81.9%) were diagnosed as suffering from parafunctional behaviors, 77.6% of whom were symptomatic.

Primary outcome after inclusion in the study

Among the 107 patients (suffering from both painful TMD and parafunctional behaviors) finally included in the study, and thus, who could follow the treatment, the therapists analyzed the overall complaint levels through the establishment of a score. In this scoring system, 0% corresponded to a 0 value of all the items in the questionnaires (previously mentioned in the Materials and methods section) and 100% to a maximum value. At V0, the average score was 32.86% (standard deviation (SD): 15.49%, minimum: 7.67%, first quartile: 21.92%, median: 30.23%, third quartile: 41.60%, maximum: 83.27%). The weighting assigned by the patients to the factors constituting the overall complaint showed that pain (70.75%) was a more important factor than functional limitation (29.25%). Regarding functional limitation, the most altered function was mouth opening (mean: 11.02/40 [SD: 9.73]), followed by mastication (mean: 12.17/60 [SD: 11.06]) and social functions (mean: 11.54/100 [SD: 29.82]).

Table 2. Features of the population.

Features of the popula	ition				
Number: 107	Female: 90 (84.1 (Age: 18y to 69)	,	Male: 17 (15.9%) (Age: 20y to 56y)	Mean age: 40y (1st Q = 2 (y = years; Q = Quartile)	8y/3rd Q = 50y)
Diagnosis: DC/TMD Axi	is 1				
Myalgia (all subtypes) 90/107 (84.1%)	Arthralgia 68/107 (63.6%)		Headache attributed to TMD 45/107 (42.1%)	Intra-articular Joint Disorders (1): 49/107 (45.8%) (2): 23/107 (21.5%) (3): 72/107 (67.3%) Subtypes: see lower	Degenerative Joint Disorder (4): 11/107 (10.3%)
pathology: 23 subjects		(3) = (1) + (2): all intra 72 subjects (95 TMJs)	-articular joint disorders:	 (4): all degenerative joint disorders 11 subjects (14 TMJs) 	
Intra-articular Joint Dis	sorders (subtypes	s) considering a	ll 95 pathological TMJs		Total 214 TMJs
Disc displacement with reduction 49 TMJs	Disc displaceme with reduction, with intermitten 19 TMJs		Disc displacement without reduction, with limited opening 15 TMJs	Disc displacement without reduction without limited opening 12 TMJs	Uncertain diagnostic > No MRI* 34 TMJs Healthy situations 85 TMJs
* Magnetic resonance im not necessary	naging (MRI) was n	ot done in thes	e cases because intra-articu	lar Joint disorders were unequ	ivocal and knowing the subtypes was
Diagnosis: DC/TMD Axi	is 2				
Pain: 70.75% Mild severity 31.76%	Moderate severity 30.84%	Severe severity 37.4%	Chronic pain 34.6%	Non-chronic pain 65.4%	Functional limitation 29.25%

TMJ: Temporomandibular joint.

Secondary objectives

Groups with severe and chronic situations

Severity: the authors observed 31.76% (n = 34) of mild clinical situations (two components of pain), 30.84% (n = 33) of moderate clinical situations (three components of pain), and 37.4% (n = 40) of severe clinical situations (four components of pain).

Chronicity: 37 subjects showed all three factors of chronicity. It was, therefore, estimated that 34.6% of the study's population experienced chronic pain.

Parafunctional behaviors

After the selection process revealed (which a proportion of 81.9% of parafunctional behaviors among 409 subjects with TMD), the level of parafunctions was assessed among the 107 subjects with parafunctions, following the treatment. The average score of daytime parafunctions, based on 9 questions, was 12.92/36. The level of nighttime parafunctions was also evaluated. The average score, based on one broad question, was 2.37/4. Parafunctional behaviors were very significantly correlated to anxiety studied via HAD (*p*-value \leq 0.001). This correlation was slightly significant to the psychological state studied via the

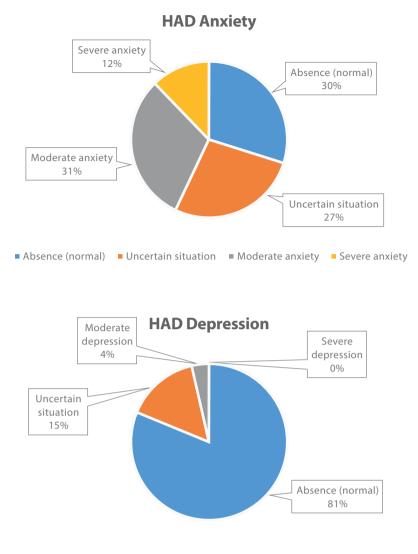
total score of SCL90 (*p*-value: 0.025) and not significant to depression studied via HAD (*p*-value: 0.192).

Psychology

Psychological state of patients studied via HAD

Concerning anxiety, the breakdown of the subjects was as follows: 29.91% displayed an absence of anxiety, with a score from 0 to 7; the situation was uncertain in 27.10%, with a score from 8 to 10; 30.84% had moderate anxiety, with a score from 11 to 14; and 12.15% suffered from severe anxiety, with a score of 15 to 21. As for depression, the breakdown of the subjects was as follows: 81.31% displayed an absence of depression, with a score from 0 to 7; the situation was uncertain in 14.95%, with a score from 8 to 10; 3.74% had moderate depression, with a score from 11 to 14; and 0% suffered from severe depression, with a score of 15 to 21 (Figure 1).

When analyzing anxiety and depression, it was highlighted that 26.17% of the subjects had scores that did not exceed the thresholds established by the authors of the scales; 30.84% exceeded the established thresholds moderately, while 42.99% exceeded them more severely.



Absence (normal) Uncertain situation Moderate depression Severe depression

Figure 1. Distribution of Hospital Anxiety and Depression Scale (HAD) scores. On the left, the diagram shows the results of the 7 items for anxiety, and on the right, the results of the 7 items for depression.

Psychological state of the patients studied via the SCL90

The proportion of subjects investigated with none of the 10 symptoms of psychopathology (traits) was 24.30%, while 75.7% had at least 1 trait; 54.29% presented at least 2 traits, and 39.05% expressed at least 3 traits (Figure 2).

Taking into consideration only the first 3 traits reported by the patient, the authors investigated what the predominant characteristics in hypertonic patients were (Figure 3). The most significant trait was the obsessive-compulsive symptom present in 36.79% of patients, followed by somatization (27.36%), interpersonal sensitivity (24.58%), depression (21.73%), anxiety (18.92%), and paranoid ideation (18.85%). The last 4 traits were rarer. Indeed, fewer than 10% of the patients suffered from phobic anxiety (9.41%), hostility (6.63%), additional traits (2.85%), and psychotism (1.9%).

Otological symptoms

Fifty-one patients (47.7%) did not show otological symptoms, while 56 (52.3%) presented at least one symptom. The more common symptoms were a sensation of ear fullness, dizziness, and the impression of hearing too loud or not loud enough. The most disturbing symptom, which was also one of the two most common ones, was the sensation of ear fullness. Otological symptoms were very significantly correlated to arthralgia (*p*-value: 0.005). There was also a slightly significant correlation with myalgia (*p*-value: 0.039), headache (*p*-value: 0.012), and parafunctions (*p*-value: 0.037) (Table 3).

SCL90 Proportion of subjects with 0; 1; 2; 3 trait(s)

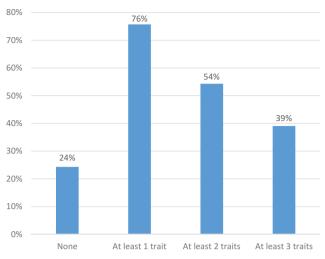


Figure 2. Proportion of subjects (1) Having none of the 10 symptoms of psychopathology (traits); (2) Having at least 1 trait; (3) Having at least 2 traits, and (3) having at least 3 traits in the Symptom Checklist 90 Revised (SCL90).

Discussion

The multicentric nature of this study made its protocol complex and acted as a source of potential bias or imprecision. The validity of the results was dependent on the methodology. In particular, the methodology used to determine that a patient was parafunctional can be criticized. However, the Oral Behaviors Checklist (OBC) does not currently present definitive cutoffs. Only temporary norms of the OBC were published in the self-report instrument scoring manual on the DC/TMD website on the 30th of October, 2018 [11]. The authors did not want to be too strict with the inclusion criteria, in order to show that the OSMC can be applied to a large population. The flow diagram showed that the study's protocol was not very selective and that it was created to include as many subjects as possible. It was considered that 81.9% of the subjects had parafunctional behaviors. The main reason for exiting the selection process was the patient's refusal to participate in a clinical study. The role of gender in the epidemiology of the TMD must be acknowledged, as 84% of the subjects were women. Parafunctional behaviors, which were closely associated with TMD, based on the methodology of the current study (81.9%), therefore deserved the therapists' attention. Parafunctional behaviors were considered as a major risk factor in developing a TMD. Scientific literature confirmed this hypothesis: the authors referred to the Orofacial Pain Prospective Evaluation and Risk Assessment (OPPERA) Study [19-21], which was the most ambitious epidemiological study on the subject. The OPPERA study consisted of taking 202 questionnaires or clinical measures in more than 3000 subjects (initially without TMD) and then submitting the subjects to follow-ups that exceeded a 10-year period in order to determine the risks of developing painful TMD. As the second most important clinical factor, parafunctional behaviors were measured based on the OBC [22], a questionnaire used in this study and of

Distribution of the 10 traits 40% 35% 30% 25% 20% 15% 10% Hostill¹¹ Additional items Psycholism Antiest problem in the statest 5% . Stonalization Opsessive compulsive 0% Lation people sonal people son First trait Second trait Third trait

SCL90

Figure 3. Distribution of the 10 traits of the Symptom Checklist 90 Revised (SCL90) in the 107 subjects studied in the first visit (V0).

labl	e 3. Otologi	cal sym	ptoms.							
Otol	ogical sympto	ms								
1. D	escription									
VO	Number of	subjects		Sympt. A	Sympt. B	Sympt. C	Sympt. D	Sympt. E	Sympt. F	Sympt. G
	Total	NONE	WITH Sympt	Ear fullness	Less hearing	Hear too loud	Hear the breath	Hear the heart	Trembling in the ear	Dizziness
	107	51	56	18	8	9	0	3	0	18
	Mean scores (from 0 to 4)	-	1.82	1.67	1.75	1.78	-	1	-	2.17
2. V	ariables influ	encing o	otologica	l symptoms	(threshold of s	5%)				
Very	/ significant v	/ariable	Sli	ghtly signific	ant variable	Not significant	t variable			
Arthralgia (p-value: 0.005)Myalgia (p-value: 0.039)Headache (p-value: 0.012)Parafunctions (p-value: 0.037)				Intra-articular Joint Disorders (p-value: 0.217) Degenerative Joint Disorder (p-value: 0.282)						

Table 3. Otological symptoms

which a recent study confirmed the validity regarding the prediction of parafunctional behaviors [7].

The authors of OPPERA concluded [19]: "The Oral Behaviors Checklist scale emerged as the strongest predictor of incident TMD among all clinical variables – both examiner assessed and self-reported. There was a clear threshold effect such that risk of TMD was elevated only in participants who reported multiple behaviors that occurred frequently. We speculated that this density of parafunctional behavior in initially TMDfree participants probably signified some form of central dysregulation, such as heightened motor activation, diminished motor inhibition, reduced proprioception, or persistent psychophysiologic reactivity."

Definitive norms have not yet been established for the OBC [11]. However, based on comparison of individuals with chronic TMD vs those without TMD, an OBC summary score of 0–16 appears to represent normal behaviors, while a score of 17–24 occurs twice as often in those with TMD, and a score of 25–62 occurs 17 times more often. As a risk factor for TMD, only a score in the 25–62 range contributes to TMD onset.

When it comes to psychology, the therapists were aware that this domain represented a source of potential bias or imprecision. For example, a subject may not actually suffer from anxiety or depression or any other psychological condition despite having had a score over the thresholds established in the tests conducted in the current study. A person diagnosed clinically with such psychological conditions requires significantly more tests conducted by a trained psychology professional. Therefore, there was an antagonism: on the one hand, international recommendations advocate the use of psychometric tests; but on the other hand, the practitioners had no competence in psychology. It is also

useful to differentiate the authors' approach from that of a specialist in psychology, who would be able to make a psychological diagnosis. Among patients with parafunctional behaviors, the analysis of the HAD and SCL90 led to the following estimations: 25% of the subjects did not show scores exceeding the thresholds established by the authors of the scales, 25% exceeded them in a moderate way, and 50% exceeded them in a more severe manner. Taking into account the patient's psychological profile can facilitate the patienttherapist relationship and make the patient aware of his or her psychological condition. The OPPERA study investigated the psychological factors related to TMD development [23]. In terms of importance in the genesis of a painful TMD, the first psychological parameter, which was somatization, only appeared in the seventh position among other parameters in the OPPERA study. However, in the current study, somatization was the second most common trait assessed via the SCL90. Indeed, it affected 27.36% of the subjects. The first trait from the SCL90 was obsessivecompulsive, which affected 36.79% of the patients. It was supposed that this trait was probably related to functional behaviors, which was one of the factors of inclusion of the study. Finally, the OPPERA study pointed out the need to use other psychometric tests, such as the perceived stress scale or the survey of past life events.

One in two patients (52.3%) presented at least one of the seven otological symptoms sought in this study. It is interesting to note that these symptoms were correlated in a very significant way to TMJ pain. A recent systematic review of scientific literature [24] confirmed the high prevalence of otological signs and symptoms. Similar to the authors' observations, the most frequently encountered symptom was the sensation of ear fullness that, according to studies, would be concomitant with TMD in 43 to 96% of cases.

Conclusion

The current study presented limitations due to a complex protocol, which was a source of potential bias or imprecision. Being aware of that, the observational component of this study led to the following three conclusions:

- Regarding the epidemiological aspect, TMD can be considered to have more of a female pathology (84%), with a marked prevalence of parafunctional behaviors (82%).
- Pain (71%) is more disabling than functional limitations (29%). In terms of pain, myalgia is predominant (84%).
- Two comorbidities deserve the therapist's attention: psychology, although it must be noted that this domain is a source of potential bias or imprecision, as most of the subjects (74%) exceeded the thresholds of psychometric scales, and the otological symptoms observed in one in two patients (52%).

Among the etiological bio-psycho-social concept of TMD, the first part of the study highlighted the importance of parafunctional behaviors and psychological factors. From this concept arises the therapeutic philosophy based on the precept, "To treat pain, study people in all their complexity" [25]. The OSMC, which, in the authors' opinion, is a very efficient method to manage parafunctional behaviors, scrupulously respects this precept. Therefore, it is the main object of the second part of the current study.

Conflict of Interest

The authors do not declare any conflict of interest.

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Appendices

Appendix 1.1. Calculation of the total score (TS).

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Ts (Total score pain (P) + fu	unctional limitation (FL))	Ts = P%*(Pfreq%*Pfreq + P (FLmastic + FLopen + FL	Pintens%*Pintens + Plife%*life + Pdrug%*Pdrug) + FL%* .soc)			
P% + FL% must be 100% (see Parameters weighted by the	e patients when assessing their	overall complaint (VAS Pain/Functional Limitation)			
Choice among these 4 poss	sibilities according to pain is	Pfreq% = Pintens% = Plife	% = Pdrug% = 25% if pain assessed on 4 components			
assessed on: - 4 parameters		Pfreq% = Pintens% = Plife% with no drug taken (Pdru	% = 33.3% if pain assessed on 3 components $ug% = 0%$)			
 3 parameters > With no drug taken > With no impact on c 	nuality of life	Pfreq% = Pintens% = Pdrug% = 33.3% if pain assessed on 3 components with no impact on quality of life (Plife% = 0%)				
- 2 parameters	,,		Pfreq% = Pintens% = 50% if pain assessed on 2 components with no drug taken and no impact on guality of life (Plife% = Pdrug% = 0%)			
Pfreq = 1 to 30	Pintens $= 1$ to 10	Plife = 1 to 10	Pdrug = 1 to 20			
FLmastic = 0 to 60	FLopen =	0 to 40	FLsoc = 0 to 100			
	·		ELS20) derived from Appendix 2.6): FLmastic: FL related			

Legend from bottom to top: FL: Functional Limitation (Jaw Functional Limitation Scale (JFLS20) derived from Appendix 2.6); FLmastic: FL related to mastication (JFLS20: items 1–6); FLopen: FL related to opening (JFLS20: items 7–10); FLsoc: FL related to social functions (JFLS20: items 11–20); Pfreq: Pain/frequency (scale from 0 to 30 days over the last month derived from Appendix 2.1); Pintens: Pain/intensity (Graded Chronic Pain Scale (GCPS v 2.0) derived from Appendix 2.5: average of the scores of items 2, 3, 4); Plife: Pain/quality of life (GCPS v 2.0 derived from Appendix 2.5: average of the scores of items 6, 7, 8); Pdrug: Pain/medication (the amount of analgesic in grams consumed per week derived from Appendix 2.2); P%: the weight of pain in the overall complaint (Visual Analog Scale (VAS derived from Appendix 1.2)). FL%: the weight of functional limitation in the overall complaint (Visual Analog Scale (VAS derived from Appendix 1.2).

Appendix 1.2. Visual Analog Scale (VAS) Pain/Functional Limitation

Date:			Subject		_	Result:		P%:	%	FL%:	%
PAIN	100%	90%	80%	70%	60%	50%	40%	30%	20%	10%	0%
EL.	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

Appendix 2.1. Evaluation of pain: Pain/frequency (unreferenced questionnaire)

Frequency of pain

Based on the last month, how many days did you have the facial pain (all days = 30 days)?

Days

Appendix 2.2. Evaluation of pain: Pain/medication (unreferenced questionnaire)

Drug-related pain (Boxes to be filled by the therapist)

Based on the last month, what are the drugs that you have taken for your facial pain?

Drug (name)	Crisis (1) or background (2)	Dose per administration	Number per day	Number of days per week	RATE (grams) per week
-------------	------------------------------	-------------------------	----------------	-------------------------	-----------------------

- (1) CRISIS: medication taken only when the pain is present.
- (2) BACKGROUND: medication taken regularly even in the absence of pain (for example, anti-migraine drug)

2015 questionnaire created by L'homme S; unreferenced.

Appendix 2.3. Oral behaviors Checklist (short version)

Activities during SLEEP	None of the time	< 1 night/ month	1-3 nights/ month	1-3 nights/ week	4-7 nights/ week
 Clench or grind teeth when asleep, based on any information you may have 					
Activities during WAKING HOURS	None of the time	A little of the time	Some of the time	Most of the time	All of the time
2. Grind teeth together, during waking hours					
3. Clench teeth together, during waking hours					
 Press, touch or hold teeth together, other than while eating (that is, contact between upper and lower teeth) Hold, tighten, or tense muscles without clenching or bringing teeth together Hold or jut jaw forward or to the side 					
7. Press tongue forcibly against teeth					
8. Place tongue between teeth					
9. Bite, chew, or play with your tongue, cheeks or lips					
10. Hold jaw in rigid or tense position, such as to brace or protect the jaw					

Oral Behaviors Checklist (OBC Version May 12 2013 (Ohrbach R)) short version (10 items: 1, 3-11).

Appendix 2.4. Explanatory Model Scale

People who have facial pain or limitations in jaw function often say that their problem is related to some combination of the following:

1. Physical factors, such as:	2. Behaviors factors, such as:	3. Stress and emotional upset, such as:
- Motor vehicle accident - Surgery - Head trauma - Assault - Arthritis	- Oral habits - Jaw posturing - Sustained talking - Yawning - Tensing the facial or jaw muscles	- Problems with family, work or school - Worry or anxiety - Feeling down or depressed
- Other medical problems	- Grinding or clenching teeth when asleep	

A. Overall, how important were the following factors in causing your facial pain problem?

		Not at all important		Extremely important		
1	Physical factors	0	1	2	3	4
2	Behavioral factors	0	1	2	3	4
3	Stress or emotional upset	0	1	2	3	4

b. Overall, how important are the following factors in aggravating (making worse) your facial pain problem?

		Not at all important		Moderately important	Extremely important	
1	Physical factors	0	1	2	3	4
2	Behavioral factors	0	1	2	3	4
3	Stress or emotional upset	0	1	2	3	4

c. Overall, how important will it be for your treatment program to include treatments for: (Note: If you are not pursuing treatment right now, how important do you think these factors would be if you were to pursue treatment?)

		Not at all important		Moderately important	Extremely important	
1	Physical factors	0	1	2	3	4
2	Behavioral factors	0	1	2	3	4
3	Stress or emotional upset	0	1	2	3	4

Appendix 2.5. Graded Chronic Pain Scale Version 2.0

1. On how many days in the last 6 months have you had facial pain? _____ Days

2. How would you rate your facial pain **RIGHT NOW?** Use a scale from 0 to 10, where 0 is "no pain" and 10 is "pain as bad as could be".

										Pain as bad
No pain										as could be
0	1	2	3	4	5	6	7	8	9	10

3. In the LAST 30 DAYS, how would you rate your **WORST** facial pain? Use the same scale, where 0 is "no pain" and 10 is "pain as bad as could be."

										Pain as bad
No pain										as could be
0	1	2	3	4	5	6	7	8	9	10

4. In the LAST 30 DAYS, **ON AVERAGE**, how would you rate your facial pain? Use the same scale, where 0 is "no pain" and 10 is "pain as bad as could be." [That is, *your usual pain* at times you were in pain.]

										Pain as bad
No pain										as could be
0	1	2	3	4	5	6	7	8	9	10

5. In the LAST 30 DAYS, how many days did your facial pain keep you from doing your **USUAL ACTIVITIES** like work, school, or housework? (every day = 30 days)

____ Days

6. In the LAST 30 DAYS, how much has facial pain interfered with your **DAILY ACTIVITIES**? Use a 0 - 10 scale, where 0 is "no interference: and 10 is "unable to carry on any activities."

										Unable to carry
No interference										on any activities
0	1	2	3	4	5	6	7	8	9	10

7. In the LAST 30 DAYS, how much has facial pain interfered with your **RECREATIONAL, SOCIAL AND FAMILY ACTIVITIES**? Use the same scale, where 0 is "no interference: and 10 is "unable to carry on any activities."

										Unable to carry
No interference										on any activities
0	1	2	3	4	5	6	7	8	9	10

8. In the LAST 30 DAYS, how much has facial pain interfered with your **ABILITY TO WORK**, including housework? Use the same scale, where 0 is "no interference: and 10 is "unable to carry on any activities."

										Unable to carry
No interference										on any activities
0	1	2	3	4	5	6	7	8	9	10

Appendix 2.6. Jaw Functional Limitation Scale – 20

For each of the items below, please indicate the level of limitation during the last month. If the activity has been completely avoided because it is too difficult, then circle '10'. If you avoid an activity for reasons other than pain or difficulty, leave the item blank.

			No	limit	ation	1	Sev	/ere	limit	atio	n
1.	Chew tough food	0	1	2	3	4	5	6	7	9	10
2.	Chew hard bread	0	1	2	3	4	5	6	7	9	10
3.	Chew chicken (e.g., prepared in oven)	0	1	2	3	4	5	6	7	9	10
4.	Chew crackers	0	1	2	3	4	5	6	7	9	10
5.	Chew soft food (e.g., macaroni, canned or soft fruits, cooked vegetables, fish	0	1	2	3	4	5	6	7	9	10
6.	Eat soft food requiring no chewing (e.g., mashed potatoes, apple sauce, pudding, pureed food	0	1	2	3	4	5	6	7	9	10
7.	Open wide enough to bite from a whole apple	0	1	2	3	4	5	6	7	9	10
8.	Open wide enough to bite into a sandwich	0	1	2	3	4	5	6	7	9	10
9.	Open wide enough to talk	0	1	2	3	4	5	6	7	9	10
10.	Open wide enough to drink from a cup	0	1	2	3	4	5	6	7	9	10
11.	Swallow	0	1	2	3	4	5	6	7	9	10
12.	Yawn	0	1	2	3	4	5	6	7	9	10
13.	Talk	0	1	2	3	4	5	6	7	9	10
14.	Sing	0	1	2	3	4	5	6	7	9	10
15.	Putting on a happy face	0	1	2	3	4	5	6	7	9	10
16.	Putting on an angry face	0	1	2	3	4	5	6	7	9	10
17.	Frown	0	1	2	3	4	5	6	7	9	10
18.	Kiss	0	1	2	3	4	5	6	7	9	10
19.	Smile	0	1	2	3	4	5	6	7	9	10
20.	Laugh	0	1	2	3	4	5	6	7	9	10

Appendix 2.7. Evaluation of otological symptoms (unreferenced questionnaire)

Based on the last 30 days, have you ever experienced sound events such as mentioned in the list below?	Never	Rarely	Sometimes	Most of the time	All of the time
 A. Ear fullness sensation, as if you change altitude (left and/or right side) B. Less hearing sensation (left and/or right side) C. Hear too loud sensation or being disturbed by surrounding sounds (left and/or right side) D. Hearing your breathing (left and/or right side) E. Hearing the beating of your heart (left and/or right side) F. Trembling sensation in the ear (left and/or right side) G. Dizziness sensation 					
Of these 7 events, which of them was the most disturbing: enter the letter (A, B, C, D, E, F, G) of the chosen event.	Event:		(A/E	B/C/D/E/F/G)
How much did this event disturb or alter your life comfort: tick the box corresponding to the degree of disruption observed.	Not at all	Yes a Little bit	Yes moderately	Yes a lot	Yes extremely
SCORING	0 POINT	1 POINT	2 POINTS	3 POINTS	4 POINTS

2015 questionnaire created by Piron A; unreferenced.

Appendix 2.8. Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week. Don't take too long over your replies: your immediate reply is best.

		_	-		
D	Α		D	Α	
- 1		I feel tense or 'wound up':			I feel as if I am slowed down:
- 1	3	Most of the time	3		Nearly all the time
- 1	2	A lot of the time	2		Very often
- 1	1	From time to time, occasionally	1		Sometimes
- 1	0	Not at all	0		Not at all
- 1	0		0		
		I still enjoy the things I used to enjoy:			l get a sort of frightened feeling like 'butterflies' in the stomach:
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to			I have lost interest in my appearance:
- 1		happen:			
- 1	3	Very definitely and quite badly	3		Definitely
- 1	2	Yes, but not too badly	2		I don't take as much care as I should
- 1	1	A little, but it doesn't worry me	1		I may not take guite as much care
- 1			0		, ,
- 1	0	Not at all	0		I take just as much care as ever
		l can laugh and see the funny side of things:			l feel restless, as I have to be on the move:
~				2	
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my			I look forward with enjoyment to
- 1		mind:			things:
- 1	3	A great deal of the time	0		As much as I ever did
- 1	2	A lot of the time	1		Rather less than I used to
- 1	1	From time to time, but not too often	2		Definitely less than I used to
- 1	0	Only occasionally	3		Hardly at all
- 1			-		
- 1		I feel cheerful:			l get sudden feelings of panic:
3		Not at all		3	Very often indeed
2		Not often		2	Ouite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			l can enjoy a good book or radio or TV program:
	0	Definitely	0		Often
	0		-		
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Verv seldom