Synopsis of Study

Date: June 21, 2015

Title: Assessment of the Efficacy of a Sensorimotor Approach after Three Sessions in Subjects with Symptomatic Craniomandibular Dysfunction (CMD) with Hypertonia: A Prospective, Multicenter Case Study.

Rationale:

The diagnosis and treatment of CMD teach us that muscle hypertonia and parafunctions are generally part of the clinical picture of this disorder.[1,2,3]

Hypertonia essentially causes facial pain and functional incapacities, as well as other symptoms: intra- and extra-articular disorders, headaches, etc.

Numerous therapies (irreversible and reversible) have been proposed to manage CMD.

The consensus is that, at least initially, reversible methods should be favored.[4]

Over many years of practice, Alain Piron, osteopath, D.O., and Paul Dieudonné, dentist, have finalized a protocol for a sensorimotor approach to symptomatic CMD with hypertonia.

This approach can be managed by osteopaths, dentists or speech therapists. It requires a patient to be actively involved in his or her treatment.

The approach is characterized to a great extent, but not exclusively, by the following factors:

- Educating the patient in the static and dynamic perception of the anatomical features that are directly involved in hypertonic CMD (jaw, tongue, lips, cervicofacial and cervicothoracic features).
- Educating the patient in managing the Freeway Space (FWS) by making use of his/her sensations.
- Educating the patient in practicing micro-movements and releasing tension synkinesis among these features.
- Developing and increasing the combined cervico-maxillo-facial perceptual potential with the aim of enhancing the coding of variables that are relevant to perception in order to counteract sensory deficits and sensory ambiguities.

To improve the credibility and scientific rigor of his therapeutic approach, Alain Piron wanted to carry out a prospective observational study to investigate the efficacy of this therapy, since the literature does not include any clinical studies of this topic.

Our comments are based on a systematic literature review, which concluded in June 2015 and was carried out on Medline, in which 124 articles about CMD and educational aspects were analyzed.

The information regarding the treatment to reduce parafunctions and hypertonia, which we extracted from the most relevant articles found in this literature search,[1,2,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21] is mainly as follows:

- Comparisons between unimodal and multimodal methods.
- Methods examined individually that do not correspond at all to our clinical strategy.

Consequently, it appears that the proposed study is both scientifically relevant and original since it does not repeat anything that has been studied to date nor the way in which it was done.

Keywords: CMD – HYPERTONIA – PARAFUNCTIONS – SENSORIMOTOR APPROACH

Study period:	
Submission to ethics committee Start of trial Last subject recruited Last session / last subject	Database freeze Statistical analysis Clinical report (summary)

Objectives:

The study aims to demonstrate the efficacy of the sensorimotor approach developed by A. Piron (taught to the patient in three sessions) regarding three parameters related to CMD: facial pain, functional incapacities and hypertonia.
The subjects in the study are 18 to 77 years old and present the following conditions: a CMD disorder caused or aggravated by hypertonia and responsible for cervico-maxillo-facial pain and/or a functional incapacity in the last 30 days.

Primary objective:

Evidence of the patient's overall relief (expressed from 0% to 100%) calculated:

- On one hand, by integrating the weighting of the pain/functional incapacity/hypertonia parameters in the patient's complaints (consideration of each subject's specific case).
- On the other hand, by integrating the changes in the pain/functional incapacity/hypertonia parameters evaluated on the basis of the comparison of questionnaires completed before (SS), during (S2 and S3) and after treatment (S4). The following questionnaires are used: intensity of pain and impact of pain on quality of life (Graded Chronic Pain Scale version 2.0 – GCPS v2.0), frequency of pain, taking medication, functional incapacities (Jaw Functional Limitation Scale – JFLS-20), and oral behaviors (Oral Behaviors Checklist, short version – OBC).

- Appended: Illustration of the calculation of the primary objective (Appendix 1) and questionnaires (Appendices 2 to 4).

Secondary objectives:

1. Evidence of a change in the **"intensity"** component of cervico-maxillo-facial pain, on the basis of the GCPS v2.0 (part 1) completed before and after treatment.
2. Evidence of a change in the **"impact on quality of life"** component of cervico-maxillo-facial pain, on the basis of the GCPS v2.0 (part 2) completed before and after treatment.
3. Evidence of a change in the **"frequency"** component of cervico-maxillo-facial pain, on the basis of the number of days with pain (in the last 30 days) evaluated before and after treatment.
4. Evidence of a change in the **"taking the most specific medication for painful attacks"** component of cervico-maxillo-facial pain (in the last 30 days), on the basis of drug consumption before and after treatment (assessed with a questionnaire).

5. Evidence of a change in functional incapacity, on the basis of the JFLS-20 completed before and after treatment.
6. Evidence of a change in in oral behaviors induced by hypertonia, on the basis of the short version of the OBC completed before, during and after [OK?] treatment.
7. Evidence of a change in dysacusis and feelings of dizziness, on the basis of a specific questionnaire (created by Alain Piron in anticipation of the study) completed before and after treatment.
8. Evidence of a change in the patient's compliance with the treatment, on the basis of a numerical scale (created by the team in anticipation of the study) completed during and after treatment.
9. Evidence of the patient's subjective impressions of the treatment, on the basis of numerical scales (created by the team in anticipation of the study) completed only after treatment.
10. Evidence of correlations between the patient's psychological state (assessed with the HAD and SCL-90R) and the therapeutic efficacy of the approach (assessed by the patient's overall relief).
11. Evidence of correlations between the patient's psychological state (assessed with the HAD and SCL-90R) and compliance with the treatment (assessed with a numerical scale created by the team in anticipation of the study).
12. Evidence of the percentage of subjects diagnosed as hypertonic among all the patients diagnosed as having CMD (whether or not included in the study) by tracking the patients with a flowchart.

- Appended: Questionnaires (Appendices 5 to 10) and flowchart (Appendix 11).

Methodology:
Prospective, multicenter case study.

Number of subjects needed: Maximum number of eligible subjects for each investigator over a period of 12 consecutive months.

Trial population:

Inclusion criteria:

Any subject presenting all of the following criteria may be included:

- ✓ Male or female subjects aged 18 to 77 years old.
- ✓ Subjects presenting the following 3 characteristics:
  1. A CMD disorder (objectivized by the DC/TMD 2014);
  2. Facial pain in the last 30 days (objectivized by the Graded Chronic Pain Scale version 2.0 (GCPS v2.0)) and/or functional incapacity (chewing, mobility, verbal and emotional communication) in the last 30 days (objectivized by the Jaw Functional Limitation Scale 20 (JFLS-20));
  3. Hypertonia (objectivized by the Oral Behaviors Checklist (OBC) short version and the Explanatory Model Scale).
- ✓ Subjects who agree to comply with the requirements of the study.
- ✓ Subjects who are of age (and know how to read and write) who have given their informed, explicit consent in advance to any procedure related to the trial, the study or the investigation conducted on human beings, with the objective of developing knowledge specific to the exercise of health care professions, as set out in Royal Decree No. 78 of 10 November 1967 on the practice of the health care professions (Act of 27 December 2005).
- ✓ Subjects insured under social security.

- Appended: Questionnaires (DC/TMD 2014) (Appendices 12 to 16) and Explanatory Model Scale (French version) (Appendix 17).

Exclusion criteria:

Any subject presenting at least one of the following criteria may not be included:

- Significant medical problems involving the following conditions:
- ✓ Severe or progressive pathology (psychiatric, neurological, cardiopulmonary, renal, hepatic, endocrinological, hematological, neoplastic, infectious, metabolic or allergic).
- ✓ Any acute trauma of the temporomandibular joint (trauma within the last 72 hours).
- ✓ Severe anxiety or severe depression, as defined by a score greater than or equal to 15 on the HAD.

- Pregnant women

- Criteria related to prior or concurrent treatments:
- ✓ Treatment with antipsychotics, anxiolytics, soporifics or muscle relaxants started within the two months preceding the study.
- ✓ Treatment with intraoral implants during the study or in the two months preceding the study.

- Criteria related to lifestyle:
- ✓ Excessive alcohol consumption (WHO definition: more than two glasses per day for a woman and more than three for a man).
- ✓ Subjects undergoing withdrawal or taking a replacement substance.

- Criteria related to the subject:
- ✓ Subjects unlikely, in the investigator's view, to comply with the instructions in the protocol.
- ✓ Subjects unlikely, on the basis of a score <2 to question "C" of the Explanatory Model Scale, to comply with the therapy.
- ✓ Subjects who had participated in a clinical trial in the previous month or were participating at the time of selection.
- ✓ Subjects without the linguistic or psychological capacity to understand and sign the informed consent form and complete the psychometric questionnaires and psychological tests.

Exclusion criteria after acceptance in the study:

In addition to becoming aware *a posteriori* of an error related to the inclusion or exclusion criteria defined above, the therapist may decide to remove a subject before completion of the study.

The motivations for early exit are as follows:

- Subject who no longer agrees to comply with the requirements of the study.
- Occurrence of a major life stressor (score greater than 40 on the Holmes and Rahe Stress Scale).
- Need to redirect the subject to a different treatment.

Any early exit from the study, whether decided on by the subject, the therapist or both together, will be recorded on a specific document, indicating the date and the reasons for the early exit.

- Appended: Early exit form (Appendix 18) and Holmes and Rahe Stress Scale (Appendix 19).

Treatment technique used:

Sensorimotor approach developed by osteopath Alain Piron: sensorimotor education with a view to obtaining an optimal FWS further to the relaxation of the masticatory, lingual and labial system. Learning of mandibular micro-movements in five directions.

The three therapeutic sessions (S1, S2, S3) are standardized so that each therapist follows a strict regimen.

For each session, each therapist must rigorously follow a decision tree developed by A. Piron that sets out:

- The therapist's actions.
- The possible interactions between the patient and the therapist.
- The patient's positions.
- The therapist's positions.
- The therapist's spoken commands.

To ensure that all therapists rigorously follow the proposed treatment regimen, each therapist:

- Has received the decision tree in written form.
- Has been trained and supervised by A. Piron during clinical sessions in the months preceding the study.

To promote learning by the subjects, they will be given a factsheet setting out the main recommendations.

Appended: Therapeutic decision tree (Appendix 20) and Factsheet of recommendations for the subject (Appendix 21)

Procedure of the trial:

Practitioners

The study is conducted by three kinds of health care professionals, all of whom have taken Alain Piron's seminar on the sensorimotor approach to CMD. The team includes nine professionals:

- 2 dentists specializing in gnathology (Sébastien L'homme (SLh) and Paul Dieudonné (PD))
- 6 osteopaths (Alain Piron (AP), Xavier Thiry (XT), Cédric Garcion (CG), Aurélien Gimenez (AG), Marco Sbarbaro (MS) and Antonio Bianco (AB))
- 1 speech therapist (Sébastien Liesens (SLi))

This kind of treatment may either be managed from start to finish by the same therapist (dentist or osteopath) or involve collaboration between a dentist and an osteopath or a dentist and a speech therapist. In this study:

- Some participants decided to work alone: PD, AP, CG, AG, MS, AB.
- Other participants decided to work in pairs: dentist SLh (diagnosis) with XT or AP or SLi (treatment).

Sites

The multicenter study is taking place:

- In Belgium, in the province of Liège, in private dentistry (PD, SLh), osteopathy (AP, XT) and speech therapy (SLi) practices.
- In France, in the cities of Paris (AG) and Nantes (CG).
- In Italy, in the cities of Brescia (AB) and Turin (MS).

Chronology

- Appointment taking

When a patient contacts the office of one of the dentists or osteopaths taking part in the study, the receptionist responsible for making appointments will ask the patient about his/her reason for consultation to determine whether the patient may suffer

from CMD. If the receptionist thinks that it is CMD or has any doubts, he/she will send the patient, by email or regular mail, all the questionnaires (general questionnaire (administrative data, general health, trauma), DC/TMD 2014, GCPS v2.0, questionnaire on the frequency of pain or taking medication, JFLS-20, OBC, HAD}. The patient will be asked to respond to the questionnaires and bring them along to the first consultation.

- SS: Selection session (patient's first visit)

During the first session, after consulting the questionnaires completed beforehand (plus questionnaire on dysacusis and Explanatory Model Scale) and carrying out a clinical examination, the therapist will establish a diagnosis and explain it to the patient.
Subjects will be selected on the basis of the inclusion criteria set out above. Subjects who meet the inclusion criteria will be informed of the nature of the study and asked to participate in it; they will be given the informed consent form, which they must read, complete and return at their next visit.
After explaining the normal functioning of the masticatory system to the patient and helping him/her to perceive potential muscle tension, the therapist will ask the patient to complete the OBC again.
The patient will also be asked to complete the SCL-90R and bring it to the next session.

- S1: First treatment session after inclusion

Chronology: SS and S1 can take place at the same time or be separated by a few days. The choice depends on each therapist's organizational model (working alone or in pairs, length of appointment available, etc.).

Therapeutic approach: The procedure for the first treatment session is described in the decision tree developed by A. Piron (see Appendix 20).

- S2: Second treatment session after inclusion

Chronology: S1 and S2 are one month apart.

Therapeutic approach: The procedure for the second treatment session is described in the decision tree developed by A. Piron (see Appendix 20).

Interim assessment: Assessment of relief (primary objective) since the previous visit one month earlier (Appendices 2 to 4) and interim assessment of compliance (Appendix 6).

- S3: Third treatment session after inclusion

Chronology: S2 and S3 are two months apart (three months between S1 and S3).

Therapeutic approach: The procedure for the third treatment session is described in the decision tree developed by A. Piron (see Appendix 20).

Interim assessment: Assessment of relief (primary objective) since the previous visit two months earlier (Appendices 2 to 4) and interim assessment of compliance (Appendix 6).

- S4: End-of-study session

Chronology: S3 and S4 are three months apart (six months between S1 and S4).

Therapeutic approach: None planned.

Final assessment at 6 months: Assessment of relief (primary objective) since the first visit six months earlier (Appendices 2 to 4), final assessment of compliance (Appendix 7), assessment of dysacusis (Appendix 5) and assessment of the patient's subjective impressions of the treatment (Appendix 8).

Assessment criteria:

Efficacy criterion

Assessment of the approach's efficacy at the end of treatment in comparison to the symptoms observed before the start of treatment for each subject:

- ✓ Overall relief of at least 50%.

Secondary criteria

- ✓ Favorable change in GCPS v2.0 score.
- ✓ Favorable change in frequency of pain.
- ✓ Favorable change in amount of medication taken to treat pain.
- ✓ Favorable change in JFLS-20 score.
- ✓ Favorable change in OBC score.
- ✓ Favorable change in problems with dysacusis and dizziness.
- ✓ Patient's favorable subjective impressions of the treatment.

Acceptability criteria

- ✓ Collection of all the data at selection (SS), at each session and at the end-of-study session (S4), as described in the protocol.
- ✓ Collection of partial data and tracking of reasons for exiting the study in a specific document (Appendix 18) in cases of early exit upon decision by the subject or the therapist.
- ✓ Collection of certain interim data at sessions S1, S2 and S3, as described in the protocol.
- ✓ Collection of the subjects' informed consent forms.
- ✓ Collection and monitoring of adverse events that occur during the study. Any serious adverse events will be noted and reported to the proponent within 24 hours.

Statistical methods

The analysis of the collected data will be descriptive. The statistical analysis of the data will be done by biostatistician Laurent Massart (University of Liège).

A value of $p<0.05$ will be considered to be statistically significant.

Chart of procedures

Study phase	Selection and inclusion	Treatment session	Treatment session	Treatment session	End-of-study session (or mail)
Name of session	SS	S1	S2	S3	S4
Days since start of assessment (single therapist: SS and S1 at same time)	D	D	D 30 (±7)	D 90 (±7)	D 180 (±7)
Days since start of assessment (pair of therapists: SS and S1 separately)	D	D 15 (±7)	D 45 (±7)	D 105 (±7)	D 195 (±7)
Months since start of assessment (single therapist: SS and S1 at same time)	Month 0	Month 0	Month 1	Month 3	Month 6
Months since start of assessment (pair of therapists: SS and S1 separately)	Month 0	Month 1	Month 2	Month 4	Month 7
Selection and general procedures	X				
Information and consent (single therapist: SS and S1 at same time)	X (given)		X (received)		
Information and consent (pair of therapists: SS and S1 separately)	X (given)	X (received)			
Inclusion/Exclusion criteria	X				
Complete CMD examination (DC/TMD 2014)	X				
Estimation of weighting of 3 parameters (pain, functional incapacity, hypertonia) in complaints as a whole	X				
Assessment of primary objective (pain, functional incapacity and hypertonia) by comparing "before-and-after" questionnaires	X		X	X	X
Assessment of measurable secondary objective "before and after" (dysacusis and dizziness)	X				X
Assessment of NON-measurable secondary objective "before and after" (subjective impressions of treatment)					X
"State" psychological examination (HAD)	X				
"Trait" psychological examination (SCL-90R) (single therapist: SS and S1 at same time)	X (given)		X (received)		
"Trait" psychological examination (SCL-90R) (pair of therapists: SS and S1 separately)	X (given)	X (received)			
Treatment		X	X	X	
Assessment of patient compliance			X	X	X
Adverse events		Monitoring and reporting throughout study			
Serious adverse events					

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Appendices

Appendix 1: L'homme S, 2015, unpublished.

Appendix 2: Von Korff M, Ormel J, Keefe FJ, Dworkin SF, "Grading the severity of chronic pain." Pain. 1992;50(2):133-49.
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Appendix 3 sup: L'homme S, 2015, unpublished.

Appendix 3 inf: Richard Ohrbach (New York University) "in development"
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Appendix 4: Richard Ohrbach (New York University) and Thomas List (University of Malmö) "in development"
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Appendix 5: Piron A, 2015, unpublished.

Appendix 6: L'homme S, Piron A, 2015, unpublished.

Appendix 7: L'homme S, Piron A, 2015, unpublished.

Appendix 8: L'homme S, Piron A, 2015, unpublished.

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Appendix 18: L'homme S, 2015, unpublished.

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Appendix 20: Piron A, 2015, unpublished.

Appendix 21: Piron A, 2015, unpublished.