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## RESEARCH ARTICLE

# Acupuncture Effect on Pain, Mouth Opening Limitation and on the Energy Meridians in Patients with Temporomandibular Dysfunction: A Randomized Controlled Trial



Vera LR. Zotelli <sup>1,\*</sup>, Cássia M. Grillo <sup>1</sup>, Maria LB. Gil <sup>1</sup>, Ronaldo S. Wada <sup>1</sup>, Jorge E. Sato <sup>2</sup>, Maria da Luz Rosário de Sousa <sup>1</sup>

 <sup>1</sup> Department of Social Dentistry of the Piracicaba Dental School, State University of Campinas, São Paulo, Brazil
 <sup>2</sup> Brazilian Medical Association, Medical College of Acupuncture, São Paulo, Brazil

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#### **KEYWORDS**

acupuncture; facial pain; meridians; placebo effect; temporomandibular joint

#### Abstract

Temporomandibular disorders (TMD), recognized as the most common conditions of chronic orofacial pain, have a multifactorial etiology. Acupuncture can help to relieve the pain and discomfort associated with these conditions, because it can rebalance the energy (Qi) circulating in the meridians. The aim of the study was to verify the effectiveness of acupuncture in treating the pain; mouth opening limitation, and energy circulating in the meridians of patients with TMD of muscular or mixed origin. This was a controlled, randomized, double-blind clinical trial conducted at the Piracicaba Dental School (FOP/Unicamp), in Piracicaba SP, Brazil. The Treatment Group received acupuncture with real penetration of the needle, and the Placebo Group received a sham treatment without needle penetration. The acupoints used were: ST6, ST7, SI18, GV20, GB20, BL10, and LI4, during treatment performed for four weekly sessions. The TMD and mouth opening were evaluated according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC). The measurements of the energy at the meridians were performed by the Ryodoraku method, before and after acupuncture in all of the sessions in both groups. The results showed no decrease in pain in the Treatment Group when compared with the Placebo Group (p = 0.2261). There was no increase in the oral opening limit in the Treatment Group compared with the Placebo Group (p > 0.05). Regarding the energy levels, after acupuncture, there was a decrease in Yang energy in all sessions

\* Corresponding author. Community Dentistry Department, Piracicaba Dental School, University of Campinas, Avenue Limeira, 901 Areão CEP: 13414-903, Piracicaba, São Paulo, Brazil.

E-mail: vera.rasera@hotmail.com (V.LR. Zotelli).

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(p < 0.05), in both groups, however, only real acupuncture was effective in maintaining the Yin energy average throughout the four sessions, with significant difference between groups (p = 0.0198). In conclusion, volunteers with TMD presented a pattern of energy deficiency and the most prevalent imbalance patterns identified were in the meridians coupled to the kidney and bladder, and in the Shao Yin (heart/kidney) and Shao Yang (triple energizer/gall bladder) energetic planes. The acupuncture points used were equally effective in reducing pain in both groups; increasing the unassisted mouth opening limitation without pain in the Treatment Group, and were also effective in preserving the Yin energy in the Treatment Group. The Yang energy decreased equally in both groups.

## 1. Introduction

The temporomandibular dysfunctions (TMD) are recognized as the most common conditions of chronic orofacial pain [1]. The pain reported by patients with TMD, is typically felt in the chewing muscles, preauricular area, or in the temporomandibular joint [2]. It has been suggested that between 40% and 75% of the population presents at least one sign of TMD, such as the presence of joint sounds in Temporomandibular Joint (TMJ); and 33% have at least one symptom such as, facial or TMJ pain [3]. TMD may be muscular and/or articular, but the literature has shown that the types of muscular origin are more prevalent [4]. Although TMD occurs in both sexes, recent studies have found a higher prevalence in women [5,6].

The etiology of TMD is multifactorial, originated by association between psychological, structural, and postural factors that unbalance the occlusion, masticatory muscles, and temporomandibular joint. Parafunctional habits, emotional tension, and stress also act as etiological factors related to alterations in the head and neck [7].

Acupuncture may not be helpful in eliminating the cause of TMD resulting from structural abnormalities, such as degenerative changes and disc displacement, however, it can mainly help relieve the pain and discomfort associated with these conditions [8]. Studies have indicated that acupuncture has analgesic effects in the short term, and therefore has an effect comparable with that of the splint for treatment of TMD of muscular origin [9]. In a review of the literature, Rosted in 2001, [10] compared data from several clinical studies and found that the most recommended acupuncture points for TMD treatment were: ST6, ST7, SI18, GV20, GB20, and BL10 as the local points in the face and neck, and LI4 as a distant point.

Traditional Chinese Medicine (TCM) is an energy medicine, that is, based on the existence of an energy structure beyond the physical body, and states that in our body energy circulates through channels or meridians that have specific points called acupoints which, when punctured, reorganize the energy circulation of the entire body. Diseases arise from disorganization of the functional energy that controls and dynamizes the organs [11]. An objective way of measuring this energy is based on the Ryodoraku method developed by Dr. Nakatami in Japan in 1947 [12]. Dr. Nakatani noted that the activity of the sympathetic nervous system could be correlated with most of the symptoms explained by the Qi of the traditional acupuncture theory [13].

Recent controlled studies have demonstrated the effectiveness of acupuncture in TMD. Borin et al [14] compared 20 women treated with acupuncture twice weekly for 5 weeks with 20 untreated women as controls and showed that acupuncture promoted a significant reduction in pain levels compared with the control group. Ferreira et al [2] evaluated 40 female volunteers in a randomized experimental group (n = 20) who received splint plus laser acupuncture, compared with the control group (n = 20) who received splint plus placebo laser and demonstrated that laser acupuncture was more effective and faster in achieving complete remission of pain symptoms after 3 months of treatment compared with the placebo laser. Ferreira et al [15] compared 10 women treated exclusively with splints, and 10 women treated with splints associated with auriculotherapy, and demonstrated that the association of treatments reduced pain more significantly and faster than the splint alone. Grillo et al [16] compared two groups of women treated with acupuncture (n = 20) and splint (n = 20)and concluded that there was reduction of pain and increase in the opening mouth limitation in both groups.

There is no study on the application of the meridian electric conductance theory for the diagnosis and treatment of TMD. Therefore, the aim of this study was to verify the effectiveness of acupuncture in the treatment of pain, mouth opening limitation and energy of the meridians, in patients with TMD.

## 2. Materials and methods

This was a double-blind, randomized, controlled clinical study conducted from July 2015 to June 2016, at the Specialization Clinic of the Piracicaba Dental School (FOP/UNICAMP), in Piracicaba SP, Brazil. The study was approved by the Research Ethics Committee of FOP-UNICAMP, under protocol No. 109/2014 and registered on the Platform of Brazilian Clinical Trials under RBR-77y2sp.

#### 2.1. Inclusion criteria

Adult patients of both sexes, aged from 20 years to 50 years, with pain due to temporomandibular disorders (TMD) of muscular or mixed origin, with or without opening mouth limitation, according to the RDC (Research Diagnostic Criteria for Temporomandibular Disorders), [17].

#### 2.2. Exclusion criteria

Patients with severe trauma or infections in TMJ, on analgesic and/or antiinflammatory medications, pregnant women,

patients who reported being afraid of needles or who were undergoing some other treatment for TMD, edentulous patients, and patients with total dental prosthesis.

#### 2.3. Recruitment/randomization

A group of 77 volunteers with TMD from the Piracicaba Dental School (students, patients, and employees) and from the municipal Dental Specialties Center of the Piracicaba city were recruited, but 34 were excluded from the study: 16 because they did not meet all the inclusion criteria, 10 because they desisted from participating, and eight for other reasons. Thus, 43 volunteers were randomized into two groups: treatment (real acupuncture) and placebo (nonpenetrating sham acupuncture). The volunteers were randomly allocated using a computer program to generate numbers.

The allocation was made by one of the acupuncturists who randomly allocated the participants to the two groups as shown in the flow chart (Fig. 1). The researcher and the volunteer were unaware of the allocation.

#### 2.4. Study design

The volunteers were treated once a week, in four acupuncture sessions. The total time used for this care was approximately 65 minutes for the first and fourth sessions and 55 minutes for the intermediate sessions. The Treatment Group received acupuncture with real needle penetration and the Placebo Group received placebo treatment with nonpenetrating sham acupuncture. The acupoints used were: ST6, ST7, SI18, GV20, GB20, BL10, and LI4 [10]. On a clinical record chart, the following information was recorded: personal and demographic data; whether or not the volunteers were knowledgeable regarding acupuncture; if they had previously undergone any treatment with acupuncture; if they were on medication; and how long they had had TMD. The TMD and the mouth opening limitation were evaluated according to RDC criteria. In both groups, measurements of energy meridians were performed by the Ryodoraku Method in the four sessions, before and after acupuncture. Pain reported by the patient was assessed using a numerical visual analogue scale (NVAS) ranging from 0 to 10.

#### 2.5. Phases of the experiment

(1) Application of the RDC questionnaire axes I and II before the first session of acupuncture; (2) positioning of the patient in the dental chair, in dorsal decubitus, to rest for 5 minutes; (3) first energy measurement (before acupuncture); (4) application of the needle protocol with real needling in the Treatment Group and with nonpenetrating sham needles in the Placebo Group; (5) removal of needles; (6) patient allowed to rest for 10 minutes; (7) second energy measurement (after acupuncture); and (8) application of the RDC questionnaire axes I and II, after the fourth session.

#### 2.6. Acupuncture application

To minimize the treatment bias, the needles were inserted by two experienced acupuncturists who received specific training (theoretical-practical of 8 hours) for calibration of the methodology used in this study. Both acupuncturists also participated in performing the needling in both groups. In order to ensure the double blind study, in both groups the same methodology was used to fix the needle, as described for the Placebo Group. The researcher was absent during the acupuncture procedure.

The acupuncture points used in this study were according to the Rosted [10] literary review for the treatment of TMD: ST6 (Jiache), ST7 (Xiaguan), SI18 (Quanliao), GV20 (Baihui), GB20 (Fengchi), BL10 (Tiazhu), and Ll4 (Hegu).

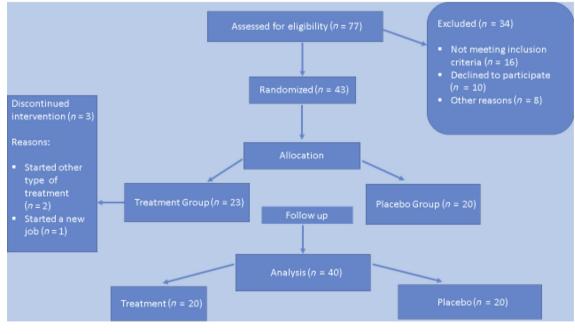


Figure 1 Flowchart.

Placebo group The volunteers received placebo acupuncture in the same acupoints with a  $0.30 \times 30$ -mm sham needle (placebo acupuncture needles) of the Asiamed brand, manufactured in Suhl. Germany. This needle is retractile and has a blunt tip and therefore does not penetrate the skin, but when it touches the skin, the patient has the sensation of puncture [18]. In order to fix the sham needle at the acupuncture point, a circular plastic device 1 cm in diameter (plastic rings for placebo needles) was used, manufactured by Asiamed, in Suhl, Germany. This device was fixed to the skin by means of a 12-mm×50 mm Steri-Strip Reinforced Skin Closures, reference R1549, manufactured by 3M Healthcare in St. Paul, MN, USA. The sham needle goes through the adhesive and just touches the skin without penetrating it. The best term used for this type of acupuncture is "nonpenetrating sham" or "noninvasive sham" [19]. The needles remained in place for 20 minutes and were then removed.

Treatment group In this group the treatment with real penetration of the needle was applied. After asepsis of the skin with 70% alcohol at the needle penetration site, the needles were inserted unilaterally, on the right side. The needles were disposable and sterilized, individually packed, size  $0.30 \times 30$  mm, special acupuncture needle, manufactured by Asiamed in Suhl, Germany. The depth of needle penetration varied considering the anatomical differences of the application sites in each patient. The needle was manipulated clockwise and counterclockwise to achieve the proper feel of the needling with acupuncture called "Deqi" [20]. The needles remained in place for 20 minutes and were then removed. To avoid bias in the research, the same methodology with use of the plastic ring and the fixing adhesive that was applied in the Placebo Group was used.

#### 2.7. Energy assessment

The energy was assessed in the four sessions. In both groups, two energy measurements were performed in each session (before and after the application of acupuncture). The first measurement (before acupuncture) was made after the volunteer had rested for 5 minutes in the dental chair. The second measurement (after removal of acupuncture needles) was performed after an interval of 10 minutes, with the patient still positioned in the dental chair.

There are 24 representative Ryodoraku points of measurement (PRRM), representing 12 acupuncture meridians, 12 of which are located in the right and left hand wrists: lung (LU9-Taiyuan), pericardium (PC7-Daling), heart (HT7-Shemen), small intestine (SI5-Yanggu), triple energizer (TE4-Yangchi), large intestine (LI5-Yangxi), and 12 others, located in the right and left feet: spleen (SP3-Taibai), liver (F3-Taichong), kidney (KI3-Taixi), bladder (BL64-Jinggu), gallbladder (GB40-Qiuxu), and stomach (ST42-Chongyang), [13].

The electrical conductance of the points was measured with the "Ryodoraku RDK RE/NKL System" device, manufactured by RDK/NKL Produtos Eletrônicos Ltda., in Brusque SC, Brazil. This apparatus is a portable acquisition unit that works directly connected to a universal serial bus port of a personal computer. The apparatus is equipped with two electrodes: one of the electrodes has a stainless steel return grip that the volunteer holds with one hand and the other is the probe manipulated by the researcher; the probe tip is designed to accommodate a cotton swab moistened with water, which touches the skin at the opposite handmeasuring points. The recommendation is to avoid contact of the operator's hands with the patient's body. The pressure of the probe on the skin can vary from 60 g to 150 g and in the present study a pressure of 100 g was established, and use of the traditional technique of direct current (200  $\mu$ A maximum in closed circuit). The probe was applied and held immobile over the point for 1 s at each measurement point (acquisition time), applying direct current of 12 V [13]. The electric conductance values were expressed in the Ryodoraku graph in  $\mu$ A, representing the left and right sides of each meridian.

#### 2.8. Pain assessment

The pain reported by the volunteer was evaluated in the four sessions, in the two groups, using a numerical visual analogue scale (NVAS) ranging from 0 (no pain) to 10 (worst possible pain), and recorded before acupuncture (initial NVAS) and after acupuncture (final NVAS), [21].

#### 2.9. Assessment of mouth opening limitation

The mouth opening limitation was evaluated in the first and fourth sessions, in the two groups, according to the guidelines of the Diagnostic Criteria for Research of Temporomandibular Disorders, RDC/DTM, [17]. The mouth opening measurement was recorded in the first session (before acupuncture) and at the end of the fourth session (after acupuncture), by placing a millimeter ruler in a vertical position, from the incisal edge of the maxillary left central incisor to the incisal edge of the mandibular left central incisor. Mouth opening was measured in three conditions according to RDC criteria: (1) unassisted painless mouth opening: the volunteer opened the mouth as far as possible, but without feeling any pain; (2) unassisted mouth opening: the volunteer opened the mouth as far as possible, in spite of feeling pain; and (3) assisted mouth opening: the volunteer opened the mouth as far as possible, in spite of feeling pain, and the professional performed a lever action with the fingers to force the volunteer's mouth opening even further.

#### 2.10. Statistical analysis

For statistical analysis, Bio Estat 5.3 (Mamirauá Institute of Sustainable Development in Tefé, Amazonas, Brazil) and Excel software (Microsoft Office Professional Plus 2013) were used.

For statistical tests, t test for two independent samples, binomial test for two proportions, t test paired samples and two-way analysis of variance (ANOVA) test with repetition were applied. A 5% level of significance was established.

For mouth opening limitation analysis, data from the first session (before acupuncture) and from the fourth session (after acupuncture) were compared using the twoway ANOVA test with repetition to compare the groups, and for exploratory purposes, the paired *t*-test was used to check the mouth opening limitation before and after acupuncture within each group.

For exploratory purposes also, the results from the first session (before acupuncture) and the final results from the fourth session (after acupuncture) were compared using the t test for paired samples to check the effectiveness of acupuncture application on the energy.

## 3. Results

### 3.1. Sample data

The initial sample consisted of 43 volunteers. Three volunteers discontinued the research, two because they started another type of treatment, and due to starting a new job. Therefore, the final sample consisted of 40 volunteers, 20 in the Treatment Group and 20 in the Placebo Group.

The results of comparison of the descriptive data of the sample between the groups are shown in Table 1.

#### 3.2. Mouth opening

When the ANOVA test was performed, there were no differences between the groups in any of the three mouth opening levels: unassisted painless mouth opening (p = 0.2337); unassisted mouth opening (p = 0.6782), and assisted mouth opening (p = 0.9685). However, for exploratory purposes, the paired *t*-test was performed to verify what occurred with the opening limitation before and after acupuncture within each group: a significant increase in the unassisted painless mouth opening limitation was observed only in the Treatment Group (p = 0.0216), (Table 2).

#### 3.3. Pain

In the pain assessment considering groups, sessions, and interactions there was no significant difference between the groups (p = 0.2261), and pain reduction occurred equally in both groups (Table 3).

#### 3.4. Energy

Relative to the energy, the mean total energy value (of all meridians together) from the first session, before acupuncture, showing how the volunteers presented at the beginning of the experiment, was compared with the mean value at the end of the fourth session. In the Treatment Group, the mean energy value in the first session was (20.8  $\mu$ A  $\pm$  9.2) and in the fourth session it was (20.8  $\mu$ A  $\pm$  9.4); there was no significant difference (p = 0.9923), the mean total energy value was retained. In the Placebo Group, however, there was significant difference (p = 0.0079), demonstrating that the mean energy value declined from the first session (22.5  $\mu$ A  $\pm$  9.4) to the fourth session (17.6  $\mu$ A  $\pm$  9.2), (Fig. 2).

When assessing each group in each one of the four sessions, the Yin energy (mean of the 6 Yin meridians) and the Yang energy (mean of the 6 Yang meridians) were analyzed separately; and when the mean value before acupuncture was compared with the mean value after acupuncture, a decrease in Yang energy was found in all sessions in the Treatment Group (p < 0.05), and the mean energy value of the Yin meridians was maintained (p > 0.05). In the Placebo Group Yin energy decreased significantly in the first session (p = 0.0055) and the Yang energy decreased in all sessions (p < 0.05) (Fig. 3).

When analyzing the Yin energy values between groups, sessions, and interactions (Table 4) there was a significant difference between the groups (p = 0.0198). In the Placebo Group the Yin energy decreased during the four sessions, whereas it was maintained in the Treatment Group.

## 4. Discussion

We emphasize that in our study, we started with groups that were statistically equal in relation to the demographic,

Groups General		Treatment Group (n = 20) Real acupuncture		Placebo Group (n = 20) Sham acupuncture		р
* TMD time, Mean (SD), y	9.2 (8)	12.8 (8	3.2)	7.6 (7.4	4)	0.0597
* Initial pain (NVAS), mean, (SD)	4.6 (2.3)	5.3 (2.	5)	3.8 (1.	8)	0.0605
* Unassisted painless mouth opening limitation,	36.7 (9.9)	35.2 (8	8.6)	38.3 (1	1.1)	0.3216
mean, (SD), mm						
* Unassisted mouth opening limitation, mean (SD), mm	45.3 (8.7)	44.6 (6	5)	46 (10.	9)	0.6177
* Assisted mouth opening limitation, mean (SD), mm	47.2 (8.3)	46.9 (5	5.2)	47.6 (1	0.7)	0.7939
* Energy, mean (SD), μA	21.7 (9.2)	20.8 (9	9.4)	22.5 (9	.2)	0.5621
** Sex	Female	18	<b>90</b> %	14	70%	0.9048
	Male	2	10%	6	30%	
** Ethnicity	White	14	70%	15	75%	0.7143
	Nonwhite	6	30%	5	25%	
** Previously treated with acupuncture	Yes	8	40%	8	40%	0.4286
	No	12	60%	12	60%	

SD = standard deviation.

\* T test independent samples.

\*\* Binomial test, two proportions.

Table 2Mean and standard deviation of mouth opening limitation in the groups, in adults with TMD. Piracicaba, 2016.

Mouth opening	Treatment group			Placebo group			
limitation Mean & (SD) mm	1 <sup>st</sup> session (before acupuncture)	4 <sup>th</sup> session (after acupuncture)	р (*)	1 <sup>st</sup> session (before acupuncture)	4 <sup>th</sup> session (after acupuncture)	р (*)	
Unassisted painless mouth opening	35.2 (8.6)	38.2 (7.9)	0.0216	38.3 (11.1)	40.1 (9.3)	0.2453	
Unassisted mouth opening	44.6 (6)	45.3 (6.4)	0.3683	46 (10.9)	45.6 (10.8)	0.6225	
Assisted mouth opening	46.9 (5.2)	47.1 (5.9)	0.6759	47.6 (10.7)	46.6 (10.6)	0.0736	

SD = standard deviation; TMD = temporomandibular disorders.

\* T test paired samples.

Table 3Mean and standard deviation of pain (NVAS, numerical visual scale) in the groups, in adults with TMD.Piracicaba, 2016.

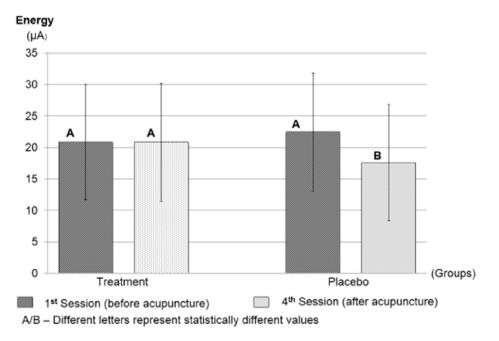
Groups	Treatme	Treatment group		Placebo group		
NVAS	Initial	Final	Initial	Final		
Mean & SD						
1 <sup>st</sup> session	5.3 (2.5)	3 (2.4)	3.8 (1.8)	2.2 (1.5)		
2 <sup>nd</sup> session	4.1 (2.9)	2.8 (2.1)	3.3 (2.3)	2 (1.9)		
3 <sup>rd</sup> session	3.9 (2.9)	2.5 (2.5)	2.9 (1.6)	1.4 (1.1)		
4 <sup>th</sup> session	3.7 (3.1)	1.9 (2.2)	2.2 (1.6)	0.9 (1.1)		
TMD = temporomandibular disorders; NVAS = numerical visual scale.						

clinical, energetic variables, and with regard to the previous experience with acupuncture conditions (Table 1).

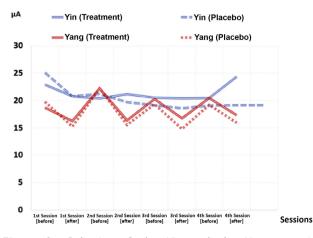
Pain, according to TCM, results from the stagnation of Qi and/or Xue (blood) in the channels and organs [22]. In our

study, we found that pain decreased in both groups after four treatment sessions, with no significant difference between groups. A similar result was found in the study by Lin et al [23], in which the two groups received cupping and laser treatment for back pain, but the Placebo Group received cupping and inactive laser (sham) on 5 consecutive days, in whose study there was reduction in pain without significant difference between the groups. The study by Irnich et al [24] for the treatment of chronic pain in the neck related to movement showed that pain reduction (after 1 week of intervention) was significantly higher in the acupuncture group compared with the massage group, but not in comparison with the group that received sham laser, in which the level of pain reduction was similar to that of the acupuncture group.

In our research, as in the two studies cited above, pain reported by the volunteer was recorded on a visual analogue scale, which is considered a subjective measure. There are some studies that suggest that placebo effects are greater for psychological and self-assessment



**Figure 2** Mean and standard deviation of the total energy value of the first session (before acupuncture) and fourth session (after acupuncture) in the groups. Piracicaba, 2016. *T* test two paired samples.



**Figure 3** Behavior of the Yin and the Yang energies throughout the four sessions, in the groups. Piracicaba, 2016.

measurements than for other more objective measures of disease activity [25]. Studies have indicated that in routine clinical practice when patients receive a known drug, efficacy of the drug is a combination of nonspecific placebo effect with the biologically active effect [26]; and in our study 40% of patients had previously experienced treatment with acupuncture (distributed in the Treatment and Placebo Groups), therefore, were already aware of the positive effect of acupuncture.

In addition, it should be noted that although the sham needle was used in the Placebo Group, many patients reported some deqi sensation, meaning that there was proprioception. This was probably due to the plastic ring and fixation adhesive, and even due to the touch of the nonpenetrating sham needle, which may have caused some pressure on the pain receptors located in the skin generating a DeQi sensation and an effect comparable with that of acupressure, whose effects deserve further studies [27]. Another explanation for the improvement of pain in the Placebo Group may be due to the professional-patient interaction [28] during the four sessions because TMD has a very significant emotional component. Regarding mouth opening limitation, the result was not significant in any of the three opening levels studied. However, the study by Grillo et al [16] comparing acupuncture and splint for TMD treatment showed that there was an increase in the mouth opening limitation in both groups. It has been documented that acupuncture can help muscle relaxation and reduces the muscle spasms, because the spasms are actually of muscular origin [8].

Regarding the energy, according to the Ryodoraku theory, individuals with well-balanced Qi would form a horizontal line across the graph, ideally 50  $\mu$ A, but values within a tolerance range of 40–60  $\mu$ A are accepted as a physiological balance. Values above or below this range indicate a degree of excess or deficiency of Qi [13]. In our study, the mean total energy value (all of the meridians) in the first session (before acupuncture) was 20.8  $\mu$ A in the Treatment Group and 22.5  $\mu$ A in the Placebo Group (Table 1), meaning that both presented an energy deficiency, although, in isolation, some meridians presented excess energy. Qi deficiency is a more frequent cause of internal and long-term pathologies, and the resulting diseases are usually chronic [29], and our study showed that the volunteers reported a mean time of 9.2 years of presenting TMD, confirming the chronicity of the TMD.

In the Treatment Group, when comparing the energy mean values of all the meridians (the total energy): the initial from the first session (20.8  $\mu$ A) and the final from the fourth session (20.8  $\mu$ A), we verified that the mean total energy values were maintained. Whereas, in the Placebo Group there was a decrease in the mean energy value from 22.5  $\mu$ A to 17.6 $\mu$ A, (Fig. 1). In the study of Lin et al [23] it was also observed that the Ryodoraku values of some meridians in the active group decreased significantly after the first treatment session, and after five sessions returned to the initial values. We could infer that the Ryodoraku method was effective in detecting measurable changes in electrical conductivity in the PRRM after acupuncture, corroborating the results of Ribeiro et al [30] that showed changes in electroconductivity at specific points detected within 5 minutes to 10 minutes after needle removal.

In our study we observed a decrease in the mean total energy value after the application of acupuncture, in most

	Source of variation	SS	df	MS	F	р
Yin	Group (G)	302.85760	1	302.85760	5.55051	0.01975
	Sessions (S)	333.77218	3	111.25739	2.03903	0.11079
	Interactions ( $G \times S$ )	93.03042	3	31.01014	0.56832	0.63670
	Within	8293.70776	152	54.56386	_	_
	Total	9023.36796	159	_	-	_
	_	-	_	-	-	_
	Source of variation	SS	df	MS	F	р
Yang	Group (G)	38.19093	1	38.19093	0.64018	0.42489
	Sessions (S)	226.76222	3	75.58740	1.26704	0.28778
	Interactions ( $G \times S$ )	18.96565	3	6.32185	0.10597	0.95648
	Within	9067.78992	152	59.65651	_	_
	Total	9351.70872	159	_	_	_

 Table 4
 Analysis of Yin and Yang energies according to groups, sessions, and interactions. Piracicaba, 2016.

ANOVA test: two-way with repetition.

ANOVA = analysis of variance; df = degrees of freedom; F = factor ratio; G = group; MS = middle square; S = Sessions; SS = sum of square.

sessions, in both groups. We also observed that this reduction in the mean value occurred mainly due to the release of energy of the Yang nature in the meridians and this fact may explain the reduction of pain that occurred in the volunteers of both groups. Throughout the sessions, the mean energy value in the Yin meridians of the Treatment Group was maintained, although in the Placebo Group, the Yin energy decreased in the first session, and the Yang energy decreased in all the sessions (Fig. 2). The pursuit of balance by decreasing Yang energy right after acupuncture is expected, because it is a less dense energy, and can be more easily released. In addition, all Yang meridians pass through the head, and in our study only points of a Yang nature were used. However, maintaining the Yin energy is considered beneficial because it is the energy of metabolization and nutrition that refers to the organs and probably the incorporation of tonification points in the protocol used could contribute to increase in the energy of these patients who presented energy deficiency. Therefore, the results of our study demonstrated that sham acupuncture may not have been totally inactive, but it was not potent enough to maintain or even increase the energy level in the meridians.

Several studies have previously shown that the placebo effect may cause changes in outcomes even with the use of more objective measures, such as those of the controlled study by Kaasinen et al [31], in which subjects were told that they would have a 50% chance of receiving caffeine, but they all received placebo caffeine, and in the outcome (compared with no treatment), the placebo induced a significant release of dopamine in the bilateral thalamus (p < 0.001), which was assessed using positron emission tomography (PET). However, our study demonstrated that the results of energy measurements in the meridians (measured by Ryodoraku) were more significant in the Treatment Group, whereas, when the self-reported pain measure (NVAS) was used, there was no difference between the groups, indicating that the placebo result tended to decrease when objective measures were used.

We emphasize that in our study the same protocol of points was used for all the volunteers. By applying an individualized protocol for each volunteer the energy balance would probably be more visible, and this will be the goal of our next study.

As limitations of the present study, the results obtained could have been even more robust if the sample had consisted of patients with TMD pain that was only of muscular origin; if there were inclusion of acupuncture points with emotional balance function in the protocol used, and if the sessions were performed in close sequential sessions.

Further studies should be conducted to elucidate the understanding of the placebo effect in acupuncture.

In conclusion according to the results demonstrated in our study, we can infer that in patients with TMD resulting from muscular or mixed origin, the acupuncture points ST6, ST7, SI18, GV20, GB20, BL10, and LI4 were equally effective in reducing pain in both groups; increasing the unassisted painless mouth opening limitation only within the Treatment Group, and were also effective in preserving the Yin energy in the Treatment Group. The Yang energy decreased equally in both groups.

#### **Disclosure statement**

The authors declare that they have no conflicts of interest and no financial interests related to the material of this manuscript.

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