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Research Article

Effectiveness of Acupuncture in Dental Surgery: A Randomized, Crossover, Controlled Trial

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ABSTRACT

Objectives: The objective of this crossover clinical study was to evaluate the effectiveness of Energy Regulation with Acupuncture in clinical occurrences in impacted lower third molar surgeries.
Methods: The sample consisted of 22 patients with two impacted third molars, in symmetrical position; divided into two groups: Test Group (TG) with Real Energy Regulation Group and Sham Group (SG) with Acupuncture without Energy Regulation function. The extraction was performed 30 days apart. Energy flow (Ryodoraku Method) and energy regulation performed before extraction were measured. Heart Rate (HR) and Blood Pressure (BP) were evaluated before and after energy regulation and after surgery, residual edema was measured by facial measurements (angle of the mandible to tragus (A-T); angle of the mandible to labial commissure (A-LC); angle of the mandible to the wing of the nose (A-WN); angle of the mandible to the corner of the eye (A-CE); angle of the mandible to the chin (A-C); and mouth opening by the interincisal distance, before and after seven days of surgery. To quantify intraoperative bleeding (ml), blood was aspirated along with the saline solution using a portable vacuum pump adaptor. The amount of saline solution used was subtracted from the final amount of aspirated fluid.
Results: Mean of bleeding was lower in TG ($p = 0.0392$). There were significant differences between groups in facial distances: A-LC ($p = 0.010$), A-WN ($p = 0.030$) and A-C ($p = 0.008$).
Conclusion: Energy regulation with real acupuncture was effective in reducing postoperative residual edema and intraoperative bleeding.

1. Introduction

Surgical removal of the impacted or semi-impacted third molars is a routine procedure performed by oral and maxillofacial surgeons [1], and the surgical planning is based on clinical and imaging examinations, which are fundamental for a decrease in clinical occurrences during the procedure and postoperatively [2]. Clinical diagnosis is invasive and involves soft tissue flaps, bone tissue removal, which can generate an inflammatory response with pain, swelling and limited mouth opening [3].

The swelling and limitation of mouth opening are triggered by the inflammatory process initiated by surgical trauma [4,5]. Usually its presence contributes to the increase of pain, since there is an increase of tissue tension [6]. It usually appears on the second and third day after extraction [6], disappearing by the fifth to seventh day [4].The conventional treatment recommended is the administration of steroidal antiinflammatory drugs and non-steroidal antiinflammatory drugs, even if they promote side effects [6].

However, the surgical technique for tooth removal causes normal intraoperative bleeding. With less bleeding, the visibility of the surgical field will be more preserved, favoring the surgeon and maintaining the patient's well-being [2].

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Its control can be performed using anesthetic solutions with vasoconstrictor, local hemostatics [7], fibrin sponge [2] and tranexamic acid [8].

However, integrative therapies, such as acupuncture, appear as a possibility of adjuvant treatment to minimize the symptoms of these occurrences, since acupuncture therapy helps the maintenance of immune function, and restores homeostasis, promotes muscle relaxation, favoring the maintenance of health [9,10].

Currently, the use of acupuncture in dentistry is increasing, being effective in the control of acute pain [10] and chronic pain [11,12] and in reducing the adverse effects of third molar surgery [13-15]. Therefore, this study aimed to evaluate the effectiveness of the energy flow regulation with acupuncture before the surgical procedure to control the clinical occurrences after the surgery.

2. Methods

2.1. Study Design

This is a double-blind, randomized clinical trial. The Study approved by the Research Ethics Committee of the Piracicaba School of Dentistry (FOP/Unicamp) under the number CAAE 69318917.0.0000.5418 and registered in the Brazilian Registry of Clinical Trials (ReBEC), under number RBR-8w9dbt.

2.2. Participants

The patients were captured at Oral and Maxillofacial Surgery Area of the Piracicaba School of Dentistry (FOP/Unicamp) The surgeries were performed during June 2017 to December 2018, with an average interval of 30 days between clinical surgical interventions. During the study a total of 174 patients were analyzed.

Twenty-two patients were selected considering both gender and aged between 18 and 30 years. Inclusion criteria: Patients without systemic diseases; women using contraceptives without a history of previous infection; with lower or semi-impacted lower third molars in symmetrical anatomical positions; and who agreed to perform the second clinical intervention after 30 days of the first. Exclusion criteria were: patients with lower third molars in antagonistic anatomical positions; patients with severe emotional disorders and patients with a homogeneous energy level between range of 40 to 60 μA which is considered within normal energy [16].

The research team was composed by 1 acupuncturist and 1 professional graduate student of the Oral and Maxillofacial Surgery Area.

2.3. Interventions

The patients were randomized to 2 study group (Fig. 1).

After reading the energy graph, the patient's most predominant energy imbalance was diagnosed. Test Group (TG) (n = 22): energy regulation with real acupuncture protocol selection can be interpreted by diagnosing some forms of energy imbalance, to cite [16].

a. Simple imbalance, with change in laterality, energy unit and movement;
b. Complex imbalance, with changes in Organs and Viscera;
c. Group Luo involvement and in the Sheng and Ke cycle;
d. Progressive regulation;
e. High and Low Imbalance;
f. General toning;
g. Overall fullness.

With a protocol example, when there is a simple imbalance involving laterality (right, left), in the lung meridian, the fullness side is found and the needling is done in order to balance the energy, reducing energy from the side with the most of it, utilizing the LU5 (Chize) points to sedate and increase energy on the side that has less of it, using LU9 (Taiyuan) point to tone.

In the Sham Group (SG) (n = 22), after the measurements, the points that belong to Yin meridians and that do not contribute to energy regulation were used: LR7 (Xiguan); LR8 (Ququan); SP5 (Shangqiu); KI4 (Dazhong).

In both groups the needles remained in place for 5 minutes and were not stimulated. The number of needles used in the test group could vary from 1 to 6 depending on the energy imbalance presented. The insertion depth followed the specifications of each point respecting the physical characteristics of the patients [17]. Qizhou needle 0.25 × 0.30 mm (Wujiang City Shenli medical & health material Co., Ltd.) and skin asepsis with cotton and alcohol 70% were used. The application was performed by a single acupuncture specialist. The data collection time was around 30 minutes, including the energy regulation procedure.

In the SG, the needling was unilateral, and in the TG, it was bilateral or unilateral, depending on the imbalance presented. After the acupuncture application, a new energy measurement was performed in order to verify the correction of the energy imbalance. In case of failure to achieve energy balance, a second energy regulation was carried out with the specific protocol [16]. After adjustment the patient was released for surgical intervention.

2.3.1. Energy Regulation

The measurement of energy flow was performed in both groups, prior to the surgical procedure. The Ryoduraku method, advocated by Nakatami in 1947, was applied. According to Nakatami, 24 points of Ryoduraku's Representative Measurement (PRRM) were defined, based on 12 bilaterally meridians and representing their energy level. They were divided into 6 hand points: LU9 (Taiyuan), PC8 (Laogong), HT7 (Shenmen), SI5 (Yanggu), TE4 (Yangchi), LI5 (Yangxi) and 6 foot points: SP3 (Taibai), LR3 (Taichong), KI3 (Taixi), BL64 (Jinggu), GB40 (Qiuxu), ST42 (Chongyang) [16] The device used was the Ryoduraku (RDK/NKL – Produtos Eletrônicos Ltda. Brusque – SC – Brazil). It is a portable drive that connects via USB to a computer of its own. The device consists of two electrodes, responsible for capturing the current signal in the patient circuit. One of the electrodes is a return rod, which the patient holds with the hand, and the other is a probe that at its end allows the placement of a cotton tip (swab) that should be moistened with water to be touched on the skin of the patient.

2.3.2. Surgical Procedure

To perform the surgery, imaging exams were requested to verify the symmetry of the teeth. The 22 patients underwent two surgical procedures with an average interval of 30 days between extractions, made by the same professional graduate student of the Oral and maxillofacial Surgery Area of the Piracicaba-Unicamp School of Dentistry (FOP Unicamp), under the supervision of a responsible professor. The clinical data of the patients and the group to which they belonged were recorded in a clinical form.

For intra-oral asepsis, 0.12% chlorhexidine mouthwash was used for 01 minute (Perigard®-Colgate-Brazil), for extraoral, mouthwash 2% chlorhexidine digluconate (Degermante) (Riohex 2% ®, Rioquimica, São José do Rio Preto, SP, Brazil) was used, followed by the placement of the surgical field. For anesthesia, the technique was the Inferior Alveolar Nerve block, Lingual Nerve block, and the anesthetic solution was 2% lidocaine with 1:100,000 epinephrine (10 μg\ml Alphacaine®, DFL, Taquara, RJ, Brazil). The incision was made by scalpel blade #15 from the alveolar ridge region posterior

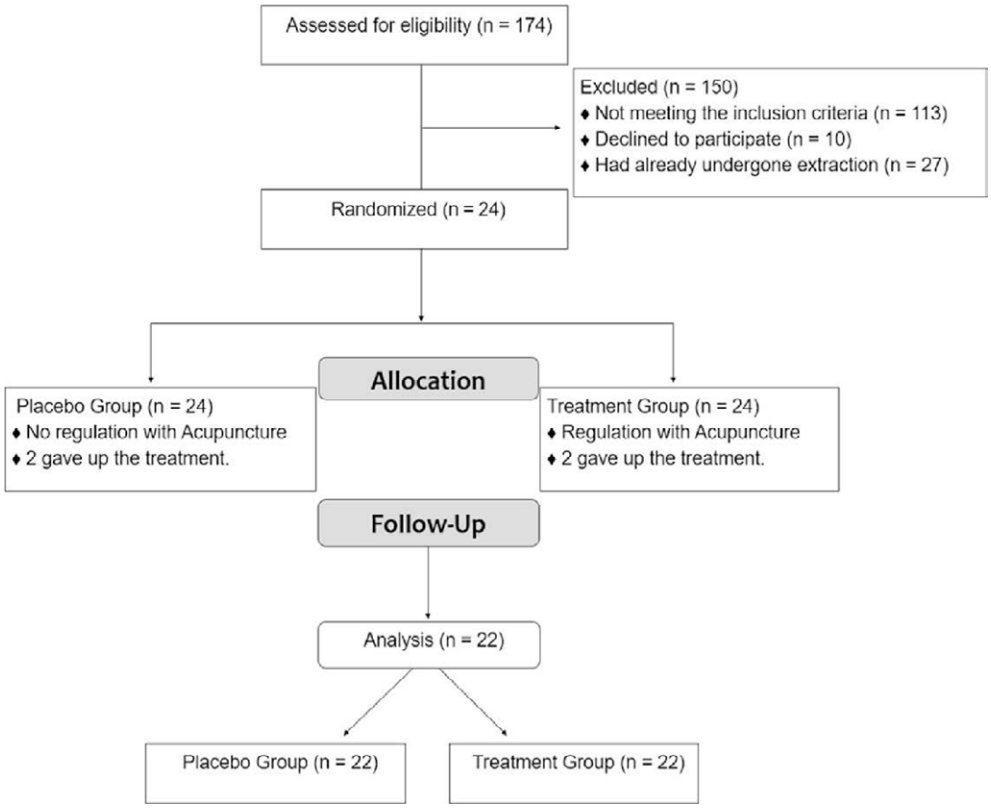

Figure 1. Flowchart of the study according to the CONSORT statement.

to the second lower molar, extended with an intramuscular incision to the mesial of the lower first molar. The mucoperiosteal flap was displaced in order to preserve blood nutrition and interdental papillae, osteotomy and odontosection, following the protocol of the surgery clinic of the Piracicaba School of Dentistry, with the use of extractors, curettes, teeth were removed from the teeth socket. The alveolus was abundantly irrigated with saline solution before suturing with a non-resorbable Seda 3-0 suture thread (Shalon Fios Cirúrgicos LTDA., Goiania, Góias, Brazil).

Standard recommendations were given to all patients, all receiving 500 mg dipyrone with a 6\6-hour dosage in case of pain, and a 12\12-hour 600 mg ibuprofen for three days. The patients were reevaluated after seven days.

2.4. Independent Variables

In addition to the variables of interest described below (Intraoperative Bleeding Quantification, Measurement of Residual Swelling, Assessment of mouth opening limitation, Blood Pressure and Heart Rate Assessment) demographic data including age and sex were collected.

2.5. Outcome

2.5.1. Intraoperative Bleeding Quantification

During the procedure, the well was irrigated with 0.9% saline solution. To quantify intraoperative bleeding, blood and saline solution were aspirated by adapting the technique described by Medeiros et al. [18], in which a disposable surgical sucker (Indusbello Ind. Com. de Prod. Méd. e Odont.Ltda, Londrina, PR, Brazil) was used, connected to a sterile hose coupled to a beaker-type ml graduated container, which was linked to the vacuum pump of the dental equipment. Blood was quantified by subtracting the amount of saline solution used during the intervention from the final amount of aspirated fluid [17].

2.5.2. Measurement of Residual Swelling

Preoperatively, facial distances were measured, as described by Neupert et al. [19]. Using a tape measure, the linear distances in millimeters between the points were measured: angle of the mandible to tragus (A-T); angle of the mandible to labial commissure (A-LC); angle of the mandible to the wing of the nose (A-WN); angle of the mandible to the corner of the eye (A-CE); angle of the mandible to the chin (A-C) (Fig. 2A). These points were marked with henna ink so that it did not lose reference between one measurement and another. These measurements were recorded on a form identifying the patient, the surgery and the group to which they belonged.

2.5.3. Assessment of mouth opening limitation

To evaluate the mouth opening, the preoperative maximum painless opening in millimeters, with a flexible millimeter ruler, was considered at the incisal edge between the left upper and lower central incisors. Measurement performed before surgery and after 7 days of postoperative (Fig. 2B). Values were noted on the form together with the facial measurements.

2.5.4. Blood Pressure and Heart Rate Assessment

Blood pressure (BP) and heart rate (HR) measurements were performed before and after energy regulation and after surgery completion.

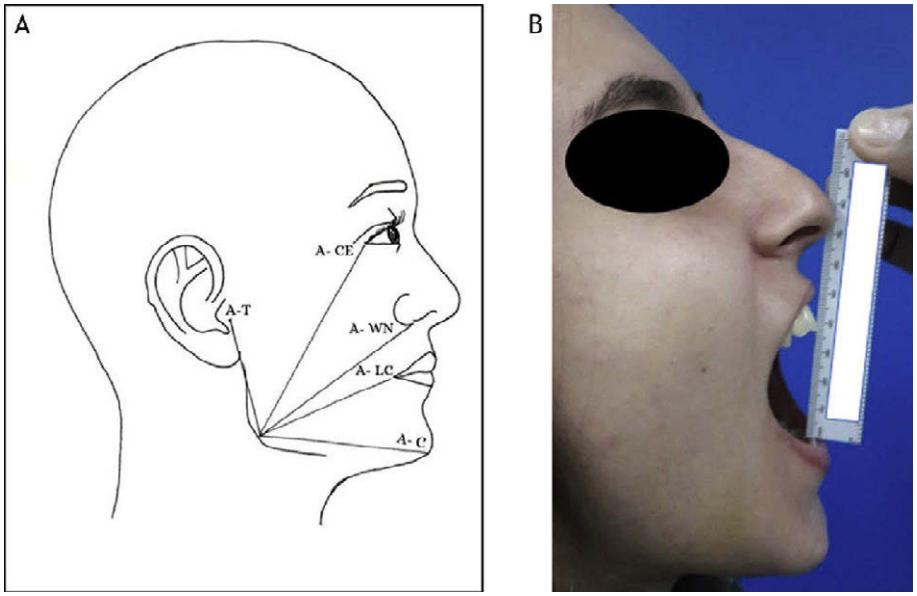

Figure 2. (A) Representative image of facial distances. A-T Angle of the Mandible to Tragus/A-CE Angle of the Mandible to Corner of Eye/A-WN Angle of the Mandible to Wing of the Nose/A-LC Angle of the Mandible to Labial Commissure/A-C Angle of the Mandible to Chin. (B) Measurement of mouth opening.

2.6. Sample size

The sample size calculation was based on preliminary results from a pilot study in which the prevalence of swelling was 80%. Two-tailed comparison test was applied, two-tailed with a significance of 5% and a test power of 80%. The required sample size was 22 patients (44 teeth) for each group. To perform the test, the website www.lee.dante.br (Laboratory of Epidemiology and Statistics) was used.

2.7. Randomization and allocation

Randomization was performed by lot prior to surgical intervention. Two envelopes were used, containing the type of procedure and the group that the patient would be part of. In one envelope was written Test Group (TG): energy regulation with real acupuncture and in the other envelope Sham Group (SG): energy regulation with placebo acupuncture and the patient chose one of the envelopes.

2.8. Blinding

The study was double-blind because the patient and Oral and maxillofacial surgeon were blinded to the acupuncture procedure.

2.9. Statistical methods

Statistical analysis was performed using Excel 2010 software and the paired t-test was used to assess age, gender. For the other variables, the Wilcoxon and Friedman tests were applied to compare the groups, performing analysis of the median 1st-3rd quartiles at the significance level: $p \leq 0.05$.

3. Results

174 patients were initially called, however 113 were out of the inclusion criteria, 10 declined to participate and 27 had already extracted a tooth. Twenty-four patients were randomized, however 2 had only one surgery and abandoned the study. Thus, the number of volunteers was 22 patients (Fig. 1).

A total of 44 extractions were performed, 22 in SG and 22 in TG, with an interval of approximately 30 days. Since this was a split-mouth study, there was no change in demographic data, the age alternated between 18 and 30 years. The average age was 21.9 years and the ratio was 63.63% women and 36.36% men, as reported in Table 1. Regarding surgery time and anesthetic consumption, we did not detect a difference (Table 1).

When comparing the groups in relation to intraoperative bleeding, it was found that the mean bleeding in the TG was 25 ml and in the SG was 35 ml, showing less bleeding in the TG ($p = 0.04$) (Table 2).

Regarding facial distances, there was a significant difference in measures of mandible to labial commissure angle ($p = 0.01$), mandible to nose wing angle ($p = 0.03$) and mandible to chin angle ($p \leq 0.01$) (Table 3).

Table 1
Distribution of demographic and clinical characteristics according to group.

	TG n = 22	SG n = 22	*p*-value
Demographic Features*			
Age X (SD)	21.90 (±2.67)	21.90 (±2.67)	0.50
gender X n (%)			
Female	14 (63.63)	14 (63.63)	
Male	8 (36.36)	8 (36.36)	
Clinic variables during surgery†			
Number of tubes (unit)	4	4	0.45
Duration of Surgery in mm	35	36.2	0.97

X = average; SD = standard deviation. TG = Test Group; SG = Sham Group.
* Test T
† Wilcoxon test $p \leq 0.05$.

Table 2
Median (1st–3rd quartiles) variables: bleeding.

	TEST GROUP	SHAM GROUP	*p*-value*
Bleeding (ml)	25 (20-40)	35 (20-50)	0.04

* Wilcoxon test $p \leq 0.05$.

Table 3
Facial measurements to the swelling and mouth opening.

		TG Median (1st–3rd quartiles)	SG Median (1st–3rd quartiles)	*p*-value*
Initial Measurement (mm)	Angle -Tragus	57.5 (50-62)	55 (50-60)	0.47
	Labial Commissure Angle	85 (75-90)	85 (80-90)	0.68
	Wing Nose Angle	100 (95-110)	100.25 (97-110)	0.65
	Corner of Eye Angle	95 (87-100)	95 (90-99)	0.67
	Chin Angle	110 (97-110.5)	110 (110-120)	0.12
Measured after 07 days (mm)	Angle -Tragus	57.5 (55-64)	60 (55-65)	0.43
	Labial Commissure Angle	90 (80-90)	97.5 (90-100)	0.01
	Wing Nose Angle	100.5 (100-110.5)	110 (105-111.5)	0.03
	Corner of Eye Angle	95 (90-100)	100 (94-100)	0.06
	Chin Angle	110 (110-120)	116 (110-130)	≤ 0.01
Initial mouth opening (mm)	Interincisal Distance (31-21)	43 (37-47)	44.5 (39-52)	0.45
Mouth opening after 07 days (mm)	Interincisal Distance (31-21)	35 (28-40)	30 (25-39)	0.13
Difference between initial and final measurements (mm)	Interincisal Distance (31-21)	6.5 (4-14)	9.5 (7-15)	0.12

* Wilcoxon test $p \leq 0.05$.

Table 4
Median (1st–3rd quartiles) heart rate and blood pressure assessments.

	Initial TG	Post Reg TG	Final TG	Initial SG	Post Reg SG	Final SG	*p*-value*
Systolic Pressure (mmHg)*	119 (110-129)	118 (109-126)	126 (118-132)	114.5 (112-120)	115 (110-120)	120.5 (114-134)	0.08
Diastolic Pressure (mmhg)*	75.5 (69-80)	72 (63-77)	77.5 (70-83)	73 (68-79)	72 (66-76)	77 (70-81)	0.07
Heart Rate (bpm)†	80.5 (76-91)	73.5 (66-88)	80 (71-85)	79.5 (71-91)	76 (68-87)	75.5 (70-87)	0.07

TG = Test Group; SG = Sham Group; Post Reg = Post Regulation.
* Wilcoxon test
† Friedman/*$p \leq 0.05$.

Blood pressure (BP) and heart rate (HR) do not differ statistically between the three times evaluated (initial, post-regulation and final) as reported (Table 4).

4. Discussion

The results show that in the TG, the intraoperative bleeding volume was lower, indicating that the analysis and selection of acupoints used for energy regulation with acupuncture, due to the imbalance observed in Ryoduraku graphs, contributed to this result. Energy balance is the basic condition necessary for health promotion, and when the imbalance between the harmonious flow of Yin and Yang energies occurs, diseases arise and there is no self-healing of the body [20].

Studies such as Lao et al. [13], Tavares et al. [14], Kassis [21] and used specific protocols for pain control; and Armond et al. [15], for swelling, anxiety and limitation of mouth opening, with little research on the benefits of using acupuncture comparing to bleeding during clinical surgical intervention.

Regarding Bleeding, the study by Luna et al. [22], that compared the effectiveness of acupuncture and herbal medicine in healthy dogs in surgery, did not observe any statistical difference in the blood coagulation time of the animals. In this study, it was found that energy regulation with acupuncture contributed to less intraoperative bleeding.

Energy regulation with acupuncture promoted improvement in homeostasis and relaxation of muscle tissue in the area adjacent to surgery, data that were observed in the evaluation of TG facial measurements in relation to the SG; this is justified since acupuncture relax the facial muscles as verified in studies for the treatment of orofacial pain [11,12].

In this study there was a statistically significant difference regarding residual swelling formation, a similar result shown in the study by Armond et al. [15], who evaluated swelling comparing groups of real acupuncture and placebo acupuncture. However, in the study by Armond et al. [15], specific points were used to control inflammation and promote muscle relaxation, different from the one proposed in this study in which points were used to promote energy regulation.

For swelling control, alternative measures are recommended as described by Zandi et al. [23], in which postoperative cold compression was used, without satisfactory results, differing from the result found in this study. The application of laser therapy is also indicated, however the results are not homogeneous, as there is a divergence from the correct dosimetry to be applied thus justifying unsatisfactory results [24,25]. Conventional practice is the administration of non-steroidal and steroidal anti-inflammatory drugs, despite the adverse responses that may be triggered [24]. Regarding the effectiveness of acupuncture therapy in swelling control, there are few reports found in the literature, thus being a field to be explored.

As third molar surgeries are often invasive, bone tissue removal is required, a procedure that promotes an inflammatory response causing pain, swelling and mouth opening limitation [3]; a careful surgical technique, surgical time control, and professional experience are some factors that can influence these inflammatory responses [6]. In this study, the results reported that, regarding the surgical time, there was no statistical difference ($p = 0.97$) and the amount of anesthetic used was 4 tubes (7.2 ml) of lidocaine 2% on average for each surgery in each group, which also showed no significant difference between them ($p = 0.45$). Just as the study was designed in a split-mouth format and with the same surgeon, these results corroborated that the inflammatory reactions were equal reducing the possible interference of these variables in the results found.

In TCM vision, surgical trauma blocks the correct flow of energy (Qi) and blood (Xue), and acupuncture promotes the unlocking of energy channels (meridians) and increases local vasodilation by releasing neurotransmitters that improve the inflammatory response [26].

Regarding HR, Uchida et al. [27] reported that heart rate decreased with deep needling regardless of Dequi's sensation,

when specific acupoint was used to control blood pressure. These results differ from this study, as heart rate variation was not significant, perhaps because acupoints were not indicated for this purpose.

Acupuncture studies when using a placebo group may consider needle action even when inserted at sites other than the treatment protocol. In the study by Lao et al. [13], who made a comparison between the real and the placebo groups, the results showed the effectiveness of the real group's analgesia. Unlike the study by Goddard et al. [27], that in both groups there was significant pain remission in patients with orofacial pain. In this study, it was observed that even with a possible effect on SG, it was not enough to promote energy regulation, since both intraoperative bleeding and facial swelling in the TG were minor.

The results found in this study corroborate the TCM theory that advocates a holistic view on treatment methods, which are related to disease-generating factors since functional and organic changes are related to a process of energy imbalance [17]. This imbalance can be produced by the environment (external factors) and food (internal factors), causing blocks and stagnation of Qi and Xue (blood) [17]. Therefore, performing preoperative energy regulation sought to eliminate these possible imbalances that could interfere with normal organic functioning [20].

The limitation of this study is related to the fact that only an energy regulation was performed (before surgery), possibly if a previous treatment had been carried out to raise and balance the energy level in a long term, they could have even more robust results. Thus, further studies are needed to assess and elucidate the effects of energy regulation with acupuncture on the body's energy balance and thus verify its ability to self-repair.

The results obtained in this clinical trial are innovative for application in dental practice, as they demonstrated that acupuncture therapy through energy regulation before dental surgical interventions could contribute to the control of intraoperative bleeding and post-surgical residual swelling, therefore, when promoting energy rebalancing by regulating the bioenergetic fields, it contributes to the process of organic repair, improving the physical responses of patients.

Declaration of Competing Interest

The authors declare that there are no conflicts of interest.

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