

# Evaluation of Acupuncture for Pain Control After Oral Surgery

## A Placebo-Controlled Trial

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**Background:** Acupuncture is increasingly being used by the general population and investigated by conventional medicine; however, studies of its effects on pain still lack adequate control procedures.

**Objectives:** To evaluate the (1) efficacy of Chinese acupuncture in treating postoperative oral surgery pain, (2) validity of a placebo-controlled procedure, and (3) effects of psychological factors on outcomes.

**Design:** Randomized, double-blind, placebo-controlled trial.

**Setting:** Dental School Outpatient Clinic, University of Maryland at Baltimore.

**Participants:** Thirty-nine healthy subjects, aged 18 to 40 years, assigned to treatment (n = 19) and control (n = 20) groups.

**Main Outcome Measures:** Patients' self-reports of time until moderate pain, time until medication use, total pain relief, pain half gone, and total pain medication consumption.

**Results:** Mean pain-free postoperative time was significantly longer in the acupuncture group (172.9 minutes) than in the placebo group (93.8 minutes) ( $P = .01$ ), as was time until moderate pain ( $P = .008$ ). Mean number of minutes before requesting pain rescue medication was significantly longer in the treatment group (242.1 minutes) than in the placebo group (166.2 minutes) ( $P = .01$ ), as was time until medication use ( $P = .01$ ). Average pain medication consumption was significantly less in the treatment group (1.1 tablets) than in the placebo group (1.65 tablets) ( $P = .05$ ). There were no significant between-groups differences on total-pain-relief scores or pain-half-gone scores ( $P > .05$ ). Nearly half or more of all patients were uncertain of or incorrect about their group assignment. Outcomes were not associated with psychological factors in multivariate models.

**Conclusions:** Acupuncture is superior to the placebo in preventing postoperative dental pain; noninsertion placebo procedure is valid as a control.

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SEVERAL STUDIES<sup>1-6</sup> have shown that acupuncture reduces postoperative pain (oral or general), but others<sup>7-10</sup> suggest that the effect of acupuncture may be largely due to a placebo effect. However, most studies are either anecdotal, lack sufficient sample size, fail to provide adequate treatment, fail to evaluate the placebo effect, or lack an adequate control group.

Different types of controls have been reported in the literature. A commonly used control is sham acupuncture, in which needles are inserted at sites other than real acupuncture points or needles are inserted at variable depths.<sup>11-14</sup> Because it has been suggested that analgesic effects can be produced even at dis-

tant sites such as the diffuse noxious inhibitory control,<sup>15,16</sup> sham acupuncture may be more appropriate for examining nonspecific, analgesic acupuncture effects than for examining the placebo effect itself. To evaluate the placebo effect, a nonneedle insertion control procedure may be more appropriate because it minimizes the physiological response. The use of a mock transcutaneous electrical nerve stimulator, which does not use a needle, is inadequate because it fails to appropriately simulate acupuncture treatment.<sup>17</sup>

The few studies<sup>18-23</sup> that have used the noninsertion placebo control procedure fail to evaluate the credibility of the procedure from the patient's point of view.<sup>19-22</sup> Placebo effects can also be due to factors that extend beyond the physical charac-

## PATIENTS AND METHODS

### PROCEDURES

Detailed methods and materials are described in our previous report.<sup>28</sup> In brief, all patients were recruited from the outpatient pool of the Oral and Maxillofacial Surgery Clinic at the University of Maryland at Baltimore Dental School. Patients were aged 18 to 40 years, in good health (American Society of Anesthesiologists class I or II), eligible for extraction of 1 mandibular (lower) partial bony impacted third molar, and had no history of prior treatment with acupuncture. Excluded patients were those who presented with any oral dental disease, those taking medications that might confound the results, those with a history of bleeding diathesis or allergy to the medication used in the study, or women who were pregnant or lactating. No race or sex was excluded from the study. After initial screening, the purposes and procedures of the study were explained, and the patients read, understood, and signed an informed consent that was approved by the Institutional Review Board of the University of Maryland. The dental procedure was performed by one surgeon (S.B.) blinded to treatment assignment. All patients were given the same local anesthetic of 3% mepivacaine hydrochloride (Carbocaine) without any vasoconstrictor. No other preoperative medication was used.

The patients were randomly assigned to either real acupuncture or placebo acupuncture immediately after the surgical removal of a partial bony impacted third molar. Randomized blocks of 4 and 6 were used to attain balanced allocation. Patients were assigned to a treatment group using sequentially numbered opaque sealed envelopes. A licensed acupuncturist (L.L.) administered all treatments and was the only investigator who knew what type of treatment the patient received. In the real acupuncture group, the acupuncture points *Hegu* (LI 4), *Jiache* (St 6), *Xiaguan* (St 7), and *Yifeng* (SJ 17) were used unilaterally on the tooth extraction side. All needles remained in place for 20 minutes, and each was manually manipulated (no electrical stimulation was applied) for 20 to 30 seconds 3 times: immediately after insertion, at the midpoint, and at the end of treatment. The "de qi" sensation (a sensation of soreness, numbness, or distention at the needling site) was obtained for each manipulation. In the placebo group, the procedure was identical to that used in the treatment group except without needle insertion into the skin. An empty plastic needle tube was taped on the bony area next to each

acupuncture point to produce some discernible sensation, and a needle with a piece of adhesive tape was then taped to the dermal surface for 20 minutes. Manipulations were made by palpating the surface of the skin with a blunt dental instrument at the same 3 points in time as the treatment group. In both groups, the patients' eyes were covered with patches so they could not view the treatment procedure. A pair of electrodes from a mock electrical stimulator was attached to the ends of the needles in the real and placebo acupuncture groups. A second treatment was given after patients reported moderate pain on a 4-point scale. For each subject, the second treatment was the same as the first treatment (acupuncture or placebo).

### ASSESSMENTS AND FOLLOW-UP

#### Pain

The pain model used<sup>29,30</sup> was developed by Cooper and Beaver and is widely accepted by both the pharmaceutical industry and the Food and Drug Administration to assess oral pain medication. Pain intensity was evaluated on a 4-point scale (0 indicates none; 1, slight/mild; 2, moderate; 3, severe) using a standardized questionnaire administered by a blinded clinical assistant.<sup>29,30</sup> Pain assessments were in 2 steps: (1) every 15 minutes after the first treatment until the reported pain reached a moderate level, at which time the patient had a second treatment, and (2) every 15 minutes for 3 hours after the second treatment. If a patient indicated no pain relief 30 minutes after the treatment, or if the intensity of pain increased, a standard analgesic medication (acetaminophen, 600 mg, with codeine, 60 mg) was administered at the patient's request. In this situation, pain scores following rescue medication were carried through as moderate or severe, according to the patient report at the time of the rescue medication request.<sup>30</sup> For each patient, assessments included self-reports of time until moderate pain, time until medication use, total pain medication consumption, total pain relief, and pain half gone.

Patients were observed on-site for 3 hours after the second acupuncture treatment or 6 hours after the first treatment if the pain did not reach a moderate level. They were asked to continue recording their pain levels every hour for 24 hours after treatment and to provide global assessments daily for 7 days. Patients who fell asleep and did not complete the evaluation form were assigned a rating of pain intensity equal to the last recording before falling asleep.<sup>30</sup> The follow-up forms were turned in on the seventh day when the patient returned to the clinic for suture removal.

teristics of such treatment,<sup>24-27</sup> and these psychological factors must also be accounted for when measuring a placebo effect. Our previous study<sup>28</sup> examined the effect of acupuncture on pain in a placebo-controlled trial. The current study further evaluates the placebo effect by assessing the association of psychological factors with study outcomes.

The study hypotheses are as follows: acupuncture is better than placebo in managing postoperative dental pain; the placebo procedure is a valid control; psychological factors are not associated with study outcomes; and acupuncture is a safe, adjunctive therapy in dental pain control.

## RESULTS

Forty-two volunteers enrolled in the study. Three patients were excluded from further participation because the anesthetic administered during surgery failed to block pain completely; they requested and received "rescue" pain medication following surgery and completed no post-surgery questionnaire. The remaining patients were randomized into treatment (n = 19) and control (n = 20) groups after surgery. There were no significant differences between the acupuncture and placebo groups on age, sex, or race (**Table 1**) based on  $\chi^2$  analyses. Nei-

## Blinding

To evaluate patient blinding, the questionnaire asked patients to indicate which treatment they believed they had received (acupuncture, placebo, or don't know) at 3 points in time: immediately after the first treatment, immediately after the second treatment, and at the end of on-site clinical observation. If patients answered either acupuncture or placebo, they were asked to indicate what led to that belief: (1) the manner, attitude, or words of the acupuncturist; (2) the manner, attitude, or words of the assistant; (3) the results of the acupuncture treatment (eg, pain intensity); or (4) the experience of the acupuncture procedure (eg, what the acupuncturist did and how it felt).

**Psychological Impact Prestudy Impact.** To assess the impact of past experience and expectations on treatment outcome, patients were given a pretreatment questionnaire. They were asked about their experience with prior dental surgery, level of pain with such surgery, and awareness of individual differences in pain as a result of the procedure. Motivation was assessed by patients ranking their reasons for participation in the study. The choices were "Curiosity: I wanted to see what acupuncture is like," "I believe acupuncture is a good treatment," "I wanted to save money," "I don't want to take pain drugs," and "Because the doctor referred me."

Patients answered the following questions to assess their knowledge of, experience with, and expectations of the effectiveness of acupuncture:

1. Do you personally know anyone who is an acupuncturist? (yes or no)
2. Have any of your friends or family members ever been treated with acupuncture? (yes or no)
3. If yes, what did they tell you about the effectiveness of the acupuncture treatment? (bad, fair, good)
4. In general, what is your impression of acupuncture? (on a 7-point scale from very negative to very positive)
5. Please rank the source of your own personal knowledge of acupuncture. (what friends have told me, personal reading in books and professional journals, popular media)
6. Acupuncture needles are much smaller in size than regular (hypodermic) needles. They may or may not produce much pain. Were you aware of this fact? (yes or no)

**Poststudy Impact.** To further assess the effectiveness of the placebo, an existing 4-question credibility assessment on

a 6-point Likert scale was modified<sup>31</sup> for pretreatment and posttreatment assessment. The posttreatment questionnaire was given at the end of the clinical observation period. The following is the wording for the posttreatment assessment:

1. After your experience here, how sure do you feel that acupuncture can relieve dental pain? (very unsure to very sure)
2. After your experience here, how sure do you think you would be in recommending acupuncture to someone else? (very unsure to very sure)
3. After your experience here, how reasonable does acupuncture as a form of treatment seem to you? (very unreasonable to very reasonable)
4. Based on your understanding of acupuncture, rate your expectations of the success of acupuncture treatment. (very pessimistic to very optimistic)

The posttreatment questionnaire also measured stress levels during and following the dental and acupuncture procedures and patients' use of meditation or self-hypnosis before, during, or after the procedure.

## Adverse Effects

The posttreatment questionnaire evaluated adverse effects of the treatment: dizziness, shallow breathing, heaviness, nausea, coughing, pain, drowsiness, soreness, numbness, or other discomfort.

## STATISTICAL ANALYSIS

Data were sent to the Department of Epidemiology, University of Maryland at Baltimore School of Medicine, and analyzed by an independent biostatistician (P.L.) who was blinded to the treatment procedures. The a priori power analysis was based on 80% power for a 2-tailed test ( $\alpha = .05$ ). Time before reporting moderate pain and total time before medication request (survival time) were evaluated with the Student *t* test and the log-rank test, and Kaplan-Meier methods were used to plot survival probabilities. The total-pain-relief scores, pain-half-gone scores, medication consumption, psychological factors, and patient conjecture about the treatment received were compared for the treatment and control groups using  $\chi^2$  analysis for proportions. The Student *t* test and the nonparametric Wilcoxon rank sum tests were used for continuous variables. Results were similar; therefore, Student *t* test results are presented in the text.

ther the surgeon-reported patient trauma from the surgical procedure nor the amount of local anesthetic administered were found to be associated with outcomes.

## EFFECTS OF ACUPUNCTURE ON PAIN AND MEDICATION CONSUMPTION

The preliminary data analysis using the Student *t* test indicated that, after the first acupuncture treatment, the mean  $\pm$  SE pain-free time was significantly longer in the acupuncture group (172.9  $\pm$  25.4) than in the placebo group (93.8  $\pm$  16.5) ( $P = .01$ ) (**Figure 1**, A). The mean number of minutes before requesting the pain rescue

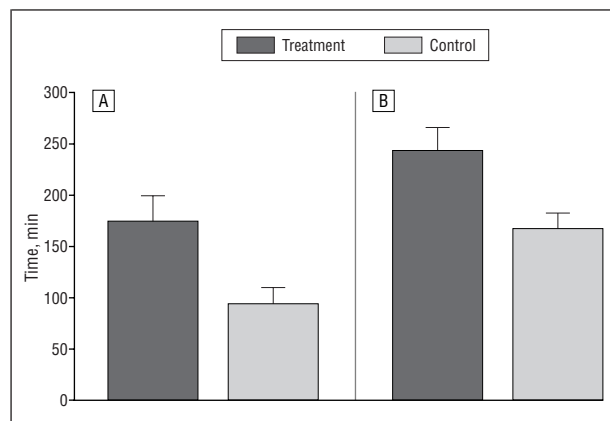
medication was significantly longer in the acupuncture group (242.1 minutes  $\pm$  23.5) than in the placebo group (166.2 minutes  $\pm$  17.2) ( $P = .01$ ) (**Figure 1**, B).

A further survival analysis using the log-rank test showed that, after the first acupuncture treatment, subjects treated with acupuncture reported longer time to moderate pain ( $P = .008$ ) (**Figure 2**, A). This difference remained significant when controlling for age and sex ( $P = .02$ , relative risk, 0.40; 95% confidence interval, 0.19-0.84), indicating that, at any point in time, the acupuncture group was less likely to experience moderate pain than the placebo group. Time until requesting pain medication was also significantly longer for the

**Table 1. Demographic Variables in Treatment and Control Groups\***

Variable	Group, No. (%)	
	Acupuncture (n = 19)	Control (n = 20)
Sex		
Male	11 (58)	11 (55)
Female	8 (42)	9 (45)
Race		
Asian	1 (5)	0 (0)
Black	1 (5)	2 (10)
Hispanic	1 (11)	1 (5)
White	15 (79)	17 (85)
Age, y		
18-22	8 (42)	8 (40)
23-27	7 (37)	10 (50)
28-34	4 (21)	1 (10)

\*No significant differences observed based on  $\chi^2$  analyses or t test (age continuous). Mean (SD) age for the acupuncture group was 23.4 (4.7) years and for the control group was 24.0 (3.8) years.



**Figure 1.** Comparisons between the treatment group (n = 19) and control group (n = 20). A, Mean  $\pm$  SE time to reach moderate pain was significantly longer in the acupuncture group (172.9  $\pm$  25.4) than in the placebo group (93.8  $\pm$  16.5); Student t test,  $P = .01$ ; Wilcoxon rank sum test,  $P = .007$ . B, Mean time  $\pm$  SE before requesting pain medication was significantly longer in the acupuncture group (242.1  $\pm$  23.5) than in the placebo group (166.2  $\pm$  17.2); Student t test,  $P = .01$ ; Wilcoxon rank sum test,  $P = .02$ .

acupuncture group than the placebo group ( $P = .01$ ) (Figure 2, B). Four patients in the acupuncture group and 1 patient in the placebo group never complained of moderate pain. There were no statistically significant differences between the acupuncture and placebo groups on total-pain-relief scores or for pain-half-gone scores after the second treatment, following a moderate pain report. Patients' pain levels for 24 hours after treatment and global assessments for 7 days were also not significantly different. Average consumption of pain medication (acetaminophen, 600 mg, with codeine, 60 mg) by the acupuncture group was significantly less than the placebo group (1.1 tablets vs 1.65 tablets, respectively;  $P = .05$ ). At 7-day follow-up, mean  $\pm$  SE use of narcotic pain medication was lower in the acupuncture group (7.7  $\pm$  2.0 tablets) than in the placebo group (11.3  $\pm$  3.0 tablets). This difference, however, was not statistically significant ( $P = .33$ ).

## BLINDING

Patients were generally unaware of the treatment they received: nearly half or more of all patients at any point in time were either uncertain of or incorrect about their group assignment (Table 2). After the first treatment, there was no significant difference between the treatment and control groups in the number of patients who believed they were receiving acupuncture (7 of 16 and 7 of 17, respectively), suggesting that the treatment and control procedures did not clearly inform patients in either group about which procedure was received. After the second treatment, more patients in the acupuncture group were certain they actually received treatment (8 of 16) and fewer of those in the placebo group thought they did as well (5 of 16). By the third observation, a significant difference existed between the 2 groups ( $P = .02$ ): significantly fewer patients in the placebo group thought they were receiving treatment (3 of 20) compared with patients in the treatment group (11 of 19), due entirely to a reported increase in pain intensity rather than to the procedure itself. Even among patients who correctly guessed that they were receiving acupuncture, only 3 reported that their responses were due to the experience with the procedure itself.

Overall, there were substantial errors in the patients' conjectures about the groups to which they were assigned: at the final assessment, only 11 of 19 patients in the treatment group and 4 of 20 patients in the placebo group made correct guesses, and the procedures bore no relationship to the guesses made.

## PSYCHOLOGICAL IMPACT

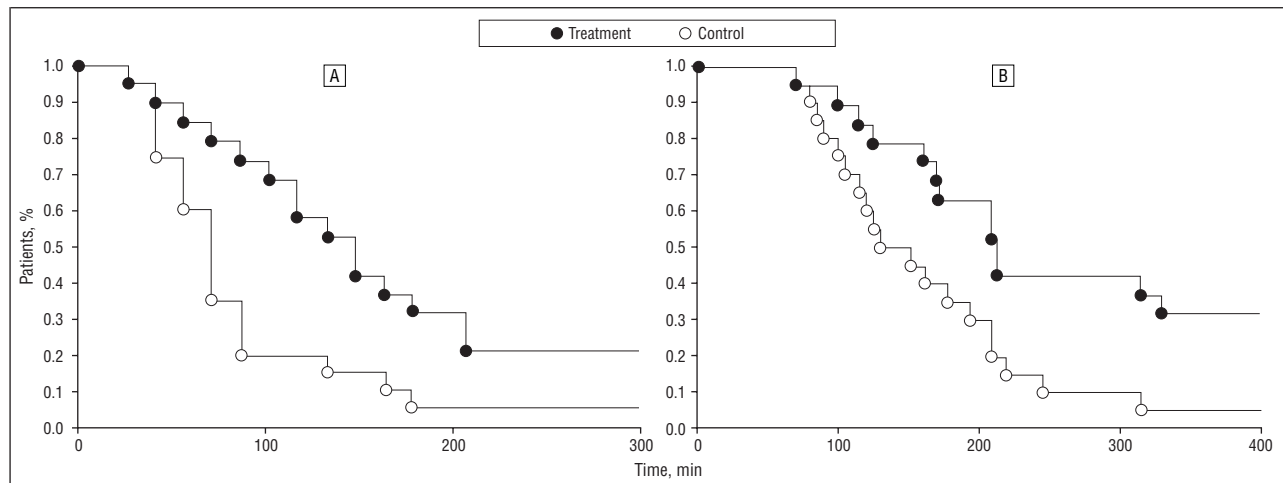
### Prestudy Impact

On the pretreatment questionnaire—which assessed possible differences between the treatment and placebo groups that might influence outcome—only 1 significant difference emerged: the treatment group had more family members who had been treated with acupuncture ( $P = .02$ ). There were no significant differences between the groups on their certainty that acupuncture could relieve dental pain ( $P = .12$ ), their certainty about recommending acupuncture to someone else ( $P = .94$ ), their belief in the reasonableness of acupuncture as a form of treatment ( $P = .48$ ), or their expectations of the success of acupuncture ( $P = .55$ ).

Most subjects in both groups indicated that their primary motivations for participation (in descending order) were a need to save money, curiosity, belief in acupuncture as a good treatment, referral by a physician, and not wanting to take drugs. None of the patients indicated belief in acupuncture as a first choice for participation, and there were no significant differences between the 2 groups on this question.

### Poststudy Impact

The treatment and placebo procedures were equally credible to both groups, suggesting that psychological effects were not determining outcomes. After experienc-



**Figure 2.** Comparisons between the acupuncture group ( $n = 19$ ) and placebo group ( $n = 20$ ) on Kaplan-Meier plots of survival using the log-rank test. A, Acupuncture group had longer pain-free time before reaching moderate pain than the placebo group ( $P = .008$ ). B, Acupuncture group had longer pain survival time before taking rescue medication than the placebo group ( $P = .01$ ).

ing the control and treatment procedures, the groups did not differ significantly on their expectations of the pain-relieving value of acupuncture, their willingness to recommend others for acupuncture, their perception of acupuncture as a reasonable treatment, or their interest in having acupuncture again themselves. There were no group differences in their use of meditation or self-hypnosis either before the procedure or during their entire time at the clinic. Four patients in each group had used meditation or self-hypnosis either before or during the dental or treatment procedures.

Stress levels before or during the dental or acupuncture procedures were not significantly different ( $P = .49$  and  $.76$ , respectively). Eleven patients (5 in the acupuncture group and 6 in the placebo group) reported experiencing stress related to the entire procedure. More patients felt the stress associated with the dental procedure rather than with the acupuncture treatment procedures. Most patients in both groups believed they were adequately informed about the study and were satisfied with the overall treatment procedures.

### ADVERSE EFFECTS

Only the placebo group experienced systemic adverse effects (dizziness, heaviness, nausea, and drowsiness), and these were most likely associated with the dental surgical procedure. The treatment group experienced significantly more localized, needling site discomfort (soreness and numbness) both during and after the acupuncture treatment than did the placebo group. This discomfort—the *de qi* sensation—is expected and required in effective acupuncture treatment.<sup>32,33</sup> One person from each group reported severe pain, which, on further questioning, was determined to be related to the dental procedure.

### COMMENT

The results of this study demonstrate the superiority of acupuncture over placebo in preventing pain before it starts, and are consistent with our previous studies.<sup>28,34</sup> However,

**Table 2. Patient Conjectures About Group Assignment for Both Treatment and Placebo Groups at 3 Points in Time**

Patient Conjectures	No. (%)		
	First Treatment	Second Treatment	End of Clinical Observation
<b>Treatment Group</b>			
Belief that they did receive acupuncture (correct guess)	7 (44)	8 (50)	11 (58)*
Uncertain	8 (50)	6 (37)	6 (32)
Belief that they did not receive acupuncture (incorrect guess)	1 (6)	2 (13)	2 (11)
<b>Placebo Group</b>			
Belief that they did receive acupuncture (incorrect guess)	7 (41)	5 (31)	3 (15)*
Uncertain	9 (53)	7 (44)	13 (65)
Belief that they did not receive acupuncture (correct guess)	1 (6)	4 (25)	4 (20)

\*The differences between patient guesses in the treatment and placebo groups were significantly different ( $\chi^2 P = .02$ ).

acupuncture was not more effective than placebo after the patient reported “moderate” pain, suggesting that acupuncture may be better at preventing acute postoperative pain than at controlling existing pain. Neither psychological factors nor study procedures had a significant effect on study outcomes; patient reports suggested that the treatment and control procedures were equally credible until pain differences between the groups increased the accuracy of their perceptions about which treatment they were receiving. This study has validated a noninsertion control model.

After the first treatment (immediately after surgery), patients could not distinguish the type of treatment they received. However, before leaving the clinic (approximately 6 hours later) when patients were asked again to guess their treatment group assignment, a significant difference emerged. These significant differences in patients’ ability to determine their treatment were due to the levels of pain experienced. That is, those who had less pain were more likely to think they had received acupuncture,

while those who had more pain were more likely to think they had not received acupuncture treatment. In addition, at the end of the study, the 2 groups showed no difference on any psychological variable assessed, including their assessment of the reasonableness of acupuncture as a treatment, or on their expectations of success.

The issues of safety and the possible adverse effects of acupuncture remain a concern. However, in our study, standardized, systematic measures were used to document adverse effects, yet no adverse effects were associated with the acupuncture procedure—suggesting that acupuncture is safe. The finding that patients in the placebo group experienced more adverse effects of dental procedures than those of the acupuncture group suggests that acupuncture may reduce some adverse effects of surgery. This has been observed by other investigators.<sup>35-37</sup> However, because of the small sample, a conclusion about this cannot be drawn.

There are limitations to this study. First, patients should not be allowed to leave the site early. Since results reported by Sung and colleagues<sup>1</sup> showed that acupuncture did have an analgesic effect after a report of moderate pain, we suspect that our failure to validate this finding may be at least partially due to some of our patients requesting pain medication in order to leave the study early. Second, because all study participants were recruited from the same dental clinic, the generalizability of these findings may be limited and need to be validated in other settings.

In conclusion, this study shows that (1) acupuncture is more effective with postoperative pain control than placebo; (2) early treatment to prevent pain is more important than treating pain after it has achieved moderate intensity; (3) our procedures are valid as a placebo control model for the scientific evaluation of acupuncture; (4) the effects of the acupuncture treatment did not appear to be influenced by patient motivation or expectation; and (5) acupuncture appears to be safe for treating dental pain. A 1998 National Institutes of Health Consensus Conference on the effectiveness of acupuncture to treat a variety of conditions made 2 important conclusions. First, many of the 2302 studies reviewed produced equivocal results because of study design problems. Second, the treatment of postoperative dental pain is a primary condition that demonstrates the efficacy of acupuncture.<sup>38</sup> This research supports these conclusions and enhances the design of valid placebo control methods. Therefore, acupuncture may be a useful adjunct to conventional analgesic therapies in the management of pain after oral surgery. However, it should be acknowledged that the real clinical value of acupuncture may be related to its cost-effectiveness and to patients' values about the use of medication and acupuncture. Further studies to evaluate these patient variables may be warranted.

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