The Efficacy of Acupuncture in the Treatment of Temporomandibular Joint Myofascial Pain: A Randomised Controlled Trial.

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Summary

Objectives
To compare the effect of real acupuncture and sham acupuncture in the treatment of temporomandibular joint myofascial pain, in order to establish the true efficacy of acupuncture.

Methods
A double blind randomised controlled trial conducted in the TMD Clinic, at the School of Dentistry, The University of Manchester. Twenty-seven patients were assigned to one of two treatment groups. Group 1 received real acupuncture treatment whilst Group 2 received a sham acupuncture intervention. Both the assessor and the patient were blinded regarding the group allocation. Baseline assessment of the outcome variables was made prior to the first treatment session, and was repeated following the last treatment.

Results
The results demonstrated that real acupuncture had a greater influence on clinical outcome measure of TMJ MP than those of sham acupuncture, and the majority of these reached a level of statistical significance.
Conclusion

Acupuncture had a positive influence on the signs and symptoms of TMJ MP. In addition, this study provides evidence that the Park Sham Device was a credible acupuncture control method for trials involving facial acupoints.
Introduction

Myofascial pain (MP) is the most common temporomandibular disorder (TMD). To date there have been many synonyms for this condition including facial arthromyalgia, TMJ dysfunction syndrome, myofascial pain dysfunction syndrome, craniomandibular dysfunction and myofascial pain dysfunction. Currently the preferred terms, according to the Research Diagnostic Criteria (RDC/TMD) developed by Dworkin et al, is myofascial pain (MP).

It has been suggested that between 50% and 75% of the population in all age groups have signs of MP at some time in their lives and a further 20%-25% of the population suffer symptoms but do not seek treatment. In addition, although more women seek treatment for this condition, the prevalence seems to be the same in both genders. Moreover, MP has been considered to be the most common temporomandibular disorder for which TMD patients seek professional care.

The aetiology of MP seems to be multifactorial, complex and largely unresolved and it has been suggested that symptoms may be due to a variety of causes, and both central and peripheral mechanisms have been implicated in the process.

Although MP symptoms may vary with the stage and progress of the condition but generally one of the following five signs or/and symptoms are present: pain or ache in the TMJ, pain on palpation of the associated muscles, limitation or deviation of mandibular movement, joint sounds and headache. It is important to realize that headache alone and joint sounds alone are not diagnostic of MP. Numerous treatments, either
single or in combination, have been proposed for the management of MP. A wide range of pharmacological, occlusal alteration, psychotherapeutic, and physiotherapeutic treatments have been used for the management of MP, and these are mainly aimed at the reduction of pain. 9, 10, 11, 12

Acupuncture has also been reported to have a beneficial role in the management of TMD MP. 13, 14, 15, 16, 17, 18,19, 20,21,22 Stomach 7 (ST 7) or "Xiaoguan" is an acupuncture point located inferior to the zygomatic arch, immediately anterior to the condyle of the mandible in the depression posterior to the masseter muscle. It's location is facilitated by palpating underneath the zygomatic arch, asking the patient to open and close the jaw whilst locating the anterior aspect of the mandibular condyle, and then asking the patient to clench the jaw, in order to locate the posterior aspect of the masseter muscle. List and

Five randomized controlled trials (RCTs) 15,25,26,27,28 strongly suggest that acupuncture has beneficial effects similar to those of stabilization splint therapy in the management of TMJ MP. However, due to confounding methodology, lack of adequate methods of acupuncture control, and lack of validation of acupoints, the true efficacy of acupuncture has yet to be ascertained.

In a systematic review 19 reported that although studies suggest that acupuncture is effective in the treatment of TMJ pain and dysfunction, no trials were found that controlled for possible placebo effects of acupuncture.

Until recently attempts at providing a control group for acupuncture which provided a
similar therapeutic setting as well as being neurophysiologically inert had been unsuccessful. A recent validation study has been published which provides evidence of a method which enables adequate blinding of the participant whilst maintaining an identical therapeutic setting to that of real acupuncture. This uses what is known as a 'Park Sham Device' (PSD). 29,30

The aim of this study is to compare the effect of real acupuncture and new sham acupuncture in the treatment of TMJ MP (Group I patients according to RDC/TMD), in order to establish the true efficacy of acupuncture.

Null Hypothesis: there is no significant improvement in the signs and symptoms in patients receiving 'real' acupuncture, compared with those receiving a 'sham' acupuncture intervention.

Methods and Materials

Study Design and Patient Selection

Ethical approval was obtained through Central Manchester LREC for a double blind, randomized controlled trial conducted in the TMD Clinic, at the School of Dentistry, The University of Manchester.

Inclusion Criteria

RDC/TMD was adopted for diagnosing Patients with of TMJ MP. Patients who had the condition for at least six months were considered for the trial. In addition to pain on the TMJ, all cases demonstrated two or more of the following diagnostic criteria:

* Pain on Palpation of the Associated Muscles,
• Limitation or deviation of mandibular movement,
• Intermittent joint sounds such clicking or cracking (but not crepitus)
• Headache may also be present.

Exclusion Criteria
• Patients with cervical trauma (whiplash/chronic cervical problems)
• Patients with systematic joint and muscle disease
• Metal allergy
• Needle phobia
• Bleeding disorders

Patients who met the inclusion criteria were informed about the study design and advised that they had equal opportunity of receiving real or sham acupuncture treatments without knowing until the trial had ended. Possible risks of acupuncture treatment were explained. They were informed that they could stop participating in the study at any time. A written informed consent was obtained by each patient who entered the trial.

35 patients who were referred to the TMD Unit, School of Dentistry, The University of Manchester were assessed for suitability and 27 patients met the inclusion criteria. Adult subjects were recruited over a period of 5 weeks (June –July 2003). They were assigned to one of two treatment groups. Group 1 received real acupuncture treatment whilst Group 2 received a sham acupuncture intervention. A computerized randomization programme was used to generate group allocation of patients, which
were concealed in opaque envelopes by a person not involved with the study. Both the assessor and the patient were blinded regarding the group allocation. However, the clinician performing either intervention was aware of the group affiliation. Patients were advised to continue any other ongoing treatment such as medication or splint therapy for the condition at the same level as usual. They were, however, requested not to commence any other new intervention. Baseline assessment of the outcome variables was made prior to the first treatment session, and was repeated following the last treatment.

The Sham Acupuncture Needle

The sham acupuncture needle looks exactly like a real needle, but is blunt and free to slide within its handle so that, when pressed, it telescopes into the handle rather than penetrating the skin (Fig 1). This needle is the same size as the real one (0.35 mm x 70mm) and it is stainless steel and manufactured by Dong Bang Acupuncture Inc, Korea.

Park Sham Device (PSD)

Both the blunt 'sham' acupuncture needles and the 'real' needles are applied through a holder (PSD) (Fig 2) which is held in place on the skin by a self adhesive pad.

Initial Assessment and Assignment

Patient details and assessment of baseline outcome measures were performed and documented by an experienced clinician involved in the TMD clinic in accordance
with standards described by Gray et al. The following outcome measures were assessed at baseline and completion of the study:

- **Patient Functional Perspective.** 10cm Visual Analogue Scale (VAS) functional scale was used. A reading of 0 cm was equal no functional impairment e.g. in eating, talking, or sleeping. A reading of 10cm meant maximal functional impairment, severely limiting the subject in all such functions.

- **Pain Intensity.** A 10cm VAS was used 0cm = no pain, 10cm = worst pain imaginable.

- **Pain Distribution.** The areas in which the patients reported having experienced pain in relation to the TMD MP was recorded on a head chart. These were divided into three sections: Area 1: The main area surrounding the TMJ; Area 2: The lower area including the neck and shoulder; Area 3: The upper area including the eye and temporal regions (Fig 3).

- **Inocor opening and lateral movement measurement.** These are reliable and valid methods for documenting and monitoring status of TMD patients. Maximal opening and pain free opening were measured in millimeters using Vernier style bite gauge. Both inter and intra-operator reliability of using this device for such measurements has been established.

- **Muscle tenderness.** The right and left masseters were palpated for the presence of tenderness. Right and left lateral pterygoid tenderness was recorded by its response to resisted vertical and lateral movements.

- **TMJ tenderness.** The presence of tenderness was detected by palpation of the
lateral and intra-auricular palpation of the right and left TMJs.

- **Headaches.** The patient was subjectively asked to report any presence of "nonspecific" headaches in connection with TMD MP.

- **Deviation.** This sign is could be an indication of spasms in the masticatory muscles. This was noted as any observable deviation of jaw movement from a vertical straight line whilst opening and closing the mouth.

- **TMJ sounds.** Clicking was detected by lateral and intra auricular palpation of the TMJ, as well as with a stereo-stethoscope. The apparatus provides a method of accurately and reproducibly detecting TMJ sounds and determining whether they emanate from the left, right or are bilateral.¹

Improvement or elimination of the above mentioned outcome measures were considered as a positive treatment outcome.

**Treatment Procedure**

Each patient received six acupuncture treatments bilaterally at ST 7 (Fig 4). These took place over a three week period and were administered by one of the authors who was experienced in the use of acupuncture.

After ST 7 was located a circular indentation was made into the skin to mark the using the end of the guide tube. The area was then disinfected with alcohol and the acupuncture needle (real or sham) was then applied to the centre of the circular mark, using a sterile technique, perpendicular to the skin, through the PSD.

**Needling Technique**
The 'real' acupuncture group received the true penetrative needle, i.e. with a sharp point. This needle was inserted 6mm-12mm into the skin until resistance or pain were felt. For the 'sham' acupuncture group, the blunt needle end only touched the skin, and the handle was able to slide 12mm down the needle. The needle was retained in position for twenty minutes in both groups with manual stimulation by tapping the needle every five minutes for ten seconds. On removal of the needle, pressure was immediately applied to the skin, using a cotton bud, for ten seconds, or until any bleeding had ceased. The acupuncture site was then re-examined and the patient once again was requested to report any reactions. The patient was then advised regarding appropriate care following acupuncture.

All patients were reassessed for all outcome measures 3 days and then 7 days following the final acupuncture session by the same blinded TMD clinician who had preformed the initial assessment. The subjects were also finally asked by the assessor whether or not they knew if they had received the real or sham intervention again through standardised questioning.

Documentation of Interventions

All treatment interventions, Pain VAS and Functional VAS and other outcome measures were recorded on standardised assessment forms. These were concealed from the assessor to maintain blinding status.

Results

35 patients were assessed for suitability and of these 27 subjects entered the trial and were randomized into two treatment groups. 7 patients did not meet the inclusion
criteria and were excluded from the study. Only 1 patient dropped out without reason from the real acupuncture group. This occurred after three treatment sessions (see Figure 5 outlining subject flowchart through the study). The following results represent data analysis of 27 subjects who underwent the randomization procedure.
Assessed for eligibility n=35

Excluded n=8
Exclusion Criteria Fulfilled: n=7
Refused to participate: n=1

Randomised (n=27)

Received acupuncture n=15
Dropout n=1
Reason: no explanation
Attended endpoint assessment n=15
Analysed n=15

Received sham acupuncture n=12
Dropout n=0
Attended endpoint assessment n=12
Analysed n=12

Fig 5
Patient Characteristics

Table 1 below illustrates the relevant baseline demographics

<table>
<thead>
<tr>
<th></th>
<th>Real Acupuncture</th>
<th>Sham Acupuncture</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Size</td>
<td>15</td>
<td>12</td>
<td>27</td>
</tr>
<tr>
<td>Age (± SD)</td>
<td>38.3 (± 13.39)</td>
<td>43.2 (± 4.04)</td>
<td>40.5 (13.63)</td>
</tr>
<tr>
<td>Female: Male sex ratio</td>
<td>13:2</td>
<td>11:1</td>
<td>14.3</td>
</tr>
<tr>
<td>Pain Duration (Mean ± SD) years</td>
<td>4.0 (± 2.2)</td>
<td>4.4 (± 2.8)</td>
<td>4.3 (± 2.4)</td>
</tr>
</tbody>
</table>

Table 1 Patient Characteristics

Outcome Measures

Functional Impairment: Both real and sham groups showed improvement in the mean VAS scores for functional impairment. However, only the real acupuncture treatment group results showed statistical significance (Table 2).

<table>
<thead>
<tr>
<th></th>
<th>Mean baseline VAS score (cm)</th>
<th>Mean endpoint VAS score (cm)</th>
<th>Mean difference (cm)</th>
<th>Paired t-Test P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real</td>
<td>5.2767</td>
<td>2.3200</td>
<td>2.9567</td>
<td>0.003</td>
</tr>
<tr>
<td>Sham</td>
<td>1.3333</td>
<td>1.2500</td>
<td>0.0833</td>
<td>0.339</td>
</tr>
</tbody>
</table>

Table 2 Functional impairment results.

Pain Intensity: Similarly, both real and sham groups showed improvement in the mean VAS for pain intensity. However, only the real acupuncture was shown to be statistically significant, whereas the sham acupuncture did not reach a level of significance (Table 3).
<table>
<thead>
<tr>
<th></th>
<th>Mean baseline VAS score (cm)</th>
<th>Mean endpoint VAS score (cm)</th>
<th>Mean difference (cm)</th>
<th>Paired T-Test <em>P</em> Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real</td>
<td>6.2133</td>
<td>2.8940</td>
<td>3.3193</td>
<td>0.001</td>
</tr>
<tr>
<td>Sham</td>
<td>1.4167</td>
<td>1.3333</td>
<td>0.0833</td>
<td>0.586</td>
</tr>
</tbody>
</table>

Table 3 Pain intensity results.

**Pain Distribution:** for the face chart, the face was divided into three areas: (i) the joint area, (ii) the temporal area and the forehead and (iii) the lower jaw area and the neck (see Fig 3). The numbers of areas affected by pain were found to be significantly reduced in the acupuncture group on the left and right sides at a statistical level. On the sham group, however, a significant improvement was not found (Table 4).

<table>
<thead>
<tr>
<th></th>
<th>Pain distribution at 2nd visit: pain distribution at baseline</th>
<th>No change</th>
<th>Wilcoxon Signed Ranks Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real Left</td>
<td>11</td>
<td>4</td>
<td>0.005</td>
</tr>
<tr>
<td>Right</td>
<td>9</td>
<td>6</td>
<td>0.005</td>
</tr>
<tr>
<td>Sham Left</td>
<td>0</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>1</td>
<td>11</td>
<td></td>
</tr>
</tbody>
</table>

Table 4 Pain distribution results

**Inter-incisor Opening and Lateral Movement**

**Maximum Opening** In this case, only the real group showed improvement which was statistically significant (Table 5).

<table>
<thead>
<tr>
<th></th>
<th>Mean baseline opening (mm)</th>
<th>Mean endpoint opening (mm)</th>
<th>Mean difference (mm)</th>
<th>Paired T-Test <em>P</em> Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real</td>
<td>36.0667</td>
<td>39.2667</td>
<td>3.2000</td>
<td>0.020</td>
</tr>
<tr>
<td>Sham</td>
<td>40.7500</td>
<td>39.2500</td>
<td>1.5000</td>
<td>0.227</td>
</tr>
</tbody>
</table>

Table 5 Maximum inter-incisor opening
**Maximum Pain Free Opening:** Both treatment groups showed improvement. However, the real acupuncture group reached a statistical level of significance and was much higher than sham group (Table 6).

<table>
<thead>
<tr>
<th></th>
<th>Mean baseline opening (mm)</th>
<th>Mean endpoint opening (mm)</th>
<th>Mean difference (mm)</th>
<th>Paired T-Test * P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real</td>
<td>28.4667</td>
<td>36.6667</td>
<td>8.2000</td>
<td>0.000</td>
</tr>
<tr>
<td>Sham</td>
<td>36.8333</td>
<td>37.1667</td>
<td>0.333</td>
<td>0.674</td>
</tr>
</tbody>
</table>

Table 6 Maximum pain-free opening

**Lateral Movement:** Whilst in the real acupuncture group there was an improvement in lateral movement to the right as well as improvement in the lateral movement to the left, these did not reach statistical level of significance in the lateral movement to the right. In the sham group, however there was no significant change in either direction (Table 7).

<table>
<thead>
<tr>
<th></th>
<th>Mean baseline opening (mm)</th>
<th>Mean endpoint opening (mm)</th>
<th>Mean difference (mm)</th>
<th>Paired T-Test * P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real</td>
<td>L 9.6667</td>
<td>10.8667</td>
<td>2.2000</td>
<td>0.060</td>
</tr>
<tr>
<td></td>
<td>R 9.2667</td>
<td>11.8000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sham</td>
<td>L 9.2500</td>
<td>9.9167</td>
<td>0.6667</td>
<td>0.194</td>
</tr>
<tr>
<td></td>
<td>R 9.5833</td>
<td>9.3833</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 7 Extent of lateral movement
Muscle tenderness

Where the presence of muscle tenderness was detected through palpation of the masseter, temporalis and lateral pterygoid muscles, improvements were made much more in the real acupuncture group when compared with the sham group (Table 8).

<table>
<thead>
<tr>
<th>Muscle</th>
<th>Improvement in tenderness</th>
<th>No change</th>
<th>Worse</th>
<th>Paired T-Test P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Masseter</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Real L</td>
<td>9</td>
<td>6</td>
<td></td>
<td>0.003</td>
</tr>
<tr>
<td>Real R</td>
<td>3</td>
<td>12</td>
<td></td>
<td>0.083</td>
</tr>
<tr>
<td>Sham L</td>
<td>0</td>
<td>12</td>
<td>2</td>
<td>0.564</td>
</tr>
<tr>
<td>Sham R</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temporalis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Real L</td>
<td>3</td>
<td>12</td>
<td></td>
<td>0.083</td>
</tr>
<tr>
<td>Real R</td>
<td>7</td>
<td>8</td>
<td></td>
<td>0.008</td>
</tr>
<tr>
<td>Sham L</td>
<td>0</td>
<td>11</td>
<td>1</td>
<td>0.317</td>
</tr>
<tr>
<td>Sham R</td>
<td>0</td>
<td>10</td>
<td>2</td>
<td>0.157</td>
</tr>
<tr>
<td>Lateral Pterygoid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Real L</td>
<td>6</td>
<td>9</td>
<td></td>
<td>0.014</td>
</tr>
<tr>
<td>Real R</td>
<td>6</td>
<td>9</td>
<td></td>
<td>0.014</td>
</tr>
<tr>
<td>Sham L</td>
<td>0</td>
<td>12</td>
<td></td>
<td>0.317</td>
</tr>
<tr>
<td>Sham R</td>
<td>1</td>
<td>11</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 8 Tenderness of masticatory muscles

Individual analysis of muscle tenderness statistically significant improvements were found on the left masseter, right temporalis, and on the right and left lateral pterygoid muscles of the group receiving real acupuncture. Within the sham group the majority showed no change from baseline to endpoint.
**TMJ Tenderness**

Where joint tenderness was found by examination of both right and left sides lateral and intra-auricular palpation showed greater improvement with real acupuncture subjects compared to the sham group. Overall, the majority of patients showed no change in the TMJ tenderness (Table 9).

<table>
<thead>
<tr>
<th>Palpation</th>
<th>Improvement in tenderness</th>
<th>No change</th>
<th>Worse</th>
<th>Paired T-Test P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lateral</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Real L</td>
<td>4</td>
<td>11</td>
<td></td>
<td>0.046</td>
</tr>
<tr>
<td>Real R</td>
<td>6</td>
<td>9</td>
<td></td>
<td>0.014</td>
</tr>
<tr>
<td>Sham L</td>
<td>0</td>
<td>12</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Sham R</td>
<td>1</td>
<td>11</td>
<td></td>
<td>0.317</td>
</tr>
<tr>
<td>Intra-auricular</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Real L</td>
<td>2</td>
<td>13</td>
<td></td>
<td>0.157</td>
</tr>
<tr>
<td>Real R</td>
<td>5</td>
<td>10</td>
<td></td>
<td>0.025</td>
</tr>
<tr>
<td>Sham L</td>
<td>0</td>
<td>12</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Sham R</td>
<td>0</td>
<td>12</td>
<td></td>
<td>-</td>
</tr>
</tbody>
</table>

Table 9 Tenderness of TMJ to palpation results.

**Headache**

Headache was assessed by asking the patient about its connection to MP. The presence of headache decreased in the real acupuncture group, compared to no improvement in the sham acupuncture group. The majority of patients, however, showed no change (Table 10).
<table>
<thead>
<tr>
<th></th>
<th>Improvement in headache</th>
<th>No Change</th>
<th>Worse</th>
<th>Wilcoxon Signed Ranks Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real</td>
<td>6</td>
<td>9</td>
<td>-</td>
<td>0.014</td>
</tr>
<tr>
<td>Sham</td>
<td>1</td>
<td>11</td>
<td>-</td>
<td>0.317</td>
</tr>
</tbody>
</table>

Table 10 Presence of headache

Mouth Deviation

The deviation values did improve slightly for the real acupuncture group, although not significantly. No deviation was found at all within the sham group (Table 12).

<table>
<thead>
<tr>
<th></th>
<th>Improvement in deviation</th>
<th>No Change</th>
<th>Worse</th>
<th>Wilcoxon Signed Ranks Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real</td>
<td>0</td>
<td>9</td>
<td>-</td>
<td>0.014</td>
</tr>
<tr>
<td>Sham</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Table 11 Deviation of mandible on mouth opening

Joint Sounds

The joint sounds values only improved in one patient for the real acupuncture group. There was no change in the values for the sham group (Table 12).

<table>
<thead>
<tr>
<th></th>
<th>Improvement in joint sounds</th>
<th>No change</th>
<th>Worse</th>
<th>Wilcoxon Signed Ranks Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Real</td>
<td>L 1 14</td>
<td>0.317</td>
<td>0.317</td>
<td></td>
</tr>
<tr>
<td>Sham</td>
<td>L 0 12</td>
<td>0.317</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 12 TMJ sounds on auscultation
Park Sham Credibility

None of the subjects believed that they had been treated with the sham needle.

Discussion

The results demonstrated that real acupuncture had a greater influence on clinical outcome measure of TMJ MP than those of sham acupuncture, and the majority of these reached a level of statistical significance. Therefore, the results support the hypothesis that there is an improvement in signs and symptoms in patients with TMJ MP who receive real acupuncture when compared with a sham acupuncture intervention. Consequently, the null hypothesis can be rejected.

Acupuncture involves the insertion of fine needles at certain points on the body surface known as acupuncture points. Although no unique structures have been found at these sites, there appears to be a relationship between acupuncture points and the presence of high densities of nervous tissue such as large nerve bundles or nerve endings either cutaneous, vascular or muscular. An important aspect of acupuncture intervention is point selection as this may involve placement of needles either locally or distally from the target area. However, local segmental points (segment approaches) are generally found to produce a more intense analgesic response. This is said to be not only due to a general widespread analgesic effect but also as a result of direct inhibition at spinal cord level. It has been proposed that using distant acupoints may produce a general body response via mid brain and hypothalamic activation, however the target specificity of distal acupoints has been questioned and their use should be approached with caution.

Helkimo demonstrated that acupuncture points often seem to coincide with those
parts of the masticatory muscles exhibiting tenderness on palpation. The same authors showed that (ST 7) corresponded with the location of tender points (latent trigger point) in the masseter muscle of the painful TMJ. It was concluded that the acupuncture point should be in the area of presenting pain or to a nearby peripheral nerve anatomically related to the disorder. This approach may also help to elucidate possible unknown aetiological and physiological mechanisms involved. In addition, it has been suggested that as few needles as possible should be used in order to discern which needle location is most effective in the management of a condition rather than a multitude of needles of unknown effect. 24

This study not only gives support to the positive findings of other research into acupuncture and TMJ MP, 13,17,25,26,27,28 but also helps to clarify that the physiological effects of acupuncture are beyond those of placebo. This is in disagreement with several meta-analysis 34,35,36 which suggest that acupuncture has no or limited effects compared to placebo, however the control methods included in these reports differ from the sham acupuncture methodology employed in the study reported here. 37,38 This RCT, therefore provides clinical evidence to support the analgesic effect of acupuncture as well as to the physiological effects, and these may well operate through the endogenous opiate mediated pathways. 19,20

Study Limitations

It was more difficult to recruit patients than anticipated. Consequently the small sample size led to differences in the mean baseline assessment outcomes between the groups.

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Due to time limitations, longer term follow up assessment was not possible. The results, therefore, only apply to the immediate effects of acupuncture. A larger study with an increased follow up period would give more conclusive results and information regarding the long term benefits of acupuncture.

**Conclusion**

The key findings of this study have been as follows:

- Acupuncture had a positive influence on the signs and symptoms of TMJ MP.
- This study provides evidence that the Park Sham Device was a credible acupuncture control method for trials involving facial acupoints.
References


37. Ryan D. Toward improving the reliability of clinical acupuncture trials: arguments against the validity of "sham acupuncture" as controls. *American*
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