

# Non-specific effects of traditional Chinese acupuncture in osteoarthritis of the hip

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**SUMMARY.** **Objectives:** The effectiveness of acupuncture treatment in patients with osteoarthritis of the hip was tested. **Design:** This is a prospective, randomized, controlled, patient- and investigator-blinded clinical trial. **Patients and Setting:** The study was performed at a university department for physical medicine and rehabilitation. Sixty-seven patients were separated into two treatment groups. **Interventions:** Group 1 (treatment) had traditional needle placement and manipulation, whereas in group 2 (control) needles were placed away from classic positions and not manipulated. In both groups needles were placed within the L2 to L5 dermatomes. **Outcome parameters were:** pain (VAS), functional impairment (hip score), activity in daily life (ADL) and overall satisfaction before treatment, and 2 weeks and 2 months after treatment. **Results:** For all parameters there was a significant improvement versus baseline in both groups 2 weeks and 2 months following treatment, but no significant difference between the two treatment groups. **Conclusions:** We conclude from these results that needle placement in the area of the affected hip is associated with improvement in the symptoms of osteoarthritis. It appears to be less important to follow the rules of traditional acupuncture techniques. © 2001 Harcourt Publishers Ltd

Keywords: Acupuncture, acupuncture research, musculoskeletal diseases, osteoarthritis, hip, clinical trial

## INTRODUCTION

Acupuncture in osteoarthritis is widely used, although there is a lack of evidence for a specific effect of acupuncture treatment in these diseases. In a systematic review, eleven studies of acupuncture for osteoarthritis were identified.<sup>1</sup> Their results are highly inconsistent and most trials suffered from methodological flaws. The most rigorous studies suggest that acupuncture is not superior to sham-treatment with needles in reducing the pain of osteoarthritis. The specific effect of acupuncture treatment in osteoarthritis of the hip has been, to the knowledge of the authors, never tested in a randomized controlled clinical trial.

Therefore, it was the aim of this study to determine whether acupuncture treatment according to the recommendations of traditional Chinese medicine is more effective than unspecific needle placement in the same dermatomes of the affected hip.

## METHODS

Approval by the Ethics Committee at Hannover Medical School (No. 1150) was obtained and the

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Declaration of Helsinki (revised version Hong Kong 1989) was adhered to. The patients for this study were recruited through advertisements in a local newspaper. To be included in the study, patients had to have typical complaints of hip arthritis with reduced range of motion and significant radiographic changes (Table 1). Exclusion criteria were mainly supposed to eliminate all factors influencing the symptoms of hip arthritis during the intervention, i.e. physical therapy or medical treatment (Table 2).

Written informed consent was obtained and patients were then randomly assigned to the treatment groups using computer generated random codes. The study design followed the recommendations for pharmacological studies for osteoarthritis of weight bearing joints.<sup>2-5</sup> Primary outcome parameters and additional parameters (Table 3) which might have influenced treatment results were recorded. The physician carrying out clinical evaluation of the study parameters was not informed about the acupuncture treatment, so

<b>Table 1 Inclusion criteria</b>
<p>1. Pain and discomfort discomfort or painful areas in the gluteal and trochanter region, pain irradiation to the lateral side of the upper limb complaints for at least 6 months pain on most days of the previous month.</p> <p>2. Movement restriction internal-rotation less than 15° or painful internal-rotation more than 15° and flexed hip less than 115°.</p> <p>3. Radiographic changes of the hip X-ray of the pelvis, not older than 1 year 2° minimum as per Kellgren-score.</p>

<b>Table 2 Exclusion criteria</b>
<p>Scars or sensibility problems around the acupuncture area Skin implantation around the acupuncture area Acute dermatosis or wounds around the acupuncture area Serious Circulatory problems (e.g. chronic venous insufficiency, gangrene) Dermatitis, contact allergies, psoriasis, herpes Immune deficiency syndrome (i.e. AIDS, iatrogenic following transplants) Damaged or implanted heart valves Systematic illnesses which during their duration could relate to the hip joint (e.g. chronic polyarthritis, metabolic illness such as gout or chondrocalcinosis) Treatment within the last four weeks which could lead to misinterpretation of the outcome, physical therapy, regular intake of analgetics or NSAID.</p>

<b>Table 3 Baseline values of primary endpoints and additional parameters with a possible influence on the treatment result. The results are the means and standard deviations. There was no difference between groups at baseline.</b>		
	<b>Verum</b>	<b>Control</b>
	F = 19 M = 14	F = 24 M = 8
<b>Primary parameters</b>		
Pain (mm on VAS)	54.6 ± 18.9	55.3 ± 23.5
Hip Function (score points) handicap	8.0 ± 3.1	8.0 ± 3.6
Life Quality (score points)	172 ± 21	161 ± 27
Over-all-assessment	76.0 ± 25.6	75.4 ± 24.0
<b>possible predictive values</b>		
Radiology (II° / III° / IV° Kellgren)	27 / 52 / 21	22 / 53 / 25
ROM (degree)	34.4 ± 20.6	35.2 ± 16.8
Coping (score Resignation points)	16.8 ± 10.3	17.4 ± 7.0
Evasion	15.8 ± 9.7	16.9 ± 7.0
Diversion	25.4 ± 9.2	22.6 ± 5.8
Depression	16.2 ± 10.8	15.7 ± 7.2
Competence	27.8 ± 10.4	28.5 ± 6.6
Anxiety	20.2 ± 10.0	20.1 ± 7.7
Expectations (score points)	5.2 ± 1.7	5.2 ± 1.7
Duration of complaints (years)	5.4 ± 3.9	4.9 ± 3.7
Age (years)	61.4 ± 8.6	63.8 ± 9.5
Height (cm)	169.4 ± 6.0	167.1 ± 6.9
Weight (kg)	75.3 ± 11.2	72.4 ± 13.2
Body-mass-index (BMI)	26.2 ± 3.1	25.9 ± 3.9

he could not decide to which treatment group each patient belonged.

The verum as well as the control treatment consisted of ten individual treatments which were performed within 3 weeks. Site selection as well as the puncture and manipulation technique for the verum treatment follow the recommendation in the standard literature for a symptomatic acupuncture treatment.<sup>6,7</sup> Within the hip area, six pressure sensitive locations ('Ah-Shi'-points) were used. In addition, the regional meridian points 'GB-30', 'GB-31', 'BL-37' and the distal meridian points 'ST-40' and 'BL-54' were chosen, as well as the master point for tendons and muscles 'GB-34'. 'GB-34' is often used in periarticular disorders with affected muscles and tendons.<sup>8,9</sup> Needle treatment was continued for 20 minutes with twisting of the needles to cause a mechanical stimulation. It was the aim of this manipulation to elicit the 'deqi'-sensation. This is a feeling of heaviness and numbness, occasionally combined with a cold or warm feeling at the acupuncture site which may extend from there to distant areas of the body. The release of the 'deqi'-sensation is considered to be an important amplifying factor for the effectiveness of acupuncture.<sup>10</sup> Needle manipulation was carried out two to three times during a treatment session.

Needle acupuncture was also performed for the control group, but the selected puncture sites were at least 5 cm away from the classical acupuncture points and their interconnecting lines (meridians) and also clear of painful pressure points (Ah-Shi or trigger points). The control treatment was in accordance with the suggestions of Vincent, with one modification:<sup>11</sup> Vincent recommended a shallow insertion of the acupuncture needles at points which were well clear of real acupoints; no manipulation of the needle should be performed. In the control treatment of this study, in contrast to the recommendations to Vincent who suggested a shallow needle insertion, the needles were inserted to the same depth in both groups. The number of needles and the time frame was the same as in the verum acupuncture. For both treatment groups, identical sets of sterile, steel, disposable needles were used (0.3 × 60 mm, SEIRIN Deutschland GmbH). The skin at the puncture sites was duly prepared with a conventional disinfecting agent. Acupuncture was carried out by a physician with sound knowledge of traditional acupuncture techniques.

### Follow-up

Clinical evaluation was performed by an independent observer not involved in the acupuncture, 1 week before the beginning of treatment (baseline) and 2 weeks (F1), 2 months (F2) and 6 months (F3) after the end of treatment. For inclusion in the follow-up evaluation, the patients were not allowed to

have started any physical therapy, medical treatment or to have planned a total hip replacement.

### Instruments

Carlsson's 'Comparative Scale', which evaluates overall patient satisfaction,<sup>12</sup> was used after 2 months (F2). To assess alterations in the quality of life, Bullinger's 'Everyday Life' questionnaire was used.<sup>13</sup> In this scale an increase in the number of points signifies a higher quality of life. Hip index according to Lequesne<sup>14</sup> determines the impairment caused by pain and restriction of range of movement. This questionnaire is accredited by the FDA for non-surgical clinical trials in OA of the hip. It registers the aspects 'pain and handicap', 'maximum walking distance' and 'restrictions of everyday functions'. The greater the point score, the greater is the extent of the impediment. For pain measurement, the Visual analogue Scale (VAS) was used. This type of pain measurement is widely employed, particularly in rheumatology<sup>15</sup> and is regarded as a reliable method for the measurement of pain intensity and pain reduction.<sup>16</sup> In a repeated pain measurement during the course of a study, only an absolute variation of above 6 mm on the VAS is regarded as pain alteration. Smaller alterations are rated as experimental fluctuation.<sup>12</sup> The credibility of a therapeutic intervention and the related expectations of the patient are regarded as decisive variables in non-specific treatment effects.<sup>17,18</sup> A modified Borkovec Expectancy Scale<sup>19</sup> was used to assess credibility and expectation. The items in this questionnaire are listed in Table 4.

### STATISTICS

The type 1 error was  $\alpha = 0.05$ ; the power was  $P = 0.80$ . MANOVA was used to test parameters between both groups at baseline, to assess whether the distribution of these variables permitted comparison. Repeated measures analysis of variance was used to compare the primary parameters of both treatment groups at measurement points F1 and F2 compared to baseline.

### RESULTS

Two hundred and thirty patients were initially evaluated in the study. Sixty-seven patients were found to meet the in and exclusion criteria. The most common reasons for exclusion from the trial were pain outside the hip area, especially low back pain, missing clinical or radiological signs of osteoarthritis of the hip, as well as other therapeutic interventions which would interfere with the acupuncture treatment. At baseline, there were no significant differences between the verum and the control groups with regard to the selected parameters (Table 3).

**Table 4 Credibility scale****I. Interest in Acupuncture, Prior Information (0–1.5 points)**

1. Have you already been interested in acupuncture?
  - 0 No, never. I have never been interested.
  - 1 Hardly, I am not so sure what it is.
  - 2 Yes, what you read in newspapers and magazines and see in TV.
  - 3 Yes, intensively, as it interests me.
2. Do you know a doctor who uses acupuncture?
  - Yes-1
  - No-0
3. Are you being treated by a doctor who uses acupuncture?
  - Yes-1
  - No-0

**II. General Acceptance of Acupuncture as a Procedure for Treatment (0–3 points)**

4. Have you already been treated with acupuncture?
  - 0 No, I have not yet been treated with acupuncture
  - 1 Yes, but my symptoms did not improve.
  - 2 Yes, and my symptoms got better
5. Would you let yourself be treated with acupuncture for other complaints (eg head or back ache)?
  - 0 Certainly not
  - 1 Only if I were certain that it would help
  - 2 It might depend on the illness
  - 3 Yes, probably
  - 4 Yes, certainly
6. Would you accept protracted treatment with acupuncture, with up to 20 appointments?
  - 0 Certainly not
  - 1 Only if I were certain that it would help
  - 2 It might depend on the illness
  - 3 Yes, probably
  - 4 Yes, certainly
7. Would you accept acupuncture treatment if you had to pay for it yourself?
  - 0 Certainly not
  - 1 Only if I were certain that it would help
  - 2 It might depend on the illness

**III. Credibility and Expectancy of Acupuncture (0–3 points)**

8. Do you think that acupuncture is an effective method of treatment?
  - 0 I think that acupuncture does not work and is therefore senseless
  - 1 I am not convinced, but perhaps it is some good.
  - 2 I don't know; I have no opinion.
  - 3 I think that acupuncture sometimes works and is therefore sensible.
  - 4 I am convinced that it is effective.
9. How reasonable and sensible do you think that the acupuncture treatment is which you will receive for your symptoms?
  - 0 I think that the treatment is senseless.
  - 1 A treatment like this does not seem to be a very good idea for my complaints
  - 2 I don't know, have no opinion.
  - 3 A treatment like this may be a good idea for my complaints.
  - 4 The treatment is probably exactly right for my complaints.
10. Would you recommend this treatment to a friend with similar complaints?
  - 0 No, I don't think so
  - 1 I don't know, have no opinion
  - 2 Yes, certainly
11. Do you think that the treatment which are now receiving will improve your symptoms?
  - 0 No, I don't think so
  - 1 I don't know, have no opinion
  - 2 Yes, certainly

To evaluate the scale the points in the answers to the individual clusters (I–III) should be summed and divided by the number of items. The sum of the values for the individual clusters. The resulting summed score can lie between 0 and 7.5.

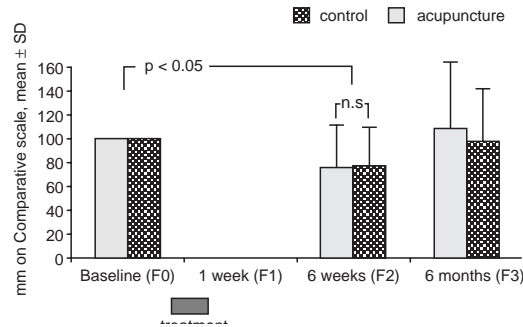
As described in Table 5, 24 patients had be excluded from the study during the follow up period at the 6 months' follow-up (F3). Since the numbers were too small for evaluation at this time point, only data from F1 and F2 were included in the final statistical analysis.

**Overall assessment**

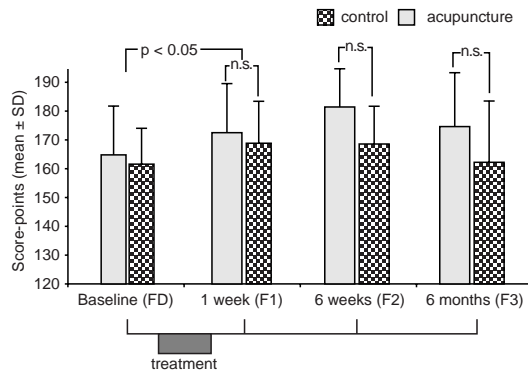
Overall complaints were set at 100% at baseline. After 6 weeks (F2) this value dropped to 76% and 75% for acupuncture and control, respectively. The difference from baseline was highly significant for

**Table 5 Overview of the control and treatment patients groups as well as the number of patients during the study**

Treatment group	Acupuncture	Control	Total
Preliminary examination	33	34	67
Treatment discontinued	0	2	2
1st Follow-up (F1)	33	32	65
Patients not turned up	1	2	3
2nd Follow-up (F2)	32	30	62
Total hip replacement	7	4	11
Excluded for other reasons	8	2	10
3rd Follow-up (F3)	17	24	41



**Fig. 1** Overall assessment of patient satisfaction on the Comparative Scale (Carlsson). Mean and standard deviation in millimetre (mm). Initial values are given as 100%. Improvement is depicted as reduction on the scale. Overall assessment measurement was carried out at the second and third follow up (F2 + F3).



**Fig. 2** Quality of life measurement, using the 'Everyday Life' questionnaire (Bullinger). Depicted are the mean and standard deviation of the scores at baseline and all three follow-up examinations.

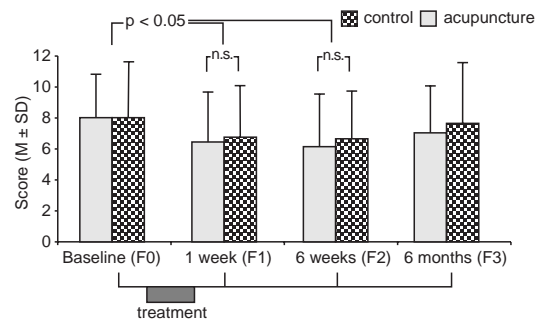
both groups and there was no difference between the groups (Fig. 1).

### Quality of life

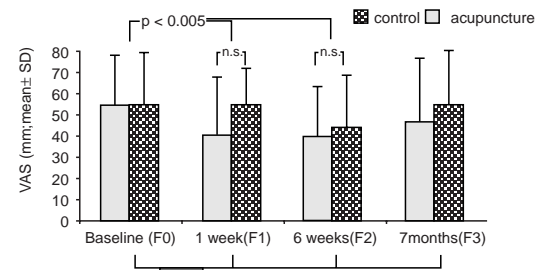
For both groups, there was a significant improvement in quality of life at F1, of approximately 5% ( $P < 0.05$ ). In the verum group this improvement lasted until the second follow-up (F2). In the control group, a reduction in the treatment effect was observed at the second follow-up (Fig. 2).

### Hip function index

At the starting point, the values of the groups were almost identical and there was a significant



**Fig. 3** Disease-related handicap as assessed by the hip function index (Lequesne). The mean and standard deviation of the scores at baseline and all three follow-up examinations are shown.



**Fig. 4** Pain intensity measured using the Visual Analogue Scale (VAS) of Huskisson. The mean values (millimetre) and the standard deviations at all four check-up examinations are shown.

reduction in the handicap after treatment ( $P < 0.05$ ). The values were approximately 1.5 points less than at the beginning of the treatment, which corresponded to approximately 18% (Fig. 3). This reduction was slightly higher after the second follow-up. The difference between the two groups after the first (F1) and second follow-up (F2) was not significant.

### Pain intensity

At the first follow-up there was a significant mean pain reduction of 18 mm on the 100 mm VAS ( $P < 0.05$ ) (Fig. 4), which corresponded to a mean pain reduction of 27%. This result is within the range of pain reduction of 33%, which is regarded as clinically relevant in the literature.<sup>20</sup> At the second follow-up, pain reduction was maintained in the verum group, whereas the placebo group showed a slight decrease in the therapeutic effect. The difference between the two groups at the first and second follow-up was not significant. It was evident but not

significant at the final follow-up that the control group showed a larger pain increase than the verum group.

### Adverse effects

A number of adverse reactions to acupuncture have been described in the literature.<sup>21</sup> For this trial, patients with skin diseases were excluded, as it has been noted that these patients may develop complications after acupuncture, e.g. allergy to chromium<sup>22</sup> or nickel<sup>23</sup> as well as psoriasis from the Koebner phenomena.<sup>24</sup> Patients with implanted heart valves,<sup>25</sup> immune deficiency syndrome,<sup>26</sup> or coagulopathy<sup>27</sup> were also excluded from the trial. During the study course, no side effects occurred.

## DISCUSSION

In a recent study, Berman conducted an RCT to test the effectiveness of acupuncture in the treatment of osteoarthritis of the knee.<sup>28</sup> In that trial, acupuncture was tested against standard care. Berman concluded that acupuncture is an effective treatment for the said disease, but a specific effect of acupuncture was not tested for, as standard care was used as control. It was the aim of our clinical trial to investigate the specific effect of acupuncture based on sound acupuncture knowledge. To test this specific effect, we used the control acupuncture, described above. To the knowledge of the current authors this is the first prospective, randomized, controlled, patient- and investigator-blinded clinical trial (RCT) on the effectiveness of acupuncture in the treatment of osteoarthritis of the hip. It was hypothesized that acupuncture treatment according to TCM is more effective than random needle placement in the affected dermatomes. This type of study design has previously been recommended for acupuncture studies.<sup>29-31</sup> As the therapeutic effects of acupuncture treatment may be prolonged, we did not use the cross-over design which is typical of drug studies (see Mendelson).<sup>32</sup>

Since acupuncture does not change the morphology of the underlying disease we assumed that our intervention would have only a reversible effect on the symptoms of hip osteoarthritis. For this reason a maximum follow-up of 6 months was selected. Our results showed a high dropout rate at 6 months, because a large number of patients had sought other medical or surgical treatment by this time. We therefore conclude that the time frame for this study was correctly selected to answer the pertinent questions. Quality of life assessment was used to determine alterations in the overall well-being during the study course. The initial mean level was 166.5 points, with a range from 42 to 210; this is slightly below the quality of life measured by Bullinger<sup>13</sup> on healthy students (173.3 points). Under these circumstances it is difficult to show improvement

with treatment of this disease entity. We therefore suggest that quality of life measurements are of limited value in the assessment of osteoarthritis of the hip and perhaps also of other joints.

Psychological events have been discussed as being partly responsible for the frequent positive effects in studies of pain treatment.<sup>33</sup> Especially pain coping and expectations of the treatment are suggested as influencing pain perception.<sup>34</sup> Therefore, coping measurement was performed with a validated questionnaire,<sup>35</sup> which showed an equal baseline for both treatment groups. After the first treatment session, a modified Credibility Scale<sup>19</sup> showed no difference between the groups concerning the expectation, acceptance and credibility for the ongoing treatment. Therefore, coping and expectation should not influence treatment results. As our RCT uses a comparison of parallel groups, the mutual influence of the patients might be a problem,<sup>33</sup> This could be excluded in the present study because all contact among patients during the trial was avoided.

In this trial, a stimulation with the same number of needles in anatomically different locations has been performed (classical acupoints vs non-acupoints). The two treatments were different with regards to: a) location and b) manipulation of the needles.

The stimulation of afferent pathways is thought to be responsible for the analgesic effect of acupuncture. The excitation of afferent A- $\delta$ -fibres can cause segmental pain modulation<sup>36</sup> as well as modulation through the activation of descending pain inhibiting systems [e.g. 37] There are hints in the literature that classic acupuncture points are in regions of increased density of A- $\delta$ -fibres.<sup>38</sup> Pricks in the verum treatment at real acupoints might have activated these receptors. For the reasons mentioned above the verum acupuncture used should have been more effective than our control treatment. However, we found the same positive effects of both acupuncture treatment modalities after 2 weeks and 2 months. Although our study did not attempt to identify the basic mechanisms of acupuncture, we have shown that in clinical practice these mechanisms are probably not effective in treating osteoarthritis of the hip.

We do not have an explanation for the positive effect of both treatments in our study population. The common feature of both treatments was needle insertion in the dermatomes of the hip region. We cannot say whether this stimulation of mechanoreceptors or the psychological effects were responsible for the improvement in all primary parameters measured. To answer this question, a third group of patients would have had to be treated with placebo acupuncture, as has previously been done.<sup>39</sup> Our active treatment was selected in accordance with the recommendations of Traditional Chinese Medicine (TCM) and all basic science knowledge of needle placements. Our control treatment should have been ineffective according to TCM, but was not. We therefore conclude that needle placement in the area

of the hip joint has a positive effect on the symptoms of hip osteoarthritis, although no special knowledge of acupuncture is needed.

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