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Chronic Epicondylitis: Effects of Real and Sham Acupuncture Treatment: A Randomised Controlled Patient- and Examiner-Blinded Long-Term Trial

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Key Words
Epicondylitis · Tennis elbow · Acupuncture · Sham acupuncture

Summary
Objective: The clinical long-term effectiveness of real and sham acupuncture treatment on differentiated pain measurement was evaluated in chronic lateral epicondylitis, an example of a tendomyotic disorder. **Methods:** Randomised, examiner- and patient-blinded controlled clinical study. Outcome measurement: pain at rest, pain on movement, pain on exertion, frequency and duration of pain. Real acupuncture (n = 23) was tested versus invasive sham acupuncture (n = 22). Ten treatments were given (2 treatments/week). Patients were examined at baseline (E1) as well as 2 weeks (E2), 2 months (E3) and 1 year (E4) after the end of treatment. In the treatment with real acupuncture, acupuncture points were selected and mechanically stimulated while in the sham group non-acupuncture points were selected. **Results:** There was no significant difference between the groups at baseline for any outcome parameter. Two weeks, 2 months and 1 year after the end of treatment there were significant reductions in all pain variables compared to baseline. At the first follow-up, significant group differences were registered for pain on motion and pain on exertion in favour to the real acupuncture group. These differences in pain intensity between the groups were no longer significant at the 2 months and 12 months follow-ups. **Conclusion:** The results suggest that, in the treatment of chronic epicondylitis, the selection of so-called real acupuncture points gives better results than invasive sham acupuncture at early follow-up. This additional effect can be interpreted as a specific effect of real acupuncture.

Schlüsselwörter
Epikondylopathie · Tennisarm · Akupunktur · Plazebo · Scheinakupunktur

Zusammenfassung
Studienziel: Die langfristige klinische Wirksamkeit von Verum- und Kontrollakupunktur wurde anhand der chronischen lateralen Epikondylopathie als Beispiel einer Myotendinose untersucht. **Methoden:** Randomisierte kontrollierte Doppelblind-Studie. Studienendpunkt: Untersuchung von 3 Schmerzqualitäten (Ruhe-, Bewegungs- und Belastungsschmerz) sowie von Schmerzhäufigkeit und -dauer. Die Verumakupunktur (n = 23) wurde mit einer invasiven Scheinakupunktur (n = 22) verglichen, innerhalb von 5 Wochen wurden insgesamt je 10 Behandlungen (2 pro Woche) durchgeführt. Bei der Verumakupunktur wurden definierte Akupunkte gewählt und stimuliert, während die Kontrollakupunktur an unspezifischen Punkten erfolgte. Die Patienten wurden vor Behandlung (E1) sowie 2 Wochen (E2), 2 Monate (E3) und ein Jahr (E4) nach Ende der Behandlung untersucht. **Ergebnisse:** Vor Behandlung gab es keinerlei signifikante Gruppenunterschiede. In beiden Gruppen waren alle Schmerzqualitäten zu allen Nachuntersuchungszeitpunkten gegenüber dem Ausgangswert signifikant reduziert. Bei der ersten Nachuntersuchung (E1) waren Bewegungs- und Belastungsschmerz nach Verumakupunktur signifikant niedriger als nach Kontrollakupunktur, bei den späteren Nachuntersuchungen waren diese Gruppenunterschiede nicht mehr signifikant. **Schlussfolgerung:** Die Ergebnisse deuten darauf hin, dass die Selektion sogenannter echter Akupunkturpunkte einer invasiven Scheinakupunktur bei der Behandlung der chronischen Epikondylopathie in der frühen Nachbehandlungsphase überlegen ist. Dieser zusätzliche Effekt kann als spezifischer Effekt der Verumakupunktur interpretiert werden.

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Introduction

It is still unclear whether acupuncture has specific effects in diseases of the locomotor system of the extremities. For example, the most rigorous studies on acupuncture in osteoarthritis suggest that acupuncture is not superior to sham needling in reducing pain from osteoarthritis: The two treatments alleviate symptoms to roughly the same degree. This could either mean that sham needling has similar specific effects as acupuncture or that both methods are associated with considerable non-specific effects [1]. The conclusion of this systematic review is supported by our own investigation which compared invasive sham needling with real acupuncture in patients with osteoarthritis of the hip [2]. On the other hand, recent trials have indicated that acupuncture may have specific effects in tendomyotic and soft tissue disorders which are not caused by degenerative joint diseases, as is the case with osteoarthritis. Kleinhenz et al. [3] demonstrated that acupuncture is superior to placebo needling in rotator cuff tendinitis. However the design of this study only made it possible to demonstrate that needling is an important part of the acupuncture effect in the treatment of chronic shoulder pain. No conclusions could be drawn as to the importance of choosing points consistent with the rules of Traditional Chinese Medicine (TCM). To test the effect of real needling, we therefore conducted a trial in which the control condition consisted of invasive sham needling. Invasive sham needling seems to be an appropriate technique to identify specific effects of correct needle placement according to TCM in comparison to random needling.

Methods

Results of this study were in part published elsewhere [4]. The present paper concentrates on the analysis of different variables of pain measurement.

Participants
The study was announced to the press. Of 205 patients, 160 were pre-selected with respect to the in- and exclusion criteria (table 1), as far as they could be assessed by telephone interview. For clinical examination, 66 patients were invited to our out-patient clinic. For inclusion, the patients had to report pressure pain on the radial epicondyle of the humerus, aggravation of pain during the wrist extension against resistance and a positive mid-finger test. 54 patients were selected in accordance with criteria for in- and exclusion and enrolled after informed consent had been given. The names of the patients were transmitted to the Department of Biostatistics of Hannover Medical School. A list with random numbers was prepared by one its members. The patients were randomised according to this list and allocated to the different treatment groups. Treatment was carried out in a 'single setting mode', i.e. contact between patients during the trial was avoided. This seems to be necessary because communication between patients in parallel group designs can influence the result of treatment [5].

Outcome Parameters
Patients were examined four times in the laboratory by a member of the Department of Physical Medicine who was not involved in the treatment protocol: before therapy (baseline, E1) and 2 weeks (E2) 2 months (E3) and 12 months (E4) after the end of therapy, the patients filled in a self-assessment questionnaire. Patients rated their complaints on a 6-point verbal rating scale (0 = no pain to 5 = intolerable pain). The examination consisted of a measurement of pain at rest, pain on motion and pain on exertion. In addition, the frequency and duration of pain periods were assessed. At baseline (E1), variables with a possible impact on the treatment effect (i.e. age, gender, disease duration) were assessed as well.

Table 1. Criteria for inclusion and exclusion

Inclusion criteria:
Patients with chronic lateral epicondylitis of the elbow (duration > 3 months)
Unilateral localisation No age limit
Understanding of the German language

Exclusion criteria:
Pain treatment with analgesics, NSAID or physiotherapy in the preceding 2 weeks
Pain treatment with steroid injections in the preceding 3 months
Earlier episodes of lateral epicondylitis of the elbow which were treated surgically or with acupuncture in the preceding 6 months
Diseases of the central or peripheral nervous system
Radial nerve entrapment Inflammatory rheumatic diseases
Gout
Radioulnar or radiohumeral osteoarthritis

NSAID = Non-steroidal anti-inflammatory drugs.

Table 2. Characteristics of patients finishing the treatment period (follow-up 1)

	Real acupuncture (n = 22)	Sham acupuncture (n = 20)
Gender (m:f)		
n	12/10	7/13
%	54.5/45.5	35/65
Age, years*	52.5 ± 8.7[a]	51.6 ± 10.0
Median duration of disease, months*	8	10.5

[a]Mean ± SD.
*No significant differences between real and sham acupuncture.

Treatment Protocol

Acupuncture
Traditional Chinese acupuncture regards treatment as being influenced by local, regional and specific points. For the acupuncture in this study, we selected points which have frequently been recommended for the treatment of epicondylitis [e.g. 6]. As local points, we selected LI 10, LI 11 and one Ah-Shi point over the muscular origin of the lateral extensor group of the forearm and L 5 in the cubital region. As regional points, we selected LI 4 and SJ 5 as influential points for the upper limb. In all 6 needles were given. The needles were inserted up to the musculature; the deqi sensation was induced by twisting the needles at the start of treatment. The needles remained in situ for 25 min.

Control Acupuncture
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 also clear of painful pressure points (Ah-Shi or trigger points). The needles were inserted in exactly the same way as in the real group and also stimulated. In all, 6 needles were given per treatment session. The time frame was the same as in the real acupuncture group.
For both treatment groups, identical sets of sterile, steel, disposable needles were used (Seirin Germany, 0.25 × 40 mm, B-type). The skin at the puncture sites was duly prepared with a conventional disinfecting agent. Acupuncture was carried out by a Chinese acupuncturist who had been trained in Korea and China and who has been treating acupuncture outpatients for 25 years.
During the treatment phase, concomitant medication or physiotherapy was not allowed.

Statistical Analysis
Based on total pain score, consisting of the subscales 1) pain at rest, 2) movement pain and 3) pain on exertion, 4) frequency and 5) duration of pain, the number of patients necessary for statistically valuable calculation was determined. The self-assessment scale for the subjective rating of pain could in total reach values between 0 and 30. It was assumed for this study that the patients in the treatment group could have a mean of 10 at the end of treatment and the patients in the control group a mean of 15. The mean standard deviation was assumed to be 5 points. On this basis, and assuming a level of significance of 5% and a power of 80%, the number of necessary cases was calculated as being 17 per group (unpaired t-test). The data was analysed with the StatView® package on an Apple Macintosh. Methods employed included the unpaired t-test for group comparisons and Wilcoxon's test for paired longitudinal comparisons. A p value of less than 0.05 was taken to be significant for this study.

Results

Assuming a drop-out rate of approximately 30%, altogether 27 patients per group were enrolled. Of these 54 randomised patients, 4 patients in the real acupuncture group and 5 patients in the sham group dropped out before treatment, without giving any reason so that 45 patients started the treatment period. During treatment, 1 patient in the real acupuncture group and 2 patients in the sham group dropped out. Table 2 contains a description of the remaining 42 patients who finished the treatment period (follow-up 1). Only data from these 42 patients were used for further calculation. Of the 45 patients who started the treatment period, only 5 had not been previously treated for epicondylitis with acupuncture. The other patients had been subjected to different treatments, mostly with local anaesthesia, exercise, immobilisation or non-steroidal anti-inflammatory drugs (NSAID). The median duration of the illness was 9 months. Three patients suffered from recurrent epicondylitis, with a duration of more than 10 years. The duration of the illness, age and gender had no influence on the results of the treatment; 3 patients dropped out during the treatment period (1 patient in the real acupuncture group dropped out during the study because of intolerable pain from acupuncture, and 2 patients in the control group gave no reason for dropping out), and 2 patients of the real acupuncture group dropped out between the 1st and

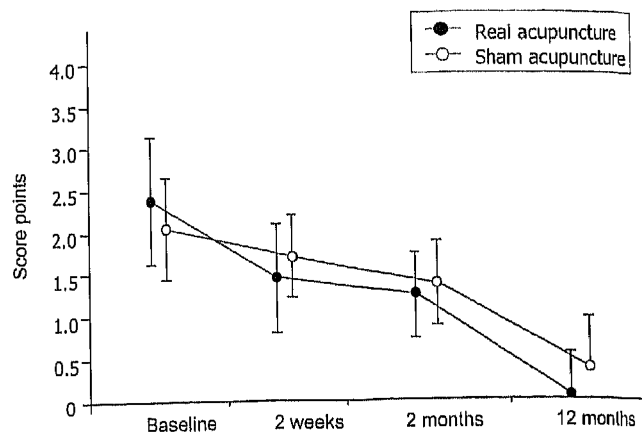

Fig. 1. Pain at rest. Mean ± SD of the verbal rating scale (0 = no pain; 6 = intractable pain) are depicted.

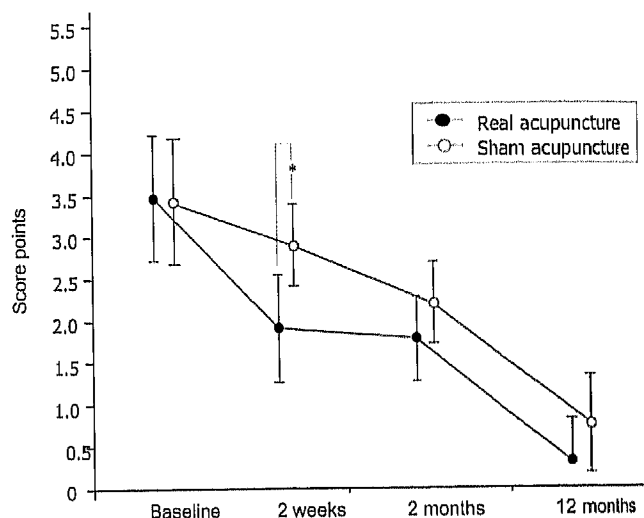

Fig. 2. Movement pain. Mean ± SD of the verbal rating scale (0 = no pain; 6 = intractable pain) are depicted. Significant differences are marked with (*).

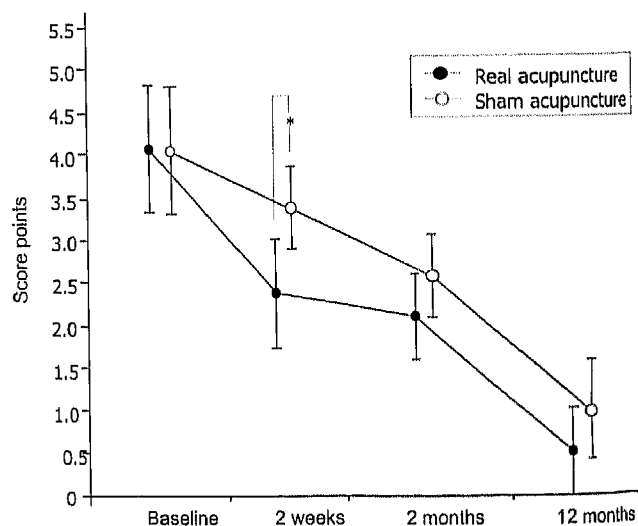

Fig. 3. Pain under exertion. Mean ± SD of the verbal rating scale (0 = no pain; 6 = intractable pain) are depicted.

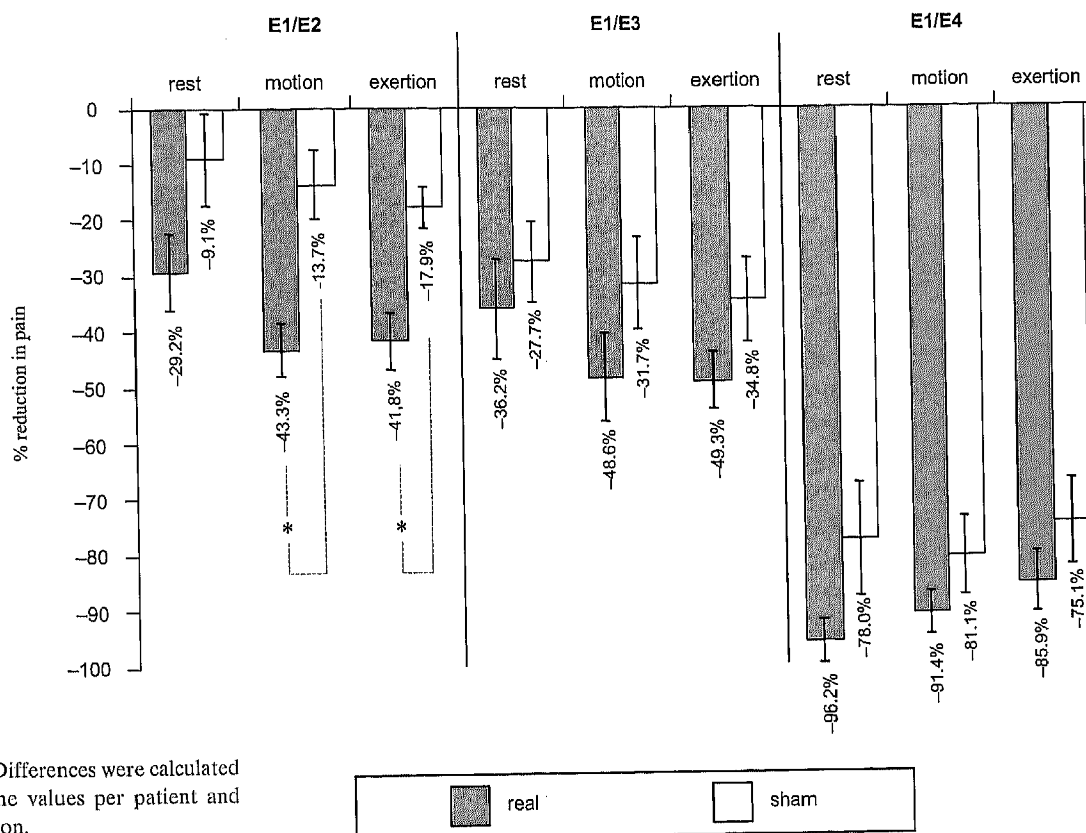

Fig. 4. Pain reduction. Differences were calculated as percentage of baseline values per patient and used for further calculation.

2nd follow-up (1 patient had an illness which was unrelated to epicondylitis and therefore could not participate in the follow-up, and 1 patient did not show up for further examination). For the final follow-up, patients were contacted by phone and asked to fill in the self-assessment questionnaires for pain measurement, which we had sent out to them. 14 patients in the real acupuncture group and 15 in the control group filled in the questionnaires correctly so that these could be used for further calculation (figs. 1–4). No special side-effects occurred, apart from the pain from acupuncture which led 1 patient to drop out.

There were no significant differences between the groups before treatment with respect to the outcome parameters. In both groups the treatment led to significant changes in the outcome parameters between the 1st and 2nd follow-up and again between the 3rd and final follow-up (p value < 0.05). The relative pain reduction compared to baseline is presented in figure 4. Significant differences between the two groups could be detected for pain on motion and pain on exertion at the 1st follow-up (figs. 2, 3). No other differences between groups were found for any outcome parameter at any follow-up. Data are shown in tables 3 and 4.

Discussion

Acupuncture is known for the amount of variation that exists in every aspect of its use. There are fundamental disagreements about whether the therapy should be understood on an 'energetic' or 'neurophysiological' basis. Interventions used in some previous studies have not reflected clinical practice that would be acceptable to many acupuncturists, which seriously limits the conclusions that can be drawn from these studies [e.g. 7, 8]. The ideal way to establish optimally effective acupuncture is a controlled comparative study looking at every relevant variable of treatment. Such a study should probably be a clinical trial rather than a laboratory experiment since no objective physiological marker for clinical effectiveness of acupuncture has yet been identified. In spite of this growing agreement about acupuncture research, there is only a small number of well-designed studies which shed some light onto the possibilities and limitations of acupuncture [9]. In particular, it is unclear if there is a specific effect of the selection and stimulation of specific acupuncture points as the insertion of a needle at any site can alleviate pain [10, 11]. The view of TCM is that the effects of acupuncture treatment are considered as a result of both the correct selection and localisation of the points and the depth of penetration and stimulation of the needles. If the objective of the study is to demonstrate the specific value of specific acupuncture treatment (which requires extended training), it is necessary to compare this specific acupuncture with a control acupuncture which is distinct from real acupuncture in critical aspects.

Although acupuncture has repeatedly been recommended as a method of treatment for epicondylitis [12], only two con-

Table 3. Results of a three-dimensional pain measurement (mean ± SD). Significant differences are given as italics

	Baseline E1	E2	E3	E4
Pain at rest				
Real acupuncture	2.30 ± 0.91	1.48 ± 0.70	1.25 ± 0.55	0.08 ± 0.28
Sham acupuncture	2.03 ± 0.80	1.73 ± 0.72	1.33 ± 0.65	0.40 ± 0.74
p value	0.32	0.26	0.70	0.13
Mean difference	0.27	–0.25	–0.075	0.32
95% CI	–0.27 to 0.81	–0.69 to 0.19	–0.46 to 0.31	–0.75 to 0.11
Pain on motion				
Real acupuncture	3.45 ± 0.86	*1.89 ± 0.75*	1.73 ± 1.04	0.31 ± 0.48
Sham acupuncture	3.40 ± 0.90	*2.83 ± 0.94*	2.20 ± 1.14	0.73 ± 1.16
p value	0.84	*0.001*	0.18	0.23
Mean difference	0.05	*–0.94*	–0.48	0.43
95% CI	–0.49 to 0.60	*–1.47 to –0.41*	–1.18 to –0.23	–1.14 to –0.29
Pain on exertion				
Real acupuncture	4.09 ± 0.83	*2.39 ± 1.13*	2.15 ± 1.14	0.54 ± 0.78
Sham acupuncture	4.05 ± 0.83	*3.30 ± 0.92*	2.53 ± 1.26	1.07 ± 1.44
p value	0.87 0.007	*0.33*	0.25	
Mean difference	0.041 0.91	*0.38*	0.53	
95% CI	–0.47 to –0.56	*–1.56 to –0.26*	–1.14 to –0.39	–1.45 to –0.39

95% CI = 95% confidence interval.

Table 4. Frequency and duration of pain episodes (mean ± SD)

	Baseline E1	E2	E3	E4
Frequency[a]				
Real acupuncture	4.23 ± 0.87	3.11 ± 1.40	2.35 ± 1.27	1.06 ± 1.76
Sham acupuncture	4.75 ± 0.64	3.85 ± 0.93	3.05 ± 1.54	1.17 ± 1.80
p value	0.033	0.054	0.13	0.87
Mean difference	0.52	0.74	0.70	0.11
95% CI	–1.0 to –0.043	–1.49 to 0.012	–1.6 to 0.20	–0.14 to 1.2
Duration[b]				
Real acupuncture	3.77 ± 1.19	2.51 ± 1.32	2.15 ± 1.31	0.77 ± 1.58
Sham acupuncture	4.10 ± 1.29	3.05 ± 1.32	2.40 ± 1.27	1.17 ± 1.92
p value	0.40	0.19	0.54	0.55
Mean difference	0.40	0.54	0.25	0.40
95% CI	–1.10 to 0.45	–1.36 to 0.29	–1.08 to 0.58	–1.77 to 0.98

[a]5-level scale: never pain – several times a month – several times a week – several times a day – continuously.
[b]5-level scale: no pain – several minutes – several hours – several days – extended period.
95% CI = 95% confidence interval.

trolled studies have been carried out on the specific activity of needle acupuncture in tennis arm ([13, 14]; results of a MEDLINE search for the years 1996 to 2001). Molsberger [14] examined the immediate effect of treatment on alleviating pain after one treatment session, using distant points in the lower extremities in the treatment group. In the control group the skin was not penetrated with a needle; the needles were stuck onto the skin. Thus in the control group the placebo effect was tested. It is not clear if the selection of the points in the treatment with real acupuncture had an effect which is specific for acupuncture because the reported effect could have been a non-specific result from puncturing at any site. It has in fact been shown for pressure [15], skin scratching [16], acupressure [17], massage [18] and vibratory stimuli [19] used in different indications and for acupuncture itself [10, 11] that mechanical stimulation of the body surface, independent of acupuncture points, can alleviate pain through counterirritation.

Haker and Lundeberg [13] used a control treatment in which the needles were inserted at the same positions as in the real treatment. However in the control group the needles were

only inserted very superficially and not stimulated. The authors could show that there was a clearly better effect of treatment in the group with real acupuncture than in the control group; thus the correct depth of insertion and the stimulation in the treatment group resulted in a higher clinical efficacy compared with the control group. The other question whether or not the selection and localisation of the acupuncture points is an essential criterion for the success of the treatment, was not addressed in this study.

Some early Western trials compared genuine acupuncture with needle insertion into either inappropriate points [20] or into sites outside traditional points or meridians [21]. Both procedures were judged to be unsatisfactory since they may have additional physiological effects. In one review [22] the 'placebo' points used in some asthma studies were criticised because other researchers believed they could be effective. Another commonly used 'placebo' control procedure is the superficial insertion without stimulation of needles at inappropriate sites [e.g. 23]. Again, this method has been criticised because it may produce physiological stimulation [24]. However the only way to assess specific treatment effects from correct point localisation (based on sound knowledge of acupuncture) is to choose a control condition which is identical in all respects to the real acupuncture except for the selection of the points. Therefore non-acupuncture points which are clearly separated from real acupuncture points should be selected as control condition but needles in the control group should be stimulated as in the verum group. Thus in the present study dealing with pain reduction in patients with chronic epicondylitis, the specific effect of acupuncture treatment with correct point localisation and stimulation of the needle was compared with sham acupuncture not using specific acupuncture points but inserting and manipulating the needles in an identical way as in the verum group.

At early follow-up the acupuncture treatment in our study was superior to a clinically relevant extent with respect to pain on motion and pain on exertion. However 2 months and 1 year after the end of treatment this effect was no longer significant. An explanation may be that the therapeutic effect was dominant at the start of the follow-up period and that, from the 2 months follow-up onwards, this treatment effect was overlapped by the natural course of the disease (spontaneous remission) [25]. On the other hand, spontaneous remission may only partially explain the reduction of complaints in both groups up to the final follow-up after 1 year because the complaints frequently recur after resumption of work or sport [25]. Therefore it appears that patients benefit from both conditions – real and invasive sham acupuncture – although this could not be strictly proved as in this study no additional control group being completely untreated was analysed.

Summarising our results, we conclude that correct selection of acupuncture points is more effective than using non-acupuncture points to treat chronic epicondylitis, at least in the early post-treatment period. However in this study with two treatment groups these effects could not be studied separately from the spontaneous course of the disease. In order to assess the natural course of the disease, it would be necessary to have an additional group of patients on a waiting list who receive neither real nor sham acupuncture.

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