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Acupuncture for frozen shoulder

肩周炎的針灸療法

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 This randomised controlled trial was undertaken to evaluate the effectiveness of acupuncture as a treatment for frozen shoulder. Thirty-five patients with a diagnosis of frozen shoulder were randomly allocated to an exercise group or an exercise plus acupuncture group and treated for a period of 6 weeks. Functional mobility, power, and pain were assessed by a blinded assessor using the Constant Shoulder Assessment, at baseline, 6 weeks and 20 weeks. Analysis was based on the intention-to-treat principle. Compared with the exercise group, the exercise plus acupuncture group experienced significantly greater improvement with treatment. Improvements in scores by 39.8% (standard deviation, 27.1) and 76.4% (55.0) were seen for the exercise and the exercise plus acupuncture groups, respectively at 6 weeks ($P=0.048$), and were sustained at the 20-week re-assessment (40.3% [26.7] and 77.2% [54.0], respectively; $P=0.025$). We conclude that the combination of acupuncture with shoulder exercise may offer effective treatment for frozen shoulder.

本文報告一項評估針灸對肩周炎的有效性的隨機對照研究。35例肩周炎病人隨機分配成兩組：運動組和運動加針灸組，並進行為期六週的治療。療效評估者在未知病人組別情況下，在治療前(基線)，治療後第6週，及第20週，利用「常數肩評估」(Constant Shoulder Assessment) 的方法評估功能靈活性，力量和疼痛程度。統計分析乃以「治療意向」原則為基礎。與運動組相比，運動加針灸組療效顯著提高。運動組和運動加針灸組在第6週時所得的改善百分數分別是39.8% (標準差，27.1)和76.4% (55.0)； $P=0.048$ 。第20週再評估時療效得以維持(分別是40.3%【26.7】和77.2%【54.0】， $P=0.025$)。我們可以總結為針灸與運動的結合可有效地治療肩周炎。

Key words:

Acupuncture;
 Exercise therapy;
 Medicine, Chinese traditional;
 Randomized controlled trial;
 Shoulder pain

關鍵詞：

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Introduction

Frozen shoulder is a common, but ill-understood disorder. It affects the glenohumeral joint, possibly involving a non-specific chronic inflammatory reaction, mainly of the subsynovial tissue, resulting in capsular and synovial thickening.¹⁻⁴ It has a number of medical synonyms including scapulo-humeral peri-arthritis, adhesive capsulitis, peri-arthritis, peri-capsulitis, stiff shoulder, and obliterative bursitis. In traditional Chinese medicine (TCM), it is termed 'shoulder at the age of 50 years'.

Frozen shoulder is used to denote a limitation of shoulder motion, without abnormalities of the joint surface, fracture, or dislocation. The onset of frozen shoulder is usually gradual and idiopathic, but it may be acute and associated with a previous history of minor injury to the shoulder joint. The disease occurs mainly in middle-aged individuals and is usually self-limiting, but the duration and severity may vary greatly.^{5,6} Most

patients recover within 2 years of the onset, although for some symptoms may last longer.^{7,8} The clinical picture of frozen shoulder is characterised by pain and restriction of the range of active and passive motion of the shoulder. Pain, which can be severe, may cause pronounced sleep disturbance. Restriction of the range of motion is usually more marked with external rotation,^{5,7,9} but less prominent with abduction and internal rotation.

Information on the treatment and prognosis of frozen shoulder is inadequate and based largely on individual practice experience rather than randomised controlled clinical trials. There is as yet no definitive agreement on the most effective form of treatment. Initial treatment is aimed at reducing inflammation and increasing the range of movement. Thus analgesic and anti-inflammatory drugs are commonly used.¹⁰ Most types of treatment focus primarily on restoration of mobility. Although physical therapies such as massage, heat application, ultrasound, interferential treatment, osteopathic and chiropractic techniques,¹¹ and stretching and isometric exercise therapy are routinely prescribed, the efficacy is variable.^{2,3,12-14} Controversial results are reported with manipulation under anaesthesia, distension arthrography, and arthroscopic surgery.¹⁵⁻¹⁸ In osteoporotic or postsurgical frozen shoulder, an open release with lysis of adhesions and capsule release is recommended. Intra-articular corticosteroid injection,^{15,19,20} and suprascapular nerve block²¹⁻²³ have also been strongly advocated. Meta-analysis of randomised controlled trials evaluating interventions for painful shoulder from 1966 to 1995, however, failed to find evidence to support or refute the efficacy of these interventions.²⁴

Acupuncture has been used for the treatment of clinical disorders in China for more than 5000 years.²⁵ It is now also valued in modern medical practice as a therapy for many medical problems, particularly where current western medicine is either ineffective or contraindicated.²⁶⁻²⁹ Acupuncture has gained increasing attention with respect to the treatment of chronic pain.³⁰⁻³² Lewith and Machin's³³ review of the efficacy of acupuncture therapy for chronic pain concluded that 'real' acupuncture treatment was significantly better than both 'sham' acupuncture and placebo. Moreover, acupuncture has been shown to cause fewer adverse reactions than the use of opioid analgesics and anti-inflammatory medications.³⁴ Richardson and Vincent³⁵ found good evidence from controlled studies that acupuncture provided effective, short-term pain relief, for both acute and chronic pain. Controlled studies on the long-term effect of acupuncture for chronic pain

are technically difficult to undertake accurately according to the studies protocol, as it is unlikely that patients with chronic pain will comply to a fixed regimen of management without considering other treatment options over a prolonged period of time. As a result, long-term follow-up data are lacking, and little evidence has been currently found to support the long-term benefits of acupuncture for the treatment of chronic pain.

Acupuncture has been reported to be effective for the treatment of frozen shoulder or shoulder arthritis. The clinical studies involved, however, were not randomised controlled trials.³⁶⁻⁴⁰ Consequently, we designed the current randomised, single-blind controlled clinical trial to investigate the immediate and medium-term effects of acupuncture, based on the principles of TCM, as a treatment for frozen shoulder.

Methods

The study was approved by the Hospital Ethics Committee. The patients selected for inclusion were men and women attending the Pain Clinic at Kwong Wah Hospital following doctors' referral, with a diagnosis of frozen shoulder. The diagnosis of frozen shoulder was based on a history of limited motion of the glenohumeral joint, with pain at the extreme of the available range. In most cases, the onset of frozen shoulder was spontaneous and gradual, while in some it was precipitated by relatively minor trauma. Inclusion and exclusion criteria for the study are listed in the Box.

Inclusion and exclusion criteria

Inclusion criteria

- (1) Shoulder pain for at least 1 month and less than 12 months' duration;
- (2) Appreciable restriction of both active and passive motion with abduction and flexion not exceeding 90° and external rotation not exceeding 30°²⁴; and
- (3) Pain at night, with inability to lie on the affected side

Exclusion criteria

- (1) History of major shoulder injury or surgery;
- (2) Clinical or radiological evidence of other pathology that could possibly account for symptoms;
- (3) Patients with evidence of cervical radiculopathy, paresis, or other neurological changes in the upper limb on the involved side;
- (4) The presence of underlying fracture, associated inflammatory arthritis, known renal or hepatic disease, haemopoietic disorder, malignancy, any mental disorder likely to interfere with the course or assessment of the disease process; and
- (5) Painful arc between 40° and 120° abduction indicative of rotator cuff disease

Patients fulfilling these criteria were asked to participate in the trial. The aim and method of the study was explained to them. After obtaining their informed consent to participate in the trial, the patients were randomly allocated to one of the two treatment groups, using the random table method. Ketoprofen (Rhône-Poulenc Rorer, Dagenham, UK) was prescribed throughout the trial period as a 'rescue' analgesic with 200 mg/d taken orally as required. No other analgesics were to be used. The patients were instructed to use the shoulder and arm normally, but within the limits of their pain. Patients who received other types of therapy during the study or failed to attend scheduled follow-up for treatment and assessment were excluded in the final analysis. The management regimen for the two treatment groups is described below.

Exercise group

The patients in this group received physiotherapy in the form of a standard group exercise programme led by the same physiotherapist each session. Treatment was scheduled twice a week for a period of 6 weeks, and each treatment session lasted for 30 minutes. Careful instructions were given to the patients when demonstrating exercises. Gentle stretching exercises, including stretching the shoulder in external rotation, internal rotation, cross-body adduction, and forward flexion, were not expected to engender substantial shoulder pain. Exercises with the arm in more than 40° of flexion or abduction were to be undertaken with caution. Patients were instructed to perform designated types of shoulder exercise (Fig 1) 10 times each morning, mid-day, and evening at home during the trial

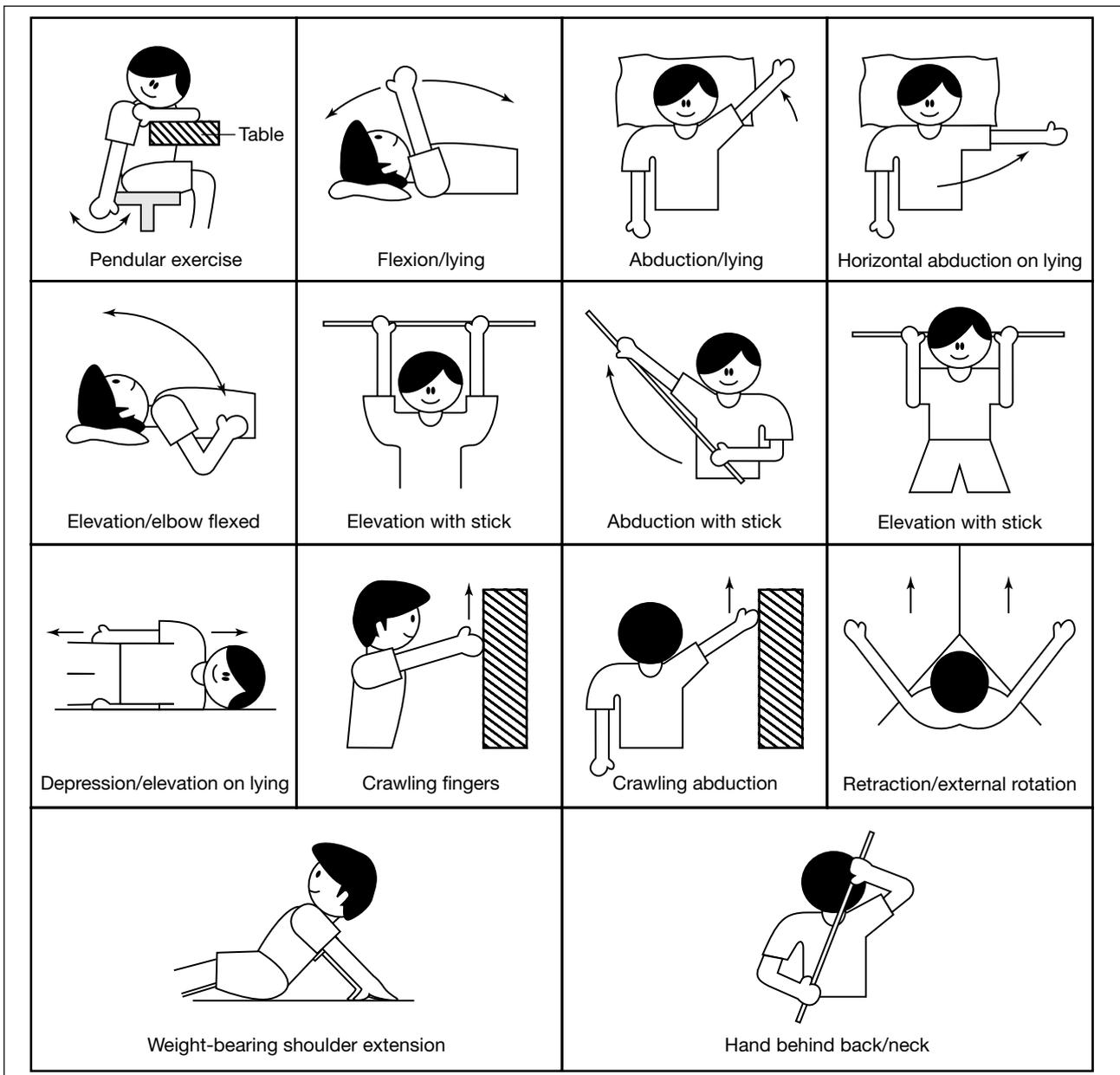


Fig 1. Shoulder exercises for home practice

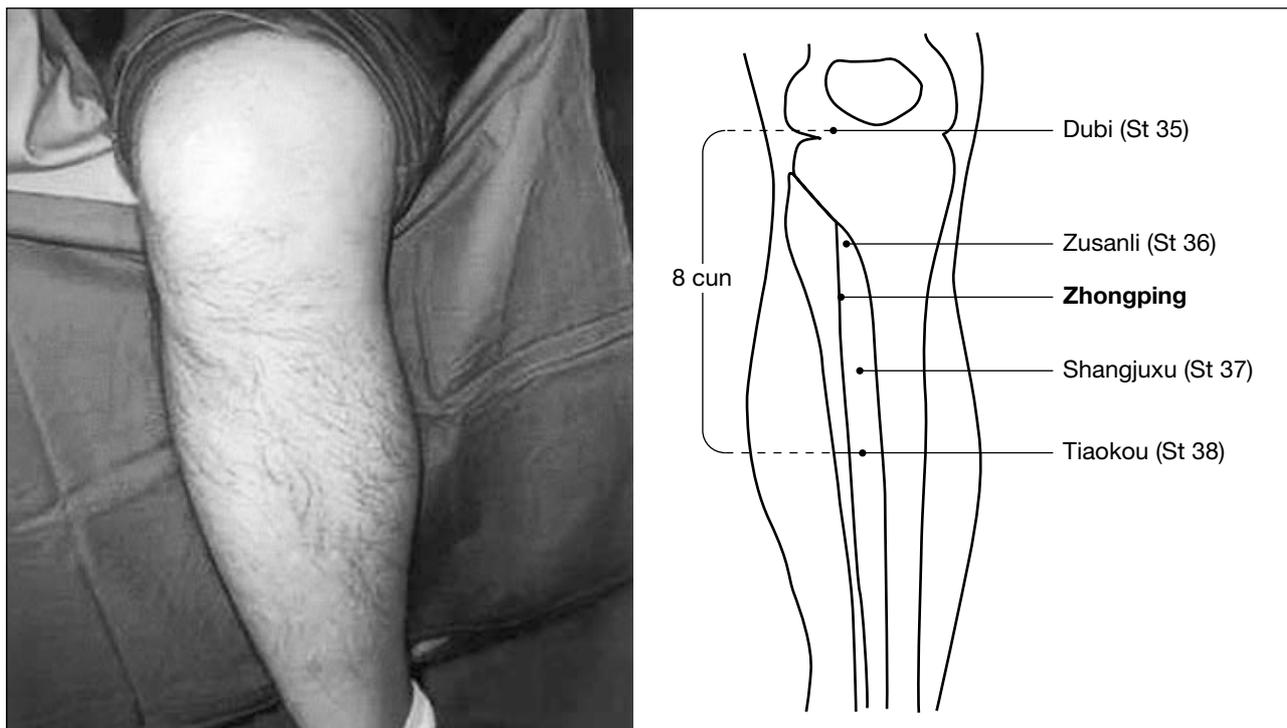


Fig 2. The location of the Zhongping acupoint

period. Home exercise monitoring cards were given to patients for record purposes. Compliance with the home exercise programme was checked by an independent assessor, using the home exercise monitoring record card.

Exercise plus acupuncture group

Both the group exercise and home exercise programme were conducted in the same way as for the exercise group. The therapist was blinded to the two groups of patients. In addition, acupuncture was administered twice a week for a period of 6 weeks by another physiotherapist, using classical Chinese acupuncture.

The physiotherapist administering acupuncture was a member of the International Acupuncture Association of Physical Therapists. The extrapoint of Zhongping was chosen (Fig 2). Contralateral needling was adopted, that is, the right-side acupoint was used for left frozen shoulder and vice versa. The acupuncture treatment was conducted as described. The patient was placed in a sitting position and the skin over the acupoint was sterilised with 75% alcohol. A sterilised 7.62 cm (3 inches) long, 30 gauge, disposable, filiform needle was forcibly inserted perpendicular to the Zhongping point to a depth of 6.35 cm (2.5 inches). This was followed by strong stimulation from wide amplitude needle rotation simultaneously with lifting and thrusting movements, to evoke a marked needling sensation (de qi), commonly described as tingling, numbness, soreness, dull pain, heaviness, or distention,

at the site of the needle insertion. The needle was retained for 20 minutes, with three 1-minute needle manipulations made over this period. During the 20-minute acupuncture treatment period, the patient completed functional exercises, elevating, abducting, adducting, and completing internal rotation and external rotation of the affected arm.

All patients were assessed by a single external observer, who was not aware of the treatment allocation. The Constant Shoulder Assessment (CSA) was used (Table 1).⁴¹ Assessment was completed prior to the commencement of treatment (baseline) and at the end of the 6th week (at the completion of treatment). Follow-up assessment was completed at the end of the 20th week.

The CSA has a maximum score of 100 points, with subjective and objective components included in a ratio of 35:65. Subjective parameters assess the degree of pain the patient experiences and his or her ability to perform normal tasks of daily living described in both activity- and position-related terms. These parameters are assessed independently before objective testing of active motion range and shoulder power is completed. The objective parameter of active motion range is based on the active range of composite movements that allow the placement of the upper limb in functionally relevant positions, with a goniometer to measure forward and lateral elevation, and positioning of the hand in relation to the head and trunk for assessment

Table 1. Constant Shoulder Assessment scale

Assessment parameters	Extent / Position	Points
Scoring for pain (maximum=15)	None	15
	Mild	10
	Moderate	5
	Severe	0
Scoring for activities of daily living (maximum=20)	<i>Activity level</i>	
	Full work	4
	Full recreation/sport	4
	Unaffected sleep	2
	<i>Positioning</i>	
	Up to the waist	2
	Up to the xiphoid	4
	Up to the neck	6
	Up to the top of the head	8
Above the head	10	
Scoring for forward and lateral elevation (maximum=20, 10 for each)	<i>Elevation (in degrees)</i>	
	0-30	0
	31-60	2
	61-90	4
	91-120	6
	121-150	8
151-180	10	
Scoring for external rotation (maximum=10)	Hand behind head with elbow held forward	2
	Hand behind head with elbow held backward	2
	Hand on top of the head with elbow held forward	2
	Hand on top of the head with elbow held backward	2
	Full elevation from on top of head	2
Scoring for internal rotation (maximum=10)	Dorsum of hand to lateral thigh	0
	Dorsum of hand to buttock	2
	Dorsum of hand to lumbosacral junction	4
	Dorsum of hand to waist (L3 vertebra)	6
	Dorsum of hand to T12 vertebra	8
Dorsum of hand to interscapular region (T7 vertebra)	10	
Power (amount of weight that can be lifted in the scapular plane)	Up to 25 lb (11.4 kg) (1 for each lb [0.5 kg] lifted)	0-25
	Total	100

of rotation. Scoring of shoulder power is based on the number of pounds of pull the patient can resist in abduction, up to a maximum of 90°. The score given for normal power is 25 points, with less given proportionately for less power. A total CSA score of 100 points indicates perfect, pain-free movement and function.

An earlier sample size calculation indicated a minimum of 13 patients should be recruited in each group, based on a 75% improvement in CSA with a 5% chance of committing a false positive error and 80% power.⁴² Statistical analysis was conducted based on the intention-to-treat principle. Specifically, all recruited patients were analysed as randomised regardless of the actual treatment received or whether they withdrew before the end of follow-up. Missing values were imputed by the last available observation of the corresponding patients. To determine the robustness of conclusions, the analysis was repeated when missing data were discarded. Comparison of the two groups at baseline (on admission) was first made

using the χ^2 -test and Mann-Whitney *U* test according to whether the variable under consideration was categorical or continuous, respectively. Then the difference in mean CSA scores within each group was evaluated using Friedman's test. Mean CSA scores and percentage of CSA improvement from baseline at each measurement visit were compared between the two groups by Mann-Whitney *U* test. The P value of each significance test was determined exactly or approximated by Monte Carlo simulation (size 10000). The Statistical Analysis System (Windows version 8.1; SAS Institute Inc., Cary, NC, US) was used for all statistical analysis.

Results

Thirty-five patients were admitted consecutively to the study over a period of 12 months. Through random sampling, 22 patients were allocated to the exercise group and 13 patients to the exercise plus acupuncture group. No patient received acupuncture as treatment

Table 2. Admission data for patients included in the trial

Baseline characteristic	Intervention		P value (group difference)
	Exercise group	Exercise plus acupuncture group	
No. of patients	22	13	
Sex ratio (M:F)	7:15	4:9	1.000*
Age (Mean; SD; range)	57.1; 8.6; 42-69 years	55.0; 7.6; 41-64 years	0.365†
Duration of symptoms (Mean; SD; range)	7.1; 3.9; 1-12 months	5.5; 1.6; 3-9 months	0.470†

* χ^2 -test

† Mann-Whitney U test

prior to the study. One patient in the exercise plus acupuncture group discontinued treatment after the second acupuncture session due to fear of needle pain, while four patients withdrew from the exercise group after 6 weeks of exercise practice. Nevertheless, all patients were considered in the subsequent analysis based on the intention-to-treat analysis.

Admission data for the patients is summarised in Table 2. There were no statistically significant differences between the two groups in terms of age, sex, and duration of symptoms. Compliance with the home exercise programme was equally good in both groups. There were no statistically significant differences between the two groups with respect to the amount of analgesic intake before, during, and after treatment (Mann-Whitney U Test: baseline, $P=0.573$; 6-week, $P=0.768$; 20-week, $P=0.921$) [Fig 3]. No patient took analgesic therapy other than ketoprofen, or received other types of therapy for the shoulder pain during the study period.

The mean CSA scores for both groups are shown in Table 3 and Fig 4. There was no statistically significant difference between the groups in terms of their baseline CSA scores ($P=0.951$) and CSA scores

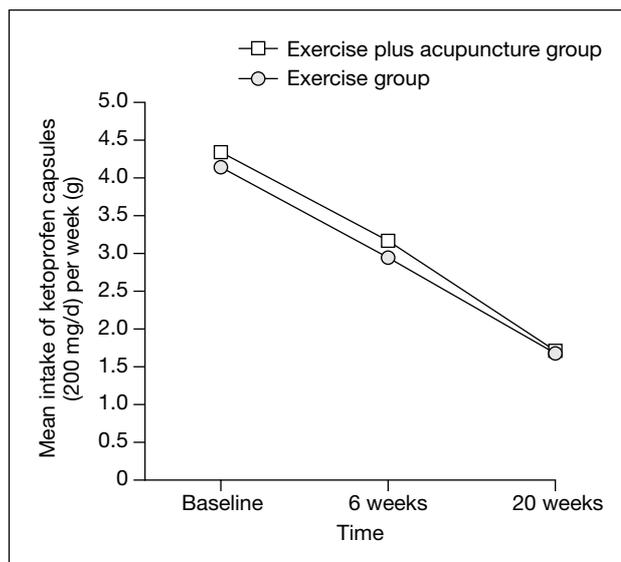


Fig 3. Analgesic intake by patients receiving treatment for frozen shoulder

at 6 weeks ($P=0.056$). The CSA scores, however, were significantly higher in the exercise plus acupuncture group compared with the exercise group at 20 weeks ($P=0.048$). Within each group, there was a significant difference among mean CSA scores measured at baseline, 6 weeks, and 20 weeks ($P<0.001$ by Friedman’s test).

Table 3. Constant Shoulder Assessment scores and percentage improvement with treatment*

	Intervention		P value (group difference)
	Exercise (Mean; SD)	Exercise plus acupuncture (Mean; SD)	
<i>Constant Shoulder Assessment scores</i>			
At baseline	42.8; 14.0	41.3; 14.9	0.951
At 6 weeks	57.6; 15.1	66.8; 10.9	0.056
At 20 weeks	57.9; 15.1	67.3; 11.5	0.048†
Non-parametric tests (Friedman’s ANOVA by ranks) comparing the Constant Shoulder Assessment scores at the three different times of assessment	$P<0.0001$	$P<0.0001$	-
<i>Percentage improvement from baseline‡</i>			
At 6 weeks	39.8%; 27.1%	76.4%; 55.0%	0.048†
At 20 weeks	40.3%; 26.7%	77.2%; 54.0%	0.025†

* Missing values were replaced by last observation of the corresponding subject

† Statistically significant

‡ Defined as (Constant Shoulder Assessment score at a week–baseline score)/baseline score x 100%

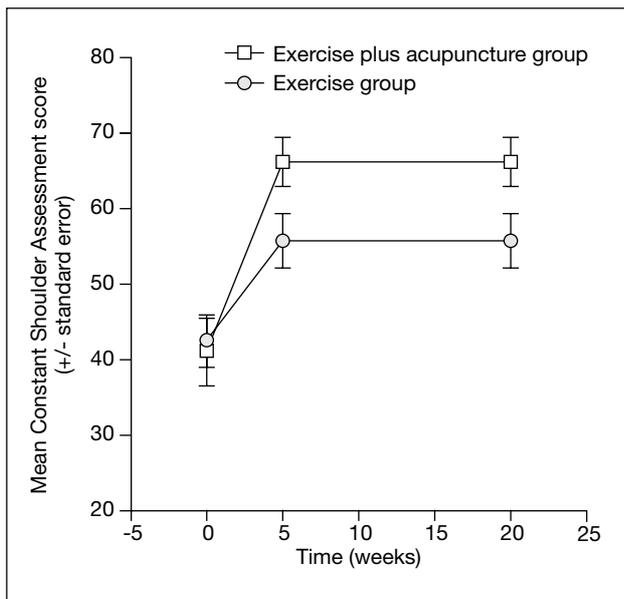


Fig 4. Constant Shoulder Assessment scores for patients receiving treatment for frozen shoulder

The percentage of CSA improvement from baseline for each patient was computed and a summary is shown in Table 3. At 6-week assessment, there was a 76.4% and a 39.8% improvement in shoulder function for the exercise plus acupuncture group and the exercise group, respectively. These relative improvements were sustained at the 20-week reassessment (77.2% and 40.3% for the exercise plus acupuncture and exercise groups, respectively). Compared with the exercise group, the exercise plus acupuncture group was significantly better after treatment at 6 weeks and on follow-up at 20 weeks ($P=0.048$ and $P=0.025$, respectively).

The analyses were repeated when all missing values were discarded. All conclusions were essentially identical with the exception of a significant difference in mean CSA scores now seen between the two groups at 6 weeks ($P=0.021$). Final conclusions were drawn, however, from the intention-to-treat analysis.

Discussion

Classically the symptoms of primary frozen shoulder have been divided into three phases:

- (1) the painful freezing phase;
- (2) the stiffening frozen phase; and
- (3) the recovery thawing phase.

In the initial painful phase, there is a gradual onset of diffuse shoulder pain lasting from weeks to months. It may take up to 2 years or longer for the pathology to resolve. Although spontaneous recovery of frozen shoulder may take place within 2 years of onset without any form of treatment, many do not improve without

appropriate treatment. In 1992, Shaffer et al⁹ reported a long-term follow-up of idiopathic frozen shoulder. The authors subjectively and objectively evaluated 62 patients who had been treated non-operatively, at between 2 years and 2 months to 11 years and 9 months follow-up. They found that 50% of patients still complained of either mild pain, stiffness, or both mild pain and stiffness of the shoulder, while 60% still showed some restriction of movement.

The aim of this study was to determine if acupuncture is an effective and safe treatment option that can enhance the speed and degree of recovery of idiopathic frozen shoulder. Exclusion criteria eliminated conditions mimicking frozen shoulder or causing severe secondary frozen shoulder, while inclusion criteria limited patient selection to those in the relatively early phase of the disease, with appreciable restriction of motion and pain. Shoulder pain for at least 1 month and less than 12 months' duration was a criterion for the study to determine whether acupuncture treatment could enhance the speed of recovery. The risks associated with acupuncture treatment are generally very minimal (such as infection and haematoma), and the rate of occurrence is very low. Acupuncture also has high patient acceptance in preference to other methods of treatment. In this study, there was no acupuncture-related complication and only one patient in the exercise plus acupuncture group discontinued treatment due to fear of needle pain.

Hansen⁴³ reported that 5-minute acupuncture treatment sessions were equally as effective for neck and shoulder pain when compared with 20-minute sessions. However, there was an imbalance between the groups studied in terms of the pretreatment visual analogue score, and this combined with the limited trial size suggests these results may not be reliable. Consequently, this study utilised the standard 20-minute treatment regimen.

The CSA was used for evaluation of progress following treatment.⁴¹ This assessment is a simple clinical tool that combines functional assessment of the shoulder with assessment of individual parameters, such as pain and daily activity. It therefore allows evaluation of progress after injury, treatment, or disease with respect to these individual parameters or in terms of overall function. The CSA is easy to use, taking only a few minutes to perform. It is reliable and valid in the overall assessment of shoulder function,⁴¹ with low inter-observer and intra-observer error rates.^{41,44} There are, however, two limitations of the CSA.⁴⁴ Firstly, assessment of power is error-prone as accurate

measurement of power is difficult to achieve. Shoulder movement is complex and consequently measurement of power in a single arc of shoulder movement is unlikely to be representative of full functional potential. Secondly, in cases of shoulder instability, such as joint dislocation, CSA fails to reflect accurately the true level of disability incurred and thus is not a reliable outcome measure for patients with complaints of instability. Frozen shoulder is characterised by pain and limitation of motion without fracture and dislocation. Joint instability and marked power loss are rarely seen in patients with frozen shoulder and thus, these limitations are not pertinent to the study population. The Constant Shoulder Assessment is, therefore, a good outcome measure to evaluate the severity, recovery, and treatment response of frozen shoulder.

Acupuncture treatment used in this clinical trial was conducted according to the principles of TCM. Ancient Chinese medicine considers human health as facing the tensions created by opposing forces in nature—the Yin and the Yang. Medical intervention carried out according to this concept aims to restore balance between the opposing energy forces. A concept of vital energy flow linking circulation to neurological function is fundamental to the practice of acupuncture. The vital life energy, Qi, is thought to flow through a set of interconnected channels, called meridians, which follow a circadian rhythm. The meridians are interconnected by Qi. Each internal organ is thought to be associated with a certain meridian, and the meridian is named after the organ concerned. Diseases and discomforts, such as pain, are classified according to the meridians they involve, whether they have a Yin (cold, hypofunctional) or Yang (hot, hyperfunctional) nature, and whether the flow of Qi is excessive or deficient. According to TCM, pain in the shoulder is associated with weakness in the ‘stomach’ and ‘spleen’, and deficiency of Qi. Frozen shoulder belongs to the group of diseases characterised by blockage of Qi, or to the Bi syndrome, that is, painful locomotor disorders. The definition of Bi in Chinese medicine is obstruction or interference with the flow of Qi and blood. It is mainly believed to be due to the deficiency of Yin and to inadequate defence of the skin against invasion by the pathogenic factors of wind, cold, and dampness into the body. The resulting stasis of Qi and blood in the channels leads to pain, aching, and stiffness in the muscle, bones, tendons, and joints.

Classical acupuncture prescriptions for frozen shoulder are designed—by selection of local, distal, and tender (ashi) points according to the course of the meridians—to relax the muscles, disperse pathogenic

factors such as excess wind, cold, and dampness, remove obstruction in the affected meridians and their collaterals, and to regulate the Qi and blood. A combination of local and distal classical Chinese acupoints are commonly used for the treatment of frozen shoulder.⁴⁵ Local points include GB 21 (jianjing), LI 15 (jianyu), LI 14 (Binao), TE 14 (jianliao), and SI 9 (jianzhen). Distal points utilised are LI 4 (hegu), LI 11 (Quchi), St 38 (Tiaokou),^{37,46} GB 34 (Yanglingquan),³⁹ and Zhongping.³⁶ Zhongping is an extra acupoint lying along the stomach meridian, the so-called Yang Ming Meridian. It is situated 1 cun below Zusanli (St 36) and about 2 cun above Shangjuxu (St 37), slightly lateral, on the medial side of the fibula (Fig 2). Cun is the Chinese proportional measure, and 1 cun is approximately 2.5 cm or the distance between the proximal and distal interphalangeal joints of the index finger of the patient. The stomach meridian has its Qi running across the shoulder. It is a Yang meridian in balance with its Yin counterpart, an imbalance of which can cause the Bi syndrome. Stimulation of the Zhongping acupoint can improve the flow of Qi across the shoulder. Moreover, the scapulohumeral region is the place where muscles converge, and Zhongping is an influential point in relation to the tendon. Acupuncture applied to this acupoint can relax the tendon and remove obstruction in the meridians to relieve pain. Contralateral needling, characterised by the contralateral selection of points is very effective in the treatment of shoulder pain. The mechanism of action is possibly the stimulation of Shu points, and hence the meridians and collaterals, on the healthy side. This, in turn, is thought to excite the meridians and collaterals on the affected side, which have been in a state of stagnation of Qi and blood, thus, to an extent, clearing and activating the meridians and collaterals, and relieving pain. Practice has proved that needling of the Zhongping point and active movement of the affected shoulder, if performed simultaneously, are particularly effective in treating shoulder pain and arthritis.³⁶ The mechanism of this synergy is not clear, but may be related to the facilitated flow of Qi across the shoulder. Needling applied to the Zhongping acupoint to treat frozen shoulder has the advantage of selection of only one point, consequent ease of treatment delivery, and good therapeutic results. Unlike local points and some distal points over the upper limb (LI 4 and LI 11),⁴⁵ Zhongping is distant from the painful site and will not interfere with shoulder exercise and assessment during the acupuncture treatment.

According to TCM, if a part of the body is not moved, then the Qi will not circulate through it, leading to stagnation. If this occurs in the shoulder joint, the

joint becomes stiff and painful. Physical exercise is important in harmonising the body (Yin) and the spirit (Yang), as well as the Qi, helping to clear and activate the meridians and collaterals. This is essential for internal harmony between various organ systems, as well as between the body and the natural environment. The improvement shown by the exercise group in this study can be explained by TCM in this way.

The therapeutic effect of acupuncture appears at its best when the patient has a feeling of needle sensation (*de qi*). During '*de qi*', the underlying muscle appears to grab the needle and hold it firmly, and propagation of one or more of these sensations may occasionally be felt along the meridian. The sensation of '*de qi*' must be distinguished from pain or discomfort due to poor needling technique. In most classical practice, the acupuncturist does not remove the needle until the '*de qi*' has dissipated, and the needle can be lifted from the tissue without effort.

Although acupuncture has been widely used to treat a variety of painful conditions, convincing scientific evidence for its efficacy is still lacking.⁴⁷⁻⁴⁹ Previous studies of acupuncture treatment provide equivocal results due to limitations in their design. The approach of using a double-blind, placebo-controlled design has many problems, including the virtual impossibility of blinding the acupuncturist, the uncertainties in choosing a control acupuncture point, and the inherent difficulties in the use of appropriate controls, such as placebo and sham acupuncture groups.^{50,51}

There are a few limitations evident in this study. Due to the inherent difficulty in long-term studies of chronic pain, as discussed previously, follow-up of patients was for a maximum of 20 weeks. Long-term follow-up is necessary, however, in order to determine whether lasting benefits of acupuncture have occurred. Failure to undertake long-term follow-up has the potential to produce false-positive outcomes, that is, positive outcomes when no real treatment effect exists.

The lack of a placebo or sham acupuncture control group in this clinical trial has made it impossible to prove whether needling was an important part of the method or whether the improvement felt by the patients in the exercise plus acupuncture group was due to the therapeutic setting and psychological phenomena.^{33,48,52,53} Although significant improvement up to 20 weeks after acupuncture treatment was seen in this study, it is possible that the '*placebogenic*' qualities of acupuncture treatment may be greater than those of placebo treatments matched to drugs.^{35,51}

The imbalance in the number of subjects allocated to the groups is a result of using the random number table as a randomisation tool. Though the two groups appeared comparable in other respects, better randomisation methods, such as block randomisation, should be utilised in future studies to ensure equal allocation across groups.

The earlier planned sample size was based on a large difference in percentage CSA improvement. This study, however, revealed a smaller difference than expected. Indeed, a post-hoc power analysis showed the power to detect the currently observed differences at 6 and 20 weeks was only approximately 41% and 43%, respectively. This lack of power, however, would lower the chance of detecting a small difference but not increase the chance of a false positive error. Moreover, the observed difference in the percentage of improvement was based on an intention-to-treat analysis. Thus the observed difference between the two treatment groups warrants the attention of further study, with more refined planning of sample size.

Following the study protocol, the two groups did not undertake the same amount of functional exercise. In addition to the group exercise (a total of 360 minutes over the treatment period) and daily home exercise, the exercise plus acupuncture group also completed shoulder exercises during the acupuncture treatment (a total of 240 minutes over the acupuncture treatment sessions). Moreover, if acupuncture is viewed as a form of analgesia, patients who had acupuncture before exercise may have demonstrated greater improvement because they had less pain during exercise. This complicates the comparisons between the two groups. The significantly better outcome of the patients receiving acupuncture in addition to exercise therapy compared with those undertaking exercise only might, to a certain extent, be due to the completion of additional shoulder exercises that were less painful.

Despite the limitations of this clinical trial, we conclude that the combination of acupuncture and physical exercise may be an effective option in the treatment of frozen shoulder. This study provides additional data on the potential role of acupuncture in the treatment of frozen shoulder, particularly for those patients not responding well to conventional therapy.

As most previous studies of acupuncture were of poor methodological quality, there is an urgent need for further well-designed clinical trials in this area. High-quality, double-blind, randomised, sham-controlled trials, using adequate and valid acupuncture

treatment regimens should be designed.⁵⁴ Future studies also need to enrol large numbers of patients, and measure both short-term and long-term outcomes. More research is also needed to establish a uniform method for defining clinical disorders, such as frozen shoulder, and to develop valid and reliable outcome measures for these conditions.

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