

A Randomized, Controlled Clinical Trial of a Treatment for Shoulder Pain

Background and Purpose. The aim of this study was to evaluate the efficacy of a physical therapy approach to the treatment of shoulder pain. **Subjects.** Sixty-six volunteers with shoulder pain believed to be of local mechanical origin were randomly allocated to either a treatment group or a control group. **Methods.** Subjects in the treatment group received 1 month of physical therapy aimed at restoring function of their shoulder muscles. Subjects in the control group received no treatment. Outcome measurements of pain intensity, range of motion (ROM), isometric muscle force, functional impairment, and self-perception of improvement were obtained by blinded assessment. **Results.** Subjects in the treatment group showed improvement in pain-free abduction and flexion ROM, functional impairment, and self-perception of improvement. The control group deteriorated slightly over the experimental period in ROM and functional impairment measures. **Conclusion and Discussion.** These results suggest that the physical therapy approach used in this study is effective in improving shoulder function in subjects experiencing pain of mechanical origin. The results also provide little evidence of spontaneous recovery over a 1-month period. [Ginn KA, Herbert RD, Khouw W, Lee R. A randomized, controlled clinical trial of a treatment for shoulder pain. *Phys Ther.* 1997;77:802-811.]

Key Words: *Clinical trial, Exercise therapy, Physical therapy, Randomized control trial, Shoulder.*

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Shoulder pain is a commonly occurring musculoskeletal complaint in medical general practice, second only to back pain,¹ with an estimated prevalence of 7% in both Sweden and the United Kingdom.^{2,3} This figure increases markedly among elderly people.^{2,4,5}

Shoulder pain affects the ability to work or function independently in the community, particularly in elderly individuals.^{1,2,4,5} A large proportion of persons with shoulder pain do not seek treatment.^{4,5} Effective treatment of shoulder disorders could decrease the risk of loss of independence or time lost from work and thus have important socioeconomic implications.

No consensus exists for the treatment of choice for shoulder dysfunction, and various physical therapy regimens are conventionally used.⁶ In addition, very few well-designed clinical studies have been conducted to evaluate the efficacy of physical therapy in the treatment of people with shoulder pain. A recent review identified 18 randomized, controlled clinical trials of physical

therapy for shoulder pain.⁷ Only 1 of these clinical trials demonstrated that physical therapy for the shoulder was effective. Nevertheless, the reviewers concluded that, because of the poor quality of these studies, the effectiveness of physical therapy for the painful shoulder could not be accurately assessed.

Successful rehabilitation of the shoulder, in our view, should be based on reestablishment of normal shoulder function and requires an understanding of normal shoulder anatomy. The anatomy of the shoulder complex reflects its requirement to achieve maximum mobility for the upper limb. The scapula, which forms the mobile base of the shoulder joint, has minimal passive suspension from the skeleton via the acromioclavicular joint and coracoclavicular ligament. At the shoulder joint, the passive structures, which elsewhere provide stability to synovial joints, are designed to facilitate mobility. The articular surfaces of the humeral head and the glenoid fossa of the scapula lack congruity; the joint capsule is thin and lax, allowing 2 to 3 cm of distraction between articular surfaces; and the ligaments are few

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This study was approved by the ethics committees of The University of Sydney and Westmead Hospital.

Some of the data presented in this report formed the basis of oral presentations at the 12th World Congress of the International Federation of Physical Medicine and Rehabilitation; March 27-31, 1995; Sydney, New South Wales, Australia; and at the 12th International Congress of the World Congress for Physical Therapy; June 25-30, 1995; Washington, DC.

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and only provide stability in limited joint ranges of motion (ROMs).^{8,9} One of the major implications of these structural modifications to increase mobility is that the shoulder region relies on muscles, more than any other region of the body, to provide adequate stability.^{8,10}

The most important muscles performing this stabilizing role at the shoulder are the four muscles of the rotator cuff¹⁰⁻¹²: supraspinatus, subscapularis, infraspinatus, and teres minor. All the rotator cuff muscles originate from the scapula and blend with the joint capsule before inserting into the humerus. They provide a medial, inferior force to the humeral head during shoulder movements in order to center it in the glenoid fossa, thus providing adequate articular surface stability to allow full range of shoulder movement.¹⁰⁻¹³ To adequately perform the stabilizing role, the rotator cuff muscles must be used in a coordinative fashion with each other as well as with the muscles that move the humerus and the scapula.¹¹⁻¹³

The aim of our study was to evaluate the effectiveness of physical therapy for shoulder pain using a randomized, controlled clinical trial. The goals of the particular physical therapy approach used were to decrease pain and to improve joint function by improving muscle function at the shoulder. The treatment was intended to establish muscle length and function, make the muscles more effective in their stabilizing roles, and reestablish coordination between movements of the scapula and the humerus.

Method

Subjects

All patients over 18 years of age with unilateral shoulder pain who were referred by general and specialist physicians to a large metropolitan teaching hospital (Westmead Hospital, Sydney, New South Wales, Australia) for physical therapy over a 30-month period and who were able to understand spoken English were eligible to participate in this study.

Subjects were excluded if their shoulder pain was due to inflammatory or neoplastic disorders, was referred from vertebral column structures, was due to trauma within the previous 4 weeks, or was bilateral. (Patients with bilateral shoulder pain were excluded because some outcome measurements relied on comparison with the contralateral side.) For the purposes of our study, shoulder pain was deemed to be referred from vertebral column structures if it was not reproduced by active shoulder movements, if it was reproduced by active overpressed neck movements (flexion, extension, rotation, and lateral flexion) or by central or ipsilateral

posteroanterior accessory movements of the cervicothoracic vertebral column,¹⁴ or if paresthesia was present in the affected upper limb.

Seventy-one volunteers, 41 female and 30 male, gave informed consent prior to participating in this study. Statistical power calculations indicated that a sample of this size would provide a better than 80% chance of detecting a difference in abduction ROM of 25 degrees assuming a standard deviation of 35 degrees, if such an effect existed.¹⁵

Procedure

Subjects underwent a standardized interview and musculoskeletal assessment before being randomly allocated, by the toss of a coin, to either a treatment group or a control (no treatment) group for a period of 1 month. Generation of a control group was possible because there was a waiting list of a least 1 month for physical therapy at the hospital concerned. Subjects allocated to the treatment group commenced treatment immediately. At the end of the experimental period, each subject was reassessed by an investigator who was unaware of the group to which the subject had been allocated.

The initial interview and musculoskeletal assessment were designed to obtain baseline measurements of pain intensity, functional disability, ROM, and isometric muscle force. At follow-up reassessment, these measurements were repeated and perceived change in symptoms over the experimental period was assessed. Additional questions were asked and musculoskeletal measurements were taken at the initial assessment and used to individually tailor treatment to suit the requirements of each subject in the treatment group. The questions concerned factors that aggravated and eased the subject's shoulder pain, and the additional measurements were performed bilaterally and included medial (internal) and lateral (external) shoulder joint ROMs, scapula resting position, scapular protraction and retraction ROMs, and length of the upper trapezius muscles.

Pain intensity was measured on a 10-cm horizontal visual analog scale (VAS) labeled "no pain" and "worst pain I have ever had" at its extremes. Immediately following performance of a standardized reaching task, each subject marked the point on the VAS that corresponded to the level of pain he or she experienced. A five-point scale of increasing difficulty with personal care was used to measure the functional disability associated with the shoulder pain, with a score of 1 represented by the statement "I can look after myself normally without causing extra pain" and a score of 5 represented by the statement "I need help in most aspects of self-care." This scale was modified from section 2 of the Oswestry Low

Back Pain Disability Questionnaire¹⁶ and field tested prior to use in this study. Perceived change in symptoms was measured at reassessment only on a five-point scale, ranging from 1 ("completely recovered") to 5 ("worsened").

Active, pain-free flexion and abduction ROMs were measured from photographs on which various bony points had been marked. Abduction angle was represented by the angle subtended by lines drawn between the first and sixth thoracic spinous processes and between the lateral angle of the acromion and the lateral epicondyle of the elbow. Flexion angle was represented by the angle subtended by lines connecting a point 6 cm below the lateral angle of the acromion, the lateral epicondyle of the elbow, and the tip of the 12th rib. To establish the test-retest reliability of these measurements, two examiners measured 10 subjects who were pain-free on two occasions 1 week apart. Both abduction and flexion measurements had high test-retest reliability, with intraclass correlation coefficients (type 2,1)¹⁷ of .90 and .88, respectively, and with 90% of measurement pairs differing by less than 5 and 6 degrees, respectively. Hand-behind-back (HBB) ROM was measured by noting the vertebral level or pelvic landmark reached by the tip of the thumb.

Isometric abduction force was measured, using a hand-held dynamometer, with the subjects positioned supine with the shoulder at 90 degrees of abduction. The maximum force generated, regardless of the presence of pain, was recorded. Hand-held dynamometry has been shown to exhibit acceptable reliability when tested on patients with strength deficits.¹⁸

The treatment used in this study was directed toward the restoration of muscle function at the shoulder, particularly the rotator cuff muscles, which have a major stabilizing role at the shoulder joint.⁹⁻¹³ The treatment for each of the subjects in the treatment group was individually determined by the treating physical therapist, based on the results of the initial musculoskeletal assessment and an evaluation of scapulohumeral rhythm dysfunction conducted by the treating physical therapist. The only treatment options available to the physical therapists providing treatment were stretching exercises for shoulder muscles that were found to be short, strengthening exercises for shoulder muscles that were found to be weak, and motor retraining aimed at restoring scapulohumeral rhythm during the performance of upper-limb tasks. The type, frequency, and duration of the stretching and strengthening exercises used were at the discretion of the treating physical therapist. All treating physical therapists viewed a training videotape prior to participation in this study, which described the

treatment options available and suggested methods of stretching, strengthening, and training muscles.

Subjects in the treatment group had physical therapy 4 to 10 times over the 1-month experimental period, as deemed necessary by the treating physical therapist, and were encouraged to continue their exercises on a daily basis at home. Ten physical therapists provided treatment over the 30-month duration of the study. After the initial assessment, the subjects in the control group had no contact with the physical therapy department until their reassessment 1 month later.

All but four reassessments were conducted at the end of the 1-month experimental period. Two subjects in the treatment group and two subjects in the control group were reassessed 1 to 2 weeks outside this period. Following reassessment, all control subjects commenced treatment and subjects in the treatment group continued to receive treatment if any symptoms remained.

Data Analysis

Between-group comparisons of median self-rated disability scores, scores for perceived change in symptoms, VAS measurements, and HBB ROM measurements at reassessment were performed using a two-tailed Mann-Whitney *U* test. A two-tailed paired-samples *t* test was used to compare differences between the treatment and control groups' mean changes in pain-free abduction and flexion ROMs and in abduction isometric force, expressed as a percentage of the force of the unaffected side. Prior to statistical analysis, one outlying data point of change in abduction force that was greater than four standard deviations from the mean was eliminated from the study. A Fisher's Exact test was used to compare the proportion of subjects whose self-rated disability scores and pain-free abduction ROM deteriorated.

Results

Of the 71 subjects who were admitted to the study, 5 subjects (7%) were unavailable for reassessment. Two subjects from the treatment group withdrew because of unrelated illness, and 2 subjects from the control group withdrew without explanation. One subject from the treatment group received a corticosteroid injection into her affected shoulder during the treatment period and therefore was not reassessed. Only data from the remaining 66 subjects are reported here.

The medical diagnoses with which subjects were referred for physical therapy are listed in Table 1. The most common diagnoses were "tendinitis" and "rotator cuff injury/tear/syndrome." Key descriptive and clinical characteristics of subjects in the treatment and control groups are presented in Table 2. Random allocation generated groups that were well matched on the vari-

Table 1.
Medical Diagnoses

Diagnosis	No. of Subjects
Tendinitis	13
Rotator cuff tear/injury	10
Rotator cuff syndrome	8
Impingement	7
Frozen shoulder	6
Periarthritis/capsulitis	5
Osteoarthritis	4
Acromioclavicular joint lesion	2
Biceps muscle tear	2
Painful arc syndrome	1
No diagnosis	8

Table 2.
Characteristics of Subjects in Treatment and Control Groups^a

	Control Group	Treatment Group
Age (y)	62.7 (20-80)	56.4 (34-85)
Duration of symptoms (mo)	4.5 (2.0-7.0)	5.0 (3.0-11.3)
Pain intensity (mm)	14 (0-40)	13 (0-40)
Self-rated disability score	2 (2-3)	3 (1-3)
Pain-free abduction range of motion (°)	86.4 (40.3)	87.1 (35.8)
Pain-free flexion range of motion (°)	97.1 (40.5)	99.8 (30.9)
Pain-free hand-behind-back range of motion (°)	10.0 (7.25-15.0)	11.0 (6.75-18.5)
Abduction force (N)	71.0 (53.2)	71.0 (53.2)

^a All values are medians (interquartile ranges in brackets), except for abduction and flexion ranges of motion and abduction force, which are means (standard deviations in brackets).

ables of age, chronicity, pain intensity, functional disability, ROM, and isometric force.

At the end of the study, the treatment group had better outcomes on two of the three self-reported outcome measurements. The median self-rated disability score was 2 ("I can look after myself normally, but it causes extra pain") in the treatment group compared with 3 ("It is painful for me to look after myself, and I am slow and careful") in the control group ($P=.03$; Fig. 1). Only 11% of subjects in the treatment group reported worse disability scores at the end of the experimental period compared with 50% of subjects in the control group ($P<.001$).

Subjects in the treatment group also reported greater improvements in symptoms. The median score for this variable was 2 ("improved a lot") in the treatment group compared with a median score of 4 ("stayed the same")

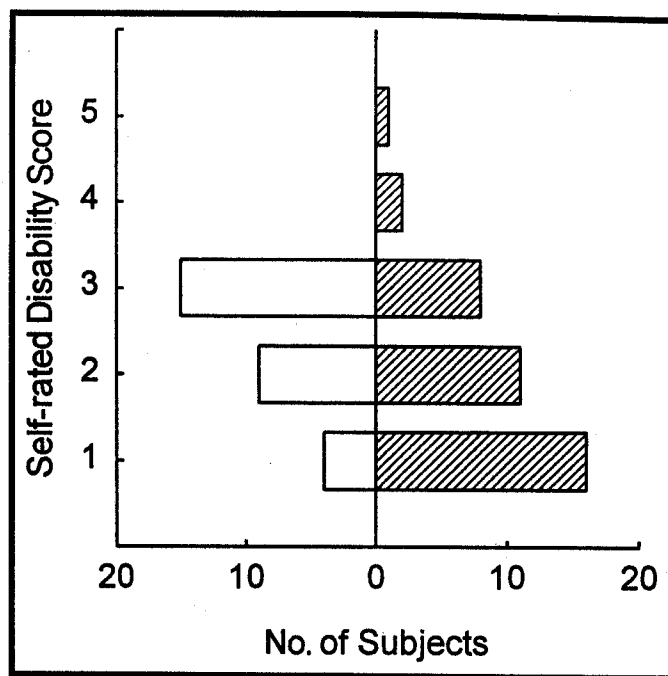


Figure 1. Distribution of self-rated disability scores for the control group (unshaded bars) and the treatment group (shaded bars) at final assessment. Lower scores denote a better outcome. Self-rated disability scores were lower in the treatment group than in the control group (Mann-Whitney U test, $P=.03$).

in the control group ($P<.001$; Fig. 2). There was not a statistically identifiable difference in the median VAS measurements obtained from the treatment group (1 mm) and the control group (21 mm) with probability at the .05 level (Fig. 3).

The treatment group demonstrated greater increases in pain-free abduction and flexion ROMs. There was a mean increase of 22 degrees in pain-free abduction ROM in the treatment group compared with a decrease of 5 degrees in the control group ($P=.006$, 95% confidence interval about mean difference of 6.7°-49.4°; Fig. 4). Additionally, 11% of subjects in the treatment group demonstrated a decrease of 10 degrees or more in pain-free abduction ROM at the end of the experimental period compared with 32% of subjects in the control group ($P=.03$). There was a mean increase of 16 degrees of flexion ROM in the treatment group compared with a mean increase of 1 degree of flexion ROM in the control group ($P=.04$, 95% confidence interval about mean difference of 0.6°-30.5°; Fig. 5). The HBB scores in the treatment group (T-9 spinous process compared with T-12 in the control group) were not different ($P=.21$; Fig. 6). The treatment group's abduction force (7.6% compared with -1.1% in the control group) was not found to be different ($P=.27$; Fig. 7).

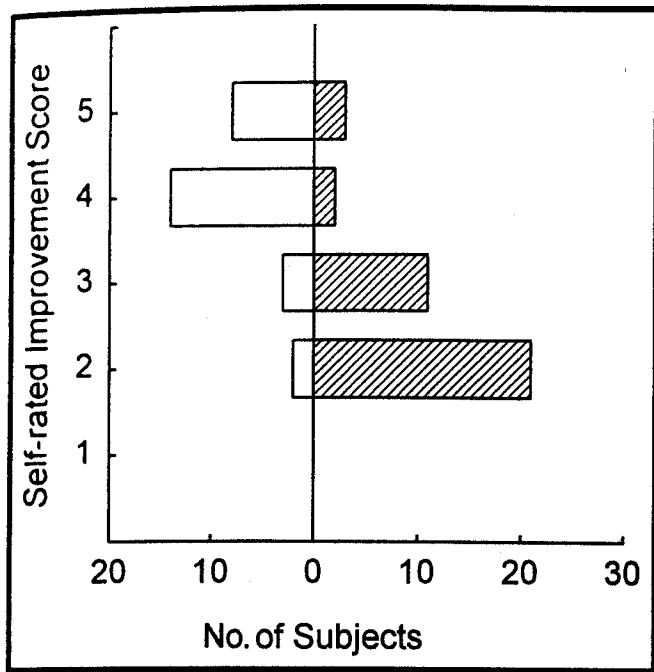


Figure 2. Distribution of self-rated improvement scores for the control group (unshaded bars) and the treatment group (shaded bars) at final assessment. Lower scores denote a better outcome. Self-rated improvement scores were lower in the treatment group than in the control group (Mann-Whitney U test, $P < .001$).

Discussion

This randomized, controlled clinical trial demonstrated that a physical therapy regimen aimed at decreasing shoulder joint pain and dysfunction by restoring normal shoulder muscle function resulted in more improvement in a variety of outcome measures, compared with no treatment, over a 1-month period. The group that received treatment attained greater increases in pain-free abduction and flexion ROMs and reported greater increases in independence with daily personal care as well as a greater reduction in shoulder symptoms.

No differences were found in the measurements of HBB ROM ($P = .21$), pain intensity on the standardized reaching task ($P = .10$), or change in abduction force expressed as a percentage of the force of the nonsymptomatic side ($P = .27$). Given the sample size used in this study, the probability of detecting an effect on change in abduction force of 20% was low (.75).¹⁵ It is more difficult to obtain precise estimates of the power of the nonparametric tests performed on the skewed HBB ROM and pain intensity measurements. Perhaps with a greater number of subjects, a statistically significant effect would have been demonstrated on these measures.

In addition, pain intensity as measured on the standardized reaching task may not have reached statistical significance in this study because the effective number of

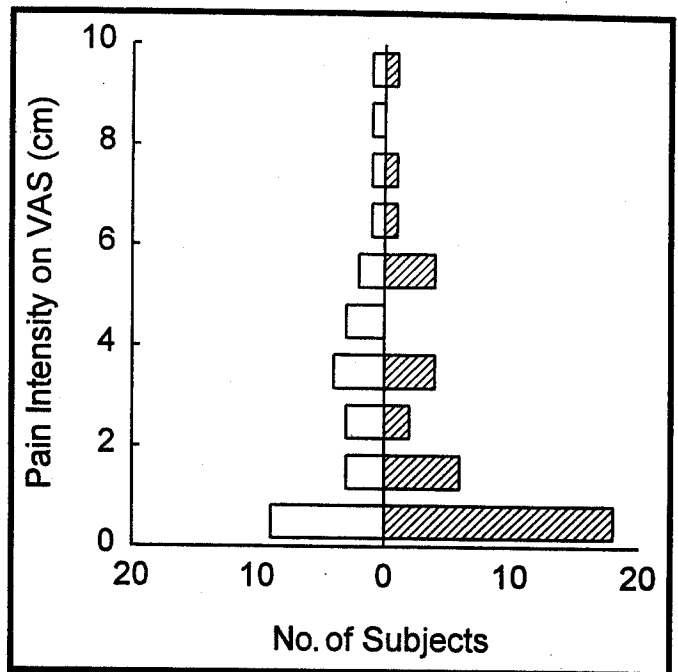


Figure 3. Distribution of pain intensity scores in the control group (unshaded boxes) and the treatment group (shaded boxes) at final assessment. Lower scores denote a better outcome. The difference between groups was not significant (Mann-Whitney U test, $P = .10$). VAS=visual analog scale.

subjects included in this measurement was much less than the 66 subjects who completed the study. This finding occurred because the reaching task used did not elicit pain in 41% of subjects at initial assessment (ie, the task was not a sufficient stimulus to elicit pain in a large proportion of subjects). Future studies would need to use a more demanding task to increase the sensitivity of measurement of pain intensity.

On average, the subjects in the control group did not demonstrate improvement during the experimental period. After 1 month of no treatment, 50% of the subjects in the control group reported worse functional disability scores and 32% showed a decrease in pain-free abduction ROM of greater than 10 degrees, compared with only 11% for both of these measures in the group receiving treatment ($P < .001$ and $P = .03$, respectively). It would seem, therefore, that access to appropriate treatment is essential to improve shoulder function and decrease shoulder pain and that shoulder pain of mechanical origin cannot be expected to recover spontaneously within 1 month. A delay in accessing treatment for shoulder dysfunction may result in increased functional disability.

Although the magnitude of the improvement in signs and symptoms in subjects receiving treatment was moderate, the clinical significance of the improvement should be assessed in light of the length of the period of

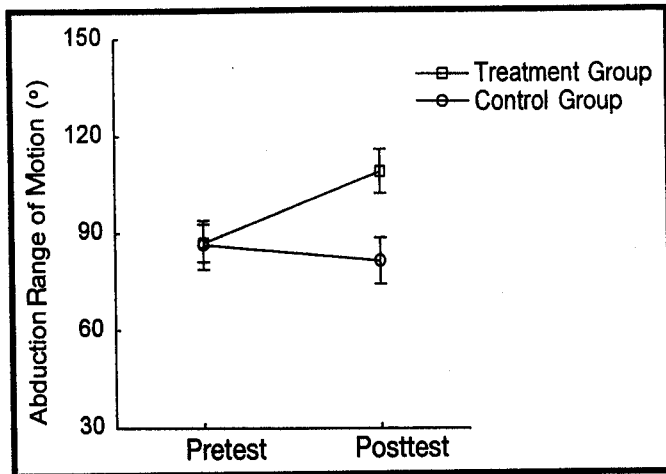


Figure 4. Pain-free abduction range of motion at the initial assessment (pretest) and final assessment (posttest) for treatment and control groups ($\bar{X} \pm SE$). Pain-free abduction range of motion improved more in the treatment group than in the control group (two-tailed paired-samples *t* test, $P = .006$).

treatment compared with the length of time that subjects had experienced shoulder pain. All subjects in the treatment group had chronic shoulder pain (ie, had been experiencing symptoms for greater than 3 months, with a median duration of 5 months). The improvement that occurred over the treatment period of only 1 month was perceived as worthwhile by these patients, who felt that they had improved "a lot" and that they could function more independently.

The use of a broad range of outcome measurements and the manner in which the exercise treatment was administered in this study, in our opinion, increase the generalizability of these results for the treatment of shoulder pain of local mechanical origin. Outcome measurements encompassing a range of important aspects associated with functional restoration of a painful shoulder problem were used, and the treatment group demonstrated improvements in a majority of these measures. Additionally, generalizability is enhanced because 10 therapists were involved in providing the exercise therapy that achieved these improvements.

Numerous features of this study ensure that the differences demonstrated between the two groups can be attributed, with reasonable confidence, to the treatment used rather than to other, extraneous variables. A random allocation process was used, and this process generated two groups well matched on demographic and baseline measurement criteria (Tab. 2). Because only three subjects in the treatment group and two subjects in the control group were unavailable for reassessment, representing a dropout rate of just 7%, differences between the two groups at the end of the study cannot be attributed to selection or selection-interaction biases.

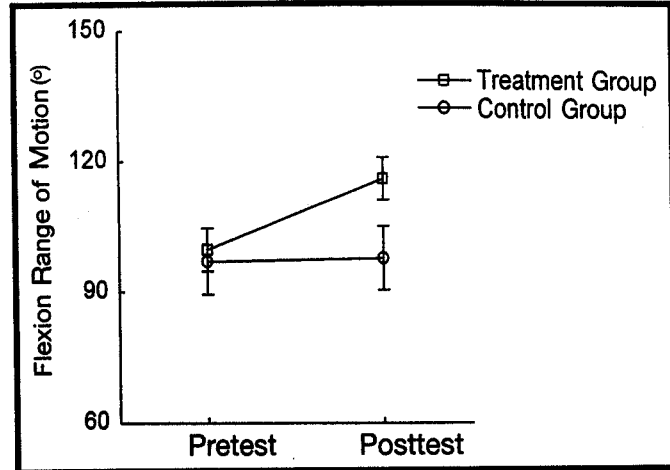


Figure 5. Pain-free flexion range of motion at the initial assessment (pretest) and final assessment (posttest) for treatment and control groups ($\bar{X} \pm SE$). Pain-free flexion range of motion improved more in the treatment group than in the control group (two-tailed paired-samples *t* test, $P = .04$).

Natural recovery and statistical regression can also be ruled out as explanations of the differences between the two groups, because the treatment group experienced better outcomes than did the control group. Additionally, observer bias was limited because all assessment and reassessment measurements were performed by investigators who were unaware of the group to which subjects had been assigned.

Because of the nature of treatment and the treatment/no-treatment design used in this study, it was not possible to keep the subjects or the therapists ignorant (blinded) as to the experimental condition for each subject. The use of a placebo treatment, which theoretically would have alleviated this threat to internal validity, was ruled out because the development of a comparable and convincing placebo treatment proved to be impossible. Therefore, the differences between the treatment and control groups in this study could be due to placebo or Hawthorne effects. It is our belief, however, that it is unlikely that either of these effects could explain the magnitude of the differences demonstrated.

Conclusion

This randomized controlled trial demonstrated that a program of physical therapy aimed at restoring muscle force, length, and control at the painful shoulder produces better outcomes than does no treatment. These results highlight the importance of muscle stretching, strengthening, and reeducation in the treatment of shoulder pain of local mechanical origin and suggest that spontaneous recovery of shoulder pain cannot be expected.

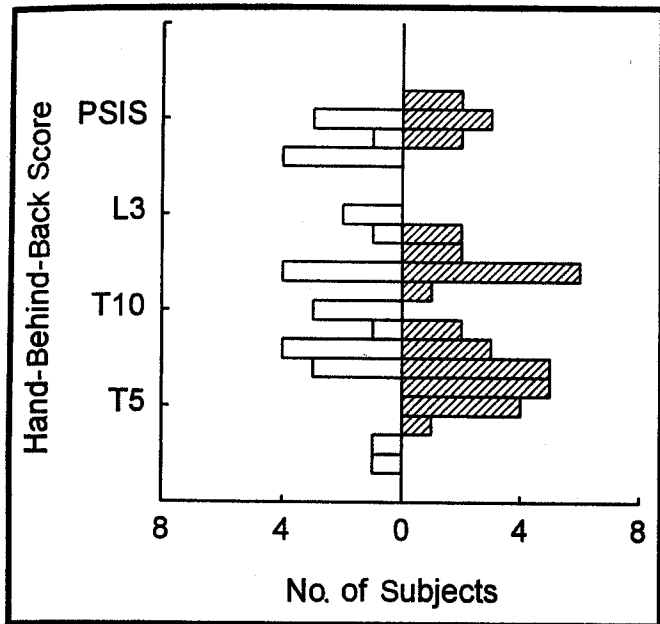


Figure 6. Distribution of hand-behind-back range-of-motion scores in the control group (unshaded boxes) and the treatment group (shaded boxes) at final assessment. The y-axis labels denote vertebral levels and pelvic landmarks. More superior landmarks denote a better outcome. The difference between groups was not significant (Mann-Whitney U test, $P=.21$). PSIS=posterior superior iliac spine.

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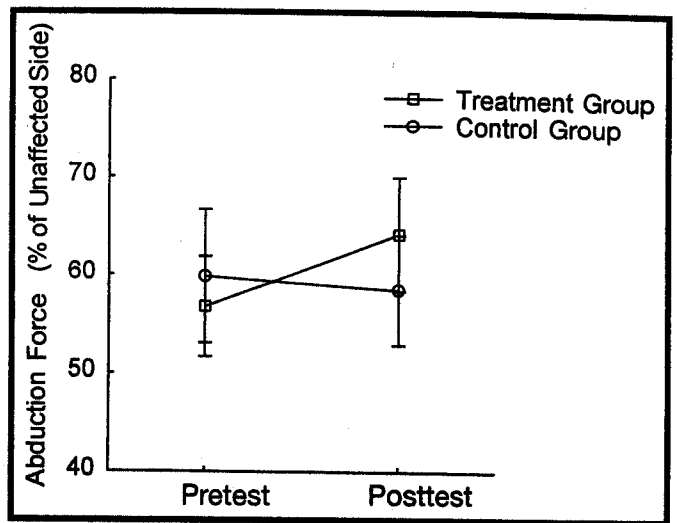


Figure 7. Abduction force at the initial assessment (pretest) and final assessment (posttest) for treatment and control groups ($\bar{X} \pm SE$). The difference between groups was not significant (two-tailed paired-samples t test, $P=.27$).

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● Invited Commentary

Ginn and colleagues are to be commended on their interesting and noteworthy article examining the effectiveness of physical therapy on shoulder pain and dysfunction. The investigators attempt to answer several questions: (1) Was physical therapy effective in treating shoulder pain? (2) Does a rehabilitation program consisting of stretching, strengthening, and muscle reeducation have an effect on mechanical shoulder pain? and (3) Do patients improve without treatment? I compliment the investigators on their ability to perform a prospective randomized controlled clinical trial.

As all physical therapists are aware, the efficacy of physical therapy for various musculoskeletal lesions has come under considerable scrutiny by many individuals. Some physicians have questioned the efficacy of physical therapy for certain shoulder conditions such as adhesive capsulitis¹ or following arthroscopic shoulder stabilization.^{2,3} Currently, numerous insurance companies are questioning the validity of specific therapeutic interventions and modalities and whether physical therapy is necessary for certain patients. Many are requesting outcome research to document physical therapy efficacy. Hence, this type of study is important and timely.

In this study, the investigators evaluated the effectiveness of physical therapy for shoulder pain. Four specific areas were assessed prior to and following a 1-month treatment program: (1) pain intensity, (2) functional disability, (3) range of motion, and (4) shoulder abduction force. The results indicated that the subjects improved in three of the four areas.

The subjects in this study exhibited a wide range of shoulder disorders. These disorders ranged from tendinitis to frozen shoulder. The majority of the disorders were rotator cuff pathologies (n=38, 58%). Eight individuals (12%), unfortunately, had no specific diagnosis. There was also a wide variation in the subjects' ages (range=20-85 years). The type of patients, chronicity of their conditions, and age may have influenced the results. In my practice, I have noted that younger patients with various orthopedic shoulder conditions recover faster and to a greater extent than do older patients. Neer⁴ reported a high rate of recovery for patients diagnosed with stage 1 impingement (<25 years of age) compared with patients with stage 2 (25-40 years of age) and stage 3 (>40 years of age) impingement. In addition, the duration of symptoms may influence the results. Patients who have exhibited a longer duration of shoulder disorders most likely will exhibit adaptive soft tissue changes; this type of patient may require a longer time period to improve. I have found this to be especially true for patients with adhesive capsulitis and patients with osteoarthritis.

The investigators performed a wide range of treatments that were individually determined by the treating therapist. The treatments focused on stretching, strengthening, and motor retraining. This represents a wide spectrum of treatment options. What types of treatments were most successful in improving the subjects' conditions? Eleven percent of the treatment group reported becoming worse and lost motion. What type of patients were they (which diagnosis), and what was their treatment?

The majority of the subjects in the treatment group improved with 4 weeks of physical therapy, whereas 50% of the subjects in the control group had worse functional disability scores and 32% of the subjects in that group exhibited a decrease in pain-free abduction range of motion. These results indicate that spontaneous recovery within 1 month does not occur. Furthermore, patients require an individualized rehabilitation program, or the condition may worsen. I have found this to be true and have explained this occurrence to physicians on numerous occasions. Did any of the subjects in the control group improve? If so, which diagnostic group showed improvement and to what extent?

The results of this study indicate moderate improvement in the subjects in the treatment group. Overall range of motion improved by 16 to 22 degrees. At the end of 4 weeks, abduction and flexion pain-free range of motion improved to approximately 105 and 115 degrees, respectively. The subjects' abduction isometric force and hand-behind-back motion improved, but this improvement was not statistically significant. These moderate levels of improvement do not underrate the study. The modest improvement may be due to the length of treatment or the type of pathology. Certain shoulder disorders improve more readily than others. As mentioned previously, young patients with tendinitis or impingement improve more rapidly; conversely, patients with complete rotator cuff tears or adhesive capsulitis improve slowly. The results of the study may have shown greater improvement if the subjects had been evaluated according to diagnosis. Additionally, I would have preferred to see the subjects evaluated using a standardized shoulder scoring system, such as the Shoulder and Elbow Society Form,⁵ which evaluates pain, motion, strength, stability, and 10 functional abilities. By using a standardized system, the validity has been established and enables other researchers and clinicians to compare results.

This study is an excellent start in answering difficult questions. But we need to know more. We need to know the who, what, and how of treating patients with shoulder pain and dysfunction. Who gets better, and who does not? What makes certain patients better, and what does

not? How should we do it—which specific treatment techniques? Again, I compliment the investigators on their study, which both documents their treatment approach and demonstrates favorable patient outcomes by using this approach.

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● Author Response

We thank Mr Wilk for his complimentary comments about our study and wholeheartedly agree with his plea for an increase in the number of clinical trials investigating the effectiveness of physical therapy.

We would like to address two issues raised by Mr Wilk in his commentary on our study. Mr Wilk asked what types of treatments were most successful. All treatment options used by the therapists in this study focused on improving aspects of shoulder muscle function. The subjects had various combinations of adaptive muscle shortening, muscle weakness, and abnormal scapulo-humeral rhythm, although most subjects had dysfunction in all of these areas. Consequently, stretching, strengthening, and muscle training were used to a different degree for each subject. In our opinion, and based on the functional anatomy of the shoulder region, these three elements of muscle function need to be normalized to decrease shoulder pain and improve functional range of motion.

As Mr Wilk implies, it would be useful to identify prognostic factors that differentiate responders and non-responders to treatment for shoulder pain. Identifica-

tion of such factors, however, was not an aim of our study and therefore our data provide little information on this issue. The literature on clinical trial methodology describes the hazards of *post hoc* analysis of subgroups.¹ As an example of such hazards, a landmark clinical trial investigating myocardial infarction demonstrated dramatic effects of aspirin in preventing reinfarction.² A *post hoc* analysis of subgroups by astrological birth sign indicated that this was true for patients born under all signs except Gemini and Libra!

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