

Manipulation of the Wrist for Management of Lateral Epicondylitis: A Randomized Pilot Study

Background and Purpose. Lateral epicondylitis (“tennis elbow”) is a common entity. Several nonoperative interventions, with varying success rates, have been described. The aim of this study was to compare the effectiveness of 2 protocols for the management of lateral epicondylitis: (1) manipulation of the wrist and (2) ultrasound, friction massage, and muscle stretching and strengthening exercises. **Subjects and Methods.** Thirty-one subjects with a history and examination results consistent with lateral epicondylitis participated in the study. The subjects were randomly assigned to either a group that received manipulation of the wrist (group 1) or a group that received ultrasound, friction massage, and muscle stretching and strengthening exercises (group 2). Three subjects were lost to follow-up, leaving 28 subjects for analysis. Follow-up was at 3 and 6 weeks. The primary outcome measure was a global measure of improvement, as assessed on a 6-point scale. Analysis was performed using independent *t* tests, Mann-Whitney *U* tests, and Fisher exact tests. **Results.** Differences were found for 2 outcome measures: success rate at 3 weeks and decrease in pain at 6 weeks. Both findings indicated manipulation was more effective than the other protocol. After 3 weeks of intervention, the success rate in group 1 was 62%, as compared with 20% in group 2. After 6 weeks of intervention, improvement in pain as measured on an 11-point numeric scale was 5.2 (SD=2.4) in group 1, as compared with 3.2 (SD=2.1) in group 2. **Discussion and Conclusion.** Manipulation of the wrist appeared to be more effective than ultrasound, friction massage, and muscle stretching and strengthening exercises for the management of lateral epicondylitis when there was a short-term follow-up. However, replication of our results is needed in a large-scale randomized clinical trial with a control group and a longer-term follow-up. [Struijs PAA, Damen PJ, Bakker EWP, et al. Manipulation of the wrist for management of lateral epicondylitis: a randomized pilot study. *Phys Ther.* 2003;83:608–616.]

Key Words: Manipulation, Tennis elbow, Treatment, pilot study, Wrist.

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Lateral epicondylitis ("tennis elbow") is characterized as pain on the lateral side of the elbow that is aggravated with movements of the wrist, by palpation of the lateral side of the elbow, or by contraction of the extensor muscles of the wrist.¹ The incidence of lateral epicondylitis in Dutch medical general practice is approximately 4 to 7 cases per 1,000 patients a year, with a peak incidence in the fifth decade.^{2,3} Lateral epicondylitis is a self-limiting complaint; without intervention, the symptoms will usually resolve within 8 to 12 months.^{4,5} Several interventions for the management of lateral epicondylitis have been described, including advising patients that the condition is self-limiting and providing encouragement, corticosteroid injections, use of orthotic devices, surgery, and use of thermal and electromagnetic modalities such as mus-

cle stretching and strengthening exercises, ultrasound, laser, massage, and electrotherapy.^{6,7}

Manipulation has frequently been used successfully for management of back and neck complaints^{8,9} and is thought to (1) free motion segments that have undergone disproportionate displacement or are felt to be hypomobile and (2) cause muscle relaxation.¹⁰⁻¹⁴ These mechanisms are thought to be associated with distribution of abnormal stresses within the joint, resulting in pain, restriction of motion, and potential inflammation.¹²

Manipulation of the wrist also has been described previously¹⁵; however, its effectiveness for management of lateral epicondylitis has not been demonstrated. The aim of our randomized clinical pilot study was to com-

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Dr Struijs, Mr Bakker, Dr Blankevoort, Dr Assendelft, and Dr van Dijk provided concept/idea/research design. Dr Struijs, Dr Damen, and Dr Assendelft provided writing and data analysis. Dr Damen provided data collection. Dr Struijs and Dr Blankevoort provided project management. Mr Bakker provided subjects, and Mr Bakker and Dr van Dijk provided facilities/equipment. Mr Bakker and Dr Blankevoort provided consultation (including review of manuscript before submission). The authors thank Jeroen Coster for administering the ultrasound, friction massage, and muscle stretching and strengthening procedures, the cooperating general practitioners for referring patients for the study, and Ms Nynke Smidt for collaboration in development of the treatment protocol and outcome measures.

This study was approved by the Medical Ethics Committee of Academic Medical Center.

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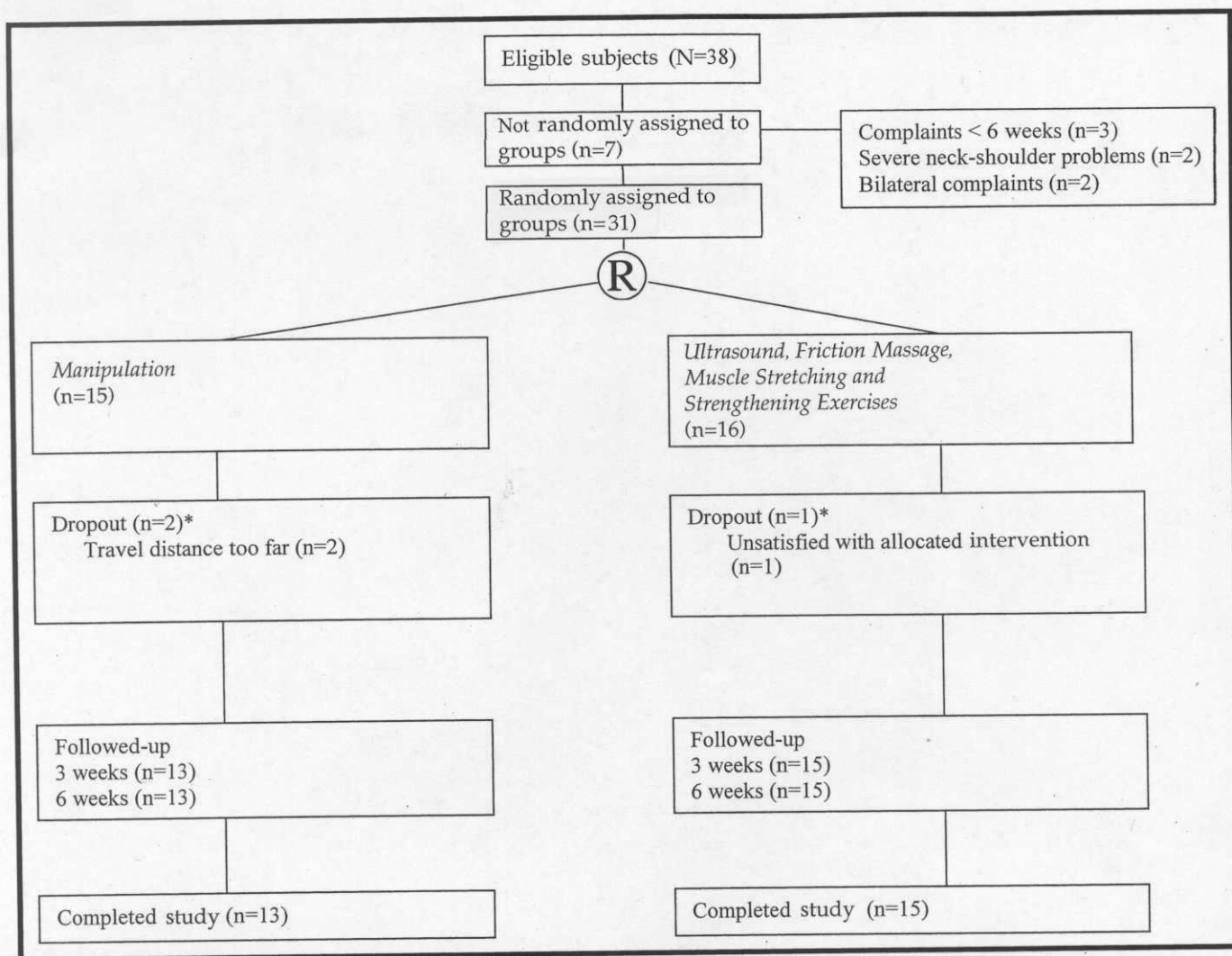


Figure 1. Flow diagram presenting the progress of the subjects in the study, including withdrawals and deviations from the protocol. ® = random assignment to study groups. Asterisk indicates subject withdrew from study before completion of intervention. The flow diagram is based on CONSORT guidelines.¹⁷

pare the effectiveness of manipulation of the wrist with the effectiveness of an intervention consisting of friction massage, ultrasound, and muscle stretching and strengthening exercises for the management of lateral epicondylitis.

Method

Between April and August 2000, patients were recruited for inclusion in our study by 10 medical general practitioners in The Hague, the Netherlands. They were referred to our research clinic if their general practitioner had made a diagnosis of lateral epicondylitis. The Dutch Guidelines for General Practitioners¹⁶ defines *lateral epicondylitis* as pain on the lateral side of the elbow that is aggravated with both pressure on the lateral epicondyle of the humerus and resisted extension of the wrist. Patients were included in our study if one of the investigators (PJD) determined that they had diagnosed lateral epicondylitis, with complaints being present for at

least 6 weeks and no longer than 6 months. Exclusion criteria were: no limitation in range of motion, as determined by the investigator; bilateral complaints; a definite decrease in pain for the last 2 weeks, as described by the patient; severe neck or shoulder problems likely to cause or maintain the elbow complaints, as determined by the investigator; treatment for the current episode; and inability to fill out questionnaires. However, because our study was a preliminary study and was not necessarily intended to find statistically significant differences, the number of requested patients was arbitrarily set at 30 patients.

The investigator (PJD) obtained patient data (eg, demographics, comorbidities) and baseline values of outcome measures before subjects were randomly assigned to study groups. After obtaining informed consent, subjects were included in the study. After inclusion, essential patient data were transferred by telephone to an inde-

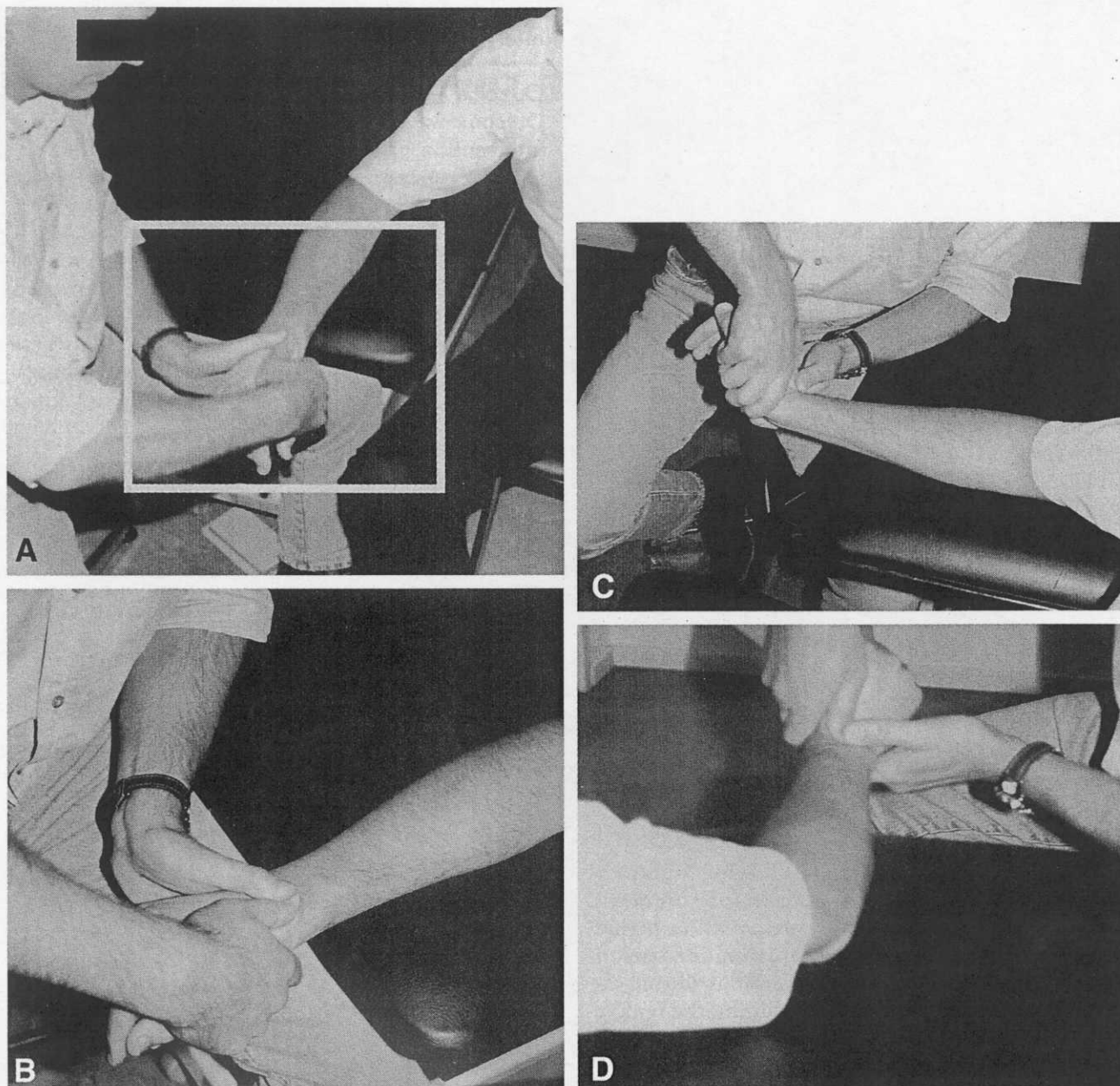


Figure 2. The manipulation. The wrist is manipulated from the neutral position (A and B) to maximal extension (C and D).

pendent researcher (PS), who drew a numbered sealed envelope. Subjects were randomly assigned to 1 of 2 groups: (1) a group that received manipulation of the wrist (group 1) or (2) a group that received ultrasound, friction massage, and muscle stretching and strengthening exercises (group 2). The independent researcher informed the physical therapist performing the randomized intervention the subject was assigned to receive, who then called the subject to arrange the first intervention session. Subjects were asked not to discuss their intervention with the investigator (PJD). Thus, the investigator remained unaware of the allocated intervention throughout the study.

Subjects

The progress of the subjects in this study, including withdrawals and deviations from the protocol, is shown in the flow diagram in Figure 1.¹⁷ Thirty-one subjects were randomly assigned to groups. Three subjects were not willing to continue their participation in the study and were regarded as dropouts: 2 subjects in group 1 who claimed after 2 and 3 intervention sessions that the distance to the physical therapy practice was too far and 1 subject in group 2 who was not satisfied with the allocated intervention after 1 session.

Procedure

Group 1. Subjects in this group were treated 2 times per week, with a maximum of 9 intervention sessions over the 6-week period of the study. All intervention sessions were conducted by the same physical therapist (EB), who was experienced in this manipulative procedure. As soon as complaints resolved, the intervention was stopped. An intervention session consisted of several manipulative maneuvers. The manipulative maneuver is a thrust technique and was performed as follows. Each subject rested the forearm of his or her affected side on a table with the palmar side of the hand facing down (Fig. 2A). The therapist sat at a right angle to the subject's affected side and gripped the subject's scaphoid bone between his thumb and index finger (Figs. 2A and 2B). He strengthened this grip by placing the thumb and index finger of his other hand on top of them. The therapist then extended the subject's wrist dorsally at the same time the scaphoid bone was manipulated ventrally (Figs. 2C and 2D). This part of the maneuver was repeated approximately 15 times. This procedure was repeated about 20 times, alternated by either forced passive extension of the wrist or extension against resistance. The duration of an intervention session was 15 to 20 minutes. No restrictions in use of the arm were imposed. No previous descriptions of this specific maneuver were found in literature. We developed the maneuver based on the wrist treatment described by Lewit.¹⁵

Group 2. Subjects in this group were using a protocol that was used in a previous large-scale trial on lateral epicondylitis.¹⁸ During the 6-week intervention period, the subjects underwent a total of 9 intervention sessions (3 sessions during the first week, 2 sessions during the second week, and 1 session per week during the remaining 4 weeks). Every session included a 7½-minute pulsed ultrasound treatment around the lateral humeral epicondyle (Sonopuls 590*).¹⁹ Pulsed ultrasound (20% duty cycle) was given with an intensity of 2 W/cm². In addition, subjects were treated with friction massage for approximately 10 minutes by the physical therapist. When pain subsided, subjects were instructed in muscle strengthening and stretching exercises by the physical therapist and were told to perform the exercises at home twice daily.²⁰ These exercises consisted of movements against resistance, rotational exercises, and occupational exercises. All sessions ended with stretching exercises of the wrist and elbow. The exercise program is described in detail elsewhere.²⁰ These exercises were intensified in 4 steps, with increasing resistance. Subjects were allowed one step up if all exercises could be performed without pain. Subjects were instructed to use the affected elbow

to their pain threshold. When pain had resolved, the intervention was stopped.

Outcome Assessment

Outcome was assessed 3 and 6 weeks after the start of the intervention. The primary outcome measure was the subjects' assessment of "global measure of improvement" on a 6-point scale (1="completely recovered," 2="much improved," 3="slightly improved," 4="not changed," 5="slightly worse," and 6="much worse"). A successful outcome was defined as "much improved" or "completely recovered." This method of dichotomizing the measurements was chosen before the study and was based on previous studies.^{8,18,21} Secondary outcome measures included severity of their main complaint, pain during the examination, pain during the day, and inconvenience during daily activities (all scored on an 11-point numeric scale, ranging from 0="no complaints" to 10="very severe complaints"). Other secondary outcome measures were pain-free grip force and maximum grip force. Grip force was measured in kilograms with a Jamar hand dynamometer[†] and was expressed as both mean improvement and improvement as a ratio of injured arm/noninjured arm.²² Other secondary outcome measures were pressure pain at the lateral epicondyle, which was measured in kilograms per square centimeter with a Pressure Threshold Meter[‡] and was expressed both as mean improvement and improvement as a ratio of injured arm/noninjured arm, and extension and the range of motion of flexion and extension of the wrist, which were measured using a goniometer. Measurements of force and range of motion used in our analysis were the mean of 3 measurements. To ascertain whether blinding was adequate, the investigator (PJD) was asked to guess the subjects' group assignment (manipulation versus ultrasound, friction massage, and muscle stretching and strengthening exercises) during the 6-week follow-up measurement.

Data Analysis

Data were analyzed using SPSS version 10.0.[§] Differences in continuous outcome measures were compared using independent *t* tests in case of normal distribution. Distribution was normal in severity of the patients' main complaint (pain during the examination and pain during the day). In case the distribution was not normal, the Mann-Whitney *U* test was applied. This was the case in inconvenience during daily activities, pain-free grip force, and maximum grip force. The dichotomous outcome, knowing the primary outcome measure (global

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Table 1.
Baseline Characteristics^a

Characteristic	Group 1	Group 2
No. of subjects	13	15
Age (y)		
\bar{X}	46.3	47.5
SD	8.4	11.5
Range	28-59	26-60
Duration of complaints (wk)		
\bar{X}	14.2	9.3
SD	12.3	6.1
Range	6-32	6-48
Sex (male/female)	9/4	6/9
Dominant arm affected (%)	76.9	73.3
Outcome measures		
Subjects' main complaint ^b		
\bar{X}	6.4	7.3
SD	1.6	1.5
Range	3-9	3-9
Pain at the moment ^b		
\bar{X}	3.9	4.4
SD	2.7	2.8
Range	2-8	2-8
Pain during day ^b		
\bar{X}	6.3	6.3
SD	1.3	1.4
Range	5-8	5-8
Inconvenience ^b		
\bar{X}	6.7	7.3
SD	2.4	1.4
Range	3-10	3-10
Pain-free grip force (PFGF) (kg)		
\bar{X}	19.7	15.9
SD	10.7	11.0
Range	2.5-40.4	1.5-38.6
Maximum grip force (MGF) (kg)		
\bar{X}	33.5	28.1
SD	13.7	14.4
Range	5.8-53.6	2.0-50.2
Ratio PFGF/MGF, noninjured arm		
\bar{X}	0.5	0.4
SD	0.3	0.3
Range	0.1-1.2	0.1-1.1
Pressure pain (kg/cm ²)		
\bar{X}	2.0	1.7
SD	0.5	0.2
Range	1.0-2.9	1.2-2.4

^a Group 1=subjects who received manipulation of the wrist, group 2=subjects who received ultrasound, friction massage, and muscle stretching and strengthening exercises.

^b Score on a numeric rating scale of 0 to 10, where 0="no complaints" and 10="very severe complaints."

measure of improvement or success rate), was analyzed using the Fisher exact test.

Results

The initial (baseline) demographic and outcome measurements were similar between the 2 groups at the $\alpha=.05$ level (Tab. 1). After 3 weeks of the intervention, our primary outcome measurements differed between groups, with the results indicating that manipulation was more effective than the other intervention used in our study: the global measure of improvement showed that 8 of the 13 subjects in group 1 were either "much improved" or "completely recovered" compared with 3 of the 15 subjects in group 2. The accompanying relative risk was 3.1 (95% confidence interval=1.0-9.2). The decreases in visual analog scale scores for the main complaint (pain during the activity that caused the most discomfort), pain at rest, pain during the day, and inconvenience were not different between the 2 groups (Tab. 2).

During the 6-week follow-up measurement, the decrease in scores for pain during the day differed between groups. The mean decrease in scores for pain during the day in group 1 was 5.2 (SD=2.4) compared with 3.2 (SD=2.1) in group 2. All other outcome measures were not different (Tab. 2).

After 3 and 6 weeks of intervention, no differences in mean improvement in range of motion was found within or between groups (Tab. 3). The average number of intervention sessions to reach a successful result ("much improved" or "completely recovered") was not different between groups. The investigator (PJD) was correct in guessing the intervention administered for 39% of the subjects (less than chance).

Discussion

Our study showed that manipulation of the wrist might have additional treatment effects compared with ultrasound, friction massage, and muscle stretching and strengthening exercises for management of lateral epicondylitis over the short term. Differences between groups were found for the primary outcome measure (global improvement) after 3 weeks of intervention (62% in group 1 versus 20% in group 2, $P=.05$) and for a secondary outcome measure (the decrease in scores for pain during the day) after 6 weeks of intervention (decrease of 2.8 points in group 1 versus decrease of 1.1 points in group 2, $P=.03$), indicating manipulation was more effective than the other interventions. The primary outcome measure was no longer statistically significant different between groups at 6 weeks. All other outcome measures showed no differences between groups. This finding was most likely due to the small number of subjects included, resulting in a low power. A *post hoc*

Table 2.
Results for Group 1 and Group 2 After 3 and 6 Weeks of Intervention^a

Outcome Measure	After 3 Weeks			After 6 Weeks		
	Group 1	Group 2	P	Group 1	Group 2	P
Global improvement, no. of subjects (%)	8/13 ^c (62%)	3/15 ^c (20%)	.05	11/13 (85%)	10/15 (67%)	.40
Subjects' main complaint, mean decrease ^b						
\bar{X}	2.6	2.1	.57	4.4	3.7	.33
SD	1.7	2.2		1.5	2.7	
Pain at the moment, mean decrease ^b						
\bar{X}	1.9	1.5	.34	3.1	2.7	.27
SD	2.7	2.6		2.5	3.4	
Pain during day, mean decrease ^b						
\bar{X}	2.6	1.7	.18	5.2 ^d	3.2 ^d	.03
SD	2.6	1.6		2.4	2.1	
Inconvenience, mean decrease ^b						
\bar{X}	3.0	2.3	.22	4.8	3.7	.19
SD	3.2	2.7		2.6	2.7	
Pain-free grip force (PFGF), mean increase (kg)						
\bar{X}	5.8	3.7	.11	14.8	8.5	.13
SD	11.1	11.5		17.3	10.6	
Maximum grip force, mean increase (kg)						
\bar{X}	1.8	-0.3	.13	6.2	4.0	.15
SD	10.0	7.4		10.5	11.7	
Ratio PFGF/MGF for noninjured arm, mean increase						
\bar{X}	0.1	0.1	.66	0.3	0.2	.31
SD	0.2	0.2		0.3	0.2	
Pressure pain, mean increase (kg/cm ²)						
\bar{X}	0.7	0.5	.12	1.6	0.7	.18
SD	1.0	0.6		2.0	0.8	
Ratio PP/PP for noninjured arm, mean increase						
\bar{X}	0.2	0.1	.20	0.3	0.3	.55
SD	0.3	0.3		0.2	0.3	

^a Group 1=subjects who received manipulation of the wrist, group 2=subjects who received ultrasound, friction massage, and muscle stretching and strengthening exercises.

^b Score on a numeric rating scale of 0 to 10, where 0="no complaints" and 10="very severe complaints."

^c Significant differences (Fisher exact test, $df=1$, $\alpha \leq .05$) between groups.

^d Significant differences (independent t test, $df=26$).

power analysis showed the power of our study, with our small sample size, to be 0.68 ($\beta = .32$), as calculated using the success rate after 3 weeks of intervention ($\alpha = .05$). This low power led to a great chance of a type II error in our study. The small sample size and resulting low power of the study implies that caution must be used in drawing definitive conclusions about the relative effectiveness of the 2 interventions used in our study. In addition, a worst-case analysis showed no differences between both groups on any outcome measure. From the results of our study, we believe no definitive conclusions about the relative effectiveness of the interventions can be drawn. Further research should be conducted, but until such research is reported, our data can be used to guide intervention.

The number of outcome measures we used might have increased the likelihood of type I error in our study.

However, the likelihood of type I error was limited by a priori deciding the hierarchy in our outcome measures. In addition, the outcome measures addressed different patient-oriented and non-patient-oriented dimensions.

Another shortcoming of our study was that only short-term effects were investigated. Although often patients are mainly interested in a fast recovery, effects over the long term might be less distinctive due to, for example, recurrence of complaints. In a recent study by Hay et al²³ comparing corticosteroid injections with nonsteroidal anti-inflammatory drugs, the initial advantage of injections subsided at long-term follow-up.

The manipulation was performed by an experienced physical therapist. Therefore, the results might be overestimated, compared with what may be expected with implementation on a larger scale with less-experienced

Table 3.
Range-of-Motion Measurements (in Degrees)^a

	Injured Arm		Noninjured Arm	
	Group 1	Group 2	Group 1	Group 2
Extension				
Baseline				
\bar{X}	63.0	60.5	64.9	64.6
SD	8.3	7.4	6.9	7.2
3 wk				
\bar{X}	64.5	63.0	65.3	64.7
SD	8.1	8.3	5.9	9.5
6 wk				
\bar{X}	62.0	64.6	63.8	65.4
SD	8.8	8.1	6.4	8.5
Range				
Baseline				
\bar{X}	110.9	112.2	115.3	117.9
SD	16.3	9.4	15.4	12.8
3 wk				
\bar{X}	112.9	113.9	116.0	123.7
SD	17.4	9.4	14.3	17.8
6 wk				
\bar{X}	118.6	121.2	119.0	123.7
SD	16.4	13.0	14.7	16.8

^a Group 1=subjects who received manipulation of the wrist, group 2=subjects who received ultrasound, friction massage, and muscle stretching and strengthening exercises. None of the possible calculable differences are statistically significant at the $P=.05$ level (independent t test and Mann-Whitney U test).

physical therapists. The subjects who received manipulation were not limited in their daily activities, the subjects who received the other intervention were restricted by the pain threshold. Therefore, the effectiveness of the manipulation might be affected by differences in co-interventions, such as this difference in restriction. In terms of baseline characteristics, differences between groups were present for the male/female distribution and duration of complaints. These differences may have introduced bias; however, sex has not been reported to be a prognostic factor² for effectiveness of interventions, and duration of complaints was longer in the group of subjects who received manipulation. The effectiveness of manipulation, therefore, may even be underestimated. In addition, in the absence of a control group, we could have been measuring the ineffectiveness of comparisons between the interventions.

Literature on manipulation of the wrist for management of lateral epicondylitis is nonexistent. In contrast, stretching of the forearm muscles as part of the intervention for lateral epicondylitis has been reported frequently.^{20,24} To achieve effective stretching, the wrist joint is moved to the endpoint of joint movement. This means movement to both maximal extension and max-

imal flexion. A secondary effect of this stretching might be the freeing up of displaced motion segments.

Despite its broad application, the mechanism by which manipulation may work is poorly understood. Manual therapy is used quite often for the spine and peripheral joints, despite of the inability of clinicians to accurately diagnose the pathway at which a manipulation is targeted. In people with low back pain and neck pain, spinal manipulation is thought to free motion segments that have undergone disproportionate displacements and to relax muscles by sudden stretching.¹²⁻¹⁴ Unwanted muscle activity in people with low back pain, in theory, can cause a limited range of motion to protect against sudden movements. Pain in these individuals often can be elicited by palpation on the insertion of these paravertebral muscles.²⁵

The advantages of the manipulation of the wrist are the potential effectiveness over the short term and the ability for the patient to maintain his or her daily activities without restrictions. In addition, manipulation might be more cost-effective due to a reduction in the number of treatments needed. Considering the relatively high prevalence of the injury, this cost-effectiveness might lead to a major cost reduction for payers.

Conclusion

The promising results of our study need replication in a large-scale randomized clinical trial that would include a control group and longer follow-up. The trial should be sufficiently powered and should compare manipulation of the wrist with the most commonly used and potentially effective conservative intervention strategies for lateral epicondylitis. Validated outcome measures should be used and evaluated over the short term, intermediate term, and long term.²¹ More physical therapists should be included, and inter-performer variability (variability in effectiveness of the manipulation among different therapists, as determined by means of a learning curve for application of the intervention) should be studied. In addition to the analysis of the effectiveness of the compared intervention strategies, a cost-effectiveness analysis should be incorporated in the trial, because reduced costs are an important advantage of the manipulative treatment. The analysis should concentrate on both direct and indirect costs.²⁶

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