Chapter 3. Results (continued)

Epicondylitis

Question #1: What are the appropriate methods and approaches for the early identification and diagnosis of epicondylitis?

Evidence Base

Articles were included for this question if they reported data that could be used for evaluation of the test in diagnosing epicondylitis, and they included ten or more patients.

Sixteen studies met the initial inclusion criteria. Six of those studies were excluded because they selected only patients who had had unsuccessful treatment for their condition (see Table 206). This is likely to engender a spectrum bias in the results, because such patients may have more severe conditions. Furthermore, the patient inclusion criteria for these trials imply that they were not intended to evaluate the diagnostic tests used, and that the diagnostic information provided was only incidental.

Ten studies remained for analysis after these exclusions. They included a total of 251 epicondylitis patients and 97 control subjects. Two (20%) were multi-center studies; the rest were conducted at a single institution. Six articles (60%) came from institutions outside the United States.

Internal Validity and Generalizability of Results

Because of the small size of the evidence base on diagnosis of epicondylitis, we will discuss the quality of literature issues related to both internal validity and generalizability of study results in the same section of this report.

Information related to these aspects of study quality was incompletely reported (see Table 207 and Table 208). The relevant data are summarized in Table 209 and Table 210. Some study aspects affect both internal validity and generalizability (e.g. age), so they were included in both sets of tables. Basic demographic information about patients (e.g. age and sex) was usually reported, but in some studies, this was not reported for the control subjects. Comorbidities were reported in only 3 of the 10 articles. Indicators of reliability in diagnostic studies (such as blinding of test operators) were rarely reported. Six studies (60%) had a potential selection bias for patients with relatively easy to diagnose conditions.

None of these studies focused exclusively on medial epicondylitis (golfer's elbow). One study[540] combined patients with lateral and medial epicondylitis (22 lateral and

2 medial). All other studies focused exclusively on lateral epicondylitis (tennis elbow).

Four articles (40%) reported only summary data on groups of patients(i.e., mean test results for cubital tunnel syndrome group and for control group), so sensitivity and specificity could not be determined from them. Two articles reported counts of positive and negative results, but did not report them both on patients and controls. There were only four articles (40%) from which both sensitivity and specificity of at least one test for epicondylitis could be calculated. Studies that report only one of these characteristics (sensitivity or specificity) are not reliable evidence on the effectiveness of a test, because they do not give assurance that the threshold was set to favor the reported characteristic at the expense of the unreported one.

Because so few articles reported sensitivity and specificity for any test for epicondylitis, and the poor quality of reporting study design and patient characteristics in these articles make it inadvisable to draw conclusions on the basis of a single study, we did not perform quantitative analyses of diagnostics for epicondylitis.

Results

A tabulation of patient selection and types of controls appears in Table 211. Nerve conduction tests are not used for diagnosis of epicondylitis because epicondylitis is not a nerve impairment syndrome. Therefore, patient selection was done on the basis of signs and symptoms (3 of the 10 articles), or by unspecified diagnostic criteria (7 of the 10 articles). Table 212 summarizes the reported types of tests and patient selection in those articles. Detailed information on study design, tests reported, patient groups, and patient inclusion/exclusion criteria for each article is found in Table 215, Table 216, Table 217 and Table 218.

Nine of the 10 articles (90%) reported only clinical signs and symptoms to diagnose epicondylitis. Table 213 lists the specific signs and symptoms that were reported as inclusion criteria for epicondylitis patients. Three studies performed clinical diagnosis but did not report the specific signs and symptoms that were assessed. Nerve conduction tests are not used for diagnosis of epicondylitis because epicondylitis is not a nerve impairment syndrome.

The only study that did not use clinical signs and symptoms to diagnose epicondylitis was Bredella[74]. This was an MRI study in which patients were "referred for MR imaging of the elbow to rule out lateral epicondylitis." The authors stated that epicondylitis is typically diagnosed clinically, and that the need for MRI only arises when "symptoms are resistant to medical management."

The resisted wrist extension test (RWE) was used most frequently in operational definitions of epicondylitis (six of the 10 articles). This test is positive if the patient feels pain or tenderness upon resisted extension of the wrist. Only 4 of the 6

actually reported RWE findings (Table 214). However, it was not possible to determine both sensitivity and specificity of the RWE test for any of these four studies. Two studies[541,542] required positive RWE findings in all patients included in the study, thus they cannot be used to assess the effectiveness of the RWE test because of selection bias. Friedman et al. did not report RWE findings in their control group, so specificity could not be determined. Wright et al. [72] had no control group, so specificity could not be determined.

Thus there were no articles in the evidence base we examined that reported sensitivity and specificity of the RWE test.

Conclusions

For diagnosis of epicondylitis, the evidence base is small and heterogeneous. None of the relevant studies are sufficiently large or well-designed to permit one to draw a strong evidence-based conclusion from them on any individual test for epicondylitis.

Table 206. Excluded Articles

Article	Reason for Exclusion
Pfaler, 1999 [543]	All patients previously treated
Pienimaki, 1998 [544]	All patients previously treated
De Smet, 1997 [545]	All patients previously treated
Pienimaki, 1997 [546]	All patients previously treated
Pienimaki, 1997 [547]	All patients previously treated
Potter, 1995 [548]	All patients previously treated

Table 207. Study Characteristics Relating to Internal Validity

Article	Funded by for-profit institution?	Inclusion criteria reported?	Exclusion criteria reported	Method of diagnosis reported	Patient selection	Comorbidity reported	Sex reported	Possible sex bias	Ages reported	Possible age bias	Duration of condition reported	Test operator blinded	Test reader blinded	Multiple readers	Method for multiple readers	Independent reference standard	Were patients given both test and reference
Benjamin, 1999 [549]	NR	Yes	Yes	Yes	Prospective	No	Yes	NC	Yes	NC	No	No	No	NR	NR	No	No
Bredella, 1999 [74]	NR	Yes	NR	Yes	Prospective	No	Yes	NC	Yes	NC	No	No	No	3	NR	No	No
Steinborn, 1999 [71]	NR	Yes	Yes	Yes	Retrospective	No	Yes	No	Yes	P	Yes	No	No	2	NR	No	No
Bauer, 1998 [550]	NR	Yes	NR	Yes	NR	No	Yes	No	Yes	No	No	No	No	NR	NR	No	No
Friedman, 1998 [73]	No	Yes	Yes	Yes	NR	Yes	Yes	No	Yes	No	Yes	Yes	No	NR	NR	No	No
Martin, 1998 [540]	NR	Yes	NR	Yes	Prospective	No	NR	GNR	Yes	P	Yes	No	Yes	2	Indep	No	No
Smith, 1994 [541]	NR	Yes	Yes	Yes	NR	No	Yes	NC	Yes	NC	Yes	No	Yes	3	Indep	No	No
Wright, 1992 [72]	NR	Yes	Yes	Yes	Prospective	Yes	Yes	NC	Yes	NC	No	Yes	No	NR	NR	No	No
Hyland, 1990 [551]	NR	Yes	Yes	Yes	Prospective	No	Yes	NC	NR	NC	Yes	No	Yes	2	Indep	No	No
Binder, 1984 [542]	NR	Yes	Yes	Yes	NR	Yes	Yes	GNR	Yes	ANR	Yes	No	No	NR	NR	No	No

Key:
Possible sex bias: No—proportion women in epicondylitis group within 20% of proportion of women in control group; P—Patients were more likely to be female; C—Controls were more likely to be female; GNR—Genders not reported for both groups; NC—Study did not contain a separate control group
Possible age bias: No—mean age of epicondylitis group within 5 years of mean age of control group; P—Patients were older than controls; C—Controls were older than patients; ANR—Ages not reported for both groups; NC—Study did not contain a separate control group
Method for multiple test readers: Indep—Independent

NR-Not reported

Table 208. Study Characteristics Relating to Generalizability of Results

Article	Years in which trial was conducted	Number of centers	Country(s) where trial was conducted	Inclusion criteria reported	Exclusion criteria reported	Are patient comorbidity reported?	Sex reported	Age reported	Duration of condition reported	Did all patients have previous conser-vative treatment?	Did any patients have previous surgical treatment?	Source of patients adequately described and generalizable to broader clinical practice?	Potential selection bias for easy cases?	Potential selection bias for difficult cases?
Benjamin, 1999 [549]	NR	Single	USA	Yes	Yes	No	Yes	Yes	No	No	No	No	Yes	No
Bredella, 1999 [74]	NR	Multiple (<5)	USA	Yes	NR	No	Yes	Yes	No	No	No	No	No	No
Steinborn, 1999 [71]	NR	Single	Germany	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	No
Bauer, 1998 [550]	NR	Single	USA	Yes	NR	No	Yes	Yes	No	No	No	No	Yes	No
Friedman, 1998 [73]	NR	Single	New Zealand	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	No
Martin, 1998 [540]	NR	Single	USA	Yes	NR	No	NR	Yes	Yes	No	No	No	Yes	No
Smith, 1994 [541]	NR	Single	United Kingdom	Yes	Yes	No	Yes	Yes	Yes	No	No	No	No	No
Wright, 1992 [72]	NR	Single	Australia	Yes	Yes	Yes	Yes	Yes	No	No	No	No	Yes	No
Hyland, 1990 [551]	NR	Multiple (>5)	Australia	Yes	Yes	No	Yes	NR	Yes	No	No	No	No	No
Binder, 1984 [542]	NR	Single	United Kingdom	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No

Key:
NR—not reported

Table 209. Quality of Reporting and Internal Validity of Results

Study characteristic	N studies reporting	Details
Whether trial was funded by a for-profit institution	1 (10%)	No for-profit funding: 1 (10%)
Patient inclusion criteria	10 (100%)	See Table 218
Patient exclusion criteria	7 (70%)	See Table 218
Method of diagnosis	10 (100%)	Clinical: 9 (90%) Non-clinical: 1 (10%)
Was selection of patients prospective or retrospective?	6 (60%)	Prospective: 5 (50%) Retrospective: 1 (10%)
Were patient comorbidities reported?	3 (30%)	Various
Was the sex distribution of patients reported?	9 (90%)	a–Percentage female: 55.5%
Was the percentage of females in the patient group within 20 percentage points of the control group?	3 (30%)	Yes: 3 (30%)
Were patient ages reported?	9 (90%)	a–Mean age: 42.3 years
Was the mean patient age within 5 years of the mean control age?	4 (40%)	Yes: 2 (20%) No, patients were = 5 years older: 2 (20%)
Was the duration of patients' condition reported?	6 (60%)	a–Mean duration: 14.6 months
Was the test operator blinded?	2 (20%)	Yes: 2 (20%)
Was the test reader blinded?	3 (30%)	Yes: 3 (30%)
Were there multiple test readers?	5 (50%)	2 readers: 3 (30%) 3 readers: 2 (20%)
What was the method for multiple test readers?	3 (30%)	Independent: 3 (30%)
Was the test compared to an independent reference standard?	0 (0%)	NA
Were all patients given the study test and the reference standard?	0 (0%)	NA

Key:
NA-not applicable
a–Calculated on a per-patient basis (i.e., weighted by number of patients in each study reporting this characteristic)

Table 210. Quality of Reporting and Generalizability of Results

Study characteristic	N studies reporting	Details
Years in which study was conducted	0 (0%)	NA
Number of centers in which trial was conducted	10 (100%)	Single: 8 (80%) Multiple (<5): 1 (10%) Multiple (>5): 1 (10%)
Country(s) were trial was performed	10 (100%)	USA: 4 (40%) Other: 6 (60%)
Patient inclusion criteria	10 (100%)	See Table 218
Patient exclusion criteria	7 (70%)	See Table 218
Were patient comorbidities reported?	3 (30%)	Various
Was the sex distribution of patients reported?	9 (90%)	a–Percentage female: 55.5%
Were patient ages reported?	9 (90%)	a–Mean age: 42.3 years
Was the duration of patients' condition reported?	6 (60%)	a–Mean duration: 14.6 months
Did all patients have previous conservative treatment?	10 (100%)	No: 10 (100%)
Did any patients have previous surgical treatment?	10 (100%)	No: 10 (100%)
Adequate reporting of study's source of patients	0 (0%)	NA
Was there a potential selection bias for easy cases?	6 (60%)	Yes: 6 (60%)
Was there a potential selection bias for hard cases?	0 (0%)	NA

Key:
NA-not applicable
a–Calculated on a per-patient basis (i.e., weighted by number of patients in each study reporting this characteristic)

Table 211. Patient and Control Group Selection in Epicondylitis Diagnosis

Type of controls	Patient selection (number of articles)		
	Symptoms/ presented	Unspecified diagnosis	Total
0	4		4
0	1		1
1	2		3
2	0		2
3	7		10

Table 212. Epicondylitis Tests and Patient Groups

Legend:

Numeric entries in each cell— Total number of articles, articles from which sensitivity and specificity can be calculated

Tests Reported	Patient selection	
	Symptoms/presented	Unspecified diagnosis
Nerve Conduction	0, 0	0, 0
Composite Nerve Conduction	0, 0	0, 0
Imaging	1, 0	2, 2
Sensory	1, 0	0, 0
Signs/Symptoms	2, 0	3, 1
Other	0, 0	3, 2

See **Table 3** for the definition of these groups

Table 213. Reported Clinical Inclusion Criteria in Studies of Lateral Epicondylitis

Article	Signs and symptoms used in diagnosis								
	RWE	RS	GR	RFE	WT	SE	MW	EA	Other
Benjamin, 1999 [549]									Clinical diagnosis
Bredella, 1999 [74]									MRI signal intensity
Steinborn, 1999 [71]	✓	✓			✓		✓		
Bauer, 1998 [550]									Clinical diagnosis
Friedman, 1998 [73]	✓	✓		✓					
Martin, 1998 [540]									Clinical diagnosis
Smith, 1994 [541]	✓								
Wright, 1992 [72]	✓		✓	✓		✓			
Hyland, 1990 [551]	✓		✓			✓		✓	
Binder, 1984 [542]	✓	✓	✓		✓				
Totals	6	3	3	2	2	2	1	1	4

Key:
RWE-pain or tenderness upon resisted wrist extension
RS-pain or tenderness upon resisted supination of forearm (also called Mill's test)
GR-grip strength
RFE-pain or tenderness upon resisted extension of middle finger
WT- weights test
SE-stretching of extensors
MW-muscle weakness
EA-pain or tenderness with extension adduction test

Table 214. Resisted Wrist Extension for the Diagnosis of Lateral Epicondylitis

Article	N	Was positive RWE a criterion for inclusion of patients in the study?	How many patients had pain or tenderness upon RWE?	Could sensitivity and specificity be derived from the published results?
Steinborn, 1999 [71]	23	No	NR	No
Friedman, 1998 [73]	17	No	4 (24%)	No
Smith, 1994 [541]	40	Yes	40 (100%)	No
Wright, 1992 [72]	17	No	16 (94%)	No
Hyland, 1990 [551]	25	No	NR	No
Binder, 1983 [542]	50	Yes	50 (100%)	No

RWE-Resisted wrist extension
NR-Not reported

Table 215. Epicondylitis–Study Design

Article	N centers	Epicon. groups	Epicon. patients	Negative groups	Negative subjects	Was the design prospective or retrospective?	What was the level of reporting?	Could sensitivity and specificity be determined?
Benjamin, 1999 [549]	Single	1	10	0	0	Prospective	Summary	No: only summary statistics reported
Bredella, 1999 [74]	Multiple (<5)	1	35	0	0	Prospective	Counts	No control group
Steinborn, 1999 [71]	Single	1	23	1	7	Retrospective	Counts	Reported by authors
Bauer, 1998 [550]	Single	1	10	1	7	NR	Summary	No: only summary statistics reported
Friedman, 1998 [73]	Single	1	17	1	7	NR	Summary	No: only summary statistics reported
Martin, 1998 [540]	Single	1	24	1	16	Prospective	Counts	Calculated by ECRI
Smith, 1994 [541]	Single	1	40	0	0	NR	Counts	Calculated by ECRI
Wright, 1992 [72]	Single	1	17	0	0	Prospective	Summary	No: only summary statistics reported
Hyland, 1990 [551]	Multiple (>5)	1	25	0	0	Prospective	Counts	No control group
Binder, 1984 [542]	Single	1	50	1	60	NR	Counts	Calculated by ECRI

Table 216. Epicondylitis–Tests Reported

Article	Signs/ Symptoms	Sensory Tests	Nerve Conduction	Composite Nerve Cond.	Imaging	Other
Benjamin, 1999 [549]	☑	☐	☐	☐	☐	☐
Bredella, 1999 [74]	☐	☐	☐	☐	☑	☐
Steinborn, 1999 [71]	☐	☐	☐	☐	☑	☐
Bauer, 1998 [550]	☐	☐	☐	☐	☐	☑
Friedman, 1998 [73]	☑	☐	☐	☐	☐	☐
Martin, 1998 [540]	☐	☐	☐	☐	☑	☐
Smith, 1994 [541]	☐	☐	☐	☐	☐	☑
Wright, 1992 [72]	☑	☑	☐	☐	☐	☐
Hyland, 1990 [551]	☑	☐	☐	☐	☐	☐
Binder, 1984 [542]	☑	☐	☐	☐	☐	☑

Table 217. Epicondylitis–Patient Groups

Article	Disorder type	Patient selection	Number of patients for which results are reported	Percent female	Mean age	Age of youngest	Age of oldest	Duration of condition be-fore treatment (months)	Shortest duration	Longest duration	Are patient comorbidities reported?
Benjamin, 1999 [549]	Epicondylitis	Unspecified diagnosis	10	30	42						No
Bredella, 1999 [74]	Epicondylitis	Symptoms/ presented	35	51	45	22	63		3	36	No
Steinborn, 1999 [71]	Normal	Healthy volunteers	7	71	25	22	29				No
Steinborn, 1999 [71]	Epicondylitis	Unspecified diagnosis	23	65	47	29	58	17.1	1	84	No
Bauer, 1998 [550]	Normal	Healthy volunteers	7	0	38.8						No
Bauer, 1998 [550]	Epicondylitis	Unspecified diagnosis	10	0	40.8						No
Friedman, 1998 [73]	Normal	Healthy volunteers	7	100	34.6						Yes
Friedman, 1998 [73]	Epicondylitis	Unspecified diagnosis	17	100	38.9			26			Yes
Martin, 1998 [540]	Normal	Healthy volunteers	16	NR	31	22	46				No
Martin, 1998 [540]	Epicondylitis	Unspecified diagnosis	24	NR	38	29	62	5.5	1	24	No
Smith, 1994 [541]	Epicondylitis	Unspecified diagnosis	40	55	40			23			No
Wright, 1992 [72]	Epicondylitis	Symptoms/ presented	17	65	44.7	36	54		2	120	Yes
Hyland, 1990 [551]	Epicondylitis	Symptoms/ presented	25	24				21.9	2	156	No
Binder, 1984 [542]	Normal	Healthy volunteers	60	NR							Yes
Binder, 1984 [542]	Epicondylitis	Unspecified diagnosis	50	68	43			4.5	1	12	Yes

Table 218. Epicondylitis–Reported Inclusion and Exclusion Criteria

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Benjamin, 1999 [549]	Clinical diagnosis of lateral epicondylitis.	Prior elbow surgery, bilateral symptoms
Bredella, 1999 [74]	Patients referred for MRI imaging of the elbow to rule out lateral epicondylitis. All had symptoms. None had corticosteroid injection in the 3 months prior to MRI.	None reported
Steinborn, 1999 [71]	Clinical diagnosis of lateral epicondylitis, based on clinical findings and history including muscle weakness, pain localized to the lateral epicondyle,and aggravation of pain by weight-bearing and resisted supination and wrist extension.	Steroid injections in the 2 months before MRI.
Bauer, 1998 [550]	Clinical diagnosis of tennis elbow.	None reported
Friedman, 1998 [73]	Patients who had been assessed or treated at a rehabilitation clinic. Inclusion criteria were clinical features such as 1) tenderness at the lateral eipcondyle; 2) pain in the elbow or lateral forearm on resisted wrist extension; 3) pain in the elbow or lateral forearm on resisted finger extension; 4) pain in the elbow or lateral forearm on resisted wrist supination.	Bilateral symptoms, history of fibromyalgia or other disability involving upper extremity.
Martin, 1998 [540]	Diagnosis of either lateral or medial epicondylitis based on history and physical exam.	None reported
Smith, 1994 [541]	Patients with unilateral epicondylitis recruited from rheumatology outpatient clinics. Localized pain and lateral epicondylar tenderness, increased pain on wrist extension.	Bilateral symptoms, cervical spine symptoms.
Wright, 1992 [72]	Patients reported lateral elbow pain of at least 6 weeks duration, and if they experienced pain during two or more of the following five tests: 1) Palpation of the lateral epicondyle; 2) Resisted wrist extension; 3) Passive stretching of the extensor muscle group; 4) Pain on gripping a hand dynamometer; 5) Pain on resisted extension of the middle finger.	Bilateral symptoms, neurological impairment, serious injury or fracture to the upper limbs, cervical or thoracic spine, history of any arthritic condition.
Hyland, 1990 [551]	Lateral elbow pain. Non-irritable symptomatic elbows in which pain provoked by activity or examination was quickly relieved with a short period of rest. Positive extension-adduction test with the forearm in supination position, and at least one of the following: pain upon resisted wrist extension, or pain upon passive stretch of the forearm extensors.	Pain of cervical origin or contribution.
Binder, 1984 [542]	Localized tenderness near the lateral epicondyle and pain on resisted wrist dorsiflexion.	Localized or generalized arthritis, abnormal ESR (undefined), positive Rose-Waaler, or neuro-logical symptoms or signs in the affected limb.

Question #2. What are the specific indications for surgery for epicondylitis?

No published studies directly address specific indications for surgery for epicondylitis. Therefore, in this section we present the characteristics of patients who have received surgery as described in published studies. Because patients enrolled in clinical trials may differ from the general population of patients encountered in general practice, these data may not accurately reflect the characteristics of most patients who have received surgery for epicondylitis. However, they represent the most comprehensive set of available information.

Evidence base

For this question, we included controlled trials and case series that described patients being surgically treated for epicondylitis. We identified 19 such studies.

Failure of conservative treatment

Nine of the 19 available studies (47.4%) reported that the main criterion for entry into the trial was the presence of epicondylitis that had failed to respond to conservative treatment. Eight of the 19 available studies (42.1%) reported no details about patient inclusion/exclusion criteria for entry into the trial.

Patient demographics

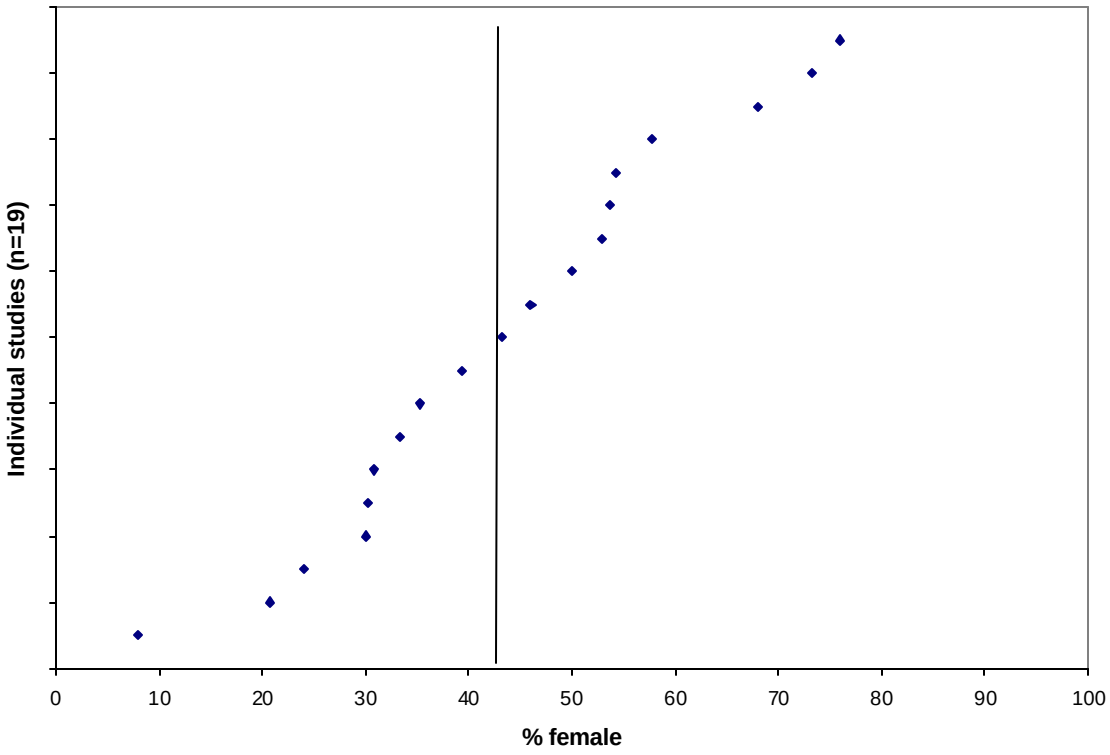
The ages and gender composition of the patient groups included in the studies are listed in Table 219. All 19 of the studies provided information about the sex of their patients. The sexes were almost equally represented in the patient groups. Overall, 43.61% of the patients were female, with a range from 7.9 to 76% female. The gender compositions of patient groups from the individual studies are shown in Figure 57. Fifteen of the 19 available studies reported information about the ages of the patients. Patients who received surgery for epicondylitis were predominantly of middle age. The mean age of the patients was 44.3 years old, with a range from 16 to 70 years of age. The mean ages and range of ages of each individual study are shown in Figure 58.

Table 219. Age and sex of patients receiving surgery for epicondylitis

Study	Number of patients	Number of males	Number of females	Percent female	Age reported as mean or median?	Age	Age of youngest patient	Age of oldest patient
Grundberg 2000 [552]	34	17	17	50.0	Mean	43	27	64
Almquist 1998 [83]	61	37	24	39.3	Mean	43.3	27	63
Bankes 1998 [553]	24	11	13	54.2	Mean	45.3	32	54
Organ 1997 [554]	34	16	18	52.9	Mean	40	28	70
Wilhelm 1996 [84]	166	70	96	57.8	Mean	44.5	21	62
Gabel 1995 [555]	26	18	8	30.8	Mean	43	17	64
Kurvers 1995 [556]	40	28	12	30.0	Mean	42	22	56
Ollivierre 1995 [557]	48	38	10	20.8	Mean	42	16	66
Newey 1994 [558]	28	13	15	53.6	Mean	44.8	NR	NR
Verhaar 1993 [559]	63	42	21	33.3	Mean	45	25	67
Wittenberg 1992 [560]	86	60	26	30.2	Mean	47.5	25	67
Vangsness 1991 [561]	38	35	3	7.9	Mean	43	21	65
Tan 1989 [562]	25	8	17	68.0	NR	NR	NR	NR
Goldberg 1988 [563]	30	8	22	73.3	NR	NR	NR	NR
Chotigavanich 1986 [564]	50	12	38	76.0	NR	NR	NR	NR
Calvert 1985 [565]	37	21	16	43.2	Mean	43.7	NR	NR
Baumgard 1982 [566]	34	22	12	35.3	Mean	48	30	67
O'Neil 1980 [567]	50	27	23	46.0	NR	NR	NR	NR
Rosen 1980 [568]	50	38	12	24.0	Mean	49	18	64

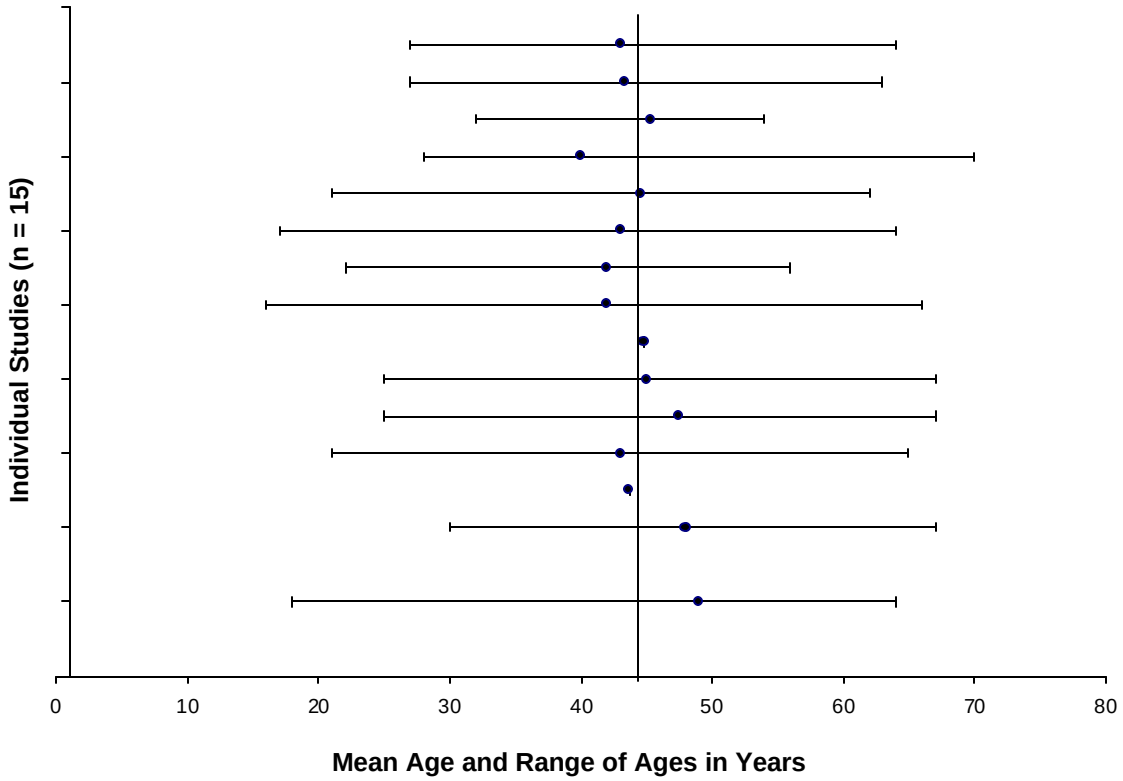
NR = not reported

Figure 57. Sex distribution in trials of surgical treatment for epicondylitis



The vertical line indicates the mean % of females

Figure 58. Distribution of patient ages in studies of surgical treatment for epicondylitis



The vertical line indicates the mean age

Signs and symptoms

Descriptions of signs and symptoms of the patients before treatment were incompletely reported. The number of studies reporting on each sign and symptom are listed in Table 220. Only six different signs and symptoms were reported on, and less than 16% of the studies reported on the presence of any given symptom or sign, as is shown in Figure 59. The mean percentages of patients with each sign and symptom reported by the studies are listed in Table 221 and shown in Figure 60.

Only three out of the 19 studies reported the duration of symptoms before treating the patients with surgery. These data are listed in Table 222. The mean duration before treatment was 27.7 months, with a range of 3 to 126 months.

Because so few studies reported on signs and symptoms, or duration of symptoms, it is difficult to arrive at a generalized characterization of patients who received surgical treatment for epicondylitis.

Table 220. Reporting of signs and symptoms in studies of surgical treatment for epicondylitis

Sign or symptom	Number of studies reporting
Clumsiness	0
Lifting test	0
Middle finger test	0
Pain	2
Resisted pronation	3
Resisted supination	1
Resisted wrist extension	1
Restricted range of motion	0
Stiffness	0
Swelling	1
Symptoms with ADLs	0
Tenderness	3
Weakness	0
Weakness of grip	0

ADL = activities of daily living

Figure 59. Reporting of symptoms and signs in studies of surgical treatment for epicondylitis

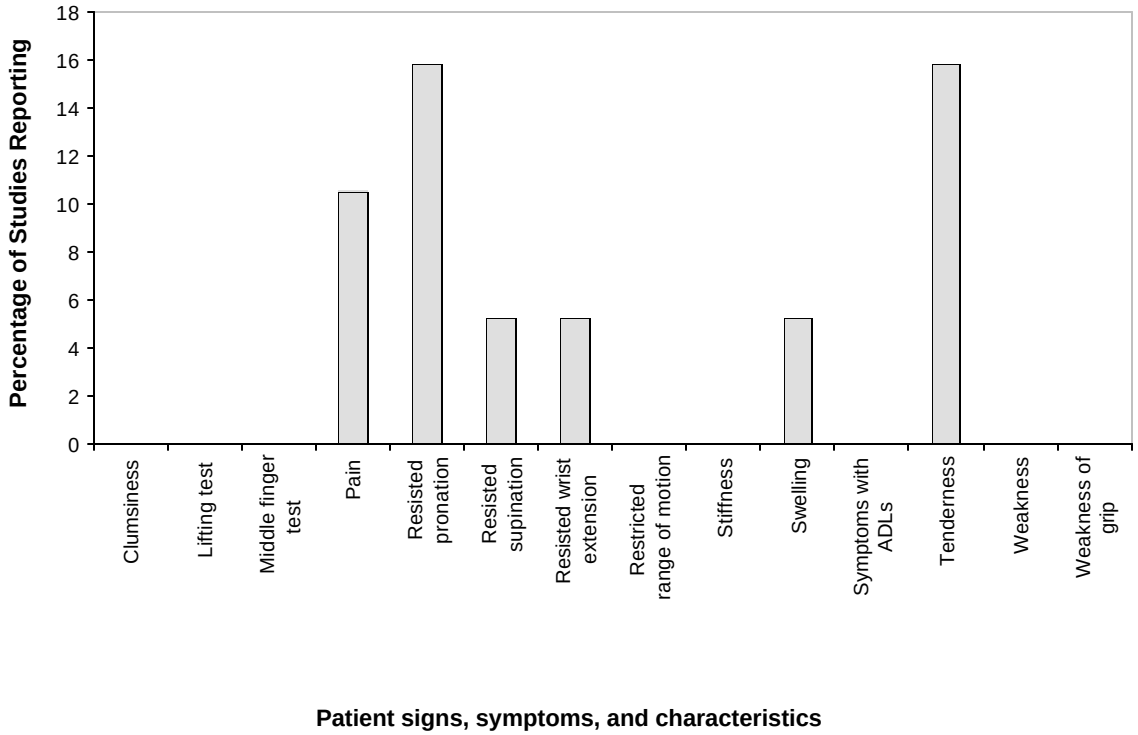


Table 221. Signs and symptoms of patients treated with surgery for epicondylitis

Study	Number of patients	Sign or symptom	Number of patients with sign or symptom	Percentage of patients
Almquist 1998 [83]	61	Pain	61	100.0
Goldberg 1988 [563]	30	Pain	30	100.0
Gabel 1995 [555]	26	Resisted pronation	26	100.0
Verhaar 1993 [559]	63	Resisted pronation	34	54.0
Baumgard 1982 [566]	34	Resisted pronation	34	100.0
Verhaar 1993 [559]	63	Resisted supination	31	49.2
Verhaar 1993 [559]	63	Resisted wrist extension	63	100.0
Goldberg 1988 [563]	30	Swelling	3	10.0
Almquist 1998 [83]	61	Tenderness	61	100.0
Gabel 1995 [555]	26	Tenderness	26	100.0
Verhaar 1993 [559]	63	Tenderness	63	100.0

Figure 60. Symptoms of patients with epicondylitis

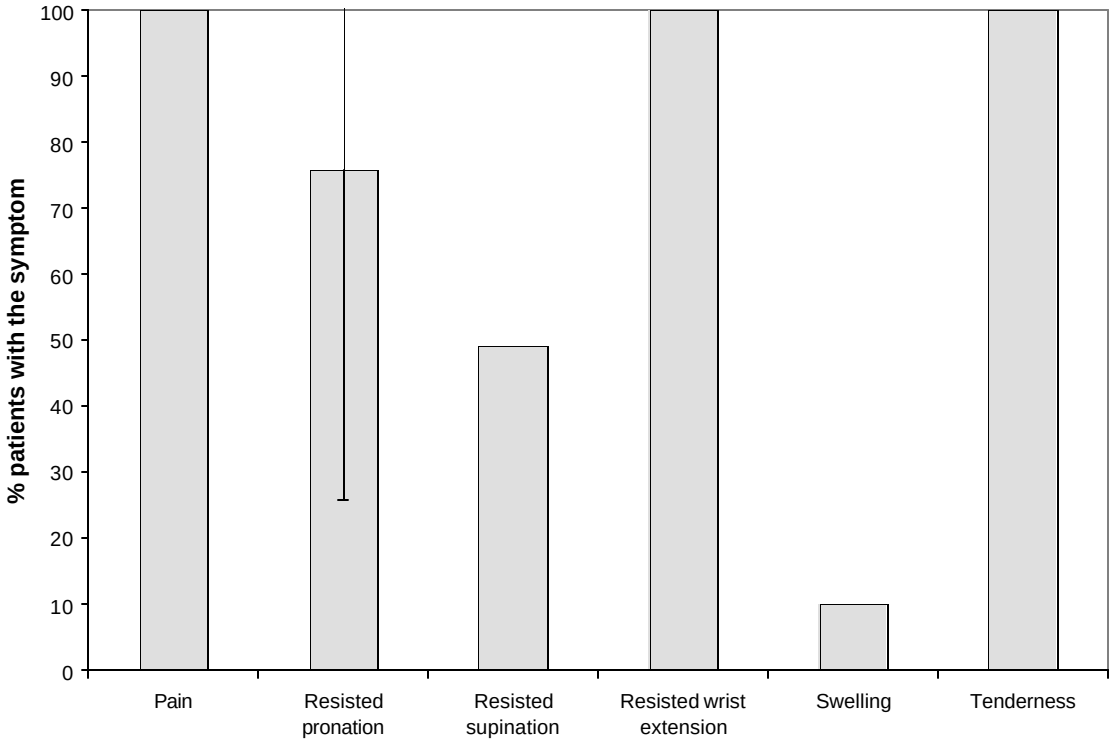


Table 222. Duration of symptoms before surgical treatment for epicondylitis

Study	Number of patients	Mean duration, months	Shortest duration, months	Longest duration, months
Grundberg 2000 [552]	34	18	3	66
Almquist 1998 [83]	61	31.3	6	72
Bankes 1998 [553]	24	32.2	11	126

Employment characteristics

Only five of the 19 studies reported employment-related data on their patients. The occupations of patients receiving surgery for epicondylitis and the percentage of patients in each study with that occupation are listed in Table 223. The number of studies reporting each occupational category are shown in Figure 61, and the reported percentages of patients with each occupation are shown in Figure 62.

The categorization of occupations used by the studies was not uniform, but in some cases, categories can be combined across studies. However, in many cases, descriptions of types of employment are unclear and there may be considerable overlap between groups. From the reported information it is not possible to determine the amount and type of arm/hand use required on a regular basis for any of the occupational groups.

Table 223. Reported occupations of patients receiving surgery for epicondylitis

Study	Occupation	Number of Patients	Number of patients with occupation	Percent of patients with occupation
Verhaar 1993 [559]	Assistive living services	63	4	6.3
Kurvers 1995 [556]	Beauty specialist	40	1	2.5
Chotigavanich 1986 [564]	Businessman	50	9	18.0
Verhaar 1993 [559]	Cleaning services	63	4	6.3
Kurvers 1995 [556]	Clerical and administrative support	40	4	10.0
Tan 1989 [562]	Clerical and administrative support	25	3	12.0
Verhaar 1993 [559]	Clerk	63	1	1.6
Verhaar 1993 [559]	Construction	63	7	11.1
Wittenberg 1992 [560]	Domestic workers	86	12	14.0
Tan 1989 [562]	Factory operator	25	3	12.0
Verhaar 1993 [559]	Farmer/gardener	63	4	6.3
Chotigavanich1986 [564]	Government officer	50	10	20.0
Kurvers 1995 [556]	Homemaker	40	8	20.0
Verhaar 1993 [559]	Homemaker	63	10	15.9
Tan 1989 [562]	Homemaker	25	7	28.0
Chotigavanich 1986 [564]	Homemaker	50	27	54.0
Tan 1989 [562]	Laborer	25	2	8.0
Chotigavanich 1986 [564]	Laborer	50	4	8.0
Verhaar 1993 [559]	Machine operator/mechanic	63	11	17.5
Kurvers 1995 [556]	Manual Worker	40	15	37.5
Wittenberg 1992 [560]	Manual Worker	86	31	36.0
Kurvers 1995 [556]	Music (organ) student	40	1	2.5
Kurvers 1995 [556]	Nurse	40	4	10.0
Tan 1989 [562]	Nurse	25	3	12.0
Verhaar 1993 [559]	Piano player	63	1	1.6
Kurvers 1995 [556]	Psychologist	40	1	2.5
Kurvers 1995 [556]	Sales workers - manager/supervisors	40	1	2.5
Wittenberg 1992 [560]	Sales workers - manager/supervisors	86	12	14.0
Verhaar 1993 [559]	Sculptor	63	1	1.6
Kurvers 1995 [556]	Teacher	40	1	2.5
Verhaar 1993 [559]	Teacher	63	1	1.6
Tan 1989 [562]	Teacher	25	4	16.0
Tan 1989 [562]	Technical	25	3	12.0
Wittenberg 1992 [560]	Typists	86	13	15.1
Kurvers 1995 [556]	Unemployed	40	2	5.0
Wittenberg 1992 [560]	Unemployed	86	6	7.0

Figure 61. Percentage of studies reporting occupations of patients with epicondylitis

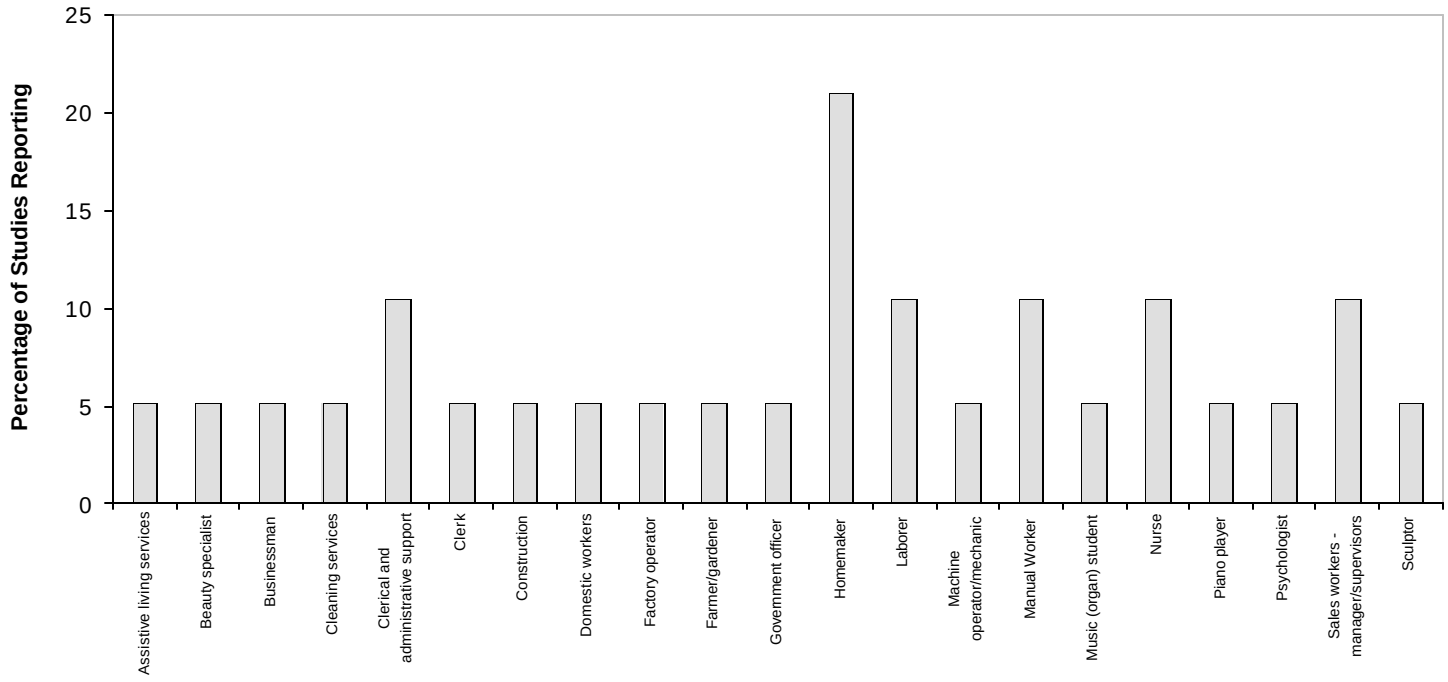
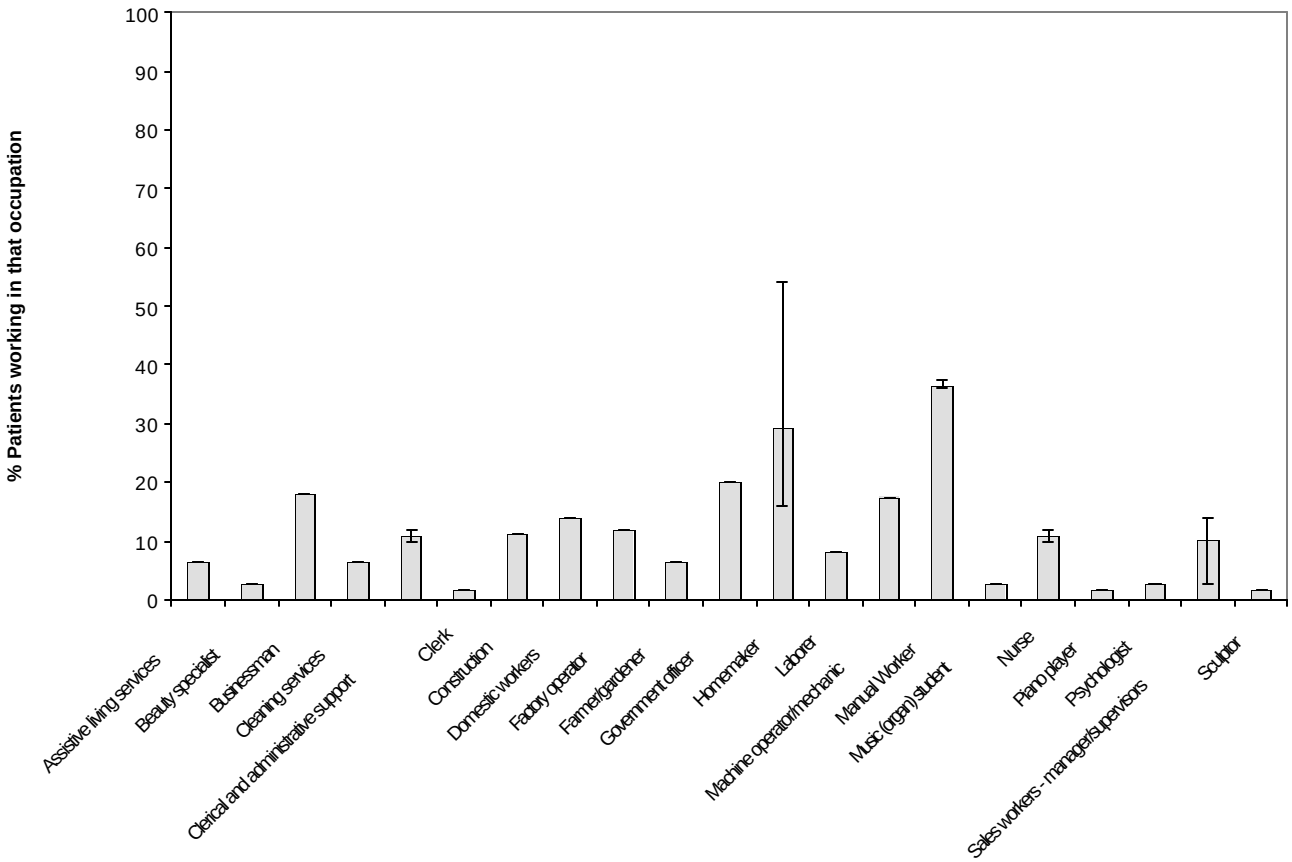


Figure 62. Percentage of patients with reported occupations receiving surgery for epicondylitis



Comorbidities

Comorbid conditions were not reported by any of the 19 studies. One study excluded patients who had carpal or cubital tunnel syndrome in addition to epicondylitis. Because of the lack of information, no conclusions can be drawn regarding the presence of comorbidities among patients receiving surgery for epicondylitis or the impact of comorbidities on whether a patient is a candidate for surgery.

Conclusions

Nineteen studies of patients who received surgery for epicondylitis were identified. A typical patient who received surgery for epicondylitis was middle-aged and equally likely to be male or female, but due to a lack of reported data, few trends or characteristics of patients who received surgery could be identified.

Question #3. What are the relative benefits and harms of various surgical and nonsurgical interventions for persons with epicondylitis?

Evidence base

We considered only controlled trials that evaluated therapies as treatments for patients with epicondylitis for this section of the report. We retrieved 57 studies that met the inclusion criteria (see the section Inclusion Criteria). Six were excluded because they contained reporting or design difficulties serious enough to preclude interpretation of the results. These studies, and the reasons for their exclusion, are shown in Table 224. Thirty-eight randomized controlled trials, four randomized crossover trials, and eight controlled trials that evaluated eighteen different types of therapies as treatments for epicondylitis were included in the answer to this question. These trials are listed in Table 225. All of the trials studied only patients with lateral epicondylitis except for that of Stahl 1997, who studied patients with medial epicondylitis, and Brattberg 1983, who studied a mixed population of patients with lateral or medial epicondylitis. We have organized our answer to this question into sub-sections, one for each type of treatment.

Table 224. Excluded studies

Study	Reason for exclusion
Simunovic 1998 [569]	Patients were treated until they improved, and only then were they crossed over to the placebo treatment. This creates a bias in favor of improvement.
Burton 1985 [570]	Insufficient details to allow comparison of patient groups. Data from control group not reported.
Heyse-Moore 1984 [571]	Patients were allocated into different treatment groups on the basis of what symptoms they presented with, and thus the treatment groups cannot be directly compared.
Rosenthal 1982 [572]	It is unclear from the few details provided whether the patients actually had lateral epicondylitis.
Day 1978 [573]	Patients were treated until they improved. This creates a bias in favor of improvement.
Baily 1957 [574]	Many patients received confounding co-interventions, such as extra injections, physiotherapy, etc. that are incompletely described.

Table 225. Trials evaluating interventions for epicondylitis

Therapies evaluated	Study	Trial Design
Acupuncture	Molsberger 1994 [575]	Randomized controlled trial
	Haker 1990 [576]	Randomized controlled trial
Bracing	Wuori 1998 [577]	Randomized controlled crossover
	Forbes 1990 [578]	Crossover
Bracing compared to physiotherapy	Solveborn 1997 [579]	Controlled trial
Bracing plus physiotherapy	Clements 1993 [580]	Controlled trial
ESWT	Rompe 1996 [581,582]	Randomized controlled trial
GAGPs injections	Akermark 1995 [583]	Randomized controlled trial
Laser	Basford 2000 [584]	Randomized controlled trial
	Papadopoulos 1996 [585]	Randomized controlled trial
	Krasheninnikoff 1994 [586]	Randomized controlled trial
	Vasseljen 1992 [587]	Randomized controlled trial
	Haker 1991 [588]	Randomized controlled trial
	Haker 1991 [589]	Randomized controlled trial
	Haker 1990 [590]	Randomized controlled trial
Laser compared to ultrasound plus massage	Vasseljen 1992 [591]	Randomized controlled trial
Manipulations	Vicenzino 1996 [592]	Randomized controlled crossover
Manipulations compared to Ultrasound plus physiotherapy	Drechsler 1997 [593]	Randomized controlled trial
Manipulations Manipulations plus bracing Manipulations plus topical NSAIDs Manipulations plus topical NSAIDs plus bracing	Burton 1988 [594]	Randomized controlled trial
Oral NSAIDs	Labelle 1997 [595]	Randomized controlled trial
	Adelaar 1987 [596]	Randomized controlled trial
	Stull 1986 [597]	Randomized controlled trial
PEMF	Devereaux 1985 [598]	Randomized controlled trial
Physiotherapy compared to ultrasound	Pienimaki 1996 [599 600]	Randomized controlled trial
Steroid injections	Stahl 1997 [601]	Randomized controlled trial
	Solveborn 1995 [602]	Randomized controlled trial
	Price 1991 [603]	Randomized controlled trial
	Kivi 1982 [604]	A-B trial
	Clarke 1975 [605]	Controlled trial

Therapies evaluated	Study	Trial Design
Steroid injection TENS Ultrasound Phonophoresis	Halle 1986 [606]	Randomized controlled trial
Steroid injections compared to manipulation	Verhaar 1995 [607]	Randomized controlled trial
Steroid injections compared to acupuncture	Brattberg 1983 [608]	Controlled trial
Steroid injection compared to Oral NSAIDs	Hay 1999 [609]	Randomized controlled trial
	Saartok 1986 [610]	Randomized controlled trial
Steroid injections Bracing Immobilization	Haker 1993 [611]	Randomized controlled trial
Surgery	Almquist 1998 [83]	Controlled trial
	Wilhelm 1996 [84]	Controlled trial
TENS	Johannsen 1993 [612]	Randomized controlled trial
Topical DMSO	Percy 1981 [613]	Randomized controlled trial
Topical NSAIDs	Demirtas 1998 [614]	Randomized controlled trial
	Schapira 1991 [615]	Randomized controlled trial
	Burnham 1998 [616]	Randomized controlled crossover
Ultrasound	Lundeberg 1988 [617]	Randomized controlled trial
	Binder 1985 [618]	Randomized controlled trial
	Haker 1991 [619]	Randomized controlled trial
Ultrasound Phonophoresis Ultrasound plus bracing Phonphoresis plus bracing	Holdsworth 1993 [620]	Randomized controlled trial
Ultrasound Phonophoresis Ultrasound plus massage Phonophoresis plus massage	Stratford 1989 [621]	Randomized controlled trial

ESWT = extracorporal shock wave therapy
GAGPs = glucosaminoglycan polysulfate
NSAID = non steroidal anti -inflammatory drug
PEMF = pulsed electromagnetic field
TENS = transcutaneous electrical nerve stimulation
DMSO = dimethylsulfoxide

What are the relative benefits and harms of low-level laser therapy for persons with epicondylitis?

The literature addressing this question consists of seven studies that compared low level laser treatment to sham laser treatment. Therefore, in this section we address the benefits and harms of laser therapy relative to sham treatment, but the literature included in this section does not allow one to determine the effectiveness of laser therapy relative to any other type of therapy.

Low level red or infrared lasers have been used to treat pain and speed healing. The lasers are thought to possess biostimulating and regenerative properties; however, the physiological basis of such properties is uncertain. Low-level lasers have also been claimed to decrease pain by increasing serotinin metabolism and by slowing nerve conduction.[584,586]

Internal validity

We identified seven studies that included a total of 320 patients that evaluated low-level laser therapy for treating epicondylitis. All seven studies were prospective double-blinded randomized controlled trials that compared laser therapy to sham laser therapy. Details of the designs of the studies relevant to the internal validity of the studies are shown in Table 226.

Two of the studies had statistically significant differences in the gender compositions between their patient groups. The Papadopoulos 1994 trial contained a sham group that was 86.7% female, and a laser group that was 57.1% female (chi-squared test, calculated by ECRI, $p = 0.002426$). The Haker 1991[589] trial contained a sham group that was 13.8% female and a laser group that was 37.9% female (chi-squared test, calculated by ECRI, $p = 0.035808$). These differences are surprising in a randomized controlled trial, and could suggest that the randomization process was not optimal. This may have influenced the reported results.

Neither the three studies by Haker, nor the study by Basford 2000, did not use intent-to-treat analysis. The three studies by Haker had quite high attrition rates (over 20%). Ignoring attrition when analyzing the data can create a bias in the results. Where possible, we have tried to compensate for this by attempting to gauge the maximum possible effect of not following this principle. Thus, we assumed that all patients who were not followed until the end of the study received unsuccessful treatment. This is a conservative assumption. However, if statistical significance is obtained under this assumption, one can be more confident that the magnitude of this design weakness is not large enough to overturn the results of a statistically significant trial. We were able to compensate for not following the intent-to-treat principle for the trials by Haker, but not for the trial Basford 2000. Our compensation did not change the conclusions of any of the trials.

Table 226. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Basford 2000 [584]	52	1	No	RCT	Yes	Double	9.6	No	NA
Papadopoulos 1996 [585]	29	1	No	RCT[a]	Yes	Double	0	Yes	NA
Krasheninnikoff 1994 [586]	48	1	NR	RCT	Yes	Double	4.2	Yes	NA
Vasseljen 1992 [587]	30	1	NR	RCT	Yes	Double	3.3	Yes	NA
Haker 1991 [588]	52	1	NR	RCT	Yes	Double	26.9	No	NA
Haker 1991 [589]	60	1	NR	RCT[a]	Yes	Double	28.3	No	NA
Haker 1990 [590]	49	1	NR	RCT	Yes	Double	20.4	No	NA

[a] may have been improperly randomized
NA = not applicable
NR = not reported
RCT = randomized controlled trial

Generalizability

Details about the patients enrolled in these trials are shown in Table 227. The mean patient age in these trials ranged from 44.3 to 48.5. Krasheninnikoff 1994 did not report the gender composition of the patient groups; the other studies reported that their patient groups were 25.0% to 72.4% female. These patient characteristics approximate those reported in published studies of the epidemiology of epicondylitis (see the Introduction), suggesting that the results of the studies are broadly generalizable beyond their particular patient groups.

The presence of various co-morbidities is incompletely reported in these studies. Some studies excluded patients with co-morbidities, indicated in Table 227 by a zero under that comorbidity. This somewhat limits the generalizability of these studies, as comorbidities are not exclusion criteria for laser treatment.

None of the studies reported any information about the occupations or employment status of the patients. The extent to which the employment characteristics of these patients may be generalized to the overall population of epicondylitis patients cannot be determined.

Table 227. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Basford 2000 [584]	52	45.1	51.9	6.4	NR	NR	NR	NR	NR	NR	NR	No	No
Papadopoulos 1996 [585]	29	45	72.4	5.8	NR	0	0	0	0	0	0	No	No
Krasheninnikoff 1994 [586]	48	48.5 (37-64)	NR	3 (1-12)	NR	0	0	NR	0	0	NR	No	No
Vasseljen 1992 [587]	30	45.5 (25-63)	50.0	3.5 (1-12)	NR	0	NR	NR	NR	NR	NR	No	No
Haker 1991 [589]	60	45.3 (33-65)	25.0	5.5 (1-60)	NR	0	NR	0	0	NR	NR	No	No
Haker 1991 [588]	52	44.3 (22-66)	34.6	9.5 (1-60)	NR	NR	NR	NR	NR	NR	NR	No	No
Haker 1990 [590]	49	46.7 (24-70)	42.8	7 (1-36)	NR	0	NR	0	0	NR	NR	No	No

NR = not reported

Results

Success of Treatment

Four studies that enrolled a total of 173 patients reported on success of treatment. This outcome was evaluated by asking the patients to rate their symptoms on categorical scales. The results are shown in Table 228 and summarized in Table 229. Effect sizes (Hedges' d) were calculated for each study using a conservative correction for attrition as discussed previously. The effect sizes of the one to 1.5 month followup time and the longest followup time for each study were combined meta-analytically using a fixed-effect model. The results of these analyses are shown in Table 230. The studies were found to not be heterogeneous by the Q-test at either time point, and thus a summary effect size is statistically valid. The summary effect sizes for both meta-analyses were positive, indicating a trend towards laser therapy being more successful, but both 95% confidence intervals contained zero, indicating that there was no statistically significant difference between success of treatment when comparing laser therapy to sham treatment. The effect sizes of are shown graphically in Figure 63 and Figure 64. A U-test of the data showed that the distribution of the effect sizes of the laser treatment groups and the sham treatment groups overlapped by 89.9% at the one to 1.5 month followup time, and 83.7% at the longest followup times. This is shown graphically in Figure 65 and Figure 66.

Because the attrition rates in the studies by Haker are high at the longest followup times (>20%), we performed an analysis to see how attrition might have affected the overall results. We originally assumed that all of the patients lost to followup had failed treatment. Using the opposite assumption, that all of the patients lost to followup had been cured, our conclusions did not change. The summary effect size was not statistically significant under either of our assumptions (Table 230). However, using the the conservative assumption, a trend towards laser therapy being more effective was observed, while under the opposite assumption a trend towards sham therapy being more effective was observed.

Data from other times of followup were not combined meta-analytically because only one or two studies reported data for each of the other times of followup.

Table 228. Results of the success of treatment with laser therapy

Study	Number of patients	Global outcome, patient-rated	Statistical significance of the difference between groups[a]
Krasheninnikoff 1994 [586]	18 sham 18 laser	Sham- at one month, 3 cured, 7 more effective, 8 unchanged. At 2.5 months, 6 cured, 5 more effective, 7 unchanged. Laser- at one month, 2 cured, 9 more effective, 7 unchanged. At 2.5 months, 6 cured, 4 more effective, 8 unchanged.	Chi-squared test At one month, p = 0.772338 At 2.5 months, p = 0.914947 Not statistically significantly different
Vasseljen 1992 [587]	13 sham 15 laser	Sham- at two weeks, 0 cured, 8 more effective, 5 no change, 2 worse. At 1.5 months, 3 cured, 5 more effective, 5 no change, 2 worse. At 5.5 months, 4 (30.7%) were successfully treated. Laser- at two weeks, 3 cured, 7 more effective, 3 no change, 2 worse. At 1.5 months, 7 cured, 5 more effective, 1 no change, 2 worse. At 5.5 months, 8 (53.3%) were successfully treated.	Chi-squared test At 2 weeks, p = 0.456057 At 1.5 months, p = 0.121335 At 5.5 months, p = 0.136037 Not statistically significantly different
Haker 1991 [589]	29 sham 29 laser	Sham: at 1.5 months, 0 excellent, 5 good, 17 improved,10 some improvement, 7 unchanged. At 3 months, 4 excellent, 7 good, 8 improved, 2 some improvement, 6 unchanged. At 6 months, 3 excellent, 6 good, 10 improved, 4 some improvement, 0 unchanged. Laser- at 1.5 months, 1 excellent, 7 good, 16 improved, 9 some improvement, 5 unchanged. At 3 months, 2 excellent, 11 good, 10 improved, 1 some improvement, 4 unchanged. At 6 months, 3 excellent, 15 good, 5 improved, 1 some improvement, 0 unchanged.	Chi-squared test At 1.5 months, p = 0.097781 At 3 months, p = 0.023323 At 6 months, p = 0.006687 Difference is statistically significant for 3 and 6 months of followup
Haker 1990 [590]	26 sham 23 laser	Sham: at 1.5 months, 1 excellent, 11 good, 9 improved, 4 some improvement, 5 unchanged. At 3 months, 1 excellent, 12 good, 6 improved, 1 some improvement, 6 unchanged. At one year, 8 excellent, 6 good, 6 improved, 3 some improvement, and 1 unchanged. Laser: at 1.5 months, 1 excellent, 4 good, 12 improved, 7 some improvement, 6 unchanged. At 3 months, 5 excellent, 7 good, 8 improved, 3 some improvement, 2 unchanged. At one year, 6 excellent, 8 good, 4 improved, 2 some improvement, 8 unchanged.	Chi-squared test At 1.5 months, p = 0.065075 At 3 months, p = 0.015251 At one year, p = 0.107943 Difference is statistically significant for 3 months of followup

[a] calculated by ECRI

Table 229. Success of treatment with laser therapy for epicondylitis

Study	Number of patients	Followup time	Which procedure was more effective?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Krasheninnikoff 1994 [586]	18 sham 18 laser	1 month	Laser	No	0.19 (-0.46 to 0.85)
		2.5 months	Sham	No	-0.11 (-0.77 to 0.54)
Vasseljen 1992 [587]	15 sham 15 laser	2 weeks	Laser	No	0.64 (-0.09 to 1.38)
		1.5 months	Laser	No	0.73 (-0.01 to 1.47)
		5.5 months	Laser	No	0.61 (-0.23 to 1.46)
Haker 1991 [589]	29 sham 29 laser	1.5 months	Laser	No	0.28 (-0.24 to 0.80)
		3 months	Laser	Yes	0.24 (-0.28 to 0.76)
		6 months	Laser	Yes	0.50 (-0.03 to 1.02)
Haker 1990 [590]	26 sham 23 laser	1.5 months	Sham	No	-0.44 (-1.01 to 0.13)
		3 months	Laser	Yes	0.43 (-0.13 to 1.00)
		12 months	Sham	No	-0.01 (-0.58 to 0.55)

[a] calculated by ECRI

Table 230. Results of meta-analysis of effect of laser therapy vs. sham therapy on global outcome

Analysis	Study	N	Effect size	95% CI	P value	Standardized residual	Outlier by std. Residual?
One to 1.5 months	Krasheninnikoff 1994 [586]	36	0.19	-0.46 to 0.85	0.56	0.20	No
	Vasseljen 1992 [587]	30	0.73	-0.01 to 1.47	0.053	1.74	No
	Haker 1991 [589]	58	0.28	-0.24 to 0.80	0.29	0.68	No
	Haker 1990 [590]	49	-0.44	-1.01 to 0.13	0.13	-2.34	Yes
Longest followup time, conservative correction for attrition	Krasheninnikoff 1994 [586]	36	-0.11	-0.77 to 0.54	0.73	-1.15	No
	Vasseljen 1992 [587]	30	0.61	-0.23 to 1.46	0.15	0.98	No
	Haker 1991 [589]	58	0.50	-0.03 to 1.02	0.062	1.26	No
	Haker 1990 [590]	49	-0.01	-0.58 to 0.55	0.96	-1.00	No
Longest followup time, opposite correction for attrition	Krasheninnikoff 1994 [586]	36	-0.11	-0.77 to 0.54	0.73	0.15	No
	Vasseljen 1992 [587]	30	-0.51	-0.51 to 1.09	0.48	1.19	No
	Haker 1991 [589]	58	-0.85	-0.85 to 0.19	0.21	-0.81	No
	Haker 1990 [590]	49	-0.77	-0.77 to 0.35	0.47	-0.21	No
Summary 1 to 1.5 months	4 RCT's	173	0.13	-0.17 to 0.43	0.39	Q = 6.77	P of Q = 0.079
Summary, longest, conservative	4 RCT's	173	0.22	-0.08 to 0.53	0.15	Q = 3.59	P of Q = 0.31
Summary longest, opposite	4 RCT's	173	-0.16	-0.46 to 0.15	0.31	Q = 1.68	P of Q = 0.64

Figure 63. Effect sizes of laser therapy compared to sham therapy as a treatment for epicondylitis, 1 to 1.5 months of followup

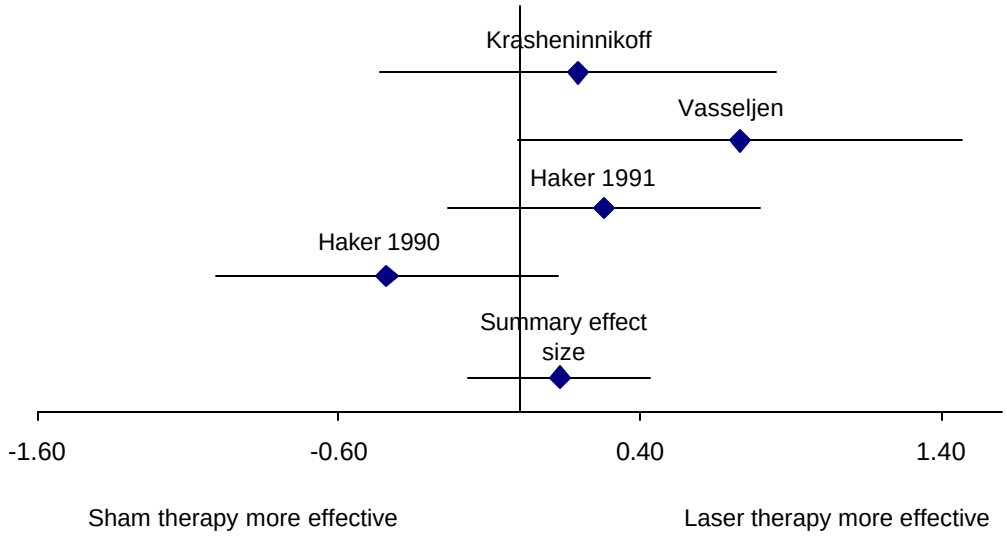


Figure 64. Effect sizes of laser therapy compared to sham therapy as a treatment for epicondylitis, longest times of followup

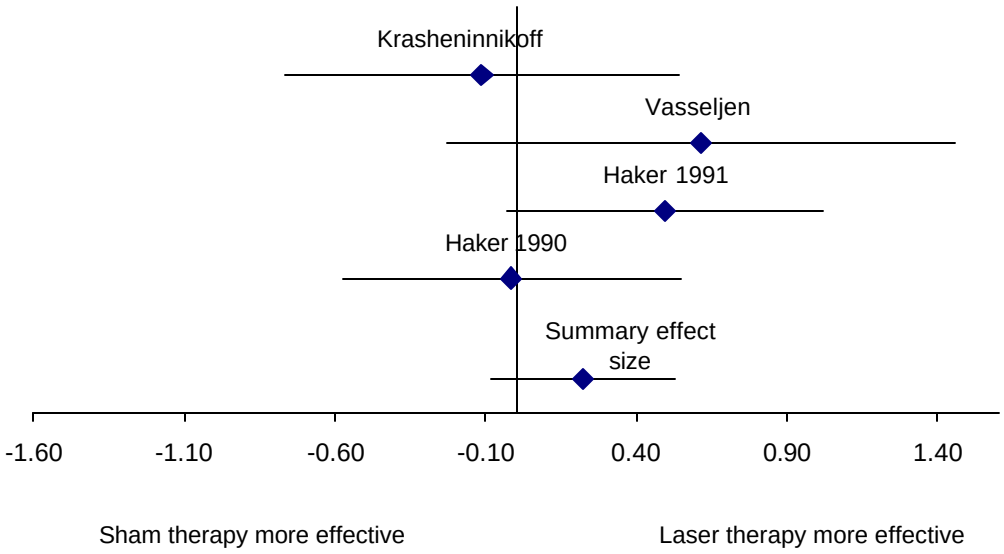


Figure 65. Overlap of effect size distributions in patients receiving laser or sham therapy, 1-1.5 months of followup

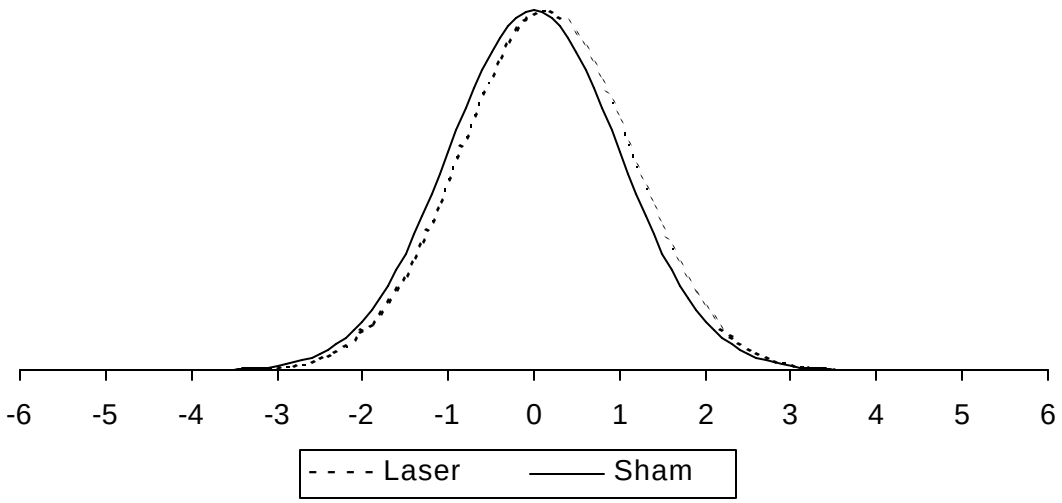
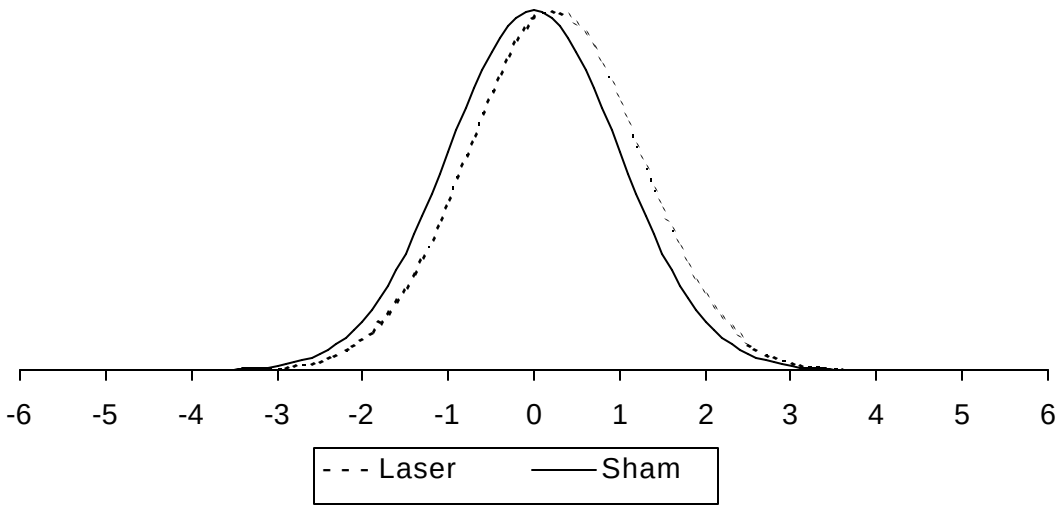


Figure 66. Overlap of effect size distributions in patients receiving laser or sham therapy, longest times of followup



Work Status

Only one study of 30 patients reported this outcome. The study counted the number of patients working or not working 5.6 months after the study began. The data from this study are summarized in Table 231 and Table 232. A statistically nonsignificant difference in work status was reported between sham treated and laser treated patients. This study could have detected a 26% or greater difference between groups, so statistical power may not be a substantial issue with it.

Table 231. Results of work status after treatment with laser therapy

Study	N patients	Time of followup	Number of patients working	Statistical significance of the difference between groups
Vasseljen 1992 [587]	13 Sham 15 Laser	5.5 months	9 sham treated patients were working and 13 laser treated patients were working	Chi-squared test [a] p = 0.262

[a] calculated by ECRI

Table 232. Work status after treatment with laser therapy

Study	Number of patients	Which procedure had more patients working?	Was the difference statistically significant?	Effect size d (95% CI)[a]	What is the minimal difference between groups the study had the statistical power to detect?
Vasseljen 1992 [587]	Sham 13 Laser 15	Laser	No	0.57 (-0.48 to 1.61)	26%

[a] calculated by ECRI

Pain

The effect of laser treatment on pain was reported by four studies of 143 patients in total. All four studies reported pain rated by the patients on visual analog scales (VAS). The data reported by the studies is shown in Table 233 and summarized in Table 234. The reported results of the studies are shown graphically in Figure 67 and the effect sizes (Hedges' d) of the longest followup times are shown graphically in Figure 68. The results for all other time points are similar to that found for the longest followup times.

Because an effect size could be calculated for only three of the studies, we did not perform a meta-analysis. None of the studies reported a statistically significant difference in pain outcomes between the two groups. However, all of the studies are small. Due to limitations in the reported data, we were only able to perform a power analysis for one of the studies. Our calculations show that the study by Vasseljen 1992 could have detected only an 86% or larger difference between the treatment groups. The other studies are of similar sizes. Thus, it is unlikely that they would have found a statistically significant difference even if the difference between groups were rather large. Therefore, these studies cannot be taken as proof that laser therapy provides no pain relief.

Table 233. Results of the effect of laser treatment on pain

Study	N patients	Pain measurements	Statistical significance of the difference between groups
Basford 2000 [584]	24 sham 23 laser	No data reported	Wilcoxon's rank sum test At 2 weeks, p = 0.551 At 1 month, p = 0.371 At 2 months, p = 0.488
Papadopoulos 1994 [585]	15 sham 14 laser	No data reported	Test not reported NS
Krasheninnikoff 1994 [586]	18 sham 18 laser	At one month, Sham- 22 median 95% CI (12 to 63) Laser- 27 median 95% CI (5 to 50)	Mann-Whitney rank sum test p >0.05
Vasseljen 1992 [587]	15 sham 15 laser	Mean (95% CI) Sham- at time 0, 3.8 (2.75 to 4.8). At 2 weeks, 3.8 (2.75 to 4.7). At 1.5 months, 3.2 (2.4 to 4.2). At 5.5 months, 0.7 (0.4 to 1.0) Laser- at time 0, 4.2 (3.2 to 5.2). At 2 weeks, 3.6 (2.2 to 4.95). At 1.5 months, 2.65 (1.5 to 3.8). At 5.5 months, 0.49 (0.2 to 0.75)	t-test at time 0, p = 0.591 at 2 weeks, p = 0.814 at 1.5 months, p = 0.504 at 5.5 months, p = 0.317

Table 234. Summary of the effect of laser treatment on pain

Study	N patients	Which procedure was most effective at treating pain?	Was the difference statistically significant?	Effect size d (95% CI)[a]	What is the minimal difference between groups that the study had the statistical power to detect?
Basford 2000 [584]	24 Sham 23 Laser	No difference	No at all followup times	0.20 (-0.37 to 0.77)[b]	NC
Papadopoulos 1994 [585]	15 Sham 14 Laser	No difference	No at all followup times	NC	NC
Krasheninnikoff 1994 [586]	18 Sham 18 Laser	Sham	No at all followup times	-0.66 (-1.33 to 0.01)	NC
Vasseljen 1992 [587]	15 Sham 15 Laser	Laser	No at all followup times	1.41 (0.61 to 2.21)	86%

[a] calculated by ECRI
[b] the direction of this effect size was chosen at random and is not to be interpreted as supporting one treatment group over the other
NC = could not be calculated from reported data

Figure 67. Effectiveness of laser therapy at treating pain

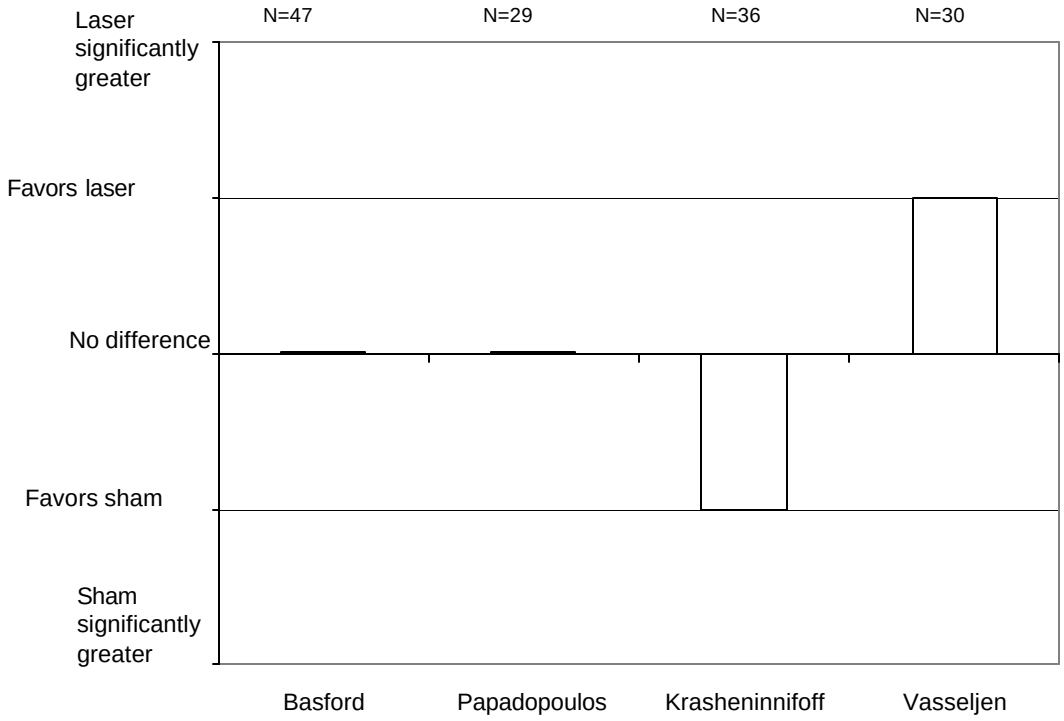
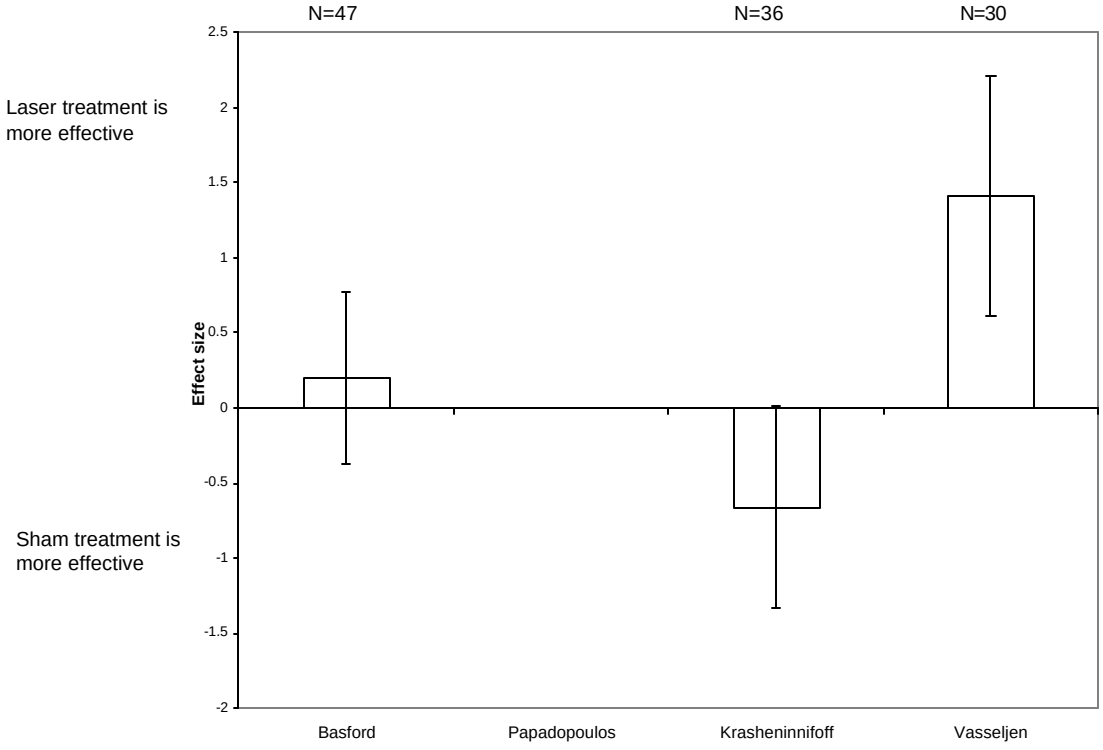


Figure 68. Effect sizes: laser treament on pain



Function and Activites of Daily Living

None of the studies reported a patient-oriented measure of these outcomes.

Quality of Life

None of the studies reported on this outcome.

Morbidity and Complications

None of the studies reported any side effects or complications of laser therapy.

Conclusions

Seven studies that included a total of 320 patients were identified that evaluated low-level laser therapy for treating epicondylitis. All seven studies were double-blinded randomized controlled trials that compared laser therapy to sham laser therapy.

A meta-analysis of the results of the four studies that reported "success of treatment" did not find a statistically significant difference in outcome between laser and sham treated patients. The four studies that reported the effect of laser treatment on pain also did not find a statistically significant difference in outcome between laser and sham treated patients. However, we were unable to perform a meta-analysis of the outcome pain, and because all of these studies were small their individual results cannot be taken as definitive proof that laser therapy has no effect on the pain of epicondylitis. Only one study examined work status of patients after laser treatment. It failed to find a statistically significant effect of laser treatment on work status and did have sufficient statistical power to detect medium or large differences between groups. However, it is difficult to draw firm evidence-based conclusions from the results of a single study.

The results of all seven small randomized double-blinded controlled trials are consistent with the results of our meta-analysis, and suggest that if there is an effect of laser therapy on epicondylitis, it is not large.

What are the relative benefits and harms of oral and topical anti-inflammatory drug therapy for persons with epicondylitis?

Non-steroidal anti-inflammatory drugs (NSAIDs) are a class of drugs that act to reduce inflammation. Most are also potent analgesics. NSAIDs used to treat epicondylitis can be taken orally or applied topically to the elbow joint. Common NSAIDs used to treat epicondylitis include diclofenac, salicylate, diflunisal, and naproxen.

Dimethylsufoxide (DMSO), although not an NSAID, has been included in this section. DMSO can be applied topically. It rapidly penetrates the skin and spreads throughout the body. It has been reported to have anti-inflammatory and analgesic properties.

The relevant literature consists of seven trials. One trial evaluated the use of DMSO as compared to placebo. Three trials compared the relative effectiveness of different types of NSAIDs. Three trials compared the effectiveness of different types of NSAIDs to placebo.

Internal validity

Seven randomized controlled trials that enrolled a total of 405 patients were included in this section of the report. The therapies used by the different trials are summarized in Table 235. Details of the designs of these trials are shown in Table 236. One double-blinded trial of 51 patients evaluated the use of topical DMSO as compared to placebo. One double-blinded trial of 206 patients compared oral diclofenac to placebo. Two double-blinded trials of 47 patients, one of which was a crossover trial, compared topical diclofenac to placebo. Two unblinded trials of 62 patients compared the effectiveness of oral diflunisal to oral naproxen. We do not consider lack of blinding in these two particular trials to be a serious design flaw. It is unlikely that knowledge of which type of NSAID was administered, by either the patients or the evaluating physician, would affect the results of the trial.

Three of the trials did not analyze their data according to the intent-to-treat principle. Two of these studies (Adelaar 1987 and Percy 1981) had attrition rates over 15%. Ignoring attrition when analyzing the data can create a bias in the results. Where possible, we have tried to compensate for this by attempting to gauge the maximum possible effect of not following this principle. Thus, we assumed that all patients who were not followed until the end of the study received unsuccessful treatment. This is a conservative assumption. However, if statistical significance is obtained under this assumption, one can be more confident that the magnitude of this design weakness is not large enough to overturn the results of a statistically significant trial. We were able to compensate for not following the intent-to-treat principle for the trial by Adelaar 1987 for one outcome, but not for any other outcomes, and we were unable to compensate for not following the intent-to-treat principle for Percy 1981 or for Stull 1986. For the one outcome of Adelaar 1987 that we were able to compensate for, the conclusions of the trial did not change.

Table 235. Summary of the treatments evaluated

Study	Group 1	Group 2
Burnham 1998 [616]	Topical diclofenac	Placebo
Schapira 1991 [615]	Topical diclofenac	Placebo
Demirtas 1998 [614]	Topical diclofenac	Topical salicylate
Labelle 1997 [595]	Oral diclofenac	Placebo
Adelaar 1987 [596]	Oral diflunisal	Oral naproxen
Stull 1986 [597]	Oral dilfunisal	Oral naproxen
Percy 1981 [613]	Topical DMSO	Placebo

Table 236. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Demirtas 1998 [614]	40	1	NR	RCT	Yes	No	0	Yes	NR
Burnham 1998 [616]	14	1	NR	RCT Xover	Yes	Double	0	Yes	NR
Labelle 1997 [595]	206	Multiple	Yes	RCT	Yes	Double	0.49	Yes	49.5
Schapira 1991 [615]	32	1	Yes	CT	Yes	Double	0	Yes	NR
Adelaar 1987 [596]	22	1	NR	RCT	Yes	No	18.2	No	NR
Stull 1986 [597]	40	1	Yes	RCT	Yes	No	5.0	No	NR
Percy 1981 [613]	51	1	Yes	RCT	Yes	Double	21.6	No	NR

RCT = randomized controlled trial
Xover = crossover
CT = controlled trial
NR = not reported

Generalizability

Characteristics of the patients are shown in Table 237. Studies of the epidemiology of epicondylitis (see the Introduction) have found that typical patients are in their mid-forties and are equally likely to be of either sex. All of the trials included patients that are similar to these characteristics except the trials by Stull 1986 and Schapira 1991 which did not report the mean age of their patient groups and the trial by Adelaar 1987 which had a mean age of 34.5 years (This is younger than the general population of patients with epicondylitis; see the epidemiology subsection of the introduction to this evidence report, as well as the answer to question two regarding epicondylitis).

The presence of various comorbidities associated with epicondylitis is incompletely reported in these studies. Some studies excluded patients with some comorbidities, indicated by a zero in Table 237 under that comorbidity. This somewhat limits the generalizability of these studies, as comborbidites may not be exclusion criteria for treatment with anti-inflammatories.

Only one of the trials reported information on the occupations of the patients (Table 238). Therefore, the extent to which the employment characteristics of these patients may be generalized to the overall epicondylitis population cannot be determined from the information available.

Table 237. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Burnham 1998 [616]	14	42.5	42.8	8.3 (2-24)	NR	NR	NR	NR	NR	NR	NR	No	No
Demirtas 1998 [614]	40	45.0 (25-61)	65	5.0 (2-13)	NR	NR	NR	NR	NR	NR	NR	No	No
Labelle 1997 [595]	206	43.7	59	NR		0	NR	0	0	NR	NR	No	No
Schapira 1991 [615]	32	(34-78)	65.6	NR	NR	NR	NR	NR	NR	NR	0	No	No
Adelaar 1987 [596]	22	34.5 (20-49)	54.5	NR	NR	NR	0	NR	NR	0	0	No	No
Stull 1986 [597]	40	NR	42.5	NR	NR	NR	NR	NR	NR	NR	NR	No	No
Percy 1981 [613]	51	47.9 (28-64)	29.4	NR	NR	NR	NR	NR	NR	NR	0	No	No

NR = not reported

Table 238. Generalizability: patient occupations

Study	Number of patients	% Patients employed	% Patients on Workers' compensatio	% Patients retired	% Patients homemakers	Reported occupations
Burnham 1998 [616]	14	NR	NR	NR	NR	NR
Demirtas 1998 [614]	40	NR	NR	NR	NR	NR
Labelle 1997 [595]	206	NR	NR	NR	NR	NR
Schapira 1991 [615]	32	NR	NR	NR	NR	NR
Adelaar 1987 [596]	22	NR	NR	NR	9.1	13.6% blue-collar worker 13.6% custodial worker 9.1% student 9.1% nurse 9.1% clerical worker 9.1% health care worker 4.5% broker 4.5% computer programmer
Stull 1986 [597]	40	NR	NR	NR	NR	NR
Percy 1981 [613]	51	NR	NR	NR	NR	NR

NR = not reported

Results

Success of Treatment-NSAIDs

Three studies reported on the success of treatment as rated by patients. The results of these trials are summarized in Table 239. Because there were two or fewer studies comparing the same NSAID treatments, no meta-analysis could be performed. The conclusions of the trials are summarized in Table 240. Two trials of a total of 51 patients reported on the relative success of treating with naproxen as compared to diflunisal. Both trials measured success by asking the patients to rate their symptoms after the course of drugs. Neither trial found a statistically significant difference between the treatment groups. However one study reported a slight advantage to taking naproxen, while the other study reported a slight advantage to taking diflunisal (Figure 69 and Figure 70). One trial of a total of 128 patients reported on the recurrence of symptoms three months after taking a course of diclofenac or placebo. There was no statistically significant difference in the rates of recurrence of symptoms between-treatment groups. The statistical power of these studies suggest that they could have detected, depending on the trial, a 17% or 22% difference between groups. Therefore, if there is a difference between any of the treatments, it is unlikely to be large.

The trial by Demirtas 1998 compared topical salicylate treatments to topical diclofenac treatments. This trial did not report any patient-oriented outcomes, and for this reason we have not tabled any of its results. Demirtas 1998 reported that topical diclofenac was more effective at treating the symptoms of epicondylitis than was topical salicylate.

Table 239. Results of the success of treatment with NSAIDs

Study	Number of patients	Success of treatment	Statistical significance of difference between groups
Labelle 1997 [595]	64 Placebo 64 NSAIDs	At 3 months: Placebo: 27 patients still had symptoms NSAIDs: 23 patients still had symptoms	Test NR P = 0.52
Adelaar 1987 [596]	9 naproxen 9 diflunisal	At 0.5 months, patient-rated global outcome: Naproxen- 0 excellent, 7 improved, 2 no change, 0 worse Diflunisal- 0 excellent, 7improved, 1 no change, 1 worse	Exact chi-squared t test NS
Stull 1986 [597]	16 naproxen 17 diflunisal	At 0.5 months, patient-rated global outcome: Naproxen- 1 excellent, 11 improved, 3 no change, 1 worse Diflunisal- 3 excellent, 13 improved, 1 no change, 0 worse	Pearson chi-squared P = 0.368

Table 240. Success of treating epicondylitis with NSAIDs

Study	Number of patients	Time of follow-up	Which treatment was more successful?	Was the difference statistically significant?	What is the minimal difference between groups the study had the power to detect?	Effect size d (95% CI)[a]
Labelle 1997 [595]	64 oral diclofenac 64 placebo	3 months	diclofenac	No	17%	1.44 (1.05 to 1.83)
Adelaar 1987 [596]	9 oral diflunisal 9 oral naproxen	0.5 months	naproxen	No	22%	0.70 (-0.20 to 1.6)
Stull 1986 [597]	17 oral diflunisal 16 oral naproxen	0.5 months	diflunisal	No	22%	-0.40 (-1.09 to 0.29)

[a] calculated by ECRI

Figure 69. Success of treating epicondylitis with NSAIDs: naproxen vs. diflunisal

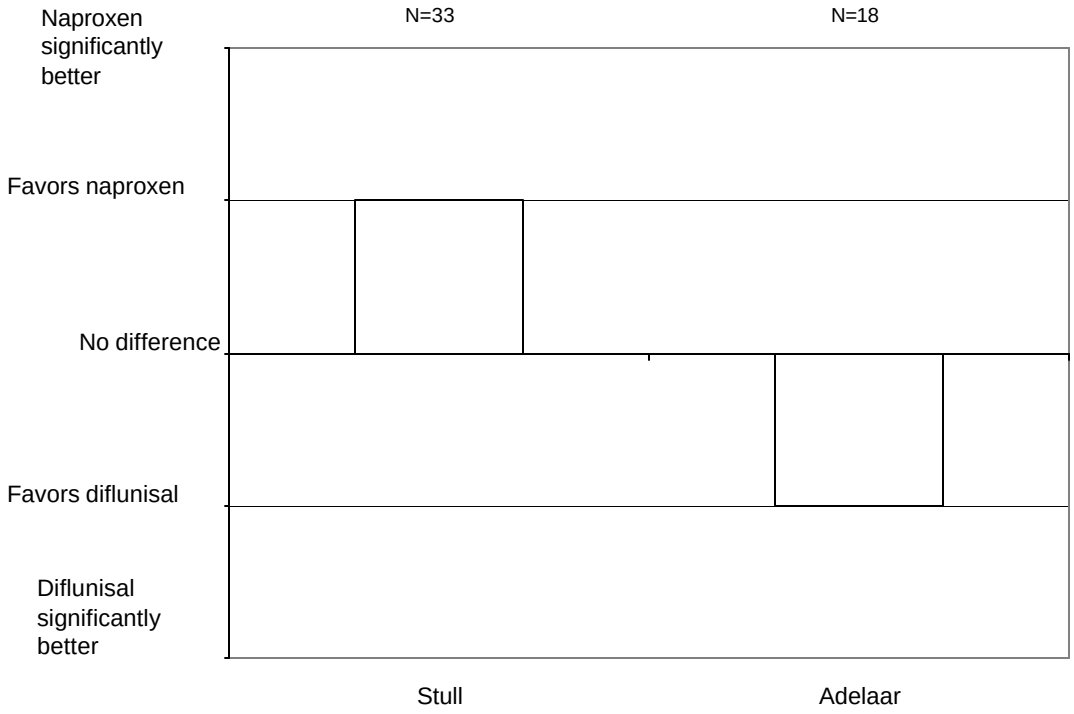
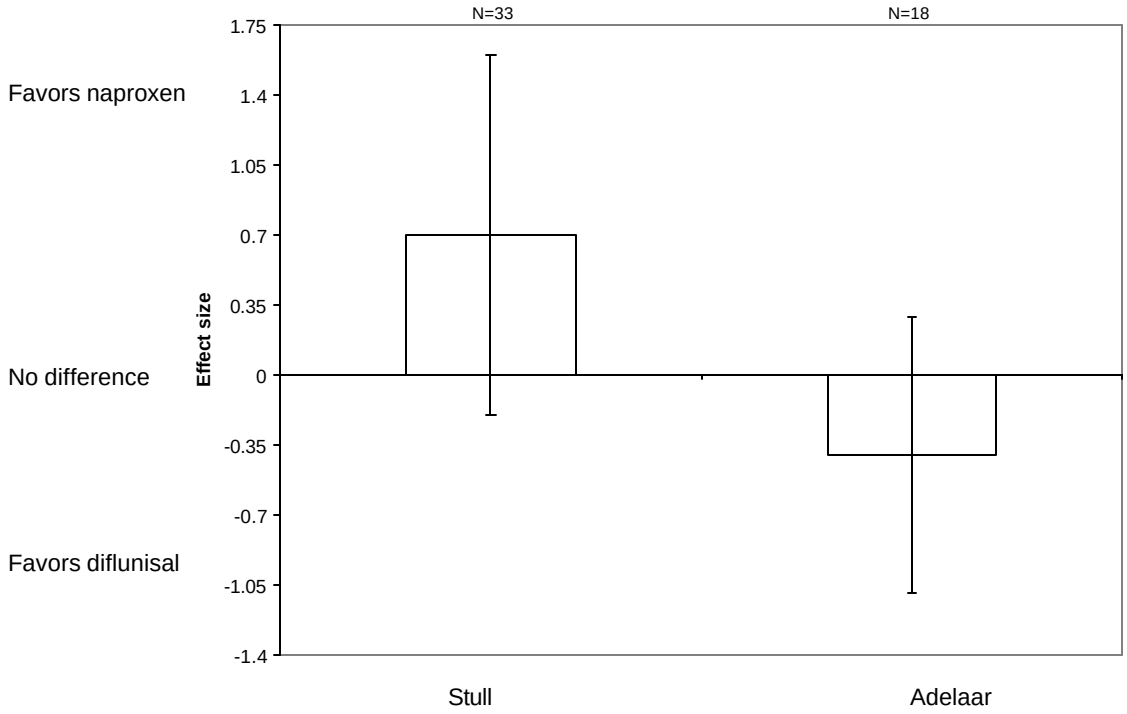


Figure 70. Effect sizes of diflunisal vs. naproxen



Success of treatment- DMSO

The trial by Percy 1981, which compared topical DMSO treatments to sham topical treatments, did not report any patient-oriented outcomes. For this reason, we have not tabled results or calculated effect sizes. However, this trial did report global outcome as rated by the treating physician. There was a trend towards the sham topical group being rated as having better outcomes than the topical DMSO group, but the difference was not statistically significant. There was insufficient information for us to calculate the statistical power of this study to detect differences between groups.

Work Status

One trial of 128 patients reported that there was no statistically significant difference in the number of work days missed due to epicondylitis between a group treated with diclofenac and a group treated with placebo. These data are shown in Table 241.

Table 241. Effect of NSAID treatment on work status

Study	N patients	Which treatment resulted in fewer sick days?	Was the difference significant?	Did the study have sufficient power?	Effect size d (95% CI)
Labelle 1997 [595]	64 oral diclofenac 64 placebo	No difference	No t-test	Could not calculate from reported information	Could not calculate from reported information

Pain

Four trials reported on pain. These studies are shown in Table 242. One of the trials, including 28 patients, compared topical diclofenac to a placebo. Two studies of a total of 62 patients compared oral naproxen to oral diflunisal. One study of 128 patients compared oral diclofenac to placebo. Because there were two or fewer trials of each combination of NSAIDs, no meta-analysis could be performed. The results reported by the studies are summarized in Table 243. Diclofenac, either topically applied or taken orally, was found to relieve pain more effectively than placebo. There was a tendency for diflunisal to relieve pain more effectively than naproxen, but only the results of the Stull study were statistically significant.

Table 242. Results of the effect of NSAIDs on pain

Study	Number of patients	Pain	Statistical significance of difference between groups
Burnham 1998 [616]	14 topical diclofenac 14 placebo	Patient-rated by VAS, mean (SD) At time 0, NSAIDs = 3.5 (1.7) Placebo = 3.5 (1.7) At 1 week, NSAIDs = 2.1 (2.1) Placebo = 3.6 (2.0)	ANOVA NS at time 0 P = 0.007 at 1 week
Labelle 1997 [595]	64 oral diclofenac 64 placebo	Patient-rated pain by VAS, mean (SD) At 1 month NSAIDs = 29.9 (26.3) Placebo = 16 (27.4)	Student t test p <0.005
Adelaar 1987 [596]	9 diflunisal 9 naproxen	Patient-rated pain, mean At time 0, diflunisal = 1.9 Naproxen = 2.1 At 2 weeks, diflunisal = 0.9 Naproxen = 1.1	Exact chi-squared t-test NS
Stull 1986 [597]	16 diflunisal 17 naproxen	Patient-rated pain relief At 2 weeks Diflunisal: 4 no pain, 9 mild pain, 3 moderate pain, 0 severe pain Naproxen: 5 no pain, 8 mild pain, 3 moderate pain, 1 severe pain	Pearson chi-squared P = 0.019

Table 243. Effect of treatment with NSAIDs on pain related to epicondylitis

Study	Number of patients	Time of follow up	Which treatment resulted in less pain?	Was the difference significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Burnham 1998 [616]	14 topical diclofenac 14 placebo	1 week	Topical diclofenac	Yes	NA	0.71 (-0.05 to -1.47)
Labelle 1997 [595]	64 oral diclofenac 64 placebo	1 month	Oral diclofenac	Yes	NA	0.51 (0.16 to 0.87)
Adelaar 1987 [596]	9 oral diflunisal 9 oral naproxen	2 weeks	Oral diflunisal	No	Cannot calculate from the reported data	Cannot calculate from the reported data
Stull 1986 [597]	17 oral diflunisal 17 oral naproxen	2 weeks	Oral diflunisal	Yes	NA	0.02 (-0.66 to 0.71)

[a] calculated by ECRI

Function

Three studies of 180 patients in total reported data relevant on patient function. The results of the studies are shown in Table 244. The results reported by the studies are summarized in Table 245. One study reported a trend, that did not reach statistical significance, towards fewer functional limitations when patients were treated with oral diclofenac as compared to placebo. The low statistical power of this study may have contributed to its failure to detect a statistically significant difference. Only large (>68.7%) differences could be detected. Two studies compared oral diflunisal to oral naproxen. One study reported no difference in functional limitations, while the other reported a statistically significant advantage in function after treatment with diflunisal.

Table 244. Results of function

Study	Number of patients	Functional assessment	Statistical significance of difference between groups
Labelle 1997 [595]	64 Placebo 64 Oral diclofenac	At one month, mean (SD) ADL: placebo -2.4 (2.8) Diclofenac- -3.3 (2.8) Arm function by VAS: placebo 21.8 (27.6) Diclofenac 18.5 (29.1)	Student t-test ADL, p = 0.52 VAS, p = 0.1
Adelaar 1987 [596]	9 Oral diflunisal 9 Oral naproxen	Patient rated function mean At time zero, dilfunisal 1.7 Naproxen 1.7 At 2 weeks, dilfunisal 0.4 Naproxen 0.4	Exact chi-squared t-test NS
Stull 1986 [597]	17 Oral naproxen 17 Oral diflunisal	Number of patients with self-reported functional limitations at 2 weeks Naproxen = 11 Diflunisal = 5	Chi-squared test[a] P = 0.039

[a] calculated by ECRI
ADL = activities of daily living

Table 245. Effect of NSAIDs on hand/arm function

Study	Number of patients	Which treatment resulted in fewer functional limitations?	Was the difference significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Labelle 1997 [595]	64 oral diclofenac 64 placebo	Oral diclofenac	No	68.7%	ADL: 0.32 (-0.03 to 0.67) VAS: 0.12 (-0.23 to 0.46)
Adelaar 1987 [596]	9 oral diflunisal 9 oral naproxen	No difference	No difference	Cannot calculate from the reported data	Cannot calculate from the reported data
Stull 1986 [597]	17 oral diflunisal 17 oral naproxen	Oral diflunisal	Yes	NA	0.80 (0.00 to 1.59)

[a] calculated by ECRI

Quality of life

None of the studies reported this outcome.

Morbidity and complications

Percy 1981 reported that topical DMSO irritated the skin at the site of application in 94% of the patients.[613] The irritation consisted of burning, itching, pain, congestion, edema, urticaria, vesicles, and dermatitis. Topical NSAIDs were reported to have few side effects except for occasional mild rashes.[615, 616] Oral NSAIDs were reported to occasionally cause gastrointestinal problems such as nausea and vomiting.[596, 595]

Conclusions

Seven randomized controlled trials of a total of 405 patients evaluated the use of oral NSAIDs, topical NSAIDs, and topical DMSO as treatments for epicondylitis. Because there were two or fewer trials studying each combination of drugs, no meta-analysis could be performed. General trends reported by the trials can be described. However, because these trends are based on the results of at most two trials, they may be subject to over-interpretation. Confirmatory studies would increase our confidence in their results. In addition, the small size of most of these studies may have contributed to their failure to reach statistical significance.

One double-blinded randomized controlled trial of 51 patients reported that physicians believed that patients treated with placebo tended to have better outcomes than did patients treated with topical DMSO. However, this trend was not statistically significant.

Two randomized controlled trials of a total of 62 patients compared oral naproxen to oral diflunisal. One study reported no statistically significant difference in outcomes when comparing patients treated with the two different drugs, and did not find a consistent trend in favor of one drug. The other study reported that diflunisal treatment consistently resulted in better outcomes. For some outcomes (pain, function) the difference reached statistical significance.

One randomized controlled trial of 128 patients compared oral diclofenac to placebo. The group treated with diclofenac had statistically significantly less pain than the placebo group, but the NSAID treatment had no statistically significant effect on hand/arm function, number of days of missed work, or global outcome. Oral NSAIDs were reported to occasionally cause gastrointestinal side effects.

One double-blinded randomized controlled trial and one double blinded randomized crossover trial, of a total of 47 patients, compared topical diclofenac to placebo. One of the studies reported no differences between the two groups for any of the outcomes, while the other study reported the group treated with the NSAID may have had some statistically significant benefit from the treatment. One randomized controlled trial of 40 patients compared topical diclofenac to topical salicylate, and reported that diclofenac was more effective for treating epicondylitis. Topical NSAIDs were reported to occasionally cause mild skin rashes.

What are the relative benefits and harms of injections of steroids, anesthetics, and other substances for persons with epicondylitis?

Injections of glucocorticoid steroids have been used to give long-lasting (days to weeks) relief from pain and inflammation at localized sites. Steroids used for this purpose include hydrocortisone, prednisone, prednisolone, methylprednisolone, triamcinolone, and betamethasone. Local anesthetics temporarily block sensory nerve conduction at the site of injection. Anesthetics used for this purpose include lidocaine, bupivacaine, lignocaine, and procaine. Injections of glucosamines are said to promote the healing of damaged joints, in particular, the damage associated with osteoarthritis.

The relevant literature consists of one trial that compared injections of glucosamines to placebo, one trial that compared the relative effectiveness of injections of different types of steroids, one trial that compared injections of anesthetics alone to injections of steroids plus anesthetics, one trial that compared injections of steroids alone to injections of steroids plus anesthetics, and two trials that compared the relative effectiveness of injections of different combinations of steroids and anesthetics.

Internal validity

The treatments evaluated by each of the studies are summarized in Table 246. Details of the study designs are shown in Table 247. One randomized double-blinded controlled study of 65 patients evaluated the effect of injections of glucosaminoglycan polysulfate as compared to placebo injections. One randomized double-blinded controlled trial of 58 patients compared a combination of methylprednisolone plus lidocaine to lidocaine alone. Two double-blinded randomized controlled trials of a total of 254 patients compared different combinations of steroids plus local anesthetics. One double-blinded controlled trial of 46 patients compared injections of hydocortisone to injections of methylprednisolone. If patients are not randomly assigned to groups, there may be important differences between these groups that could contribute to any observed differences in outcomes.

One trial compared injections of a steroid to injections of a steroid plus a local anesthetic. This trial (Kivi 1982) was an unblinded A-B trial, in which the patients were given steroid injections for 6 months, and then were given a steroid plus an anesthetic for an additional 6 months. In addition, another group of patients was treated with injections of steroid plus anesthetic only, but the results from this group were pooled with that of the cross-over treatment group. Lack of blinding of the patient and the evaluating physician to the treatment type can alter measurements of treatment effect as discussed previously.

Three of the seven trials did not analyze their data according to the intent-to-treat principle. Ignoring attrition when analyzing the data can create a bias in the results.

Where possible, we have tried to compensate for this by attempting to gauge the maximum possible effect of not following this principle. Thus, we assumed that all patients who were not followed until the end of the study received unsuccessful treatment. This is a conservative assumption. However, if statistical significance is obtained under this assumption, one can be more confident that the magnitude of this design weakness is not large enough to overturn the results of a statistically significant trial. Due to incomplete data reporting, we were unable to compensate for attrition in any of these trials.

Table 246. Summary of the treatments

Study	Injections group 1	Injections group 2
Akermark 1995 [583]	glucosamines	Placebo injection
Clarke 1975 [605]	hydrocortisone	methylprednisolone
Stahl 1997 [601]	methylprednisolone plus lidocaine	lidocaine
Solveborn 1995 [602]	triamcinolone plus lidocaine	triamcinolone plus bupivacaine
Price 1991 [603]	lignocaine plus triamcinolone or lignocaine plus hydrocortisone	lignocaine
Kivi 1982 [604]	methylprednisolone	lidocaine plus betamethasone

Table 247. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Akermark 1995 [583]	65	Multiple	NR	RCT	Yes	Double	7.7	No	NA
Stahl 1997 [601]	58	1	No	RCT	Yes	Double	0	Yes	NA
Solveborn 1995 [602]	109	1	NR	RCT	Yes	Double	42.2	No	NA
Price 1991 [603]	145	1	Yes	RCT	Yes	Double	0	Yes	51.7
Kivi 1982 [604]	88	1	NR	A-B	Yes	No	13.6	No	NA
Clarke 1975 [605]	46	1	Yes	CT	Yes	Double	0	Yes	NA

RCT = randomized controlled trial
CT = controlled trial
NA = not applicable
NR = not reported

Generalizability

Characteristics of the patients included in these studies are shown in Table 248. Studies of the epidemiology of epicondylitis (see the Introduction) have found that typical patients are in their mid-forties and are equally likely to be of either sex. All

of the trials included patients similar to the typical epicondylitis patient except for the study by Stahl 1997, which included a group of patients who were predominantly male (76% male). The trial by Clarke 1975 did not report sufficient data on sex or age to be able to determine whether the results of the study are generalizable or not.

The presence of various comorbidities associated with epicondylitis is incompletely reported in these studies. Some studies excluded patients with some comorbidities, indicated in Table 248 by a zero under that comorbidity. This somewhat limits the generalizability of these studies, as comorbidities may not be exclusion criteria for receiving injections of anethestics, steroids, or glucosamines.

Occupations and employment status of the patients are shown in Table 249. Only two of the studies reported any data on the occupations of their patient groups. Therefore, the extent to which the employment characteristics of these patients may be generalized to the overall epicondylitis population cannot be determined from the information available.

Table 248. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Stahl 1997 [601]	58	42	24.1	4.5	NR	0	0	0	0	NR	NR	No	No
Akermark 1995 [583]	65	44 (27-60)	44.6	11 (3-36)	NR	NR	NR	NR	NR	0	NR	No	No
Solveborn 1995 [602]	109	43.8	NR	8.2	NR	NR	NR	NR	NR	NR	NR	No	No
Price 1991 [603]	145	46 (19-65)	48.9	6 (2-38)	NR	NR	NR	NR	NR	NR	NR	No	No
Kivi 1982 [604]	88	43 (22-64)	43.2	NR	NR	NR	NR	NR	NR	NR	NR	No	No
Clarke 1975 [605]	46	NR	NR	NR	NR	0	NR	NR	NR	NR	NR	No	No

NR = not reported

Table 249. Generalizability: patient occupations

Study	Number of patients	% Patients employed	% Patients on Workers' compensatio	% Patients retired	% Patients homemakers	Reported occupations
Stahl 1997 [601]	58	NR	NR	NR	NR	46.6% white collar workers 29.3% manual laborers
Akermark 1995 [583]	65	NR	NR	NR	NR	NR
Solveborn 1995 [602]	109	NR	NR	NR	NR	NR
Price 1991 [603]	145	NR	NR	NR	NR	NR
Kivi 1982 [604]	88	NR	NR	NR	18.1	18.1% heavy manual labor 29.5% office work
Clarke 1975 [605]	46	NR	NR	NR	NR	NR

NR = not reported

Results

Glucosamines

One double-blinded randomized controlled trial of a total of 65 patients evaluated the effect of injections of glucosamines as compared to placebo injections on epicondylitis. The patients received weekly injections for five weeks. The study evaluated two different patient-oriented outcomes: success of the treatment, and pain when carrying out activities of daily living (ADL), as rated by the patient on a visual analog scale (VAS). The reported data are shown in Table 250 and summarized in Table 251. For both outcomes, glucosamine injections had a statistically significant effect 1 to 3 months after treatment, but by six months the differences between the two groups had become statistically insignificant.

The study reported that 40.6% of the patients treated with glucosamines experienced pain at the site of the injection and 6.3% developed hematomas at the site of injection, compared to 17.9% of the placebo group who experienced pain, and 0% who developed hematomas at the site.

Table 250. Results of treating epicondylitis with injections of glucosamines

Study	Outcome measurement	Treatment group	N patients	Time in months	Number of failures (%)		Statistical test	P value
Akermark 1995 [583]	Number of treatment failures	GAGPS	32	1	11 (34.4%)		Mantel-Haenszel	0.12
		placebo	28	1	17 (60.7%)			
		GAGPS	32	1.5	4 (12.5%)			0.011
		placebo	28	1.5	12 (42.9%)			
		GAGPS	32	3	6 (18.8%)			0.051
		placebo	28	3	12 (10.7%)			
		GAGPS	32	6	9 (28.1%)			0.22
		placebo	28	6	13 (46.4%)			
	Pain-patient rated	**Treatment group**	**N**	**Months**	**Mean**	**SD**	**Statistical test**	**P value**
		GAGPS	32	0	62.8	15.4	ANOVA	NS
		placebo	28	0	58.6	17.9		
		GAGPS	32	1	44.1	19.9		0.051
		placebo	28	1	48.4	20.8		
		GAGPS	32	1.5	30.3	20.7		0.0053
		placebo	28	1.5	40.5	25.6		
		GAGPS	32	3	30.7	24.7		0.021
		placebo	28	3	40.8	27.7		
		GAGPS	32	6	33	25.3		0.18
		placebo	28	6	37.3	30.1		

[a] calculated by ECRI

Table 251. Results of treating epicondylitis with injections of glucosamines

Study	Number of patients	Outcome	Followup time	Which treatment was more effective?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Akermark 1995 [583]	32 GAGPS 28 placebo	Number of treatment failures	1 month	GAGPs	No	0.59 (0.01 to 1.17)
			1.5 months	GAGPs	Yes	0.90 (0.19 to 1.61)
			3 months	GAGPs	No	0.64 (0.00 to 1.28)
			6 months	GAGPs	No	0.43 (-0.16 to 1.02)
	32 GAGPS 28 placebo	Patient rated pain	1 month	GAGPs	No	0.21 (-0.08 to 0.95)
			1.5 months	GAGPs	Yes	0.44 (-0.08 to 0.95)
			3 months	GAGPs	Yes	0.38 (-0.13 to 0.89)
			6 months	GAGPs	No	0.15 (-0.35 to 0.66)

GAGPS = glucosaminoglycan polysulfate
[a] calculated by ECRI

Different types of steroids

One double-blinded controlled trial of 46 patients compared injections of hydrocortisone to injections of methylprednisolone for treating epicondylitis. The data reported from this trial are shown in Table 252 and summarized in Table 253. The trial reported on whether the treatments were successful in treating the pain of epicondylitis, and on whether the pain recurred after six months. No statistically significant difference in either of these outcomes was found between treatment with the two different steroids. Injections of these steroids were reported to cause pain and bruising in a low percentage of patients. There was no statistically significant difference in the rates of such side effects between the two steroids. The study had the statisticaly power to detect fairly small (19-23%) differences between groups. This suggests that if there is a difference between groups, it is not large.

Table 252. Hydrocortisone compared to methylprednisone for treating epicondylitis

Study	Outcome measured	Number of patients	Number of patients considered to have a successful treatment	Statistical signficance of the difference between groups
Clarke 1975 [605]	A success was two pain-free visits; a failure was three injections without improvement over the course of 2 months	48 methylprednisone 55 hydrocortisone	21 methylprednisone 20 hdrocortisone	Test NR NS
	Recurrence of symptoms by mailed questionnaire 6 months later	24 methylprednisone 23 hydrocortisone	16 methylprednisone 10 hydrocortisone	Test NR NS

Table 253. Hydrocortisone compared to methylprednisone for treating epicondylitis

Study	Outcome measured	Number of patients	Which steroid was more effective?	Was the difference statistically significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Clarke 1975 [605]	Success of treatment	48 methylprednisone 55 hydrocortisone	methylprednisone	No	19%	0.17 (-0.27 to 0.61)
	Recurrence of symptoms by mailed questionnaire	24 methylprednisone 23 hydrocortisone	methylprednisone	No	23%	0.52 (-0.13 to 1.2)

[a] calculated by ECRI

Glucocorticoids plus anesthetics compared to anesthetics

One randomized double-blinded controlled trial of 58 patients compared a combination of methylprednisolone plus lidocaine to lidocaine alone. In addition to the injections, all patients in this trial received oral NSAIDs, physical therapy, and were advised to rest the affected arm. The patients each received a single injection. The trial evaluated the pain the patients were experiencing as rated by the patient.

The data are shown in Table 254 and summarized in Table 255. The patients treated with the steroid plus the anesthetic had statistically significantly less pain at 1.5 months, but not at longer followup times, than did patients treated only with an anesthetic.

Table 254. Results of treating epicondylitis with anesthetics compared to anesthetics plus glucocorticoids

Study	Outcome measured	Treatment group	N patients	Time in months	Outcome mean (SE)	Statistical significance of difference between groups
Stahl 1997 [601]	Patient-rated pain	Methylprednisolone plus lidocaine	43	0	3.7 (0.26)	T test p >0.5
		lidocaine	30	0	3.5 (0.24)	
		Methylprednisolone plus lidocaine	43	1.5	1.5 (0.3)	T test p <0.03
		lidocaine	30	1.5	2.2 (0.29)	
		Methylprednisolone plus lidocaine	43	12	0.5 (0.18)	T test p >0.5
		lidocaine	30	12	0.6 (0.17)	

Table 255. Effectiveness of treating epicondylitis with anesthetics compared to anesthetics plus glucocorticoids

Study	Number of patients	Time of followup	Which treatment was most effective?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Stahl 1997 [601]	43 Methylprednisolone plus lidocaine 30 lidocaine	0 months	No difference	No	-0.13 (-0.60 to 0.33)
		1.5 months	Methylprednisolone plus lidocaine	Yes	0.39 (-0.08 to 0.86)
		12 months	Methylprednisolone plus lidocaine	No	0.09 (-0.37 to 0.56)

[a] calculated by ECRI

Glucocorticoids plus anesthetics compared to glucocorticoids

One A-B trial compared injections of lidocaine plus betamethasone to injections of methylprednisolone. The data reported by the trial are shown in Table 256 and summarized in Table 257. The trial reported the success of the treatment as rated by the patient (global outcome). Steroids plus anesthetics were found to be more effective than steroids alone, but the difference did not reach statistical significance. The study was large enough to detect fairly small differences in outcomes between the groups. The trial also reported the number of work-days the patients missed due to their epicondylitis. There was insufficient data reported about work status to determine if the difference was statistically significant.

Table 256. Results of trials comparing steroids to steroids plus anesthetics as a treatment for epicondylitis

Study	Outcome measured	Number of patients	Reported data	Statistical signficance of the difference between groups
Kivi 1982 [604]	Success of treatment, at 12 months	47 Betamethasone and lidocaine 21 methylprednisolone	Steroid plus lidocaine: 36 excellent, 7 good, 3 same, 1 worse Steroid: 16 excellent, 3 good, 2 same, 0 worse	Chi-squared test p = 0.057
	Days off work, at 12 months	47 Betamethasone plus lidocaine 21 Methylprednisone	Steroid plus lidocaine: Mean 16.4 days off Steroid: Mean 12.2 days off	Cannot calculated from the reported data

NC = could not calculate from the reported data

Table 257. Effectiveness of steroids compared to steroids plus anesthetics as a treatment for epicondylitis

Study	Outcome measured	Number of patients	Which treatment was most effective?	Was the difference statistically significant?	What was the minimal difference between groups the study had the power to detect?	Effect size d (95% CI)[a]
Kivi 1982 [604]	Success of treatment	47 Betamethasone plus lidocaine 21 Methylprednisone	Betamethasone plus lidocaine	No	8%	0.13 (-0.39 to 0.64)
	Days off work	47 Betamethasone plus lidocaine 21 Methylprednisone	Methylprednisone	Not reported; cannot determine from reported data	Cannot calculated from the reported data	Cannot calculate from the reported data

[a] calculated by ECRI

Different combinations of glucocorticoids plus anesthetics

Two double-blinded randomized controlled trials of a total of 254 patients compared different combinations of steroids plus local anesthetics as a treatment for epicondylitis. One of the trials compared triamcinolone plus lidocaine to triamcinolone plus bupivacaine (Solveborn 1995). The other trial compared lignocaine alone to lignocaine plus hydrocortisone, lignocaine plus 10 mg of triamcinolone, and lignocaine plus 20 mg of triamcinolone (Price 1991). The trial by Solveborne 1995 did not report any data or statistics, but reported only that patients receiving bupivacaine had a better outcome two weeks after the injection than did patients receiving the lidocaine. The data reported by Price 1991 are shown in Table 258 and summarized in Table 259. Price 1991 reported that at one month, the group treated only with lignocaine had significantly less improvement than did the other groups, but that this difference was not statistically significant by 6 months. Price 1991 reported that some of the patients who received injections of triamcinolone experienced skin atrophy at the site of injection.

Table 258. Results of the study by Price 1991: patient-reported pain on VAS

Study	Treatment group	N patients	Months	Outcome mean (95% CI)	Effect size d (95% CI)[a]
Price 1991 [603]	Ligno	29	1	46 (37-55)	
	Ligno +hydro	29	1	28 (18-38)	3.66 (2.82 to 4.50)
	Ligno + triam	29	1	17 (10-25)	6.78 (5.44 to 8.12)
	Ligno + 10 triam	23	1	27 (18-37)	3.99 (3.05 to 4.93)
	Ligno + 20 triam	28	1	28 (19-37)	3.86 (2.98 to 4.74)
	Ligno	27	2	35 (26-43)	
	Ligno +hydro	27	2	30 (19-41)	0.99 (0.42 to 1.55)
	Ligno + triam	27	2	20 (10-30)	3.13 (2.34 to 3.93)
	Ligno + 10 triam	22	2	29 (17-40)	1.16 (0.55 to 1.77)
	Ligno + 20 triam	24	2	22 (14-31)	2.98 (2.18 to 3.77)
	Ligno	25	6	12 (8-17)	
	Ligno +hydro	26	6	24 (14-35)	-2.83 (-3.60 to -2.05)
	Ligno + triam	27	6	18 (7-28)	-1.40 (-2.01 to -0.80)
	Ligno + 10 triam	22	6	35 (21-48)	-4.52 (-5.60 to -3.44)
	Ligno + 20 triam	27	6	33 (22-45)	-4.55 (-5.58 to -3.52)

[a] calculated by ECRI, using lignocaine as the control group in each case. A positive effect size indicates the treatment group had less pain than the control group

Table 259. Summary of the study by Price 1991

Study	Number of patients	Time of followup	Which treatment was more successful?	Was the difference statistically significant?	Relevant effect size d (95% CI)
Price 1991 [603]	29 Ligno 29 Ligno +hydro 30 Ligno + triam 27 Ligno + 10 triam 29 Ligno + 20 triam	1 month	Lignocaine plus triamcinolone	Yes	6.78 (5.44 to 8.12)
		2 months	Lignocaine plus triamcinolone	No	3.13 (2.34 to 3.93)
		6 months	Lignocaine	No	NA

Ligno = lignocaine
Hydro = hydrocortisone
Triam = triamcinolone

Conclusions

One randomized double-blinded study reported that injections of glucosamines are effective in treating the symptoms of epicondylitis in the short term (less than 6 months) as measured by global outcome and patient-reported pain. However, injections of glucosamines were found to have a high rate of side effects- 40% of patients experienced pain at the site of injection, and 6% developed hematomas at the site of injection.

One randomized double-blinded study reported that injections of methylprednisolone plus lidocaine were statistically significantly more effective at treating pain than were injections of lidocaine.

One randomized double-blinded study reported that injections of lignocaine plus triamcinolone were statistically significantly more effective at treating pain than were injections of lignocaine or injections of lignocaine plus hydrocortisone.

One randomized double-blinded study reported that injections of triamcinolone plus bupivacaine were more successful at treating epicondylitis than were injections of triamcinolone plus lidocaine.

One study reported a trend towards more successful treatment of epicondylitis after injections of methylprednisolone than after injections of hydrocortisone. However, this study was of less than optimal design, which makes it problematic to come to a definitive evidence-based conclusion on the basis of its results.

One study reported no difference in rates of successful treatment or number of work-days missed after treatment with injections of methylprednisolone as compared to injections of betamethasone plus lidocaine. This study had sufficient statistical power to have detected relatively small differences between-treatment groups. However, design flaws in this study make it problematic to come to a definitive evidence-based conclusion on the basis of its results.

What are the relative benefits and harms of ultrasound and phonophoresis therapy for persons with epicondylitis?

Ultrasound has been used as a therapy for the treatment of musculoskeletal pain. Ultrasound has been said to increase blood flow, membrane permeability, and to alter connective tissues and nerve conduction speed.[622,623] Phonophoresis refers to using ultrasound to drive a drug suspended in a coupling medium into the tissues.[623]

The relevant literature on this topic consists of three trials comparing ultrasound to sham or no treatment, and two trials comparing ultrasound to phonophoresis of hydrocortisone.

Internal validity

Two studies of 82 patients in total compared ultrasound alone to phonophoresis of hydrocortisone. Three studies of a total of 220 patients compared ultrasound treatment to sham or no treatment. Details of the study design are shown in Table 260. All of the studies were randomized controlled trials. All except for the study by Holdsworth 1993 were double-blinded; the study by Holdsworth 1993 blinded only the patients to the treatment administered. Lack of blinding of the evaluating physician is a design weakness. If the evaluating physician is aware of the treatment given, it is possible that he/she may unconsciously bias the patient's reponses by giving leading instructions.[474]

Two of the studies did not analyze their data according to the intent-to-treat principle. Ignoring attrition when analyzing the data can create a bias in the results. However, we were unable to compensate for the attrition from these two studies due to incomplete data reporting.

Table 260. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Holdsworth 1993 [620]	42	1	NR	RCT	Yes	Patients	14.3	No	NA
Haker 1991 [619]	45	1	NR	RCT	Yes	Double	28.9	No	NA
Stratford 1989 [621]	40	1	No	RCT	Yes	Double	0	Yes	NA
Lundeberg 1988 [617]	99	1	NR	RCT	Yes	Double	0	Yes	NR
Binder 1985 [618]	76	1	NR	RCT	Yes	Double	0	Yes	NA

RCT = randomized controlled trial
NA = not applicable
NR = not reported

Generalizability

Details of the patient groups are shown in Table 261. Studies of the epidemiology of epicondylitis (see the Introduction) have found that the typical patient with epicondylitis is in the mid-forties and equally likely to be male or female. All of the patient groups enrolled in these trials are similar in mean age and gender composition to the typical patients.

The presence of various comorbidities associated with epicondylitis is incompletely reported in these studies. Some studies excluded patients with some comorbidities, indicated in Table 261 by a zero under that comorbidity. This limits the generalizability of these studies, as combordities are not usually an exclusion criterion for treatment with ultrasound or phonophoresis.

None of the studies reported any information on patient employment characteristics. Therefore, the extent to which the employment characteristics of these patients may be generalized to the overall epicondylitis population cannot be determined from the information available.

Table 261. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Holdsworth 1993 [620]	42	45.3 (22-62)	35.7	NR	NR	0	0	0	0	NR	NR	No	No
Haker 1991 [619]	45	49.3 (34-67)	44.4	8.5 (1-60)	NR	NR	NR	NR	NR	NR	NR	No	No
Stratford 1989 [621]	40	43.3	50.0	4.3	NR	NR	NR	0	NR	NR	NR	No	No
Lundeberg 1988 [617]	99	38 (21-68)	43.4	NR	NR	0	NR	0	0	NR	NR	No	No
Binder 1985 [618]	76	43.3 (29-65)	63.2	4.6 (1-12)	NR	0	NR	0	0	NR	NR	No	No

NR = not reported

Results

Success of Treatment

Two studies of a total of 59 patients measured the success of ultrasound treatment. One of these studies compared ultrasound to phonophoresis, while the other compared ultrasound to sham ultrasound. These data are shown in Table 262 and summarized in Table 263. One study measured treatment by asking the patients to rate their condition as excellent, improved, or the same/worse, while the other study asked the patients to rate their condition on a 10 cm visual analog scale (VAS). The studies reported no statistically significant difference between ultrasound treatment and sham treatment, and no statistically significant difference between ultrasound and phonophoresis treatment. Although the Holdsworth 1993 study was so small (n=16 patients) it could only have detected a 82.5% or larger difference, the Haker 1991 study could have detected a 20% or greater difference. Hence, this latter study suggests that that, if there is an effect of ultrasound on patient-rated treatment success, it is not large.

Table 262. Results of treating epicondylitis with ultrasound

Study	Number of patients	Reported outcome	Statistical significance of difference between groups
Holdsworth 1993 [620]	7 Phonophoresis 9 Ultrasound	At 1.5 months, mean (SE) patient-rated global outcome on VAS Phonophoresis: 49.6 (12.4) Ultrasound: 63 (12.2)	ANOVA p >0.05
Haker 1991 [619]	21 Ultrasound 22 Sham	At 3 months, patient-rated global outcome Ultrasound: 8 excellent, 8 improved, 5 same or worse Sham: 10 excellent, 7 improved, 5 same or worse	Mann-Whitney U-test NS

Table 263. Success of treating epicondylitis with ultrasound

Study	Number of patients	Time of followup	Which treatment was more successful?	Was the difference statistically significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)
Holdsworth 1993 [620]	7 phonophoresis 9 ultrasound	1.5 months	Ultrasound	No	82.5%	0.33 (-0.55 to 1.20)
Haker 1991 [619]	22 sham 21 ultrasound	3 months	Sham	No	20%	-0.19 (-0.79 to 0.41)

Work Status

None of the studies reported data applicable to this outcome.

Pain

Three studies of a total of 161 patients reported pain after treating epicondylitis with ultrasound. One of these studies compared ultrasound alone to phonophoresis, while the other two studies compared ultrasound to sham or no treatment. The data from these studies are shown in Table 264 and summarized in Table 265. The study comparing ultrasound to phonophoresis reported no statistically significant difference in pain between the two treatment groups. It was, however, too small to detect differences between the treatment groups of less than 50%.

One of the studies comparing ultrasound to sham or no treatment reported no statistically significant difference in pain between-treatment groups, while the other study reported a significant decrease in pain experienced by the group treated with ultrasound as compared to the untreated group. However, the effect sizes we calculated for both of these studies suggested a statistically significant effect of ultrasound as compared to no or sham treatment.

Table 264. Effect of ultrasound treatment on pain related to epicondylitis

Study	Number of patients	Reported outcome: patient-reported pain on VAS	Statistical signficance of difference between groups
Stratford 1989 [621]	10 phonophoresis 9 ultrasound	At 2.5 months, mean (SD) Phonophoresis: 21.8 (30.4) Ultrasound: :28.3 (17)	ANCOVA P = 0.87
Lundeberg 1988 [617]	33 ultrasound 33 No treatment 33 sham	At 3 months, mean (SD) Ultrasound 2.8 (0.3) No treatment 2.1 (0.5) Sham 2.4 (0.3)	Wilcoxon's rank sum test NS
Binder 1985 [618]	38 Ultrasound 38 No treatment	0.5 months, mean Utlrasound 0.75 No treatment 2.2 1 months, mean Ultrasound 3.4 No treatment 1.5 2 months, mean Ultrasound 4 No treatment 1.7	Wilcoxon's rank sum test At 1 month p <0.01 At 2 months p <0.005

Table 265. Pain experienced by patients treated with ultrasound

Study	Number of patients	Time of followup	Which treatment resulted in less pain?	Was the difference statistically significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Stratford 1989 [621]	10 phonophoresis 9 ultrasound	2.5 months	Phonophoresis	No	54.3%	0.26 (-0.34 to 0.86)
Lundeberg 1988 [617]	33 ultrasound 33 No treatment 33 sham	3 months	Ultrasound	No	Could not calculate from the reported data	Vs. no: 1.68 (1.12 to 2.24) Vs. sham: 1.32 (0.79 to 1.85)
Binder 1985 [618]	38 Ultrasound 38 No treatment	1 and 2 months	Ultrasound	Yes at both times of followup	NA	1 month: 0.60 (0.14 to 1.06) 2 months: 0.66 (0.20 to 1.12)

[a] calculated by ECRI

Function and Activities

One study reported data on patient-reported function and activities of daily living. This study compared phonophoresis to ultrasound, and measured pain upon performing activities of daily living, function as rated by VAS, and the ability to perform recreational activities. No statistically significant difference for any of the outcomes was reported; however, the study could have detected only a 73.6% or larger difference between the groups, so it could have missed clinically important effects. The reported results are shown in Table 266 and summarized in Table 267.

Table 266. Effect of ultrasound on hand/arm function

Study	Number of patients	Patient-reported hand/arm function- VAS	Statistical signficance of the difference between groups
Stratford 1989 [621]	10 phonophoresis 9 ultrasound	At 2.5 months, mean (SD) Phonophoresis 78.8 (23.7) Ultrasound 66 (25)	ANCOVA p >0.05

Table 267. Function after treatment with ultrasound

Study	Number of patients	Followup time	Which treatment resulted in more effective function?	Was the difference statistically significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Stratford 1989 [621]	10 phonophoresis 9 ultrasound	2.5 months	phonophoresis	No	73.6%	0.50 (-0.39 to 1.39)

a: calculated by ECRI

Quality of Life

None of the included studies reported on this outcome.

Morbidity and Complications

None of the included studies reported data applicable to this outcome.

Conclusions

Two randomized controlled trials of 82 patients in total compared ultrasound treatment to phonophoresis of hydrocortisone as a therapy for epicondylitis. Neither study reported statistically significant differences between-treatment groups for any of the outcomes. When interpreting these results, it is important to keep in mind that both studies may have been too small to be able to detect clinically relevant differences between-treatment groups.

Three randomized controlled trials of 220 patients in total compared ultrasound treatment to sham ultrasound treatment or no treatment as a therapy for epicondylitis. All three of the studies reported a trend towards better outcomes in the groups treated with ultrasound. However, this difference reached statistical significance in only one of the studies. Although low statistical power may explain the negative results of the two "nonsignificant" studies, further research is required to demonstrate this.

What are the relative benefits and harms of bracing, physiotherapy, and manipulation as therapy for persons with epicondylitis?

Splints, braces, and other supportive devices to be worn around the elbow are advocated by some as a therapy for epicondylitis. The devices are said to reduce the stresses to the forearm extensor muscle origin by providing a counterforce brace and thus allow the area to rest and heal while not interfering with normal activity.[78,624,625] Most braces used to treat epicondylitis consist of a band that straps tightly around the forearm just below the elbow. Physiotherapy for the treatment of epicondylitis refers to programs that generally aim gradually to stretch and strengthen the tendons and muscles of the forearm, in hopes that this will allow the affected area to resist stresses more effectively.[626] Manipulation refers to forced movements of the affected limb. Practitioners claim that manipulation returns out-of-place body parts to their original sites and releases adhesions.[75]

The relevant literature that addresses this question consists of one trial that compared manipulation to no treatment, and four trials that evaluated the relative effectiveness of different types of braces and physiotherapy.

Internal validity

Details of the designs of the trials are shown in Table 268. We identified one randomized double-blinded crossover study of 15 patients that evaluated a manipulative technique (contralateral glide) as compared to a placebo manipulation and no manipulation.

We included four studies that enrolled a total of 273 patients that evaluated braces as therapy for epicondylitis. Two crossover trials and one controlled trial compared braces to either a placebo brace or no treatment. A controlled trial of 185 patients compared a brace to physiotherapy. None of these four studies were blinded. Lack of blinding of the patient to the type of treatment, particularly when using subjective outcome measures, can alter measurements of treatment effect because patients might unconsciously rate their condition differently in order to please the clinician.[474] Lack of blinding of the evaluating physician may result in the physcian unconsciously biasing the patient's responses by giving leading instructions.[474]

Compliance was low in the two longer term trials. In the trial by Clements 1993, only 52.6% of the patients followed the prescribed regimen. In the trial by Solveborn 1997, compliance was initially high (88.1%), but at the longest followup time (3 months) compliance had dropped to 55%.

Statistical analysis was not intent-to-treat in the trials by Solveborn 1997 or Clements 1993. Both of these trials had attrition rates greater than 15%. Ignoring attrition when analyzing the data can create a bias in the results. Where possible, we have tried to compensate for this by attempting to gauge the maximum possible effect of not following this principle. Thus, we assumed that all patients who were not followed until the end of the study received unsuccessful treatment. This is a

conservative assumption. However, if statistical significance is obtained under this assumption, one can be more confident that the magnitude of this design weakness is not large enough to overturn the results of a statistically significant trial. We were not able to compensate for attrition in the trial Clements 1993 due to incomplete data reporting, but we were able to compensate for attrition in the trial by Solveborn 1997. Compensating for attrition did not change the conclusions of this trial.

Table 268. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Wuori 1998 [577]	50	1	No	RCT Xover	Yes	No	0	Yes	NA
Solveborn 1997 [579]	185	1	NR	CT	Yes	No	29.2	No	88.1
Vicenzino 1996 [592]	15	1	NR	RCT Xover	Yes	Double	0	Yes	NA
Clements 1993 [580]	19	1	NR	CT	Yes	No	15.8	No	52.6
Forbes 1990 [578]	19	1	Yes	Xover	Yes	No	0	Yes	NA

NR = not reported
RCT = randomized controlled trial
CT = controlled trial
Xover = crossover
NA = not applicable

Generalizability

Details of the patient characteristics are shown in Table 269. Studies of the epidemiology of epicondylitis (see the Introduction) have found that the typical patient is in the mid-forties and is equally likely to be male or female. Forbes 1990 did not report the ages of the patients. The mean ages of the patient groups in the other studies are all in the mid-forties. Solveborn 1997 did not report the sexes of the patients. The trial by Clements 1993 was predominantly male (73.7%), and the trial by Forbes 1990 was predominantly female (84.2%). It is possible these patient groups may be composed of atypical patients.

The presence of various comorbidities associated with epicondylitis is incompletely reported in these studies. Some studies excluded patients with some comorbidities, indicated in Table 269 by a zero under that comborbidity. This somewhat limits the generalizability of these studies, as comorbidities are not exclusion criteria for the treatments evaluated in this section.

The occupations and employment status of the patients are shown in Table 270. Only one study reported any information about the employment status of its patients. Therefore, the extent to which the employment characteristics of these patients may be generalized to the overall epicondylitis patient population cannot be determined from the information available.

Table 269. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Wuori 1998 [577]	50	44.5	46	7.5	NR	NR	NR	0	NR	NR	NR	No	No
Solveborn 1997 [579]	185	43.5 (19-71)	NR	12.3 (0-72)	NR	NR	NR	NR	NR	NR	NR	No	No
Vicenzino 1996 [592]	15	44 (22-62)	53.3	8 (2-36)	NR	NR	NR	NR	NR	NR	NR	No	No
Clements 1993 [580]	19	42.4 (33-54)	26.3	NR	NR	0	0	NR	NR	NR	NR	No	No
Forbes 1990 [578]	19	NR	84.2	NR	NR	NR	NR	NR	NR	NR	NR	No	No

NR = not reported

Table 270. Generalizability: patient occupations

Study	Number of patients	% Patients employed	% Patients on Workers' compensatio	% Patients retired	% Patients homemakers	Reported occupations
Wuori 1998 [577]	50	NR	NR	NR	NR	NR
Solveborn 1997 [579]	185	NR	NR	NR	NR	NR
Vicenzino 1996 [592]	15	NR	NR	NR	NR	NR
Clements 1993 [580]	19	NR	NR	NR	10.5	21.0% food services 15.7% mechanic/repairman 5.2% nurse 5.2% librarian 5.2% engineer 5.2% office worker
Forbes 1990 [578]	19	NR	NR	NR	NR	NR

NR = not reported

Results

Manipulation

One randomized controlled crossover trial of 15 patients compared a contralateral glide manipulation technique to no manipulation and to a placebo manipulation (Table 271). Patient-reported pain (VAS) and function (activities of daily living; ADL) were measured before treatment, and 24 hours after each treatment. Outcomes after each treatment were not directly compared. Instead, pre-post outcome measurements were compared. There were no statistically significant changes in these patient-oriented outcomes for any of the treatments. Statistical significance was defined as $p < 0.05$, but the test used was not described. The reported data were insufficient for effect size of power calculations.

Table 271. Effect of treatment with manipulation on epicondylitis

Study	Number of patients	Which treatment was more effective?	Was the difference statistically significant?	Was the effect size statistically significant?	Did the study have sufficient power to detect the observed difference?
Vicenzino 1996 [592]	15 manipulation 15 placebo	No difference	No	Could not calculate from the reported data	Could not calculate from reported data

Braces and physiotherapy

Success of Treatment

One trial that compared wearing a brace for several months to receiving regular physiotherapy reported on this outcome. The data are shown in Table 272 and summarized in Table 273. For both followup times, physiotherapy was statistically significantly more successful than was bracing.

Table 272. Results of treating epicondylitis with bracing or physiotherapy

Study	Number of patients	N patients treated successfully (%)	Statistical significance of difference between groups
Solveborn 1997 [579]	91 Bracing 85 Physiotherapy	At 1 month, Bracing 56 (61.5%) Physiotherapy 80 (95%) At 3 months, Bracing 23 (25.3%) Physiotherapy 38 (44.7%)	Chi-squared test At 1 month, p <0.0001 At 3 months, p <0.01

Table 273. Success of treating epicondylitis with bracing or physiotherapy

Study	Number of patients	Time of followup	Which treatment was more successful?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Solveborn 1997 [579]	91 Bracing 84 Physiotherapy	1 and 3 months	Physiotherapy	Yes	At 1 month: -1.39 (-1.99 to -0.79) At 3 months: -0.44 (-0.79 to -0.08)

[a] calculated by ECRI

Work Status

The trial by Solveborn 1997 reported the number of days patients were unable to work due to their condition. These data are shown in Table 274 and summarized in Table 275. At three months and nine months of followup, the group treated with physiotherapy had statistically significantly fewer days of not working than did the group treated with bracing.

Table 274. Results of treating epicondylitis with bracing or physiotherapy on work status

Study	Number of patients	Mean number of days off work	Statistical significance of difference between groups
Solveborn 1997 [579]	91 Bracing 94 Physiotherapy	At 1 month: bracing 14 Physiotherapy 14 At 3 months: Bracing 20 Physiotherapy 13 At 9 months: Bracing 24 Physiotherapy 14	Chi-squared test At 1 month NS At 3 months p <0.01 At 9 months p <0.01

Table 275. Effect of treating epicondylitis with bracing or physiotherapy on work status

Study	Number of patients	Which treatment resulted in fewer days off work?	Was the difference statistically significant?	Effect size
Solveborn 1997 [579]	91 Bracing 94 Physiotherapy	Physiotherapy	No at 1 month Yes at 3 and 9 months	Could not calculate from the reported data

Pain

The crossover trial by Wuori 1998 asked the patients to rate their pain before, during, and after tests of grip strength while wearing various types of braces. There were no statistically significant differences in pain reported from tests wearing the different types of braces (data shown in Table 276 and summarized in Table 277). However, the trial by Wuori 1998 had insufficient power to detect differences between the groups of less than 64%.

The trial by Clements 1993 reported that patients who had been treated with a brace plus physiotherapy for a month had statistically significantly less self-reported pain than did patients treated only with physiotherapy (t-test; $p < 0.05$). The trial by Solveborn 1997 reported that all times of followup the patients treated with physiotherapy reported less pain than did the patients treated by bracing (data shown in Table 276 and summarized in Table 277).

Table 276. Results of treatment with bracing on pain related to epicondylitis

Study	Number of patients	Pain reported by patients	Statistical significance of difference between groups
Wuori 1998 [577]	50 Count'Rforce brace 50 Airprene brace 50 Placebo brace	Mean (SD) Before other tests CountRforce 1.3 (1.7) Airprene1.4 (1.9) Placebo 1.4 (1.8) During other tests CountRforce 3.4 (2.1) Airprene 3.3 (2.3) Placebo 3.4 (2.4) After other tests CountRforce1.5 (1.7) Airprene 1.7 (2.1) Placebo 1.4 (1.8)	ANOVA Before other tests NS During other tests NS After other tests NS
Solveborn 1997 [579]	91 Bracing 94 Physiotherapy	1 month Bracing 39 (22) Physiotherapy 27 (21) 3 months Bracing 32 (21) Physiotherapy 20 (22) 9 months Bracing 19 (19) Physiotherapy 13 (20)	Paired t-test 1 month $p < 0.0001$ 3 months $p < 0.0001$ 9 months $p < 0.045$

Table 277. Effect of treatment with bracing on pain related to epicondylitis

Study	Number of patients	Which treatment resulted in less pain?	Was the difference statistically significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Wuori 1998 [577]	50 Count'Rforce brace 50 Airprene brace 50 Placebo brace	Airprene brace	No	64%	Before other tests: CountRforce -0.06 (-0.45 to 0.34) Airprene 0.00 (-0.39 to 0.39) During other tests: CountRforce 0.00 (-0.39 to 0.39) Airprene -0.04 (-0.43 to 0.35) After other tests: CountRforce 0.06 (-0.34 to 0.35) Airprene 0.15 (-0.24 to 0.54)
Clements 1993 [580]	10 bracing plus physiotherapy 9 physiotherapy	Bracing plus physiotherapy	Yes t-test	NA	Could not calculate from the reported data
Solveborn 1997 [579]	91 Bracing 94 Physiotherapy	Physiotherapy	Yes	NA	1 month:056 (0.26 to 0.85) 3 months: 0.56 (0.26 to 0.85) 9 months: 0.31 (0.02 to 0.60)

[a] calculated by ECRI

Function

Clements 1993 reported no statistically significant difference between patients treated with a brace plus physiotherapy and patients treated only with physiotherapy.[580] Although statistical power could not be calculated from the data provided, this study was small (n = 19), suggesting that only large differences could be detected.

Table 278. The Effect of Bracing plus Physiotherapy on Function

Study	Number of patients	Which treatment resulted in greater function?	Was the difference statistically significant?	Was the effect size statistically significant?	Did the study have sufficient power to detect the observed difference?
Clements 1993 [580]	10 bracing plus physiotherapy 9 physiotherapy	Bracing plus physiotherapy	No	Could not calculate from the reported data	Cannot calculate from the reported data

Quality of life

None of the studies reported on this outcome.

Morbidity and Complications

No morbidity or complications were reported by the studies.

Conclusions

Three crossover trials and two controlled trials evaluated the effectiveness of physiotherapy, elbow bracing, and manipulation as treatments for epicondylitis. Because only one study evaluated manipulation, only two evaluated short-term effects of braces, only one evaluated bracing vs. physiotherapy, and only one evaluated bracing plus physiotherapy, it is difficult to draw firm evidence-based conclusions from the available data.

Simply wearing an elbow brace is reported by two studies to have no effect on pain. One study reported that wearing a brace regularly over the course of several months is not as effective in treating epicondylitis as is physiotherapy, but a different study reported that wearing a brace regularly in addition to physiotherapy may be more effective than physiotherapy alone. One manipulative technique, the contralateral glide procedure, may have some benefit for the treatment of epicondylitis. These general trends are drawn from at most two studies per outcome. Confirmatory studies would strengthen confidence in these results.

What are the relative benefits and harms of acupuncture therapy for persons with epicondylitis?

Stimulation of acupuncture points is thought to induce the release of endorphins and thus induce an analgesic effect.[627] The relevant literature that addressed this question consists of two trials that compared acupuncture to sham acupuncture.

Internal validity

We identified two randomized controlled trials of a total of 134 patients that evaluated the effect of acupuncture on epicondylitis. Details of the designs of the trials are shown in Table 279. The trial by Molsberger 1994 was double-blinded. The trial by Haker 1990 was blinded as to rater only, and thus is susceptible to bias from a placebo effect.

One trial (Haker 1990) treated the control group with superficially inserted needles, while the other trial (Molsberger 1994) treated the control group with blunt probes at a different site. The appropriate control group to use in trials of acupuncture is unclear. Attempts at performing sham acupuncture, including inserting needles at other sites, inserting needles only superficially, and only stimulating the skin with a blunt probe, have been reported to have similar physiological effects as true acupuncture.[627] Therefore any comparison of acupuncture to placebo may yield a greater apparent effect than any comparison of acupuncture and sham acupuncture. However, comparing acupuncture to no treatment does not control for any placebo effect.

Table 279. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Molsberger 1994 [575]	48	1	NR	RCT	Yes	Double	0	Yes	NA
Haker 1990 [576]	86	1	NR	RCT	Yes	Rater	4.7[a]	Yes	NA

[a]: Attrition at longest follow up time (12 months)

Generalizability

Details of the patient characteristics are shown in Table 280. Studies of the epidemiology of epicondylitis (see the Introduction) have found that the typical patient is in the mid-forties and that approximately equal proportions of men and women are affected. The patients in both studies are similar to this profile.

The presence of various comorbidities associated with epicondylitis is incompletely reported in these studies. Both studies excluded patients with certain comorbidities, indicated in Table 280 by a zero under that comorbidity. This somewhat limits the

generalizability of these studies, as comborbidities are not generally exclusion criteria for treatment with acupuncture.

Neither study reported employment characteristics of their patient groups. Therefore, the extent to which the employment characteristics of these patients may be generalized to the overall epicondylitis patient population cannot be determined from the information available.

Table 280. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Molsberger 1994 [575]	48	47.9	54.2	15.4	NR	0		NR	NR	NR	NR	No	No
Haker 1990 [576]	86	46.9 (25-70)	34.9	9 (1-120)	NR	0	NR	0	0	NR	NR	No	No

Results

Success of Treatment

Both studies reported on the global outcome success of treatment. The data reported by the studies are shown in Table 281 and summarized in Table 282. Both studies reported that acupuncture was statistically significantly more successful than control treatment at early followup times (two to four weeks). Only one of the trials followed the patients for longer than two weeks, and it reported that at longer followup times the difference between the groups was not statistically significant. The results of the shorter followup times of the studies are shown graphically in Figure 71. We calculated an effect size (Hedges' d) for each study. At all followup times, the effect sizes indicated that patients treated with acupuncture had statistically significantly better outcomes. Figure 72 displays the effect sizes for the shorter followup times.

Table 281. Results of global assessment of acupuncture

Study	Number of patients	Global assessment patient-reported	Statistical significance of difference between groups
Haker 1990 [576]	44 acupuncture 38 control	Acupuncture- 1 month: 7 excellent, 15 good, 17 well improved, 4 improved, 1 same or worse 3 months: 14 excellent, 19 good, 3 well improved, 4 improved, 3 same or worse 12 months: 26 excellent, 8 good, 3 well improved, 1 improved, 2 same or worse Control- 1 month: 2 excellent, 6 good, 17 well-improved, 3 improved, 10 same or worse 3 months: 7 excellent, 14 good, 9 well improved, 3 improved, 2 same or worse 12 months: 13 excellent, 16 good, 2 well improved, 2 improved, 2 same or worse	Mann-Whitney U test P<0.01 at 1 month, NS at 3 and 12 months
Molsberger 1994 [575]	24 acupuncture 24 control	At 2 weeks Acupuncture- 19 treated successfully Control- 6 treated successfully	Chi-squared p <0.01

Table 282. Success of treating epicondylitis with acupuncture

Study	Number of patients	Time of followup	Which treatment was more successful?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Haker 1990 [576]	44 Acupuncture 38 Control	1 month	Acupuncture	Yes	0.84 (0.39 to 1.29)
		3 months	Acupuncture	No	0.44 (0.00 to 0.88)
		12 months	Acupuncture	No	0.75 (0.30 to 1.20)
Molsberger 1994 [575]	24 Acupuncture 24 Control	2 weeks	Acupuncture	Yes	1.32 (0.58 to 2.06)

[a] calculated by ECRI

Figure 71. Success of acupuncture: statistical tests

The results of Haker were statistically significant at 1 month only.

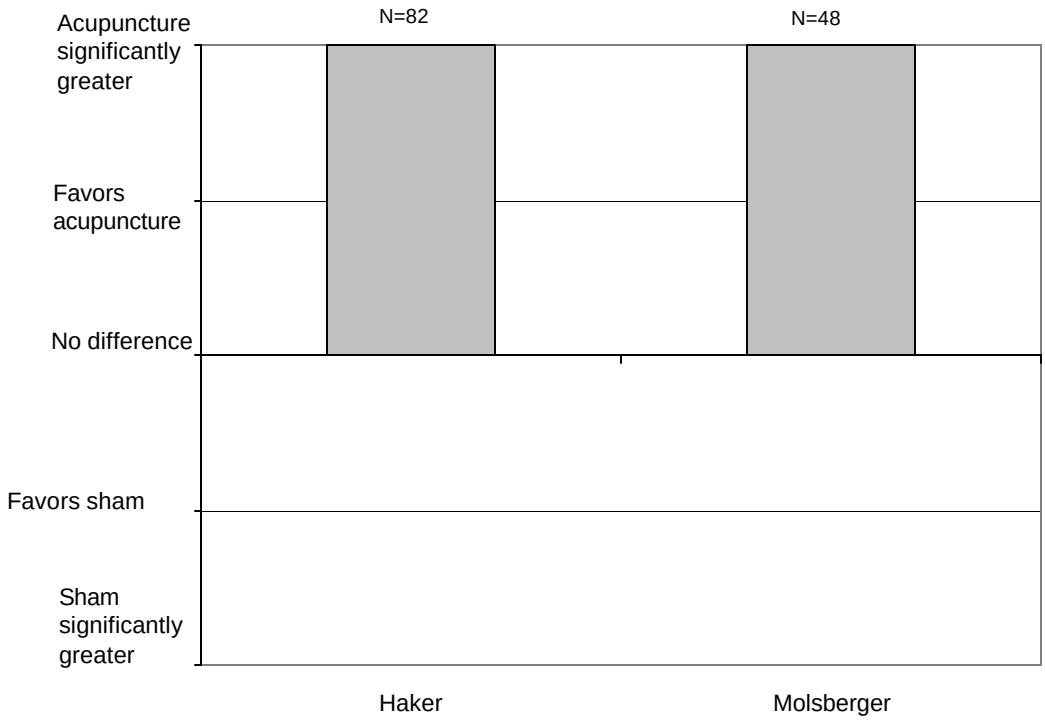
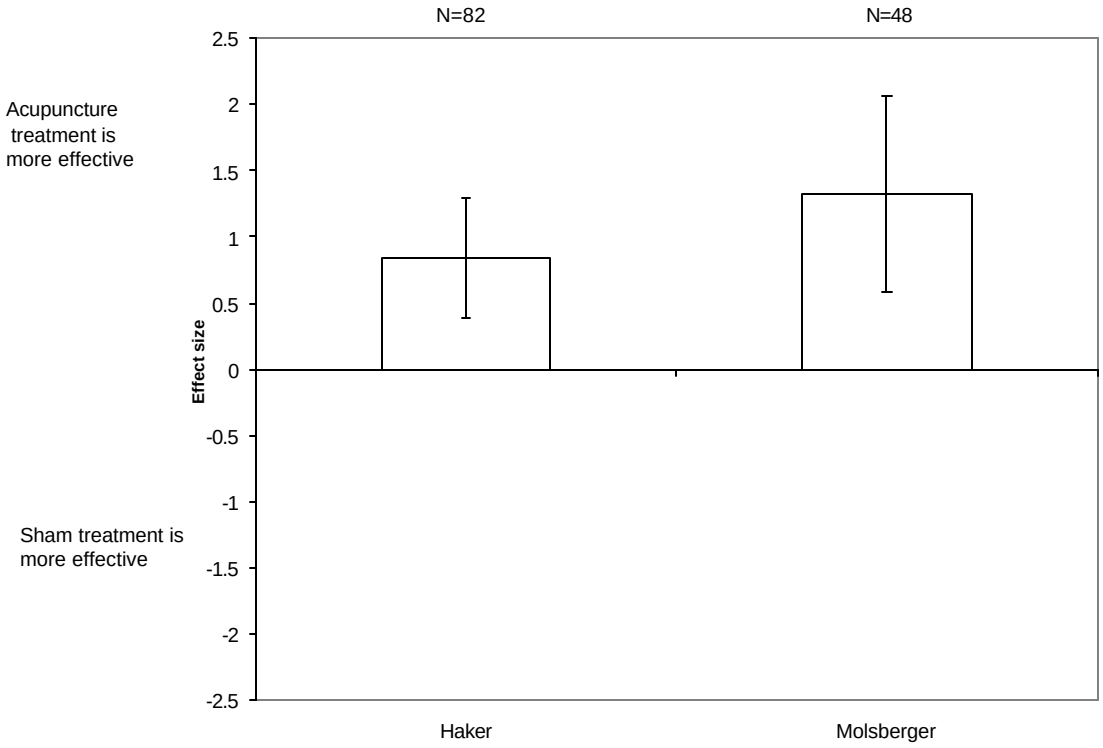


Figure 72. Success of acupuncture: effect sizes



The results of Haker are presented for the 1 month time point only.

Work Status

Neither of the included studies reported on this outcome.

Pain

The study by Molsberger 1994 reported on the degree of relief the patients had from their pain and on how long the relief lasted after the treatment. The group treated with acupuncture had significantly greater pain relief and the pain relief lasted significantly longer than it did in the control group. The data reported for this outcome are shown in Table 283 and summarized in Table 284.

Table 283. Results of the effect of acupuncture treatment on pain related to epicondylitis

Study	Pain measured by	Number of patients	Reported outcome	Statistical significance of difference between groups
Molsberger et al. 1994 [575]	Patient-rated relief of pain	24 Acupuncture 24 Control	Acupuncture- mean 55.8 SD 2.95 Control- mean 15 SD 2.77	t-test p <0.01 for both outcomes
	Patient-rated duration of the relief of pain	24 Acupuncture 24 Control	Acupuncture- mean 20.2 SD 21.54 Control- mean 1.4 SD 3.5	

SD = standard deviation

Table 284. Effect of acupuncture treatment on pain related to epicondylitis

Study	Number of patients	Time of followup	Which treatment resulted in less pain?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Molsberger 1994 [575]	24 Acupuncture 24 Control	2 weeks	Acupuncture	Yes	Relief of pain: 14.02 (11.16 to 16.89) Duration of pain relief: 1.20 (0.58 to 1.81)

[a] calculated by ECRI

Function and Activities

Neither of the studies reported either of these outcomes.

Quality of life

Neither of the studies reported this outcome.

Morbidity and Complications

No complications or morbidity were reported by either study.

Conclusions

Two randomized controlled trials of a total of 134 patients evaluated the effect of acupuncture on epicondylitis. Both studies reported patients treated with acupuncture had better global outcomes and greater pain relief than did patients treated with sham acupuncture at relatively short (2-4 weeks) followup times. The effect seemed to diminish at longer followup times. However, this latter observation was based on only one study so additional data are needed to confirm it.

What are the relative benefits and harms of surgical treatment for persons with epicondylitis?

Surgical techniques used to treat epicondylitis can be divided into four broad categories: denervation, nerve decompression, excision of tissues, and lengthening of the extensor tendon (ERCB).[83] Further information about these categories is provided in the Introduction. The relevant literature addressing this question consists of two studies evaluating the relative merits of different surgical procedures. Neither study compared surgical treatment to no or sham treatment, and neither study compared surgical treatment to nonsurgical treatments, so the absolute effectiveness of surgical treatment cannot be determined.

Internal validity

We identified two controlled trials of surgical techniques for the treatment of epicondylitis. These trials enrolled a total of 227 patients. Details of the study designs are shown in Table 285. The study by Almquist 1998 is a retrospective case-controlled trial. Patients treated with limited surgical resection of the lateral extensor aponeurosis (limited fasciectomy) were compared to patients treated with either limited resections or wide resections plus rotation of the vascular pedicle of the anconeus muscle into the defect created by the excision of tissue. Patients were chosen consecutively from the records of one clinic. A major difficulty with this study is that the group of patients treated with limited fasciectomy plus anconeous transfer had all been previously treated with fasciectomy only, with poor results, while the other two groups had not had previous surgical treatments. Hence, the patients in these two groups were different prior to the study.

The study by Wilhem 1996 was a historically controlled study that compared three different surgical techniques. The groups in this study were not treated at the same time, i.e., all of the denervation surgeries were performed from 1970 to 1990, all of the denervation plus decompression surgeries were performed from 1980 to 1990, and all of the denervation plus disinsertion surgeries were performed after 1991. Because the different groups were not treated during the same time periods, other factors aside from the surgical techniques, such as improvements in general post-operative care, could have affected the results.

The study by Wilhelm 1996 did not use intent-to-treat analysis. Ignoring attrition when analyzing the data can create a bias in the results. Where possible, we have tried to compensate for this by attempting to gauge the maximum possible effect of not following this principle. Thus, we assumed that all patients who were not followed until the end of the study received unsuccessful treatment. This is a conservative assumption. However, if statistical significance is obtained under this assumption, one can be more confident that the magnitude of this design weakness is not large enough to overturn the results of a statistically significant trial. We were able to compensate for not following the intent-to-treat principle for the trial

by Wilhelm 1996, and found that the conclusions of the study did not change after compensation.

Neither study blinded the patients or the evaluating physician to the type of treatment, which can bias the results.

Table 285. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Almquist 1998 [83]	61	1	No	CT	No	No	0	Yes	NA
Wilhelm 1996 [84]	166	1	NR	CT	No	No	11.4	No	NA

CT = controlled trial
NR = not reported
NA = not applicable

Generalizability

Characteristics of the patient groups are shown in Table 286. Our analysis of patients treated with surgery for epicondylitis (see the answer to Question 2) found that the typical patient was of either sex and in their mid-forties. The patients in both studies fit this profile.

Neither study reported on the presence of comorbidities or employment characteristics. Therefore, the extent to which these patient groups can be generalized to the overall epicondylitis population cannot be determined from the information available.

Table 286. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Almquist 1998 [83]	61	43.9 (27-63)	39.3	27.3 (6-72)	NR	NR	NR	NR	NR	NR	NR	No	No
Wilhelm 1996 [84]	166	44.5 (21-62)	57.8	NR	NR	NR	NR	NR	NR	NR	NR	No	No

NR = not reported

Results

Success of Treatment

The study by Wilhem 1996 reported that patients treated with denervation alone rated their outcomes more positively than did patients treated with denervation plus decompression or with denervation plus disinsertion. These data are reported in Table 287 and summarized in Table 288. The difference in outcomes was statistically significant between the denervation and denervation plus decompression groups, but was not statistically significant between the denervation and the denervation plus disinsertion groups. The denervation plus decompression group rated their outcomes statistically significantly more positively than did the denervation plus disinsertion group.

Table 287. Results of the success of surgery at treating epicondylitis

Study	Number of patients	Success of treatment	Statistical significance of difference between groups
Wilhem 1996 [84]	39 denervation 46 denervation and disinsertion 81 denervation and decompression	Denervation: 29 excellent, 4 good, 2 fair, 1 poor Disinsertion: 30 excellent, 7 good, 3 fair, 2 poor Decompression: 36 excellent, 13 good, 16 fair, 10 poor	Chi-squared test Denervation vs. disinsertion p = 0.159 Denervation vs. decompression P = 0.0071 Disinsertion vs. decompression p = 0.033

Table 288. Success of surgery at treating picondylitis

Study	Number of patients	Which treatment was most successful?	Was the difference significant?	Effect size d (95% CI)[a]
Wilhem 1996 [84]	39 denervation 46 denervation and disinsertion 81 denervation and decompression	Denervation	Yes, between denervation and decompression Yes, between decompression and disinsertion No, between denervation and disinsertion	Disinsertion: 1.13 (0.71 to 1.55) Denvervation: 0.75 (0.36 to 1.14)

[a] calculated by ECRI using decompression plus denervation as the control group

Work Status

Almquist 1998 reported on the number of patients able to resume normal work after treatment. These data are reported in Table 289 and summarized in Table 290. Wide fasciectomy plus anconeus transfer was reported to have a better outcome than did fasciectomy alone or limited fasciectomy plus anconeus transfer. The difference, however, was not statistically significant, despite the fact that the study

had sufficient power to detect a difference between groups as small as 3%. Hence, this negative finding is probably not the consequence of a small sample size.

Table 289. Results of surgical treatment on work status

Study	N patients	Percentage of patients able to return to normal work	Statistical significance of the difference between groups
Almquist 1998 [83]	16 fasciectomy 31 wide fasciectomy plus anconeus transfer 14 limited fasciectomy plus anconeus transfer	Fasciectomy - 81% Wide fasciectomy plus anconeus transfer - 96% Limited fasciectomy - 86%	Chi-squared test P>0.05

Table 290. Effect of surgical treatment on work status

Study	N patients	Which treatment resulted in more patients returning to work?	Was the difference significant ?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Almquist 1998 [83]	16 fasciectomy 31 wide fasciectomy plus anconeus transfer 14 limited fasciectomy plus anconeus transfer	Wide fasciectomy plus anconeus transfer	No	3%	Wide fasciectomy: 1.05 (-0.25 to 2.35) limited fasciectomy: 0.17 (-0.90 to 1.25)

[a] calculated by ECRI with fasciectomy alone as the control group

Pain

Almquist 1998 reported that patients treated with wide fasciectomy plus anconeus transfer had more pain relief than did patients treated with fasciectomy. This difference was reported to be statistically significant. Patients treated with wide fasciectomy plus anconeus transfer were reported to have more pain relief than patients treated with limited fasciectomy plus anconeus transfer, but the difference in outcomes between these two groups was not statistically significant. These data are reported in Table 291 and summarized in Table 292.

Table 291. Results of surgical treatment on pain

Study	N patients	Percentage of patients with pain relief	Statistical significance of the difference between groups
Almquist 1998 [83]	16 fasciectomy 31 wide fasciectomy plus anconeus transfer 14 limited fasciectomy plus anconeus transfer	Fasciectomy - 62% Wide fasciectomy plus anconeus transfer- 87% Limited fasciectomy - 86%	Chi-squared test P<0.05 between wide plus transfer and fasciectomy only

Table 292. Effect of surgical treatment on pain

Study	N patients	Which treatment resulted in more pain relief?	Was the difference significant?	Effect size d (95% CI)[a]
Almquist 1998 [83]	16 fasciectomy 31 wide fasciectomy plus anconeus transfer 14 limited fasciectomy plus anconeus transfer	Wide fasciectomy plus anconeus transfer	Yes, between wide plus transfer and fasciectomy; No, between wide plus transfer and limited	Wide fasciectomy: 0.76 (-0.05 to 1.56) Limited fasciectomy: 0.69 (-0.31 to 1.68)

[a] calculated by ECRI with fasciectomy alone as the control group

Function and Activities

Neither of the included studies reported patient-oriented measurements of these outcomes.

Quality of Life

Neither of the included studies reported on this outcome.

Morbidity and Complications

Morbidity and complications related to the surgery were not reported by either study. Wilhem 1996 did describe the length of time required to recover from surgery. Denervation required only 2.7 weeks of recovery, as compared to 5.7 weeks to recover from denervation plus disinsertion and 11.7 weeks to recover form denervation plus decompression. These differences were reported to be statistically significant. These data are summarized in Table 293.

Table 293. Length of time after surgery before returning to work

Study	Number of patients	Which treatment had the shortest recovery time?	Was the difference significant?
Wilhem 1996 [84]	39 denervation 46 denervation and disinsertion 81 denervation and decompression	Denervation	Yes

Conclusions

One retrospective case-controlled study of 61 patients compared fasciectomy, wide fasciectomy plus anconeus transfer, and re-operation of failed fasciectomy to include an anconeus transfer. This study reported that patients treated with wide fasciectomy plus anconeus transfer had better outcomes than did patients treated with either fasciectomy or re-operation of failed fasciectomy to include an anconeus transfer. However, the design of this study was not optimal, and precludes one from making a firm evidence-based conclusion.

One non-parallel historically controlled trial of 166 patients reported that simple denervation lead to statistically significantly better global outcome and greater pain relief than did denervation plus decompression. Simple denervation was also reported to lead to better global outcome, and greater pain relief, than did denervation plus disinsertion, but the difference was not statistically significant. However, design difficulties with this study preclude one from using its results to make a firm evidence-based conclusion.

What are the relative benefits and harms of transcutaneous electrical nerve stimulation therapy for persons with epicondylitis?

Transcutaneous electrical nerve stimulation therapy (TENS) refers to applying an electrical current across the skin. TENS has been reported to relieve pain and stimulate wound healing. The scope of our answer to this question is determined by the scope of the published literature. The relevant literature consists of one study that compared TENS to sham TENS treatment.

Internal validity

One double-blinded randomized crosover trial was identified that employed transcutaneous electrical nerve stimulation therapy (TENS) for treating epicondylitis. Details of this study are shown in Table 294. The study treated one patient group with a Rebox device, which delivers a low-current voltage to the patient. The control group received sham treatment with a disabled Rebox device. After ten treatments, the groups spent a week receiving no treatment, then they received the opposite treatment.

Analysis and reported data are for only those who completed the entire trial (not intent-to-treat). Ignoring attrition when analyzing the data can create a bias in the results. However, attrition in this trial was not substantial (8.6%).

Table 294. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Johannsen 1993 [612]	35	1	NR	RCT	Yes	Double	8.6	No	NA

Generalizability

The characteristics of the patients are shown in Table 295. The mean age of the patients was 43, which is similar to that reported in studies of the epidemiology of epicondylitis (see the Introduction). However, the patients were predominantly male (82.9% male). Studies of the epidemiology of epicondylitis (see the Introduction) have indicated that patients with epicondylitis are equally likely to be of either sex. Thus, this may be an atypical group of patients. No information as to the occupations or employment status of the patients was reported. The study excluded patients with various comorbidities. This limits the generalizability of the study, as comorbidities are not generally exclusion criteria for treatment with TENS.

Table 295. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Johannsen 1993 [612]	35	43 (36-58)	17.1	6 (3-12)	NR	0	0	0	0	NR	NR	No	No

Results

Three outcomes were reported by this study; none were patient-oriented. Because no patient-oriented outcomes were reported, we have not shown any tables of data or performed any analysis. We will, however, briefly discuss the outcomes and results reported by this study. Grip strength was measured using a dynamometer with both the elbow extended and flexed. Mean improvements were reported. The amount of pain the patient experienced while lifting a 2 kg weight with the elbow extended and the forearm pronated was also measured and reported as mean improvements. For all three outcomes, differences between the treatment groups were statistically insignificant until the complete course of ten treatments had been administered, at which time a statistically significantly better outcome was found for the patients receiving TENS.

Conclusions

One randomized controlled crossover trial of 35 patients reported that patients treated with TENS had statistically significantly better outcomes than did patients receiving sham treatment. However, none of the reported outcomes were patient-oriented, and reaching definitive evidence-based conclusions from the results of a single trial is problematic. Further research into this treatment is necessary.

What are the relative benefits and harms of pulsed electromagnetic field therapy for persons with epicondylitis?

Pulsed electromagnetic fields (PEMF) have been said to speed healing, alleviate pain, and reduce inflammation. The scope of our answer to this question is determined by the scope of the published literature. The relevant literature consists of one trial that compared PEMF therapy to sham PEMF therapy.

Internal validity

One double-blinded randomized controlled trial of 30 patients that evaluated pulsed electromagnetic fields (PEMF) as a therapy for epicondylitis was identified. The study design is summarized in Table 296. The gender compositions of the two groups appears to be different, but chi-squared tests calculated by ECRI indicate the difference is of borderline statistical significance (p = 0.06).

Table 296. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Devereaux 1985 [598]	30	1	NR	RCT	Yes	Double	0	Yes	NA

Generalizability

Only patients diagnosed with epicondylitis who had a positive thermographic pattern with a hot area near the lateral epicondyle were included in the trial. Data on what percentage of epicondylitis patients in general who have such a thermographic pattern are not available. Thus, it is unclear whether these patients are typical epicondylitis patients. Other characteristics of these patients are shown in Table 297. The mean age (43.3 years) and percent female (43.3%) are similar to those found in studies of the epidemiology of epicondylitis (see the Introduction). No information as to the occupations or employment status of the patients was reported. The study did exclude patients with some comorbidities, which further limits the generalizability of the trial as comorbidities are not exclusion criteria for treatment with PEMF.

Table 297. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Devereaux 1985 [598]	30	43.8	43.3	10.0	NR	0	NR	0	0	0	NR	No	No

Results

The patients were evaluated every two weeks for the ability to lift weight, pain upon wrist dorisflexion, effect on work, pain during common activities of daily living (ADL), tenderness over the elbow, and grip strength. Data were only reported for grip strength, not for any of the patient-oriented outcomes. Grip strength was statistically significantly more effective at 6 weeks evaluation in the group given PEMF as compared to the group given sham treatment. However, examination of the data indicates that this difference is primarily the result of a mean decrease in grip strength at 6 weeks in the sham-treated group. For all of the other outcomes, at all time points, there were no reported statistically significant differences between the treatment groups. However, this study was small (n = 30), so it is possible that it lacked sufficient power to detect a statistically significant difference between the treatment groups. Because data reporting was incomplete, power calculations cannot be performed for this study.

Table 298. Success of treating epicondylitis with PEMF

Study	Number of patients	Which treatment was more effective?	Was the difference statistically significant?	Was the effect size statistically significant?	Did the study have sufficient power to detect the observed difference?
Devereaux 1985 [598]	15 PEMF 15 Sham	PEMF	No Wilcoxon rank sum test	Cannot calculate from the reported data	Cannot calculate from the reported data

PEMF = pulsed electrical magnetic field

Conclusions

A single double-blinded randomized controlled trial of 30 patients reported that there were no statistically significant differences in the signs and symptoms of epicondylitis between patients treated with PEMF and patients receiving sham treatment. When interpreting the results of this trial, it must be kept in mind that the small size of the trial may have prevented the results from reaching statistical significance.

What are the relative benefits and harms of extracorporal shock-wave therapy for persons with epicondylitis?

Extracorporal shock wave therapy (ESWT) refers to passing a shock wave through a localized area of the body. It has been reported to relieve pain.[581] The relevant literature consists of one published study that compared ESWT to a sham ESWT procedure.

Internal validity

Two manuscripts by the same group have been published evaluating ESWT as a treatment for epicondylitis. Both manuscripts refer to the same study; the earlier manuscript includes fewer patients.[582] Therefore, only the later manuscript is discussed in this report.[581] Details of the study design are shown in Table 299. The study was a randomized controlled trial. Neither the patients nor the evaluating physicians were blinded to the type of treatment received. Lack of blinding of the patient to the type of treatment, in particular when using subjective outcome measures, can alter measurements of treatment effect because patients might unconsciously rate their condition differently in order to please the clinician.[474] If the evaluating physician is aware of the treatment given, it is possible that he/she may unconsciously bias the patient's responses by giving leading instructions.[474]

The trial did not analyze the data by the intent-to-treat principle. Ignoring attrition when analyzing the data can create a bias in the results. For this particular trial, we were unable to compensate for the failure to follow the intent-to-treat principle. The attrition rate from this trial was substantial (13.0%) and thus may have biased the results.

Table 299. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Rompe 1996 [581]	115	1	NR	RCT	Yes	No	13.0	No	NA

NR = not reported
NA = not applicable
RCT = randomized controlled trial

Generalizability

Characteristics of the patient groups enrolled in the trial are shown in Table 300. All of the patients had been diagnosed with lateral epicondylitis. The mean age of the patients was 42.9, and the patient group was 50.4% female. These patient characteristics match those reported in published studies of the epidemiology of epicondylitis (see the Introduction), suggesting that the results of the study are generalizable beyond this particular patient group. The study did not report any

information as to the occupations or employment status of the patients. The study excluded patients with arthritic changes of the elbow, which may limit its generalizability to the overall epicondylitis patient population.

Table 300. Generalizability information: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Rompe 1996 [581]	115	42.9 (26-61)	50.4	22.9 (10-120)	NR	0	NR	NR	NR	NR	NR	No	No

Results

The reported patient-oriented results are shown in Table 301 and summarized in Table 302. The patients were asked to rate their improvement in pain and function. There is a statistically significant better outcome for patients treated with ESWT as compared to sham therapy at all followup times. We calculated an effect size for each time point and outcome and this is shown in Table 301.

Table 301. Results of treating epicondylitis with ESWT

Study	Outcome	Treatment group	N	Time of followup months	Reported outcome				Statistical test	Hedges' d (95% CI)[a]
					Excellent	Good	Acceptable	Poor		
Rompe 1996 [581]	Patient-rated improvement in pain and function								Chi-squared test[a] P<0.000001 at all time points	
		ESWT	50	1	11	16	18	5		2.76 (2.22 to 3.31)
		Sham	50	1	0	10	16	24		
		ESWT	50	1.5	10	16	18	6		3.05 (2.48 to 3.62)
		Sham	50	1.5	0	6	10	34		
		ESWT	50	6	6	11	13	21		1.20 (0.78 to 1.62)
		Sham	50	6	0	3	12	35		
	Pain at night, patient-rated	ESWT	50	0	34.6 (15.8)				Fisher's exact test p >0.05 at time 0, p <0.001 at all other times	-0.21 (-0.61 to 0.18)
		Sham	50	0	31.2 (16)					
		ESWT	50	1	13.2 (9.9)					1.49 (1.04 to 1.93)
		Sham	50	1	34.6 (17.6)					
		ESWT	50	1.5	7.7 (8.8)					1.91 (1.44 to 2.38)
		Sham	50	1.5	35.1 (18.1)					
		ESWT	50	6	7.3 (8.7)					1.48 (1.04 to 1.93)
		Sham	50	6	27.3 (16.8)					

[a] calculated by ECRI

Table 302. Effect of ESWT on epicondylitis

Study	Number of patients	Which treatment resulted in the greatest improvement?	Was the difference statistically significant?	Was the effect size statistically significant?
Rompe 1996 [581]	50 ESWT 50 Sham	ESWT, at 1, 1.5, and 6 months	Yes	Yes

ESWT = extracorporal shock wave therapy

Conclusions

One randomized controlled trial of 100 patients reported that patients treated with ESWT had statistically significantly greater improvements in pain and arm function than did patients given sham treatment. However, it is difficult to reach firm evidence-based conclusions from the results of this trial because the lack of blinding and lack of intent-to-treat analysis of this trial may have affected its results.

What are the relative benefits and harms of various combinations of therapy for persons with epicondylitis?

Internal validity

Five studies that compared combinations of therapies are discussed in this section. The therapies used are summarized in Table 303. Some of the data from the trials by Holdsworth 1993 and Straford 1989 were also included in the section on ultrasound therapy. Details of the study designs are summarized in Table 304.

All of the trials are randomized controlled trials. Three of the five trials were not blinded. The trial by Stratford 1989 was double-blinded as to whether patients received ultrasound or phonophoresis, but the patients were aware of their status as regards massage therapy or not. Likewise, the trial by Holdsworth 1993 blinded the patients as to whether they received ultrasound or phonophoresis, but the patients were aware of their status as regards being assigned an elbow brace or not. None of the studies reported on compliance with the prescribed treatments.

The study Holdsworth 1993 did not use intent-to-treat analysis. This study had a high attrition rate (14.3%). Ignoring attrition when analyzing the data can create a bias in the results. We were not able to compensate for not following the intent-to-treat principle for this trial because of the nature of the data reported.

Table 303. Summary of trials of mixed therapies for epicondylitis

Study	Treatments compared
Drechsler 1997 [593]	Manipulations plus home exercise
	Ultrasound plus physiotherapy plus home exercise
Holdsworth 1993 [620]	Ultrasound
	Ultrasound plus brace
	phonophoresis
	Phonophoresis plus brace
Vasseljen 1992 [591]	Laser
	Ultrasound plus deep friction massage
Stratford 1989 [621]	Ultrasound
	Ultrasound plus deep friction massage
	Phonophoresis
	Phonophoresis plus deep friction massage
Burton 1988 [594]	Manipulation
	Manipulation plus brace
	Manipulation plus cream
	Manipulation plus cream plus brace

Table 304. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Drechsler 1997 [593]	18	1	NR	RCT	Yes	No	0	Yes	NR
Holdsworth 1993 [620]	42	1	NR	RCT	Yes	Patients	14.3	No	NA
Vasseljen 1992 [591]	30	1	NR	RCT	Yes	No	0	Yes	NA
Stratford 1989 [621]	40	1	No	RCT	Yes	Double	0	Yes	NA
Burton 1988 [594]	33	1	Yes	RCT	Yes	No	0	Yes	NR

RCT = randomized controlled trial
NR = not reported
NA = not applicable

Generalizability

Details of the patient characteristics are shown in Table 305. Epidemiology studies of epicondylitis (see the Introduction) have found that the typical patient is in the mid-forties and of either sex. All of the patient groups of these studies fit this profile.

The presence of various comorbidities associated with epicondylitis is incompletely reported in these studies. Some studies excluded patients with various comorbidities, indicated in Table 305 with a zero under that comorbidity. This

limits the generalizability of the studies, as comorbidities are not usually exclusion criteria for the treatments discussed in this section.

None of studies reported any information as to patient occupations or employment status. Therefore, the extent to which the employment characteristics of these patients may be generalized to the overall population of epicondylitis patients cannot be determined from the available data.

Table 305. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Drechsler 1997 [593]	18	45.9 (30-57)	55.6	NR	0	0	NR	0	0	NR	0	No	No
Holdsworth 1993 [620]	42	45.3 (22-62)	35.7	NR	NR	0	0	0	0	NR	NR	No	No
Vasseljen 1992 [591]	30	45.5 (25-70)	56.7	2.1 (1-12)	NR	0	NR	NR	NR	NR	NR	No	No
Stratford 1989 [621]	40	43.3	50.0	4.3	NR	NR	NR	0	NR	NR	NR	No	No
Burton 1988 [594]	33	45.1	48.5	1.2	NR	NR	NR	NR	NR	NR	NR	No	No

NR = not reported

Results

Manipulations plus exercise compared to ultrasound plus physiotherapy

The study by Drechsler 1997 compared a combination of manipulations designed to increase mobility of the elbow plus a regimen of home exercises to a combination of ultrasound, physiotherapy, and home exercises. This study measured grip strength, self-reported difficulties in performing activities, and measurements of upper limb tension. The data recorded for the patient-oriented outcome difficulties in performing activities are shown in Table 306 and summarized in Table 307. The authors performed an analysis of variance (ANOVA) on their data and found that patients treated with manipulations plus home exercises had fewer difficulties in performing activities of daily living than patients treated with ultrasound, physiotherapy, and home exercises. The difference in outcomes was statistically non-significant at 1.5 months of followup, but was statistically significant by 3 months of followup.

Table 306. Treating epicondylitis with ultrasound plus physiotherapy compared to manipulations

Study	Number of patients	Patient-reported difficulties in performing ADL	Statistical significance of difference between groups
Drechsler 1997 [593]	10 US, physiotherapy 8 Manipulations	Mean (SD) At 1.5 months US + physio: 1.9 (0.233) Manipulations: 1.875 (0.295) At 3 months US + physio: 2.1 (0.0314) Manipulations: 1.5 (0.189)	ANOVA At 1.5 months, NS At 3 months, $p < 0.05$

US = ultrasound
Physio = physiotherapy

Table 307. Treating epicondylitis with ultrasound plus physiotherapy compared to manipulations

Study	Number of patients	Which treatment was most successful?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Drechsler 1997 [593]	10 US, physiotherapy 8 Manipulations	Manipulation	At 1.5 months, No At 3 months, Yes	At 1.5 months, 0.11 (-0.77 to 0.99) At 3 months, 4.24 (2.66 to 5.82)

[a] calculated by ECRI
US = ultrasound

Ultrasound with or without bracing

Holdsworth 1993 compared groups treated with ultrasound combined with elbow bracing therapy to groups treated with ultrasound only. The data reported by Holdsworth 1993 are shown in Table 308 and summarized in Table 309. Holdsworth 1993 reported that the addition of bracing to either ultrasound or phonophoresis had no statistically significant effect on patient-rated success of the treatment. However, this trial could have detected only an 83% or larger difference between groups. Therefore, its small size may have caused it to miss clinically important effects.

Table 308. Results of treating epicondylitis with ultrasound plus bracing

Study	Number of patients	Patient-rated success of treatment on VAS	Statistical significance of difference between groups
Holdsworth 1993 [620]	7 Phonophoresis 10 Phonophoresis plus bracing 9 ultrasound 8 Ultrasound plus bracing	1.5 months mean (SE) Phonophoresis: 49.6 (12.4) Phonophoresis + bracing: 55.9 (16.1) Ultrasound: 63 (12.2) Ultrasound + bracing: 62.6 (11.3)	ANOVA NS

Table 309. Treating epicondylitis with ultrasound plus bracing

Study	Number of patients	Which treatment was more successful?	Was the difference statistically significant ?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Holdsworth 1993 [620]	7 Phonophoresis 10 Phonophoresis plus bracing 9 Ultrasound 8 Ultrasound plus bracing	Phonophoresis	No	83.5%	Phonophoresis: 0.33 (-0.55 to 1.21) 0.15 (-0.73 to 1.03) 0.01 (-0.87 to 0.89)

[a] calculated by ECRI using ultrasound as the comparison group

Ultrasound plus massage compared to laser

Vasseljen 1992 compared laser therapy to a mixture of ultrasound and deep friction massage. Each patient received eight treatments. Pain (physician-rated) was measured after all the treatments had been administered, and four weeks later. The group treated with ultrasound plus massage had significantly less pain ($p < 0.01$; ANOVA) after treatment than did the group treated with laser therapy.

Ultrasound plus massage compared to ultrasound

Stratford 1989 compared ultrasound plus deep friction massage to ultrasound alone. Each patient received nine treatments over the course of five weeks. The results are shown in Table 310 and summarized in Table 311. The study did not find a statistically significant difference between any of the treatment combinations. However, the study could have only detected a 42% or larger difference between the groups. Therefore, it was too small to detect a small to moderate clinically important effect.

Table 310. Results of treating epicondylitis with ultrasound plus massage as compared to ultrasound

Study	Type of Treatment	Number of patients with successful treatment	Statistical significance of difference between groups
Stratford 1989 [621]	10 Phonophoresis 10 Phonophoresis plus massage 9 Ultrasound 11 Ultrasound plus massage	3 phonophoresis 2 phonophoresis plus massage 1 ultrasound 4 ultrasound plus massage	Chi-squared test[a] Phonophoresis with or without massage P = 0.61 Ultrasound with or withour massage P = 0.19

[a] calculated by ECRI

Table 311. Success of treating epicondylitis with ultrasound plus massage as compared to ultrasound

Study	Number of patients	Which treatment was most successful?	Was the difference statistically significant ?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Stratford 1989 [621]	10 Phonophoresis 10 Phonophoresis plus massage 9 Ultrasound 11 Ultrasound plus massage	Ultrasound plus massage	No	42%	Phonophoresis: 0.71 (-0.65 to 2.07) Phonophoresis plus massage: 0.43 (-1.0 to 1.85) Ultrasound plus massage: 0.95 (-0.39 to 2.28)

[a] calculated by ECRI with ultrasound as the comparison group

Manipulation plus bracing

Burton 1988 compared manipulations to improve mobility of the elbow to manipulations plus bracing, manipulations plus a topical anti-inflammatory cream, and a combination of all three therapies. Burton 1988 measured patient-rated hand-arm function. The data are shown in Table 312 and summarized in Table 313. No statistically significant differences between groups were found. However, this study lacks the statistical power to detect less than a 67% difference between the therapies, and thus could not have detected small to moderate clinically important effects.

Table 312. Results of treatment of epicondylitis with combinations of manipulation, bracing, and topical anti-inflammatories

Study	Number of patients	Mean (SD) of patient-rated function VAS			Effect size d (95% CI)[a]
Burton 1988 [594]	8 Bracing plus manipulation 8 Bracing plus cream plus manipulation 9 Cream plus manipulation 8 Manipulation	Initial measure	Bracing plus manipulation	3.2 (0.4)	0.0 (-0.88 to 0.88)
			Bracing plus cream plus manipulation	3.6 (1.0)	0.35 (-0.54 to 1.23)
			Cream plus manipulation	3 (0.7)	-0.19 (-1.07 to 0.68)
			Manipulation	3.2 (1.2)	
		1 week	Bracing plus manipulation	2.8 (0.8)	0.00 (-0.88 to 0.88)
			Bracing plus cream plus manipulation	2.8 (1.4)	0.00 (-0.88 to 0.88)
			Cream plus manipulation	2.5 (0.7)	-0.29 (-1.17 to 0.59)
			Manipulation	2.8 (1.2)	
		2 weeks	Bracing plus manipulation	2.5 (1.1)	0.00 (-0.88 to 0.88)
			Bracing plus cream plus manipulation	2.5 (1.7)	0.00 (-0.88 to 0.88)
			Cream plus manipulation	1.7 (0.6)	-0.63 (-1.53 to 0.26)
			Manipulation	2.5 (1.6)	
		4 weeks	Bracing plus manipulation	1.6 (1.0)	0.08 (-0.79 to 0.96)
			Bracing plus cream plus manipulation	1.5 (1.6)	0.00 (-0.88 to 0.88)
			Cream plus manipulation	1 (0.8)	-0.44 (-1.33 to 0.44)
			Manipulation	1.5 (1.3)	

[a] calculated by ECRI with manipulation as the comparision group

Table 313. Treatment of epicondylitis with combinations of manipulation, bracing, and topical anti-inflammatories

Study	N patients	Which treatment resulted in greater function?	Was the difference statistically significant?	Minimal difference the study had the power to detect	Where any of the effect sizes statistically significant?
Burton 1988[594]	8 Bracing plus manipulation 8 Bracing plus cream plus manipulation 9 Cream plus manipulation 8 Manipulation	Bracing plus cream plus manipulation	No for all followup times ANOVA test p >0.05	67%	No

Morbidities and complications

None of the included studies reported any complications or morbidities.

Conclusions

Five randomized controlled trials evaluated various combinations of therapies for the treatment of epicondylitis. Because no two trials evaluated the same combinations, no meta-analysis could be performed. One trial of 18 patients found that patients treated with manipulation plus a home exercise program had fewer difficulties in performing activities of daily living than did patients treated with a combination of ultrasound, physiotherapy, and home exercise. The other four trials did not find statistically significant differences between-treatment groups. However, these studies were small, which may have prevented them from detecting clinically important differences between the treatment groups. One of these studies reported a trend towards phonophoresis being rated as more successful than ultrasound, phonophoresis plus bracing, or ultrasound plus bracing. One of these studies reported a trend towards ultrasound plus deep friction massage being rated as more successful than ultrasound, phonophoresis, or phonophoresis plus deep friction massage. One of these studies reported no statistically significant functional differences after treatment with various combinations of bracing, manipulation, and topical anti-inflammatory cream. One of these studies reported a trend towards less pain experienced by patients treated with ultrasound plus deep friction massage than those treated with laser therapy.

No firm evidence-based conclusions as to the effectiveness of these combinations of therapies can be reached from the results presented by these trials. Four of the studies included too few patients to be able to have detected small but clinically meaningful effects of the therapies. Although the fifth study did find a statistically significant difference between groups for one outcome, it was a small study (n = 18)

that did not blind either the patients or the evaluating physicians to treatments. Further studies are required to corroborate this study's results.

What are the relative benefits and harms of different therapies for persons with epicondylitis?

Internal validity

Seven studies were identified that directly compared the efficacy of different therapies for treating epicondylitis. Details of the therapies compared by these studies are summarized in Table 314. One of the trials (Brattberg 1983) was not randomized; the rest of the trials are randomized controlled trials. Three of the trials did not use blinding, and two blinded only the evaluating physician, not the patients.

Only two of the studies (Hay 1999 and Halle 1986) used intent-to-treat analysis. Attrition rates were fairly low (less than 10%) in four out of the five studies that did not use intent-to-treat analysis. However, in the study by Saartok 1986 attrition rates were greater than 10%. Ignoring attrition when analyzing the data can create a bias in the results. Where possible, we have tried to compensate for this by attempting to gauge the maximum possible effect of not following this principle. Thus, we assumed that all patients who were not followed until the end of the study received unsuccessful treatment. This is a conservative assumption. However, if statistical significance is obtained under this assumption, one can be more confident that the magnitude of this design weakness is not large enough to overturn the results of a statistically significant trial. We were able to compensate for not following the intent-to-treat principle in all of the trials included in this section. This compensation suggests that failure to follow the intent-to-treat principle did not alter the conclusions of any of these trials.

The trial by Hay 1999 is a multi-center trial that may be potentially confounded by co-interventions. By 12 months of followup, approximately 35-38% of the patients in all groups had received some unspecified treatment in addition to their assigned treatment. Because approximately equal numbers of patients in each group received additional treatments, it is possible that these interventions did not affect the results of the trial. However, the types of interventions are not specified. Thus, it is theoretically possible that patients in one group received different co-interventions than did patients in other groups, and thus the co-interventions could affect the results of the trial.

Table 314. Summary of the trials comparing different therapies for epicondylitis

Study	Treatments compared Group 1	Group 2
Hay 1999 [609]	Injection of methylprednisolone and lidocaine	Naproxen, 500 mg 2X/day Placebo pills
Pienimaki 1996 [599]	Physical therapy	Ultrasound
Verhaar 1995 [607]	Injection of triamcinolone and lidocaine	Deep friction massage and manipulations, 12 times over 4 weeks
Haker 1993 [611]	Injection of bupivacaine and triamcinolone	Epicondylitis clasp, worn daily for 3 months Elbow immobilized in splint, worn daily for 3 months
Halle 1986 [606]	Injection of hydrocortisone and lidocaine TENS	Ultrasound Phonophoresis of hydrocortisone
Saartok 1986 [610]	Injection of betamethasone	Naproxen, 250 mg/day for 2 weeks
Brattberg 1983 [608]	Injection of steroids, unspecified type, unspecified number of injections	Acupuncture at five points in the region of the elbow. One to two treatments per week for four weeks

TENS = transcutaneous electrical nerve stimulation therapy
NSAID = non steroidal anti-inflammatory drug

Table 315. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Hay 1999 [609]	182	Multiple	NR	RCT	Yes	Rater	0.55	Yes	NR
Pienimaki 1996 [599]	42	1	NR	RCT	Yes	Rater	7.1	No	NA
Verhaar 1995 [607]	106	1	No	RCT	Yes	No	2.8	No	NA
Haker 1993 [611]	76	1	NR	RCT	Yes	Double	6.6	No	NA
Halle 1986 [606]	48	1	NR	RCT	Yes	No	0	Yes	NR
Saartok 1986 [610]	21	1	NR	RCT	Yes	Double	14.2	No	NR
Brattberg 1983 [608]	63	1	NR	CT	Yes	No	4.8	No	NA

RCT = randomized controlled trial
CT = controlled trial
NR = not reported
NA = not applicable

Generalizability

Details of the patient characteristics are shown in Table 316. The patients in all of the trials appear to be fairly typical of epicondylitis patients in general (see the epidemiology subsection in the Introduction). However, the Saartok trial appears to be predominantly male (19.0% female), and the Haker trial is also predominantly male (25.0% female); studies of the epidemiology of epicondylitis suggest that the general population is approximately 50% female. Thus, these two trials may be drawn from special subpopulations and their results may not be generalizable.

Some of the studies excluded patients with various comorbidities, indicated by a zero under that comorbidity. This limits the generalizability of the studies, as comorbidities are not usually exclusion criteria for the treatments discussed in this section.

Patient employment characteristics are incompletely reported in these studies (Table 317). Therefore, the extent to which the employment characteristics of these patients may be generalized to the overall epicondylitis patient population cannot be determined from the information available.

Table 316. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Hay 1999 [609]	182	NR	42.8	NR	NR	0	NR	NR	NR	0	NR	No	No
Pienimaki 1996 [599]	42	42 (31-53)	59.5	NR	NR	0	0	0	0	NR	NR	No	No
Verhaar 1995 [607]	106	43	47	8	NR	0	NR	0	0	NR	NR	No	No
Haker 1993 [611]	76	47.8	25	5 (1-36)	NR	0	NR	0	0	NR	NR	No	No
Halle 1986 [606]	48	(20-59)	54.1	NR	NR	NR	NR	0	0	NR	NR	No	No
Saartok 1986 [610]	21	45	19.0	NR	NR	NR	NR	NR	NR	NR	NR	No	No
Brattberg 1983 [608]	63	(30-60)	36.5	NR	NR	NR	NR	NR	NR	NR	NR	No	No

NR = not reported

Table 317. Generalizability: occupations

Study	Number of patients	% Patients employed	% Patients on Workers' compensatio	% Patients retired	% Patients homemakers	Reported occupations
Hay 1999 [609]	182	62.6	NR	NR	NR	NR
Pienimaki 1996 [599]	42	30.9	NR	NR	NR	NR
Verhaar 1995 [607]	106	NR	NR	NR	NR	NR
Haker 1993 [611]	76	NR	NR	NR	NR	NR
Halle 1986 [606]	48	NR	NR	6.3	29.1	33.3% blue collar workers 31.3% white collar workers
Saartok 1986 [610]	21	NR	NR	NR	NR	NR
Brattberg 1983 [608]	63	NR	NR	NR	NR	NR

NR = not reported

Results

NSAIDs compared to corticosteroid injections

Two randomized controlled trials of a total of 203 patients compared oral NSAIDs (naproxen) to corticosteroid injections (methylprednisolone and betamethasone). Both studies measured pain and function. In addition, they rated the overall success of the treatments. One of the studies reported no statistically significant difference in outcomes between the study groups, while the other study reported that the patients treated with corticosteroid injections had statistically statistically significantly better outcomes than did patients treated with oral NSAIDs or with placebo. The patient-oriented outcomes reported by these two studies are shown in Table 318 and summarized in Table 319. The study that reported no significant difference in outcomes (Saartok 1986) only had a total of 21 patients, and thus may have been too small for the difference in outcomes between its patient groups to reach statistical significance. We calculated that this study could have detected a 36% or greater difference between its groups. The fact that the Hay trial found a larger difference than this suggests that the results of these two trials are truly different, and not simply the result of a lack of statistical power on the part of the Saartok trial. As discussed previously, it is possible that the Hay trial was confounded by co-interventions.

Table 318. Results of treating epicondylitis with NSAIDs as compared to steroid injections

Study	Number of patients	Global assessment-patient rated categories	Statistical significance of difference between groups
Hay 1999 [609]	52 corticosteroid injection 53 NSAIDS 56 placebo	Corticosteroid injections: 22 complete recovery, 26 improvement, 3 no change, 1 worse, 0 much worse NSAIDs: 3 complete recovery, 27 improvement, 16 no change, 7 worse, 0 much worse Placebo: 2 complete recovery, 26 improvement, 23 no change, 4 worse, 1 much worse	Mann-Whitney U test p <0.05 injections compared to NSAID and injections compared to placebo
Saartok 1986 [610]	11Corticosteroid injection 10 NSAIDs	Corticosteroid injections: 1 much improved, 5 improved, 2 no change, 4 worse, 0 much worse NSAIDs: 0 much improved, 6 improved, 3 no change, 1 worse, 0 much worse	Mann-Whitney U test NS

Table 319. Success of treating epicondylitis with NSAIDs as compared to steroid injections

Study	Number of patients	Time of followup	Which treatment was more successful?	Was the difference statistically significant?	Minimal difference the study had the power to detect	Effect size d (95% CI)[a]
Hay 1999 [609]	52 steroid injection 53 oral NSAIDs 56 placebo	One month	Injection of corticosteroids	Yes	NA	Steroids vs. placebo: 0.57 (0.18 to 0.95) NSAIDs vs. placebo: -0.08 (-0.46 to 0.30) Steroids vs. NSAIDs: 1.31 (0.88 to 1.73)
Saartok 1986 [610]	11 steroid injection 10 oral NSAIDs	2 weeks	No difference	No	36%	0.54 (-0.33 to 1.42)

[a] calculated by ECRI
NSAID = non steroidal anti-inflammatory drug

Acupuncture compared to corticosteroid injections

One controlled trial of 63 patients compared acupuncture treatment to injections of corticosteroids. This trial reported only patient-rated pain. Patients were followed for different times after the treatment, with a mean followup time of 5.8 months, and a range of 2 to 9 months. Statistical tests performed by the authors indicated that acupunture treatment was statistically significantly more successful at relieving pain than was corticosteroid treatment. The data are summarized in Table 320. The calculated effect size agrees with the statistical tests performed by the authors. However, when interpreting the results of this trial it must be kept in mind that all of the patients had been found to be unresponsive to treatment with corticosteroid injections before being enrolled in the trial.

Table 320. Success of treating epicondylitis with acupuncture as compared to steroid injections

Study	Number of patients	Pain-patient rated categories	Statistical significance of difference between groups	Effect size d (95% CI)[a]
Brattberg 1983 [608]	34 acupuncture 26 corticosteroid injection	Acupuncture: 8 no pain, 9 slight pain, 4 better, 3 improved, 10 unchanged, 0 worse Injections: 2 no pain, 6 slight pain, 0 better, 8 improved, 6 unchanged, 4 worse	Chi-squared test P<0.05 Statistically significant	-0.59 (-1.09 to -0.08)

[a] calculated by ECRI

Physiotherapy compared to corticosteroid injections

One randomized controlled trial of 106 patients compared a combination of exercises and deep friction massage designed to improve mobility of the elbow to injections of corticosteroids. The reported results for the other patient-oriented outcomes are shown in Table 321 and summarized in Table 322. Manipulation and massage were found to be statistically significantly less effective than are injections of corticosteroids at treating pain and are rated as less effective by patients. Statistically significantly more patients treated with corticosteroid injections returned to work, but the effect size calculated for this outcome did not reach statistical significance.

Table 321. Results of treating epicondylitis with physiotherapy as compared to steroid injections

Study	Number of patients	Outcome measured	Outcome measurement At 1.5 months	Statistical significance of difference between groups
Verhaar 1995 [607]	52 corticosteroid injection 51 Manipulations and massage	Global assessment - patient rated categories	corticosteroid injection: 18 excellent, 18 good, 10 moderate, 6 poor Manipulations and massage: 1 excellent, 12 good, 15 moderate, 23 poor	Chi-squared test P<0.001
		Pain - patient rated categories	Injection: 22 absent, 20 slight, 9 moderate,1 severe Manipulations and massage: 3 absent, 19 slight, 22 moderate, 7 poor	Chi-squared test p <0.001
		Return to work	Injection: 9 resumed work, 15 still working, 9 unable to work, 19 did not work and still do not Manipulations and massage: 4 resumed work, 14 still working, 13 unable to work, 20 did not work and still do not	Chi-squared test p <0.05

Table 322. Success of treating epicondylitis with manipulations compared to injections of steroids

Study	Number of patients	Time of followup	Which treatment was more successful?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Verhaar 1995 [607]	52 steroid injection 51 manipulation	1.5 months	Injections of corticosteroids	Yes (Chi-squared test)	Global assessment: 1.15 (0.74 to 1.56) Pain:1.02 (0.61 to 1.43) Return to work: 0.10 (-0.29 to 0.48)

[a] calculated by ECRI

Bracing or immobilization compared to corticosteroid injections

One randomized controlled trial of 76 patients compared forearm elbow bracing, immobilization of the elbow, and corticosteroid injections. The authors report that after two weeks, the group treated with the corticosteroid injections had a statistically significantly better result for the outcome patient-rated pain than did the other two treatment groups. At longer followup times, however, the authors report there was no statistically significant difference between the treatment groups. The

data from the longer followup times were not reported. The calculated effect size agrees with the statistical tests performed by the authors. The data are summarized in Table 323.

Table 323. Results of bracing, injections, and splinting compared

Study	Number of patients	Patient-rated improvement in pain	Statistical signficance of the difference between groups	Effect size d (95% CI)[a]
Haker 1993 [611]	17 bracing 19 corticosteroid injection 19 immobilization / splinting	At 0.5 months, bracing 1 excellent, 1 good, 4 improved, 3 somewhat improved, 8 no change injections 3 excellent, 10 good, 2 improved, 3 somewhat improved, 1 no change splinting 0 excellent, 1 good, 6 improved, 6 somewhat improved, 6 no change	Chi-squared test Injections vs. bracing p = 0.000055 Injections vs. splinting p = 0.000427 Splinting vs. bracing p = 0.000001 Injections are most effective	Bracing: 1.04 (0.36 to 1.71) Splinting: 1.19 (0.51 to 1.86)

[a] calculated by ECRI using corticosteroid injections as the comparison group

TENS, ultrasound, phonophoresis, and injections of corticosteroids compared

One randomized controlled trial of 48 patients compared four different treatments for epicondylitis: TENS, ultrasound, phonophoresis of hydrocortisone, and injections of corticosteroids. This study measured patient-reported pain in several ways, and combined the results into a summary percentage. The authors report that there was no statistically significant difference in outcomes between any of the treatment groups. The calculated effect sizes agree with the results of the authors' statistical tests. However, the study was small and this may be the reason why the difference in outcomes between the groups did not reach statistical significance. The data reported by this study are shown in Table 324 and summarized in Table 325.

Table 324. Results of comparing injections, TENS, phonophoresis, and ultrasound

Study	Number of patients	Global outcome	Statistical significance of difference between groups
Halle1986 [606]	12 Corticosteroid injection 12 phonphoresis 12 TENS 12 ultrasound	Corticosteroid injection: 63% improved, 25% unchanged, 12% worse phonophoresis: 65% improved, 12% unchanged, 23% worse TENS: 56% improved, 23% unchanged, 21% worse ultrasound: 69% improved, 12% unchanged, 19% worse	Kruskal-Wallas ANOVA test NS

Table 325. The study by Halle 1986 lacks statistical power

Study	Number of patients	Followup time	Which treatment was most effective?	Was the difference statistically significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Halle 1986 [606]	12 injections 12 phonophoresis 12 ultrasound 12TENS	0.13 month	Corticosteroid injections	No	31%	Phonophoresis: -0.67 (-1.49 to 0.15) TENS: -0.02 (-0.82 to 0.78) Ultrasound: -0.53 (-1.35 to 0.28)

[a] calculated by ECRI using injections as the control group

Physiotherapy compared to ultrasound

One randomized controlled trial of 42 patients compared ultrasound treatment to a regimen of stretching, strengthening, and conditioning exercises. This study reported only one patient-oriented outcome, return to work. The reported results for this outcome are shown in Table 326 and summarized in Table 327. The study may be too small (n = 39) for its results on patients returning to work to have reached statistical significance.

Table 326. Results of physiotherapy compared to ultrasound

Study	Number of patients	Number of patients not working	Statistical significance of difference between groups
Pienimaki 1996 [599]	19 ultrasound 20 Physiotherapy	6 ultrasound 2 physiotherapy	Chi-squared test p = 0.355

Table 327. Physiotherapy compared to ultrasound

Study	Number of patients	Followup time	Which treatment resulted in more patients returning to work?	Was the difference statistically significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Pienimaki 1996 [599]	19 ultrasound 20 physiotherapy	2 months	Physiotherapy	No	31%	0.77 (-0.20 to 1.74)

[a] calculated by ECRI

Conclusions

One randomized controlled trial of 106 patients reported that patients treated with injections of corticosteroids had better outcomes than did patients treated with manipulations and deep friction massage. One randomized controlled trial of 76 patients reported that patients treated with injections of corticosteroids had better outcomes than did patients treated with braces or immobilization.

Two randomized controlled trials of a total of 203 patients compared oral NSAIDs to injections of corticosteroids. One study did not find a statistically significant difference between the groups. The other study reported that patients treated with injections of corticosteroids had better outcomes than did the patients treated with oral NSAIDs. This study may have been confounded by co-interventions administered to the patients in addition to their allocated treatment.

One randomized controlled trial of 63 patients reported that patients treated with acupuncture had better outcomes than patients treated with corticosteroid injections. However, this study included only patients previously found to be unresponsive to injections of corticosteroids.

Two randomized controlled trials, one comparing TENS, ultrasound, phonophoresis, and injections of steroids, the other comparing physical therapy to ultrasound, reported no statistically significant differences between-treatment

groups. However, both trials may have been too small to be able to have detected clinically meaningful differences between-treatment groups.

Thirty-eight randomized controlled trials, four randomized crossover trials, and eight controlled trials of a total of 3147 patients evaluated eighteen different types of treatments for epicondylitis and reported 73 different outcomes. The studies tend to be small, and there are too few studies addressing each treatment to allow any definitive evidence-based conclusions to be made. Two tentative conclusions can be reached: Laser therapy does not appear to be an effective treatment for epicondylitis, and patients with epicondylitis who were treated with acupuncture had better global outcomes and greater pain relief than patients given sham acupuncture.

Question #4. Is there a correlation between specific clinical findings and specific treatment outcomes among patients with epicondylitis?

In addressing this question, we consider whether published literature suggests that there are clinical findings that predict positive or negative outcomes after treatment for epicondylitis. The studies we considered all attempted to identify predictors by using regression techniques or by comparing outcomes in different groups of patients with different pre-treatment clinical findings.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, not all of the retrieved studies met our more specific inclusion criteria for this question. These latter studies, and the reason we did not consider them for this question are shown in Table 328.

Table 328. Excluded studies

Author	Reason for exclusion
Seegenschmiedt et al. 1998 [628]	Incomplete description of multivariate analysis (did not describe all variables and unclear description of some variables)
Gabel and Morrey 1995 [555]	Stratified study that did not examine any correlations that were also examined by at least two other studies
Verhaar et al. 1993 [559]	Stratified study that did not examine any correlations that were also examined by at least two other studies

Evidence base

After these exclusions, there remained three studies with a total of 160 patients.

Study quality

The criteria used to evaluate study quality were identical to those described in Question 4 for carpal tunnel syndrome. Table 329 shows relevant quality characteristics of studies that met the inclusion criteria for this question. All studies performed some type of multiple regression analysis. Two were prospective and one was retrospective.

Table 329. Study quality

Author/year	Prospective?	Methods used to identify predictor variables
Kurvers et al. 1995 [556]	No	Multiple regression
Stratford et al. 1989 [621]	Yes	Multiple regression
Gerberich et al. 1985 [629]	Yes	Multiple logistic regression

Results

Table 330 shows the relationship of specific clinical findings to treatment outcomes in those studies that used regression to identify predictor variables. There are three such studies with a total of 160 patients. Also presented in this table are non-clinical variables (e.g. age, gender) to show all of the variables used in each multiple regression (the variables relevant to the present question are bolded in Table 330).

Only one study reported on each combination of outcome and clinical finding. All three studies reported correlations between variables and global assessment of the success of the treatment. None of the studies reported correlation coefficients or p-values.

Stratford et al. included only two clinical findings in their multiple regression analysis: grip strength and site of pain.[621] They found that grip strength did not correlate with treatment outcome, but site of pain did. Patients with pain over the origin of the extensor carpi radialis longus (ECRL) had better outcomes than did patients with pain elsewhere. Patients with pain over the origin of the extensor carpi radialis brevis (ECRB) had poorer outcomes than did patients with pain elsewhere.

Gerberich et al. incorporated only two clinical findings into their analysis: severity of pain before treatment, and degree of functional limitations before treatment.[629] They reported no statistically significant correlation between the degree of functional limitations and success of the treatment, but found a correlation between severity of pain and success of the treatment. Patients with severe pain had poorer outcomes than patients with milder pain.

Kurvers et al. included only one clinical finding in their analysis: timing of the onset of symptoms (acute or gradual).[556] They found no statistically significant correlation between the timing of the onset of symptoms and the success of the treatment.

Table 330. Relationship between specific clinical findings and treatment outcomes among patients with Epicondylitis (multiple regression analysis)

Author/year	N	Treatment	Outcomes	Variables used in multiple regression												
				Age	Gender	Hobbies	Comorbidity (ulnar neuritis)	Duration of symptoms	**Functional limitations**	**Site of pain**	**Severity of pain**	**Grip strength**	**Timing of onset (acute or gradual)**	Compliance with rest	Use of hydrocortisone cream	Number of treatments
Kurvers et al. 1995 [556]	38 (ME)	Surgery	Global outcome (level of symptoms)	NS	NS	NS	Sig	–	–	–	–	–	NS	–	–	–
Stratford et al. 1989 [621]	40 (LE)	Ultrasound	Global outcome (success/failure)	NS	NS	–	–	NS	–	Sig	–	NS	–	NS	–	–
Gerberich et al. 1985 [629]	82 (LE)	Ultrasound	Global outcome (improvement)	NS	NS	–	–	NS	NS	–	Sig	–	–	–	NS	Sig (males) NS (females)

LE – Lateral epicondylitis
ME – Medial epicondylitis
aVariables in boldface indicate clinical findings

Conclusions

None of the three studies that addressed this question evaluated the relationship between the same combination of clinical findings, outcomes, and treatment type. One study reported that the site of pain could be used to predict response to treatment, one reported that the severity of pain could be used to predict response to treatment, and one reported that the timing of onset of symptoms (acute vs. gradual) did not correlate with the response to treatment. Because only one study addressed each outcome, it is difficult to reach firm evidence-based conclusions from the available data.

Question #5. Is there a correlation between duration of symptoms and specific treatment outcomes among patients with epicondylitis?

In addressing this question, we consider whether published literature suggests that duration of symptoms predicts positive or negative outcomes after treatment for carpal tunnel syndrome. The studies we considered all attempted to identify predictors by using regression techniques or by comparing outcomes in different groups of patients with different duration of symptoms.

Excluded studies

No studies were excluded due to failure to meet the question-specific criteria.

Evidence base

Seven studies with a total of 319 patients addressed this question.

Study quality

The criteria used to evaluate study quality were identical to those described in Question 4 for carpal tunnel syndrome. Seven studies were identified that reported treatment outcomes stratified or analyzed by duration of symptoms. These studies are listed in Table 331. Four studies (two prospective and two retrospective) performed multiple regression to identify predictor variables. The remaining three studies (one prospective and two retrospective) used stratification or alternative statistical comparisons.

Table 331. Study quality

Author/year	Prospective?	Methods used to identify predictor variables
Bankes and Jessop1998 [553]	No	Not described
Seegenschmiedt 1998 [628]	No	Multiple regression
Kurvers 1995 [556]	No	Multiple regression
Newey and Pattterson1994 [558]	No	Stratification
Verhaar 1993 [559]	Yes	chi-square test for linear trends
Stratford 1989 [621]	Yes	Multiple regression
Gerberich 1985 [629]	Yes	Multiple logistic regression

Results

The treatments and outcomes used in studies that performed a multiple regression are shown inTable 332. Two studies using ultrasound therapy found no statistically significant correlation between duration of symptoms before treatment and response to treatment with ultrasound. One surgical trial also found no statistically significant correlation between duration of symptoms and treatment outcome. The remaining trial was the largest trial and the only trial using radiotherapy, and this trial found a significant correlation between shorter duration of symptoms and a better treatment outcome.

Three studies used stratification or statistical techniques that did not control for the effects of other predictor variables (Table 333) All three studies evaluated surgical treatments. Two studies (one prospective, one retrospective) reported no statistically significant correlation between duration of symptoms and success of surgical treatment, while one retrospective study reported a significant correlation between shorter duration of symptoms and a better treatment outcome.

Table 332. Relationship between duration of symptoms and treatment outcomes among patients with Epicondylitis (multiple regression analysis)

Author/year	N	Treatment	Outcomes	Mean duration of symptoms (range)	Statistical significance (duration associated with better outcome)	Other variables examined
Seegenschmiedt and Keilholz 1998 [628]	104 (LE and ME)	Radiotherapy	Global outcome (Response to treatment)	15 months (6-86 months)	Sig (shorter duration - <12 months)	Immobilization in plaster (sig), other variables not reported
Kurvers et al. 1995 [556]	38 (ME)	Surgery	Global outcome (level of symptoms)	12 months (6-30 months)	NS	Age, gender, timing of symptom onset, comorbid conditions, hobbies
Stratford et al. 1989 [621]	40 (LE)	Ultrasound	Global outcome (success/failure)	NR	NS	Age, gender, compliance, grip strength, site of pain
Gerberich et al. 1985 [629]	82 (LE)	Ultrasound	Global outcome (improvement)	9.8 months	NS	Age, gender, severity of pain, degree of functional limitations, use of hydrocortisone cream, number of treatments

LE – Lateral epicondylitis
ME – Medial epicondylitis
NS – Not signficant

Table 333. The relationship between duration of symptoms and treatment outcomes among patients with Epicondylitis (stratification or univariate statistical comparisons)

Author/ year	N	Treatment	Outcomes	Mean duration of symptoms (range)	Statistical significance (duration associated with better outcome)
Bankes and Jessop 1998 [553]	20	Surgery	Global outcome (patient improvement)	32.2 (11-126)	NS
Newey and Pattterson 1994 [558]	27	Surgery	Global outcome (pain relief)	32.5 (8-108)	Sig (shorter duration)
Verhaar 1993 [559]	57	Surgery	Global outcome (patient satisfaction)	NR	NS

LE – Lateral epicondylitis
ME – Medial epicondylitis
NS – Not signficant

Conclusions

Seven studies examined whether duration of symptoms correlated with treatment outcomes. These studies employed three different treatments, so this correlation might be altered if these treatments have differential success rates. Only one of the four studies that employed multiple regression found a statistically significant relationship between symptom duration and outcomes, and this study was retrospective. One of three studies that stratified patients according to their duration of symptoms found a statistically significant correlation with treatment outcomes. This study was also retrospective. Consequently, although there is some evidence to suggest a relationship, it is contradictory and not strong. Two prospective studies that employed multiple regression did not find such a relationship. Both were of patients who had received ultrasound. These latter data seem to suggest that there is not a strong correlation between symptom duration and treatment outcome. However, currently available evidence about use of ultrasound in patients with epicondylitis or de Quervain's disease does not allow firm evidence-base conclusions, and the effectiveness of ultrasound for carpal tunnel is suspect. Thus, lack of treatment effectiveness could obscure potential relationships between symptom duration and treatment-related outcomes. Therefore, one cannot draw firm evidence-based conclusions from currently available data.

Question #6. Is there a relationship between patient characteristics and specific treatment outcomes among patients with epicondylitis?

In addressing this question, we consider whether published literature suggests that there are demographic variables that predict positive or negative outcomes after treatment for carpal tunnel syndrome. The studies we considered all attempted to identify predictors by using regression techniques or by comparing outcomes in different groups of patients with different pre-treatment demographic characteristics.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, not all of the retrieved studies met our more specific inclusion criteria for this question. These latter studies, and the reason we did not consider them for this question are shown in Table 334.

Table 334. Excluded studies

Author	Reason for exclusion
Seegenschmiedt et al. 1998 [628]	Study did not report whether demographic variables were included in the multiple regression analysis
O'Neil 1980 [567]	Stratified study that conducted a demographic variable/outcome comparison not performed by any other study

Evidence base

After these exclusions, there remained six studies with 277 patients.

Study quality

The criteria used to evaluate study quality were identical to those described for Question 4 for carpal tunnel syndrome. Table 335 shows the studies that met the inclusion criteria for this question. Three studies (two prospective and one retrospective) performed multiple regression to identify predictor variables. The remaining three studies (one prospective and two retrospective) performed stratification or alternative statistical comparisons.

Table 335. Study quality

Author/year	Prospective?	Methods used to identify predictor variables
Gabel and Morrey1995 [555]	No	Statistical analysis (method not described)
Kurvers 1995 [556]	No	Multiple regression
Newey and Pattterson1994 [558]	No	Stratification
Verhaar 1993 [559]	Yes	chi-square test for linear trends
Stratford 1989 [621]	Yes	Multiple regression
Gerberich 1985 [629]	Yes	Multiple logistic regression

Results

Three studies that addressed this question performed multiple regression to identify predictor variables (Table 336). Two of the studies treated patients with ultrasound and one used surgical treatment. None of the three studies found a statistically significant correlation between age and outcome, or gender and outcome. One study reported that there was no statistically significant correlation between patients with hobbies involving knitting or needlework and outcomes. The only study that examined co-morbidities reported that patients with coexistent ulnar neuritis had a poorer outcome after surgery than did patients without ulnar neuritis.

Three other studies performed stratification or statistical comparisons that did not control for the effects of other predictor variables (Table 337). All studies evaluated surgical treatments. Age was the only relevant variable reported by all of these studies, and none found a statistically significant correlation between age and treatment outcome.

Table 336. Relationship between patient characteristics and treatment outcomes among patients with Epicondylitis (multiple regression analysis)

Author/ year	N	Treatment	Outcomes	Variables used in multiple regression												
				Age[a]	**Gender**	**Hobbies**	**Comorbidity (ulnar neuritis)**	Duration of symptoms	Functional limitations	Site of pain	Severity of pain	Grip strength	Timing of onset (acute or gradual)	Compliance with rest	Use of hydrocortisone cream	Number of treatments
Kurvers et al. 1995 [556]	38 (ME)	Surgery	Global outcome (response to treatment)	NS	NS	NS	Sig	–	–	–	–	–	NS	–	–	–
Stratford et al. 1989 [621]	40 (LE)	Ultrasound	Global outcome (success/failure)	NS	NS	–	–	NS	–	Sig	–	NS	–	NS	–	–
Gerberich et al. 1985 [629]	82 (LE)	Ultrasound	Global outcome (improvement)	NS	NS	–	–	NS	NS	–	Sig	–	–	–	NS	Sig (males) NS (females)

LE – Lateral epicondylitis
ME – Medial epicondylitis
NS – Not significant
[a]Variable in boldface indicate patient characteristics

Table 337. The relationship between duration of symptoms and treatment outcomes among patients with Epicondylitis (stratification or univariate statistical comparisons)

Author/year	N	Treatment	Outcome	Age
Gabel and Morrey1995 [555]	26 (LE)	Surgery	Global outcome (Excellent to poor)	NS
Newey and Patterson1994 [558]	28 (LE)	Surgery	Global outcome (Pain relief)	NS
Verhaar 1993 [559]	63 (LE)	Surgery	Global outcome (Level of satisfaction)	NS

LE – Lateral epicondylitis
NS – Not significant

Conclusions

Six studies reported data that addressed this question. Three of them used multiple regression to identify predictor variables. All three studies found no statistically significant correlation between gender or age and response to treatment. One study found no such correlation between certain hobbies and response to treatment. The only study that examined co-morbidities reported that patients with co-existant ulnar neuropathy had significantly poorer outcomes than patients without ulnar neuropathy. However, it is difficult to reach evidence-based conclusions from the results of a single study.

Question #7: What are the surgical and nonsurgical costs or charges for treatment of epicondylitis?

According to Medicare Provider Analysis and Review (MEDPAR), average total charges per patient for the DRG (diagnosis-related group) of major shoulder/elbow procedures with comorbidities or complications are $9,008.94 (calculated by dividing total charges by number of discharges). For the DRG shoulder, elbow or forearm procedures, except major joint procedures, without comorbidities or complications, average total charges per patient are $7729.16. The Median Costs for Hospital Outpatient Services Dataset contains median costs for services that are reimbursed under Medicare for the hospital outpatient prospective payment system. The reported median cost for strapping of the elbow or wrist is $62.61 (cost of open release was not reported by this database).

Question #8. For persons who have had surgery to treat epicondylitis, what are the appropriate methods for preventing the recurrence of symptoms, and how does this vary depending on subject characteristics or other underlying health problems?

This question distinguishes between symptom recurrence and continued symptoms after failed treatment. Rates of recurrence, possible reasons for recurrence, and recommended strategies to avoid recurrence have not been addressed by the available literature. In the absence of controlled trials, no analysis may be performed and no conclusions may be drawn

Question #9: What instruments, if any, can accurately assess functional limitations in an individual with epicondylitis?

We address this question in the same manner that we addressed Question 9, Carpal Tunnel Syndrome. The reader is referred to that section of this evidence report for detail. Briefly, we define an instrument that can accurately assess functional limitations in an individual with epicondylitis as one that has test-retest reliability, internal reliability, content validity, concurrent validity, predictive validity, and responds to treatment.

Evidence base

Three studies with a total of 122 patients met the inclusion criteria (see the section Inclusion Criteria). These studies are listed in Table 338. The functional assessment instruments evaluated by them are listed in Table 339.

Table 338. Trials of functional assessment instruments that met the inclusion criteria

Study	Instruments evaluated[a]	N subjects	Outcome measurements
Overend 1999 [315]	PRFEQ	50	Validity Test-retest reliability
Stratford 1993 [630]	F-VAS	40	Validity Response to treatment
Stratford 1987 [631]	F-VAS	32	Validity Response to treatment Test-retest reliability

a The full names of the instruments and descriptions of the instruments are given in Table 339.

Table 339. Instruments evaluated to measure functional limitations associated with epicondylitis

Instrument	Abbreviation	First described by	Scoring system	Subjects covered	Extent of use[a]
Patient-rated forearm evaluation questionnaire	PREFQ	Overend 1999 [632]	Functional categories	Common activities of daily living	Not widely used
Functional visual analog scale	F-VAS	Stratford 1987 [631]	VAS	Not described	Not widely used

a a search of Medline for the assessment instrument found that there were fewer than 3 studies reporting the use of each of the instruments

Study quality

Internal validity

Studies evaluating instruments need not include a separate control group, because each patient acts as his/her own control. All of the studies included in this section are single-arm prospective cohort studies. Factors relating to the quality of the studies are shown in Table 340. None of the studies administered and scored the instruments with evaluators who were blinded to the identity, history, and other test scores of the patients. Studies that did not use blinded evaluators may be subject to bias.

Table 340. Details of study design

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective	Blinding	% Attrition	Intent to treat analysis	% Compliance
Overend 1999 [632]	50	1	No	Cohort	Yes	No	6	No	NA
Stratford 1993 [630]	40	1	NR	Cohort	Yes	No	0	Yes	NA
Stratford 1987 [631]	32	1	No	Cohort	Yes	No	0	Yes	NA

NA = not applicable

Generalizability

An important factor in evaluating assessment instruments is the patient group. In order to accurately evaluate the instrument, it is important that the test group be similar to the patients that the instrument will be used to evaluate in clinical practice. Details of the patient groups are shown in Table 341. The mean ages and gender composition of the patient groups are similar to that reported in epidemiology studies of epicondylitis (see the Introduction). None of the studies reported on the presence of co-morbid conditions that may have contributed to functional limitations. None of the studies reported any information as to the occupations or employment status of the patients.

Table 341.Study generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of conditon mean and range months	% Patients with diabetes	% Patients with arthritis	% Patients with prevous relevant injuries	% Patients with other relevant nerve impingement conditons	% Patients with peripheral neruopathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Overend 1999 [632]	50	45	48.9	NR	NR	NR	NR	NR	NR	NR	NR	No	No
Stratford 1993 [630]	40	43	50	4.2	NR	NR	NR	0	NR	NR	NR	No	No
Stratford 1987 [631]	32	44.9 (32-61)	NR	3.7 (0-12)	NR	NR	NR	NR	NR	NR	NR	No	No

NR = not reported

Results

Test-retest reliability

Both instruments (F-VAS and PRFEQ) are reported to give consistent results when administered to the same subjects on different days (Table 342).

Table 342. Results of test-retest reliability tests

Study	Number of patients	Tests evaluated	Time between test administrations	Type of statistical comparison being made	Was the instrument reliable?
Overend 1999 [632]	50	PRFEQ	NR	Correlation coefficient r = 0.89	Yes
Stratford 1987 [631]	32	F-VAS	4 days	Correlation coefficient r = 0.85	Yes

NR = not reported

Internal reliability

None of the included studies reported data relevant to this aspect of instrument evaluation.

Content validity

None of the included studies reported data that addressed this aspect of validity.

Response to treatment

Stratford reported that scores on the F-VAS increase as patients are successfully treated for epicondylitis (Table 343).

Table 343. Results of response to treatment tests

Study	Number of patients	Test evaluated	Treatment	Time of testing months	Effect size Hedges' d (95% CI)[a]	Was the instrument responsive to treatment?
Stratford 1993 [630]	40	F-VAS	Not reported	1	0.97 (0.22 to 1.72)	Yes
Stratford 1987 [631]	32	F-VAS	Ultrasound	1.5	1.60 (1.04 to 2.16)	Yes

a calculated by ECRI

Concurrent validity

All three trials compared the scores on the assessment instruments to pain-free hand grip strength, as is shown in Table 344. A moderate correlationm (r = 0.36) between hand grip strength and the results of the PRFEQ was reported. Stratford 1993 and Stratford 1987 reported the scores on the F-VAS correlated well with hand grip strength.

The instruments were not validated against any other measurements of hand/arm function.

Table 344. Results of validity tests

Study	Number of patients	Test evaluated	Type of statistical comparison being made	Validated against	Was the instrument valid by this measurement ?
Overend 1999 [632]	50	PRFEQ	Intraclass correlation coefficient r = -0.36	Hand grip strength	Yes, but r is low
Stratford 1993 [630]	40	F-VAS	Interclass correlation coefficient r = 0.53	Hand grip strength	Yes
Stratford 1987 [631]	32	F-VAS	Interclass correlation coefficient r = 0.66	Hand grip strength	Yes

Predictive validity

None of the included studies reported data relevant to this aspect of instrument evaluation.

Conclusion

Three studies evaluated two different instruments as ways to measure functional limitations of patients with epicondylitis. The results of the studies are summarized in Table 345. Neither assessment instrument was shown to be a useful instrument for evaluating functional limitations in persons with epicondylitis. However, it is difficult to reach firm evidence-based conclusions about the instruments evaluated in this report due to the limited evidence base.

Table 345. Utility of assessment instruments for evaluating functional limitations associated with epicondylitis

Instrument	Is the instrument			Strength of Evidence
	Valid?	Responsive to treatment?	Reliable?	
Patient-rated forearm evaluation questionnaire	No	NR	Yes	One study of 50 patients
Functional visual analog scale	Yes	Yes	Yes	Two studies of 72 patients by the same group

NR = not reported

Question #10: What are the functional limitations for an individual with epicondylitis before treatment?

This question addresses the functional limitations of individuals before receiving conservative or surgical treatment for epicondylitis. Our objective is to catalogue these limitations, and not to address the effectiveness of these treatments. We address the effectiveness of conservative and surgical treatments in Question 3.
The available literature governs our approach to the present question. Hence, we consider functional status rather than functional limitations, because no published studies specifically addressed the latter. In addition, the only available data operationally defines functional status in terms of scores on certain written tests. Therefore, we also address functional status in these terms. The validity and reliability of these written tests is discussed in Question 9. Study inclusion criteria are described under Methods.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, not all of the retrieved studies met our more specific inclusion criteria for this question. These latter studies, and the reason we did not consider them for this question are shown in Table 346.

Table 346. Excluded studies

Author	Reason for exclusion
Pienimaki and Vanharanta 1998 [544]	Study reported that patients received prior treatment

Evidence base

Two studies (with a total of 82 patients) remained that addressed this question after the above exclusion.

Internal validity

Aspects of study quality that are most relevant to the present question are shown in Table 347. Because we are cataloging functional status rather than using it to determine treatment effectiveness, randomization and the use of control groups are not of paramount importance here. Therefore, Table 347 does not depict these aspects of study design. However, the following variables are important: attrition rates, whether the trial was prospective, and whether the raters of functional status (in this case the patients) were blinded to the treatment the patient received. Attrition was low (6%) or non-existent in the two included studies. Both were unblinded prospective case series. Because it is difficult to blind patients to the treatment received, we are considering unblinded studies to be of acceptable quality for this question.

Table 347. Study quality

Author	Number of patients	Number of centers	Funded by a for-profit agency?	Prospective	Blinding	% Attrition	Intent to treat analysis	% Compliance
Overend 1999 [632]	50	1	No	Yes	No	6	No	NA
Stratford 1987 [631]	32	1	No	Yes	No	0	Yes	NA

NA – Not applicable

Generalizability

Selected patient characteristics are presented in Table 348. Both studies reported mean age of patients and percent female, one study reported duration of symptoms, and no studies reported comorbidities or severity of disease. Mean age and percent female patients were consistent with the numbers reported by epidemiologic studies (see Introduction section, epicondylitis, subheading epidemiology).

No study reported information concerning patient employment or occupation (Table 349). Therefore, one cannot determine the generalizability of these studies in terms of occupational variables.

Table 348. Patient characteristics

Author	Number of patients	Mean age (range)	% female	Duration of condition (range)	% Patients with diabetes	% Patients with arthritis	% Patients with prevous relevant injuries	% Patients with other relevant nerve	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe	Did the study exclude patients with mild
Overend 1999 [632]	50	45	48.9	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Stratford 1987 [631]	32	44.9 (32-61)	50	Mean: 111 days (3-364)	NR	NR	NR	NR	NR	NR	NR	NR	NR

NR – Not reported

Table 349. Patient occupation

Author	Year	ID#	Number of patients	% Patients employed	% Patients on Workers Compensation	% Patients retired	% Patients homemakers	Reported Occupations
Overend	1999	[632]	50	NR	NR	NR	NR	NR
Stratford	1987	[631]	32	NR	NR	NR	NR	NR

NR – Not reported

Results

Table 350 shows the results of the two studies that addressed this question. Overend (1999) excluded patients with prior surgery or elbow injection (within the last 30 days), but there is still uncertainty about whether some patients received prior treatment.[632] Stratford (1987) did not report whether patients had received prior treatment. Both studies used different functional status scales, so their results are not directly comparable. They found similar mean or median values in their pre-treatment study groups (between 30-40% of the maximum score).

Table 350. Studies with pre-treatment functional limitation data for patients with lateral epicondylitis

Study	N	Study Design	Stratified subgroups	n	Scale	Overall mean pre-treatment functional status score (SD)	% of maximum score
Overend (1999) [632]	50	Stratified case series	Male Female	24 23	PRFEQ (0-10 scale)	2.8 (1.9) 4.1 (2.1) p = 0.033[a]	28 41
			Subacute LE Chronic LE	35 12		3.6 (2.0) 3.1 (2.2) p = 0.475[a]	36 31
			Work-related LE Non-work-related LE	21 26		4.2 (2.3) 2.8 (1.7) p = 0.022[a]	42 28
			Total group	47		3.4 (2.1)	34
Stratford (1987) [631]	32	Prospective case series	NA	NA	PFF (0-8)	Median: 3	37.5

[a]Calculated by ECRI
PFF – Pain-Free Function Index
PRFEQ – Patient Rated Forearm Evaluation Scale

Conclusions

This question is addressed by only two studies comprised of a total of 82 patients. Although these studies suggest that the functional difficulties experienced by patients with epicondylitis are increased by 30% to 40%, the low number of studies and patients makes it difficult to arrive at an evidence-based answer to this question.

Question #11: What are the functional limitations of an individual with epicondylitis after treatment?

This question considers the functional limitations of an individual after they have received conservative or surgical treatment for epicondylitis. In addressing it, our objective is to catalogue these limitations, and not to address the effectiveness of these treatments. We address the effectiveness of conservative and surgical treatments in Question 3.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, one of the retrieved studies did not meet our more specific inclusion criteria for this question. This study, and the reason we did not consider it for this question is shown in
Table 351.

Table 351. Excluded studies

Author	Reason for exclusion
Stratford et al., 1987[631]	Study reports median value for successes and failures but does not report the number or percentage of successes and failures.

Evidence base

After this exclusion, there were no studies that met the general or question-specific inclusion criteria.

Conclusion

There were no studies that met the inclusion criteria for this question. Therefore, it cannot be answered in an evidence-based fashion.