participant and care provider blinding in these trials.

Comparability of baseline characteristics (item 4)

Two trials (Andersen 1987; Lubbert 2008) only provided baseline characteristics, split by treatment group, at follow-up rather than for the full study population at randomisation. Andersen 1987 only provided separate group data for fracture type and displacement; and Hoofwijk 1988, only for age and gender. The reported characteristics were comparable in both cases. Separate group data were provided for age, gender, side of fracture, AO classification, type of trauma, prior sports activity and professional work were reported and generally comparable in Lubbert 2008.

Care programme comparability (item 7)

Neither Andersen 1987 nor Hoofwijk 1988 provided sufficient information to evaluate the possibility of confounding through differences between the intervention groups in other aspects of care programmes. Andersen 1987 reported that all participants were encouraged to move the shoulder as soon as possible. However, participants allocated to figure-of-eight bandages were also advised to see their general practitioner for checks and adjustments to their bandages at two days, and once and two weeks after application. Lubbert 2008 described identical care programmes.

External validity

Description of inclusion and exclusion criteria (item 8)

All the included trials were considered to have provided sufficient information of inclusion and exclusion criteria to define their intended study populations.

Definition and quality of outcome measurement (item 9 and 10)

The variety of outcome measures reported by the trials is evident from inspection of the individual entries in the Characteristics of included studies. Outcome measurement was inadequately defined in Andersen 1987, which also used an unvalidated overall scoring system.

Length of follow-up (item 11)

The length of overall up was rated as inadequate in Andersen 1987 (maximum 17 weeks) and adequate in Hoofwijk 1988 (6 months or over). Follow-up was 12 months or over for the review of medical records in Lubbert 2008.

Summary of overall risk of bias

Altogether the lack of confirmation of allocation concealment, absence of blinding, inadequate treatment of withdrawals in Andersen 1987 and Hoofwijk 1988 point to a high risk of bias in these trials. In contrast, particularly given effective allocation concealment and blinding, Lubbert 2008 seemed to be at low risk of bias.

Effects of interventions

Two studies (234 participants) compared figure-of-eight bandage versus arm sling. Data from these studies were not pooled. One study (120 participants) compared low-intensity pulsed ultrasound for fracture placebo.

Authors of one trial responded to requests for additional data to be used in the analyses Lubbert 2008 provided standard deviations (SDs) of the outcomes. Hoofwijk 1988 did not have available the data we needed to calculate the radiographic outcomes.

Comparison 1: Immobilisation with figure-of-eight bandage versus arm sling

Bandage immobilisation was compared with sling immobilisation in two trials, but there were no outcome data in common for pooling (Andersen 1987; Hoofwijk 1988).

Pain (see Analysis 1.1: Analysis 1.2)

Pain was assessed in both trials. Andersen 1987 evaluated this outcome using an unvalidated score, but the results for pain from movement were identical at the follow-up examination. Hoofwijk 1988 reported a statistically significant difference in favour of the arm sling for pain after 15 days (mean difference (MD) 0.80, 95% confidence interval (CI) 0.34 to 1.26; VAS: 0 (no pain) to 10 (worst pain)). There was no statistically significant difference between the two groups for the duration of consumption of painkillers (MD 0.60 days, 95% CI -0.82 to 2.02).

Shoulder function (see Analysis 1.3; Analysis 1.4)

Shoulder function was assessed in both trials. Andersen 1987 evaluated this outcome using an unvalidated score, but concluded that the functional results for the two groups were identical. Hoofwijk 1988 measured this outcome by using subjective criteria: there was no statistically significant difference in the number of participants with ‘good function’ (risk ratio (RR) 1.06, 95% CI 0.96 to 1.04). Hoofwijk 1988 also evaluated the time to clinical fracture consolidation, here treated as a proxy for recovery, and found no statistically significant difference between the two groups (MD 0.20 weeks, 95% CI -0.10 to 0.50).

Health-related quality of life

Neither of the included studies reported a validated health-related quality of life measure.

Time to return to previous activities (see Analysis 1.5)

Hoofwijk 1988 found no significant difference between groups in the time to return to school/ework activities (MD 0.10 weeks, 95% CI -0.74 to 0.94) and sports activities (MD -0.60 weeks, 95% CI -1.48 to 0.28).

Functional impairment and clinical outcomes (see Analysis 1.6: Analysis 1.7)
Apêndice

Hoefwijk 1988 found no statistically significant differences in the number of participants with subjectively rated good cosmetic appearance post healing of their fracture (RR 1.01, 95% CI 0.77 to 1.31). Andersen 1987 concluded that the cosmetic results of the two groups were identical. There were more, although not significantly, participants that were dissatisfied with treatment in the figure-of-eight bandage group of Andersen 1987 (9/34 versus 2/27; RR 3.57, 95% CI 0.84 to 15.18); and two more participants of this group had been withdrawn from the trial; one refused to use the bandage and the other found it too painful. Additionally, Andersen 1987 reported that people in this group experienced more discomfort and functional impairment.

Radiographic outcomes (see Analysis 1.8)

Radiographic outcomes were evaluated in both trials; however, in Hoefwijk 1988, the number of participants assessed was not available. All fractures healed in Andersen 1987, who found no statistically significant differences in the number of participants with their fracture position maintained or improved (RR 1.07, 95% CI 0.89 to 1.29).

Complications

Andersen 1987 evaluated complications of the treatment but they did not specify these complications and used a non-validated score system to appraise this outcome.

Comparison 2: Therapeutic ultrasound versus placebo

Therapeutic ultrasound was compared with placebo in one study (Lubbert 2008).

Pain (see Analysis 2.1; Analysis 2.2)

Pain was assessed using a visual analogue scale (VAS) and consumption of painkillers. There were no statistically significant differences between the two groups in VAS (MD -0.04, 95% CI -0.61 to 0.53) or consumption of painkillers (MD 4.33 tablets/28 days, 95% CI -14.67 to 23.33).

Shoulder function (see Analysis 2.3)

Lubbert 2008 measured number of days to clinical fracture consolidation, here treated as a proxy for subjectively assessed recovery. There was no statistical significant difference between LIJPS and placebo (MD -0.32 days, 95% CI -5.85 to 5.21).

Health-related quality of life

Health-related quality of life was not evaluated in Lubbert 2008.

Time to return to previous activities (see Analysis 2.4)

There were no statistically significant differences between the two groups in number of days to return to house hold activities (MD -2.86 days, 95% CI -6.59 to 0.87), professional work activities (MD 1.95 days, 95% CI -2.18 to 6.08). The difference in the time to return to sport activities was marginally in favour of LIJPS (MD -2.27 days, 95% CI -4.54 to 0.00).

Function al impairment and clinical outcomes

Lubbert 2008 assessed clinical fracture consolidation as reported above.

Radiographic outcomes

Radiographic outcomes were not evaluated in Lubbert 2008.

Complications (see Analysis 2.5)

Skin irritation was reported for one participant in each group; the other "minor adverse side effects" were not enumerated. Notably, three participants in the placebo group, whose data were not included in the analyses, discontinued their treatment because of transducer failure or too much pain.

There was no statistical significant difference between the two groups for subsequent surgery; five in each group had surgery because of lack of fracture healing: the remaining LIJPS group participant had surgery for the removal of a painful bone spike.

Subgroup analyses

Our plans to study the outcomes in different age groups and for different fracture types were prevented by the lack of data.

DISCUSSION

Summary of main results

Whilst there are several options for conservative treatment for middle third clavicle fractures, we found only three randomised or quasi-randomised controlled trials (354 participants) eligible for inclusion in this review. The available evidence from two trials comparing the figure-of-eight bandage with an arm sling found no statistically significant differences in outcome between the two groups, with the exception of significantly higher pain scores at 15 day follow-up in one trial (Hoefwijk 1988) for the bandage group. The difference in the pain scores (0.8 out of 10) is, however, of only marginal clinical significance. While data were unavailable to confirm this, discomfort during bandage wear was reported to be greater in Andersen 1987. Overall, however, the available evidence from these two trials does not allow definitive conclusions about which intervention is better. The third trial provided no evidence that application of therapeutic ultrasound accelerates recovery, including clinical fracture healing, or affects outcome after clavicle fractures.

Overall completeness and applicability of evidence

The search strategy of this review was designed, within reason, to locate all possible relevant trials. It included key electronic databases, including clinical trials registers, and contact with experts in the field. We included only randomised or quasi-randomised controlled trials in this review to restrict the possible selection bias.

The three included trials were not sufficient to evaluate the relative effectiveness of different conservative treatment to middle
third clavicle fractures; attributable to the lack of available data and the impossibility of gathering the missing data. The trials that compared sling and bandage treatment (Andersen 1987; Hoofwijk 1988) were conducted in the 1980s and the missing data were not recorded. The trial that verified the effectiveness of therapeutic ultrasound treatment (Lubbert 2008) found no differences between the experimental and control groups for the recorded outcomes. In accordance with the planning of this review, two included trials (Andersen 1987; Hoofwijk 1988) assessed adolescents and adults, and one trial (Lubbert 2008) assessed participants more than 18 years old; but with the data available we could not develop any subgroup analyses evaluating any association of age, skeletal maturity, fracture type, or fracture displacement, with outcome.

Quality of the evidence
Two of the included three studies were conducted in the 1980s when study quality and reporting were poorly developed. The number of participants with data available for Andersen 1987 and Hoofwijk 1988 was small and the interpretation of the results may be compromised by the lack of power. Future trials should be adequately powered so that the results can be more realistic and a type II error can be avoided. Other deficiencies of these two studies are limited length of follow-up and the non-use of validated instruments to measure outcome.
Lubbert 2008 was of high methodological quality; and low risk of bias. Despite being a multi-centre study, it lacked power to determine whether therapeutic ultrasound is a beneficial intervention after clavicle fracture.

Potential biases in the review process
This review was conducted following criteria and methods set out in a published protocol. It is possible but unlikely that we have missed potentially eligible trials. Our search strategy has been maintained and updated by the contact author (ML). The databases searched included LILACS, which captures studies from Latin America. Chinese studies reach the Cochrane Central Register of Controlled Trials through the Chinese Cochrane Centre. We approached the authors of our included studies. We received unpublished data (standard deviations) from one study (Lubbert 2008); the missing data of Hoofwijk 1988 was no longer available. Potential authors of unpublished trials have been sent requests searching for information and trial reports.

Agreements and disagreements with other studies or reviews
The results of this review are consistent with one published review (Złowodiński 2005). Our review adds consistent information for current clinical practice by applying more rigorous methodology, restricting the included studies to randomized or quasi-randomised trials and performing a broader literature search that includes non-English literature. We also plan future updates in the light of new evidence.

AUTHORS’ CONCLUSIONS

Implications for practice
Despite the high incidence of middle third clavicle fracture and the many types of conservative treatment available, very few randomised or quasi-randomised controlled trials have examined this issue. There is insufficient evidence from two trials to establish the relative effects on final functional outcome of the figure-of-eight bandage and an arm sling, although the bandage may be associated with more early pain and discomfort during use. Currently, based on the results of one underpowered trial, there is no evidence of enhanced recovery, specifically accelerated clinically-determined fracture healing, to support the use of therapeutic ultrasound treatment for these fractures. Health professionals involved in managing these injuries should continue to manage patients with mid-shaft clavicle fractures using established techniques, taking into consideration the nature of the fracture, their own experience and the circumstances of the patient.

Implications for research
Randomised controlled trials of conservative methods of treatment, including further trials comparing contemporary conservative interventions, such as an arm sling versus the figure-of-eight bandage, for clavicle fractures are warranted. These should meet current standards in the planning, conduct and reporting of randomised controlled trials, and be adequately powered. It would be useful if randomisation was stratified by skeletal maturity, and adult and adolescent subgroups were reported separately. Validated health-related quality of life, pain, and shoulder function tests should be used.

ACKNOWLEDGEMENTS
The review authors would like to thank Dr Michael Callaghan, Professor Bill Gillespie, Dr Helen Handoll, Associate Professor Peter Herbison, Dr Vicki Livingstone, Mr Amar Rangan and Dr Janet Wale for their helpful comments on this protocol and review. We also thank Lindsey Elstub and Joanne Elliott for their assistance in preparing the protocol and review.
Thanks are also extended to the authors of included trials who responded to requests for additional information/data: Dr Pieter
References to studies included in this review

Andersen 1987 [published data only]
Andersen K. Personal communication November 2008.

Hoofwijk 1988 [published data only]
van der Werken C. Personal communication August 2008.

Lubbert 2008 [published and unpublished data]
Lubbert PH. Personal communication August 2008.

References to studies excluded from this review

Talbot 2008 [unpublished data only]
Talbot N. Personal communication September 2008.

Thompson 2005 [published data only]

References to ongoing studies

Robert 2008 [unpublished data only]
Robertie BE. Personal communication September 2008.

Additional references

Allman 1967

Allman 2003

Andersen 1987

Cheung 2008

Constant 1987

Eiff 1997

Higgins 2006

Hoofwijk 1986

Hudak 1996

**Jensen 1985**


**Jeray 2007**


**Koteleszki 2006**


**Lazanus 2001**


**McKee 2006**


**Muller 1991**


**Neer 1984**


**Nordqvist 1998**


**Nordqvist 1998**


**Nowak 2000**


**Postacchini 2002**


**Reville 1976**


**Robinson 1998**


**Robinson 2004**


**Stanley 1988**


**Wainer 1992**


**Złowodiński 2005**


* Indicates the major publication for the study
### CHARACTERISTICS OF STUDIES

**Characteristics of included studies** [author-defined order]

**Andersen 1987**

<table>
<thead>
<tr>
<th>Methods</th>
<th>Method of randomisation: Random numbers table.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assessor blinding: Not possible.</td>
</tr>
<tr>
<td></td>
<td>Intention-to-treat analysis: Likely, but outcome data for participants who had withdrawn from the trial or were lost to follow-up were not presented.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Participants</th>
<th>Location: Denmark.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of participants (N): 79 participants with acute middle third clavicle fractures.</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria:</td>
</tr>
<tr>
<td></td>
<td>- People with middle third clavicle fractures.</td>
</tr>
<tr>
<td></td>
<td>- Aged &gt; 13 years.</td>
</tr>
<tr>
<td></td>
<td>- Patient informed consent.</td>
</tr>
<tr>
<td></td>
<td>Exclusion criteria:</td>
</tr>
<tr>
<td></td>
<td>- Perforation of the skin or primary neurovascular symptoms.</td>
</tr>
<tr>
<td></td>
<td>- Age (median (range)): figure-of-eight = 19 years (14-81); sling = 19 years (14-66).</td>
</tr>
<tr>
<td></td>
<td>Gender: not specified.</td>
</tr>
<tr>
<td></td>
<td>Sides: not specified.</td>
</tr>
<tr>
<td></td>
<td>Classification of injury: not specified, just fracture types (two-fragments, one intermediary fragment and two or more intermediary fragments) and fracture dislocations (undisplaced, minor displacement, major displacement).</td>
</tr>
<tr>
<td></td>
<td>Assigned: 45 / 34 [figure-of-eight / sling].</td>
</tr>
<tr>
<td></td>
<td>Assessed: 34 at median period of 12 weeks (10-16) / 27 at median period of 13 weeks (10-17) [figure-of-eight / sling].</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Timing of intervention: after diagnosis.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Duration of treatment: 3 weeks.</td>
</tr>
<tr>
<td></td>
<td>Duration of rehabilitation: not specified.</td>
</tr>
<tr>
<td></td>
<td>Intervention 1 (figure-of-eight bandage):</td>
</tr>
<tr>
<td></td>
<td>After 2 days, and 1 and 2 weeks, this method was checked and adjusted by participants' own general practitioner. This immobilization was used for 3 weeks. All participants were stimulated to move the shoulder as soon as possible.</td>
</tr>
<tr>
<td></td>
<td>Intervention 2 (arm sling):</td>
</tr>
<tr>
<td></td>
<td>Simple sling was used only as long as the patient felt a need for it. All participants were stimulated to move the shoulder as soon as possible.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Length of follow-up:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The figure-of-eight group lasted a median interval of 12 weeks (10-16) and the sling group lasted a median interval of 13 weeks (10-17); the figure-of-eight group also was assessed at 2 days, 1 and 2 weeks.</td>
</tr>
<tr>
<td></td>
<td>Outcome:</td>
</tr>
<tr>
<td></td>
<td>1. Functional: duration of bandaging, discomfort from treatment, severity of discomfort, duration of discomfort, number of visits on general practitioner, use of analgesics, duration of pain,</td>
</tr>
</tbody>
</table>
**Andersen 1987** (Continued)

- Duration of functional impairment, duration of sick leave/disability, and complications (not specified).
- Clinical: deformity at fracture site, skin problems, neurovascular symptoms, impairment of shoulder motion, weakness of shoulder muscles, pain from movement, and tenderness of fracture site.
- Anatomical: radiographic examination - healing of fracture, amount of callus and displacement.

**Notes**

- Eleven participants in the figure-of-eight group were withdrawn from the study.
  - 1 = refused bandage,
  - 2 = bandage removal,
  - 1 = DVT,
  - 2 = fracture displacement,
  - 6 = defaulted the follow-up examination.

Seven participants in the sling group were withdrawn from the study.
- 1 = confined to bed (5 weeks),
- 1 = treatment with Velpeau (1 week),
- 1 = suffered hemiplegia,
- 4 = defaulted on follow-up examination.

The outcomes were evaluated by an unvalidated score system.

**Risk of bias**

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors' judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment</td>
<td>Unclear</td>
<td>Random numbers table was used; however, details to ascertain that allocation was concealed were not provided.</td>
</tr>
</tbody>
</table>

**Hoofwijk 1988**

**Methods**

- **Method of randomisation**: Participants were randomised by opening of pre-numbered envelopes.
- **Assessor blinding**: Not possible.
- **Intention-to-treat analysis**: Likely, but outcome data for participants who had withdrawn from the trial or were lost to follow-up were not presented.

**Participants**

- **Location**: Department of Surgery, Saint Elisabeth Hospital, Tilburg, The Netherlands.
- **Number of participants**: 155 participants with 157 acute middle third clavicle fractures.
- **Inclusion criteria**:
  - People with middle third clavicle fractures and outpatient treatment;
  - Aged > 14 years;
  - Agreement of the patient.
- **Exclusion criteria**:
  - People with re-fractures;
  - Open fractures;
  - Concomitant injuries of vessels or nerves or on the same extremity.
### Hoofwijk 1988 (Continued)

| Age (mean / SD): figure-of-eight bandage - 24.4 / 12.5 years; arm sling - 25.4 / 14.5 years.  
| Gender (female / male): figure-of-eight bandage - 22 / 56; arm sling - 22 / 57.  
| Side (left / right): 85 / 72.  
| **Classification of injury:** not specified, just fracture displacement (undisplaced and displacement) and multiple fragment fractures (with or without shortening).  
| **Assigned:** 78 / 79 (figure-of-eight bandage / arm sling).  
| **Assessed:** 74 / 78 at mean period of 10 (6-36) months (figure-of-eight bandage/ arm sling).  

### Interventions

**Timing of intervention:** after diagnosis.  
**Duration of treatment:** not known, probably 3 weeks.  
**Duration of rehabilitation:** not specified.  
**Intervention 1 (figure-of-eight bandage):** Details not specified.  
**Intervention 2 (arm sling):** Details not specified.

### Outcomes

**Length of follow-up:** Length of follow-up was mean of 10 months (range 6 to 36 months). Follow up was conducted on the first and third day after the accident, after 1, 2, and 3 weeks, and after at least 6 months.  
**Outcomes:**  
1. Functional impairment and clinical outcomes: pain degree - VAS (18 and 15 days), analgesic consumption, consolidation clinically, mobility of shoulder and muscular strength.  
2. Radiographic outcomes: length and displacement before and after consolidation of the fracture*.  
3. Resource use: resumption of school/work and sports activities.  
4. Safety (success or failure of treatment and adverse events): cosmetic appearance.  
* Participant numbers (N) were not reported.

### Notes

Four participants in the figure-of-eight bandage group were withdrawn from the study (could not be found).  
One participant in the arm sling group was withdrawn from the study (could not be found).  
Radiographic outcomes were not analysed in the review because participant numbers for each intervention was not known despite contacting the authors.

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>Participants were randomised to the two treatment groups by opening of pre-numbered envelopes; however, details to ascertain that allocation was concealed were not provided.</td>
</tr>
</tbody>
</table>
### Method of randomisation

Consecutive numbered transducers were delivered in packs of four. Each hospital supply contained two randomly assigned active transducers and two placebo transducers (block randomisation) to ensure equal partitioning of both treatment regimens in all hospitals. Randomisation took place at the site of the manufacturer. The placebo transducers looked identical to the active ones and could only be identified by a unique serial number that was exclusively known by the manufacturer and was needed for decoding at the completion of the entire study.

**Blind of outcomes assessors**: Assessor blinding was made.

**Intention-to-treat analysis**: Likely, but data of those patients who withdrew could not be collected.

### Location

Six hospitals in the Netherlands participated in the study (Meander Medical Centre - Amersfoort, Onze Lieve Vrouwen Gasthuis Hospital - Amsterdam, Reinier de Graaf Hospital - Delft, Saint Antonius Hospital - Nieuwegein, Diakonessen Hospital - Utrecht, University Medical Centre Utrecht - Utrecht).

### Number of participants (N)

120 participants with acute middle third clavicle fractures.

**Inclusion criteria**:
- People with middle third clavicle fractures;
- Acute fracture (< 5 days);
- Aged ≥ 18 years;
- Monotrauma;
- Understanding of Dutch language and written informed consent.

**Exclusion criteria**:
- Aged < 18 years;
- Multiple trauma;
- Re-fracture;
- Pathological fracture;
- Open fracture or imminent skin perforation;
- Metaphysis fracture;
- No possibilities for follow up.


**Gender (female / male): LIPUS: 6 / 44; control (placebo): 10 / 39.**

**Side (left / right): LIPUS: 32 / 26; control (placebo): 22 / 27.**

**Classification of injury: AO system (A1, A2, A3, B1, B2, B3, C1, C2, C3).**

**Assigned**: 61 / 59 [LIPUS / control (placebo)].

**Assessed**: 52 / 49 [LIPUS / control (placebo)]. *Follow up ranged between 12 and 43 months.

*Data assessed by personal contact with the authors.*

### Interventions

**Timing of intervention**: up to 5 days after the diagnosis.

**Duration of treatment (mean)**: LIPUS ± 25.38 days; control (placebo) ± 24.43 days (mean difference 0.95; 95% CI -3.72, 1.81, p = 0.49).

**Duration of rehabilitation**: it was not done.

All participants were treated by passive support for their own convenience. Free arm movements within pain range were allowed from day 1.

**Intervention 1 (LIPUS)**

LIPUS delivers an ultrasound signal intensity of 30 mW/cm² SAWA, with a burst width of 200 μs in 1.5 MHz sine waves, pulsed at 1 kHz.

**Intervention 2 (Placebo)**
Control (placebo): transducers produced no signal, but showed similar messages on the display screen and could not be distinguished from active transducers.

**Outcomes**

*Length of follow-up:*
Length of follow-up (mean): LIPIUS 29.64 months and placebo 30.08 months, ranged between 12 and 43 months*. All participants were seen in the outpatient clinic approximately 1 week after starting the treatment and again roughly 2, 4, 6 and 8 weeks after trauma.

**Outcomes:**
1. Functional impairment and clinical outcomes: clinical fracture consolidation, pain (VAS), analgesics consumption.
2. Resource use: resumption of household activities, work and sports.
3. Safety (success or failure of treatment and adverse events):
   - Adverse effects: skin irritation
   - Need of operative procedure

*Data assessed by personal contact with the authors.

**Notes**
Nine participants in the LIPIUS group were withdrawn from the study (diary not completely filled).
Ten participants in the control group were withdrawn from the study (seven diary not completely filled and three transducer failure).

**Risk of bias**

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment</td>
<td>Yes</td>
<td>Double blind randomised placebo-controlled trial. For each participating hospital were delivered consecutive numbered transducers in packs of four (two LIPIUS and two placebo).</td>
</tr>
</tbody>
</table>

< less than
> more than
≥ more or equal than
AO: Arbeitsgemeinschaft für Osteosynthesefragen
CI: confidence interval
DVT: deep-venous thrombosis
ITT: intention-to-treat
LIPIUS: low-intensity pulsed ultrasound
kHz: kilohertz
MHz: megahertz
mW/cm²: milliWatt per square centimetre
µs: microsecond
SATA: spatial average, temporal average
VAS: visual analogue scale
Characteristics of excluded studies  [ordered by study ID]

<table>
<thead>
<tr>
<th>Study</th>
<th>Reason for Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talbot 2008</td>
<td>This study, logged in the National Research Register (UK), was intended to be a randomised trial of shoulder brace versus arm sling in 100 adults with isolated closed middle third clavicle fractures. It was planned to start in April 2002; however, the contact author indicated that for a variety of reasons this study never took place.</td>
</tr>
<tr>
<td>Thompson 2005</td>
<td>Not a randomised or quasi-randomised controlled trial.</td>
</tr>
</tbody>
</table>

Characteristics of ongoing studies  [ordered by study ID]

Roberti 2008

<table>
<thead>
<tr>
<th>Trial name or title</th>
<th>Conservative treatment of middle clavicular fractures with Kinesio clavicular tape and sling vs sling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Location: Amsterdam, The Netherlands. Number of participants (N): 128 patients with middle third clavicle fractures. Inclusion criteria: 1. Patients with a midclavicular fracture; 2. In the age from 12 to 60 years; 3. With an informed consent. Exclusion criteria: 1. Age less than twelve or greater than sixty years; 2. A pathological fracture; 3. An open fracture; 4. A fracture older than 28 days after injury; 5. A fracture in the proximal or distal third of the clavicle; 6. An associated neurovascular injury with objective neurological findings on physical examination; 7. An inability to comply with the follow-up; 8. A lack of consent; 9. Good understanding of Dutch language by word and in writing; 10. The use of psychopharmacological drugs.</td>
</tr>
</tbody>
</table>
Interventions

**Intervention 1 (Experimental group):**
The experimental group gets the Kinesio davicle tape application during 3 weeks in combination with sling treatment.

**Intervention 2 (Placebo):**
The control group gets the sling treatment in combination with a placebo tape application.

Outcomes

**Length of follow-up:**
Not available yet.

**Primary outcome**
- Quality of life measured by the DASH (Disabilities of the Arm, Shoulder and Hand) questionnaire.

**Secondary outcome**
- VAS (visual analogue scale);
- Non-union percentage;
- SF-36;
- Constant score.

Starting date

**Period of study:**
Planned start date: 01 October 2008.
Planned closing date: 01 October 2010.

Contact information

Roberti, Barbara E.
Amsterdam, The Netherlands
Email: b.e.roberti6@rug.nl

Notes
## DATA AND ANALYSES

### Comparison 1. Figure-of-eight bandage versus Arm sling

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Pain: Visual analogue scale (0 (no pain) to 10 (worst pain))</td>
<td>1</td>
<td></td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Totals not selected</td>
</tr>
<tr>
<td>1.1 Pain on 1st day</td>
<td>1</td>
<td></td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Not estimable</td>
</tr>
<tr>
<td>1.2 Pain on 8th day</td>
<td>1</td>
<td></td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Not estimable</td>
</tr>
<tr>
<td>1.3 Pain on 15th day</td>
<td>1</td>
<td></td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Not estimable</td>
</tr>
<tr>
<td>2 Pain: Duration of painkiller consumption (days)</td>
<td>1</td>
<td></td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Totals not selected</td>
</tr>
<tr>
<td>3 Shoulder function: number of participants with ‘good function’</td>
<td>1</td>
<td></td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>Totals not selected</td>
</tr>
<tr>
<td>4 Recovery: time to clinical fracture consolidation (weeks)</td>
<td>1</td>
<td></td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Totals not selected</td>
</tr>
<tr>
<td>5 Time to return to previous activities</td>
<td>1</td>
<td></td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Totals not selected</td>
</tr>
<tr>
<td>5.1 Resumption of school/ work (in weeks)</td>
<td>1</td>
<td></td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Not estimable</td>
</tr>
<tr>
<td>5.2 Resumption of sports activities (in weeks)</td>
<td>1</td>
<td></td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Not estimable</td>
</tr>
<tr>
<td>6 Cosmetic appearance: good result post fracture healing</td>
<td>1</td>
<td></td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>Totals not selected</td>
</tr>
<tr>
<td>7 Patient dissatisfaction with course of treatment</td>
<td>1</td>
<td></td>
<td>Risk Ratio (M-H, Fixed, 95% CI)</td>
<td>Totals not selected</td>
</tr>
<tr>
<td>8 Radiographic outcome: unchanged or improved fracture position on healing</td>
<td>1</td>
<td></td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>Totals not selected</td>
</tr>
</tbody>
</table>

### Comparison 2. Low-intensity pulsed ultrasound versus Placebo

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Pain: Visual analogue scale (0 (no pain) to 10 (worst pain))</td>
<td>1</td>
<td></td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Totals not selected</td>
</tr>
<tr>
<td>2 Pain: Number of painkillers (tablets/28 days)</td>
<td>1</td>
<td></td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Totals not selected</td>
</tr>
<tr>
<td>3 Recovery: time to clinical fracture consolidation (days)</td>
<td>1</td>
<td></td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Totals not selected</td>
</tr>
<tr>
<td>4 Time to return to previous activities</td>
<td>1</td>
<td></td>
<td>Mean Difference (IV, Fixed, 95% CI)</td>
<td>Totals not selected</td>
</tr>
</tbody>
</table>
4.1 Resumption of household activities (days) 1 Mean Difference (IV, Fixed, 95% CI) Not estimable
4.2 Resumption of professional work (days) 1 Mean Difference (IV, Fixed, 95% CI) Not estimable
4.3 Resumption of sport (days) 1 Mean Difference (IV, Fixed, 95% CI) Not estimable
5 Adverse events and subsequent surgery 1 Risk Ratio (M-H, Fixed, 95% CI) Totals not selected
  5.1 Number with skin irritation 1 Risk Ratio (M-H, Fixed, 95% CI) Not estimable
  5.2 Number who had surgical procedure 1 Risk Ratio (M-H, Fixed, 95% CI) Not estimable

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**Analysis 1.1. Comparison of Figure-of-eight bandage versus Arm sling, Outcome 1: Pain: Visual analogue scale (0 (no pain) to 10 (worst pain)).**

**Review:** Conservative interventions for treating middle third clavicle fractures in adolescents and adults

**Comparison:** Figure-of-eight bandage **versus** Arm sling

**Outcome:** Pain: Visual analogue scale (0 (no pain) to 10 (worst pain))

| Study or subgroup | Figure-of-eight bandage | | Arm sling | | | Mean Difference | Mean Difference |
|-------------------|--------------------------|------------------|-----------|-----------------|-----------------|-----------------|
|                   | N                        | Mean(Std) |           | N                    | Mean(Std) | N                    | Mean(Std) | 95% CI       | 95% CI       |
| 1 Pain on 7th day | Hoofwijk 1988            | 74        | 5.32 (1.9) | 78                  | 5.25 (2.2) | 0.07                  | 0.58, 0.72 |
| 2 Pain on 8th day | Hoofwijk 1988            | 74        | 3.3 (2)    | 78                  | 2.98 (1.9) | 0.32                  | 0.30, 0.34 |
| 3 Pain on 10th day| Hoofwijk 1988            | 74        | 2.6 (1.5)  | 78                  | 1.8 (1.6)  | 0.80                  | 0.34, 1.26 |

Factors: Figure-of-eight bandage vs. Arm sling
### Review: Conservative Interventions for treating middle third clavicle fractures in adolescents and adults

**Comparisons:**
- Figure-of-eight bandage vs. Arm sling

**Outcomes:**
- Pain: Visual analogue scale (0 [no pain] to 10 [worst pain])

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Figure-of-eight bandage</th>
<th>Arm sling</th>
<th>Mean Difference</th>
<th>N/SD</th>
<th>95% CI</th>
<th>N/SD</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Pain on 1st day</td>
<td>74 (1.9)</td>
<td>78 (2.3)</td>
<td>0.07</td>
<td>0.48, 0.72</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hoofiwijk 1988</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

Favours figure-of-eight bandage

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<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Figure-of-eight bandage</th>
<th>Arm sling</th>
<th>Mean Difference</th>
<th>N/SD</th>
<th>95% CI</th>
<th>N/SD</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Pain on 2nd day</td>
<td>74 (2.1)</td>
<td>78 (1.9)</td>
<td>0.32</td>
<td>0.30, 0.34</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hoofiwijk 1988</td>
<td></td>
<td></td>
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<td></td>
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Favours figure-of-eight bandage

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**Conservative interventions for treating middle third clavicle fractures in adolescents and adults (Review)**

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