Apêndice

Hodak 1996

Jerray 2007

Jupiter 1987

Khan 2008

Khan 2009

Kotelschnicki 2006

LaVelle 2003

Lazarou 2001

Lyons 1990

Manske 1985

Marri 2003

McKee 2006

Meiser 2006

Mullaji 1994

Neer 1984

Nooden 1994

Nooden 1998

Nowak 2000

Paigenferst 1992

Postacchini 2002

Pyper 1978

Revill 1976

Robinson 1998

Robinson 2004

Strassner 2007

Verborgt 2005

Ware 1992
Wilkins 1983

Wu 1998

Zlowodzki 2005

* Indicates the major publication for the study
# Characteristics of Studies

**Characteristics of included studies** *(ordered by study ID)*

**Kabak 2004**

| Methods | Method of randomisation: the randomisation was done using a computer-based randomisation technique.  
Assessor blinding: not mentioned.  
Participant blinding: not mentioned.  
Blinding of care providers: it was not possible due to the type of treatment.  
Intention-to-treat analysis: no, in that it was not specified to which group the 3 participants lost to follow-up belonged.  
Loss of follow-up: 3 participants did not respond to the requests for follow-up. |
| --- | --- |
| Participants | Place: hospital in Turkey.  
Period of study: 01/03/1996 to 30/07/2000.  
Number of participants (N): 36 enrolled, 33 analysed.  
Inclusion criteria:  
- Adults  
- People with non-union of the middle third of the clavicle (six months after the initial fracture)  
- Radiographic evidence of complete displacement of the fracture fragments  
- Gross motion at the fracture site  
- Pain and dysfunction or neurologic complaint  
Exclusion criteria:  
- Skeletal immaturity  
- Proximal or distal end clavicular non-union, or both  
- Bilateral fractures  
- Refusal to participate in the study  
Age:  
- Total of patients (mean/SD/range): 41.4/11.6/19-66 years  
- LC-DCP group (mean/SD/range): 42.7/11.4/21-66 years  
- DCP group (mean/SD/range): 40.0/11.9/19-59 years  
Gender:  
- Total of participants (male/female): 19/14  
- LC-DCP group (male/female): 9/8  
- DCP group (male/female): 10/6  
Side of injury: not specified.  
Classification of injury:  
- Arophic non-union (little or no visible callus)  
- Hypertrophic non-union (excessive callus)  
Assigned:  
- 36 participants  
- LC-DCP group: number of participants was not mentioned  
- DCP group: number of participants was not mentioned  
Assessed:  
- 33 participants assessed at least 18 months |
Kabak 2004  (Continued)

- LC-DCP group: 17 participants (13 atrophic and 4 hypertrophic)
- DCP group: 16 participants (12 atrophic and 4 hypertrophic)

### Interventions

**Timing of intervention**
- LC-DCP group: the mean interval between fracture and surgery was 11.4 months (range 6-19 months)
- DCP group: the mean interval between fracture and surgery was 10.2 months (range 6-26 months)

**Intervention 1**
- Open reduction and internal fixation with 3.5mm AO LC-DCP plate

**Intervention 2**
- Open reduction and internal fixation with 3.5mm AO DCP plate

**Rehabilitation**
The postoperative interventions of two groups were identical:
1. Immobilisation using a sling for a short period;
2. Passive exercises (pendulum and overhead) and elbow flexion;
3. Progressive strengthening exercises;
4. Full overhead activities were permitted after clinically and radiographic fracture healing.

### Outcomes

**Length of follow-up**
- The follow-up was 44.2 months (range 18-72 months)
- All patients were clinically evaluated in the first, third, sixth, and 12-month visits, and in the last follow-up visit

**Primary outcomes**
- Presence of pain
- Treatment failure: re-operation
- Shoulder function: DASH

**Secondary outcomes**

*Functional impairments and clinical outcomes:*
- Time to return to work (in weeks);
- Limited range of motion.

*Radiographic outcomes:*
- Time to clinical and radiographic union (weeks).

**Adverse outcomes:**
- Plate removal;
- Complications.

### Notes

In participants with atrophic non-union: sclerotic bone ends were excised and the medullary canals of both fragments were opened up and an intercalary segment of iliac crest graft was fashioned to fit between the two clavicular segments.

In the case of an hypertrophic non-union: the extra callus build up and excessively hypertrophic bone were shaved down to a normal clavicular size to facilitate fitting of the plate.
### Kabak 2004 (Continued)

<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 using a computer-based randomisation technique. But it was not mentioned when the randomisation was done and details were not described to ascertain that allocation was concealed.</td>
</tr>
</tbody>
</table>

### Lee 2007

#### Methods

- **Method of randomisation**: alternation. “Patients were treated with a Knowles pin or a plate in turn.”
- **Assessor blinding**: the outcomes assessors were not blind.
- **Participant blinding**: not mentioned.
- **Blinding of care providers**: it is not possible due to the type of treatment.
- **Intention-to-treat analysis**: no, in that it was not specified to which group the 7 participants lost to follow-up belonged.

**Loss of follow-up**: 7 participants were lost to follow-up:
- mortality (1)
- psychological disorders (2)
- relocation (4).

#### Participants

- **Place**: Taiwan.
- **Period of study**: between 1999 and 2002.
- **Number of participants (N)**: 69 participants.
- **Inclusion criteria**:
  - adults > 50 years old
  - People with middle third clavicle fractures
  - People who underwent open reduction and internal fixation
- **Exclusion criteria**:
  - People who had associated injuries that required a stay in intensive care or any other department
- **Age**:
  - Total of participants (mean/range): 59.0/50.81 years
  - Knowles pin group (mean/range): 60.4/50.81 years
  - Plate group (mean/range): 56.7/52–79 years
- **Gender**:
  - Total of participants (male/female): 36/26
  - Knowles pin group (male/female): 19/13
  - Plate group (male/female): 17/13
- **Side of injury not specified.**
- **Classification of injury**:
  - The fractures were classified as:
    - open fractures
    - transverse fractures
    - oblique and spiral fractures
    - comminuted fractures
    - symptomatic non-union.
Lee 2007 (Continued)

Assigned
- 69 participants
- Knowles pin group: number of participants was not mentioned
- Plate group: number of participants was not mentioned

Assessed
- 62 participants were assessed at period of 30 months
- Knowles pin group: 32 participants
- Plate group: 30 participants

Interventions

Timing of intervention
Not mentioned

Intervention 1
- Open reduction and internal fixation with Knowles pin

Intervention 2
- Open reduction and internal fixation with plate (DCP)

Rehabilitation
The postoperative interventions of two groups were identical:
1. immobilisation using a sling for 2 to 4 weeks;
2. participants were told to avoid work with heavy loads or aggressive exercise using the involved extremities during the following 2 months.

Outcomes

Length of follow-up
- The length of follow-up was 30 months

Primary outcomes
- Pain: VAS and analgesics consumption (5 days post-operation)
- Treatment failure: re-operation
- The Constant and Murley scores

Secondary outcomes
Functional impairments and clinical outcomes:
- Wound size
- Operative time

Radiographic outcomes:
- Union rate in 6 months
- Final union rate

Adverse outcomes:
- Symptomatic hardware
- Hardware removal
- Wound infection

Economic data:
- Hospital stay

Notes
Indications for surgery: 21 participants with persistent separation of the fracture with a gap more than half the diameter of the clavicle; 12 with associated fractures (5 ribs, 4 upper extremities, 2 lower extremities, and 1 scapula); 6 with severe displacements and tension of the skin; 3 painful non-unions; 2 open fractures; 2 for cosmetic reasons; and 16 with intolerable pain.
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Lee 2007  (Continued)

Iliac crest bone grafts were used around the fracture sites of 7 participants who had severe comminuted fractures or non-union - not specified to which group they belonged.

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>Quasi-randomised: alternation, “patients were treated with a Knowles pin or a plate in turn”.</td>
</tr>
</tbody>
</table>

Shen 2008

Methods

Method of randomisation: in the operating theatre, the patients were allocated to one of two treatment groups according to sequentially-opened sealed envelopes based on a computer-generated randomisation list.

Assessor blinding: *follow-up evaluations were done by the same non-participating surgeons. All participants had sufficient records and at follow-up all participants were interviewed according to protocol and examined by the non-participating surgeons, who contributed with similar numbers of cases to each group (*p = 0.29), which should have prevented surgeons from being a confounding variable. The cases were randomised after the initial assessment, so the evaluator was blinded to the group allocation.

Participant blinding: *the participants were blinded to the surgical method.

Blinding of care providers: it is not possible due to the type of treatment.

Intention-to-treat analysis: baseline data reported for all participants but overall outcome data for participants who had a re-operation were not presented.

Loss of follow-up: 16 participants lost to follow-up at 12 months

<table>
<thead>
<tr>
<th>3D plate group</th>
<th>4 participants lost to follow-up:</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Re-operation due to delayed union (1);</td>
<td></td>
</tr>
<tr>
<td>* Did not attend for examination (3).</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Superior plate group</th>
<th>12 participants lost to follow-up:</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Re-operation due to delayed union (8);</td>
<td></td>
</tr>
<tr>
<td>* Did not attend for examination (4).</td>
<td></td>
</tr>
</tbody>
</table>

* Data obtained through personal contact with the authors.

Participants

Place: *Zhejiang Province TCM Hospital, Zhejiang TCM University Hospital and a level-1 academic trauma centre located in Hangzhou, the capital of Zhejiang Province, China.


Number of participants (N): 133 participants.

Inclusion criteria

* Adults
* People with completely displaced middle third clavicle fractures, amenable to plate fixation with a minimum of three screws in both fragments

Exclusion criteria

* Open fractures
* Age under 18 or over 60 years
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Shea 2008  (Continued)

- Fracture in the proximal or distal clavicle
- Fracture associated with nerve or tendon injuries
- Multiple injuries
- Additional fractures in the same or contra-lateral limb
- Previous fracture in the injured clavicle
- Abnormal function in the uninjured side
- Inflammatory joint disease
- Cerebrovascular disease or other severe medical illness and the inability to give informed consent or to complete questionnaires

**Age**
- Total of participants (mean/range): 44.2/18-69 years
- 3D plate group (mean/range): 43.8/26-60 years
- Superior plate group (mean/range): 44.7/18-51 years

**Gender**
- Total of participants (male/female): 75/58
- 3D plate group (male/female): 39/29
- Superior plate group (male/female): 36/30

**Side of injury**
- Total of participants (left/right): 56/77
- *3D plate group (left/right): 13/54
- *Superior plate group (left/right): 43/23

**Classification of injury**
The fractures were classified as:
- Comminuted
- Spiral

**Assigned**
- 133 participants
- 3D plate group: 67 participants (51 comminuted and 16 spiral fractures)
- Superior plate group: 66 participants (45 comminuted and 21 spiral fractures)

**Assessed**
- 117 participants were assessed at period of 12 months
- 3D plate group: 63 participants
- Superior plate group: 54 participants

**Interventions**

**Timing of intervention**
The operation was usually performed within two days of admission.

**Intervention 1**
- Open reduction and internal fixation with 3D plate (3.5 mm reconstruction plate). Here the plate was fixed superiorly on the main distal fragment and anteriorly on the main proximal fragments

**Intervention 2**
- Open reduction and internal fixation with superior plate (3.5 mm reconstruction plate). Here the plate was 'S' shaped and fixed on the superior surface

**Rehabilitation**
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Shen 2008 (Continued)

‘In hospital, participants were instructed on early motion exercises of the fingers, wrist, and elbow. Shoulder immobilisation was applied for 2 to 6 weeks, based on the participants’ level of comfort. A sling was applied for 6 weeks. The same instructions were used for all the cases.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Length of follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The participants underwent clinical and radiological assessment at four and 12 months after operation by independent surgeons.</td>
</tr>
<tr>
<td>Primary outcomes</td>
<td>• Treatment failure: re-operation (delayed union).</td>
</tr>
<tr>
<td>Secondary outcomes</td>
<td>• Symptomatic participants (symptoms not specified).</td>
</tr>
<tr>
<td>Functional impairment and clinical outcomes:</td>
<td>• Operative time.</td>
</tr>
<tr>
<td>Radiographic outcomes:</td>
<td>• Delayed union.</td>
</tr>
<tr>
<td></td>
<td>• Radiographic healing of the fracture (not specified what kind).</td>
</tr>
<tr>
<td>Economic data</td>
<td>• Hospital stay</td>
</tr>
</tbody>
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Notes | * Data obtained by personal contact with the authors. |

Risk of bias

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> more than
3D: three dimensional
AO: Arbeitsgemeinschaft für Osteosynthesefragen
DASH: Disabilities of the Arm, Shoulder and Hand questionnaire
DCP: dynamic compression plate
ITT: intention-to-treat
LC-DCP: low-contact dynamic compression plate
mm: millimetres
SD: standard deviation
VAS: visual analog 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>Jubel 2002</td>
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<tr>
<td>Lee 2008</td>
<td>Not a randomised or quasi-randomised controlled trial.</td>
</tr>
<tr>
<td>Ros Y Codomiau 2000</td>
<td>Not a randomised or quasi-randomised controlled trial.</td>
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<tr>
<td>Shen 1999</td>
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