Evidence for Operative vs Nonoperative Treatment of Clavicle Shaft, Proximal Humerus, and Humeral Shaft Fractures.

Robert J. Strauch MD
Professor of Orthopaedic Surgery
Columbia University, New York

Carrying Coals to Newcastle

Newcastle
The Clavicle:

Operative vs Nonoperative:
- Nonunion?
- Function?
- Are outcomes worse if you wait until it becomes a nonunion?

Mid-Shaft Clavicle Fractures:

Operative vs Nonoperative:
- Lateral: 15%
- Mid: 80%
- Medial: 5%


Clavicle fractures in adults. Our findings, however, indicate that closed treatment of such fractures, including those with fragment displacement, results in normal, painfree function, despite functional shortening in nearly half of the cases.
CLOSED TREATMENT OF DISPLACED MIDDLE-THIRD FRAC TURES OF THE CLAVICLE GIVES POOR RESULTS
JAMES W. SELL, MICHAEL R. MAGUIRE, LYNN A. CROSBY
From Creighton University, Omaha, USA.

We found that initial shortening at the fracture of >20 mm had a highly significant association with nonunion (p = 0.0001) and the chance of an unsatisfactory result. Final shortening of 20 mm or more was associated with an unsatisfactory result, but not with nonunion. No other patient variable, treatment

We now recommend open reduction and internal fixation of severely displaced fractures of the middle third of the clavicle in adult patients.


Treatment of Acute Midshaft Clavicle Fractures: Systematic Review of 2144 Fractures
On behalf of the Evidence-Based Orthopaedic Trauma Working Group
Michael Greydanus MD, Melvin A. Sato, MD, Peter M. Culver, MD
Rich Arora, MD* and Michael D. M中华人民, MD*

In a RCT comparing plating and nonoperative treatment of 100% displaced midshaft fractures, Smith et al. reported a nonunion rate of 24% (12/50) for nonoperative treatment and 0% (0/50) for plating. In the nonoperative group, 30% developed some symptoms of upper extremity neurologic complaints with overhead use of the arm compared with 6% in the operative group. In the nonoperative group, 44% had complaints about the cosmetic appearance of their shoulder. However, in the plating group, 30% of the patients requested hardware removal after healing of their fracture.


• Never Published
Deficits Following Nonoperative Treatment of Displaced Midshaft Clavicular Fractures

McKee: 2006

Clavicular shortening was associated with a trend toward decreased abduction strength, and shortening of 2 cm was associated with a trend toward greater patient dissatisfaction. This may account for the significant level of residual disability detected by the patient-based outcome measures following nonoperative care of displaced midshaft fractures of the clavicle. We...

Conservative treatment of fractures at the middle third of the clavicle: The relevance of shortening and clinical outcome

JSES: 2006

score was 84 (range, 62-100). Of the patients, 34 (25.8%) were dissatisfied with the result of their management. Final clavicular shortening of more than 18 mm in male patients and of more than 14 mm in female patients was significantly associated with an unsatisfactory result. (J Shoulder Elbow Surg 2006; 15: 1211-1241)
How about 4.5 randomized clinical trials on the issue? That should give us the answer!

But none of them used shortening as inclusion criteria, only complete displacement.
Prospective, but not randomized

Patients chose their own treatment

ORIF better at 6 weeks but at 24 weeks and 5 years no difference in functional outcome scores

Nonunion rate:
- Nonop: 23% vs Operative: 2.4%

Complications:
- Secondary surgery higher in ORIF group: 27% vs 17% - not significant
- No increased problems with delayed surgery for nonunions in the nonoperative group

Outcome measures: DASH and Constant:
- NO difference at all time points
- May not be sensitive enough
The clavicle trial: 9 month follow up

- Nonunion rate:
  - At 3 months: equal radiographic nonunion rates of 28%
  - At 9 months: ORIF had less radiographic nonunions compared to nonop rx—0.8% vs 11%

- Outcomes: No difference at 9 months
  - ORIF better earlier, however
Clavicle trial conclusion:

Our conclusion is that the outcome of a united midshaft clavicle fracture is good, regardless of whether the patient was treated operatively or nonoperatively. Both treatment modalities are safe, with few substantial complications demonstrated in this study population. The rate of radiographically evident nonunion at 9 months was significantly reduced by surgical intervention, and functional recovery and patient satisfaction were better at both 6 weeks and 3 months. There was also a high rate of secondary surgical intervention (11%) in nonoperatively treated patients. Overall, we think that surgical treatment for a displaced midshaft clavicle fracture should be offered to patients, and this paper can provide clear, robust data to help patients to make their choice.

RCT summary:

- 2007: Canadian—Pro surgery
  - Function better, less nonunion
- 2012: Finland—Pro surgery
  - Function equal, less nonunion
- 2017: Woltz—Anti surgery
  - Function equal, OK to wait and see
- 2017: Ahrens UK—Pro surgery
  - No difference in outcomes, less nonunions

What about fixing them later? Does it increase complications?
• There are three kinds of lies: Lies, damn lies, and meta-analyses!
Surgical Versus Nonsurgical Treatment for Midshaft Clavicle Fractures in Patients Aged 16 Years and Older

A Systematic Review, Meta-analysis, and Comparison of Randomized Controlled Trials and Observational Studies

Diederik P.J. Smewing, MD, Bertie J.C. van der Ven, MD, Fabio Heitzreiter, MD, PhD, Tim K. Timmers, MD, PhD, Mark van Heijl, MD, PhD, Mays C. Kuyt, MD, PhD, Rolf H.H. Grewe, MD, PhD, Oliver A.J. van der Meijden, MD, PhD, and Roderick M. Hooewerf, MD, PhD

Investigation performed at UMCU Traumacenter, Utrecht, the Netherlands

Conclusion: This meta-analysis of high-quality studies showed that surgical treatment of MCFs results in fewer nonunions, fewer malunions, and an accelerated return to work compared with nonsurgical treatment. A meta-analysis of surgical treatments need not be restricted to randomized trials, provided that the included observational studies are of high quality.

---

So which is better for YOUR clavicle fracture: Operative or Nonoperative

- Surgery will result in less nonunions.
  - But the surgery may not be more difficult or have a worse outcome if you have nonunion surgery after initial nonop treatment
- Unless you are an overhead athlete, your function may be similar with op vs nonop unless you have 2 cm of shortening
- Recovery is quicker with surgery

---

Proximal humerus fractures

- Is surgery better than no surgery for 3 or 4 part fractures in older people?
2011: Sweden

Hemiarthroplasty versus nonoperative treatment of displaced 4-part proximal humeral fractures in elderly patients: a randomized controlled trial

Per Oden, MD, Leif Ahlberg, MD, PhD, Leif Persson, MD, PhD, Jenny Sertling, MD, Jan Tidermark, MD, PhD

Conclusion: The results of the study demonstrated a significant advantage in terms of pain and range of motion in favor of HA, as compared to conservative treatment in elderly patients with a displaced 4-part fracture of the proximal humerus. The main advantage of HA appeared to be less pain while there was no difference in RUM (range of motion) in patients with a least one of the outcome measures such as complication, clinical results, radiological

2014: Meta-analysis

Operative vs. nonoperative treatment for comminuted proximal humeral fractures in elderly patients: a current meta-analysis

Jin QI, Xue-Feng DENG, Yu-Mei WANG, Xiao-Bing WANG, Xiao LI, Eis YU

Conclusion: Compared with operative treatment for closed comminuted proximal humeral fractures in elderly patients, conservative treatment can effectively reduce the risk of additional surgery and complications. However, there is no statistical difference between operative and nonoperative treatment in terms of clinical outcomes.
Cochrane review: 2015

Interventions for treating proximal humeral fractures in adults (Review)

Main results

We included 28 intervention reviews (105 RCTs; 294,746 participants). Most of the 18 outcome measures comparisons were tested by small single-centre trials. The main exception was the surgical versus nonsurgical treatment comparison tested by eight trials, except for a large randomized trial. Due to these trials could not be pooled. The quality of the evidence was either low or very low for all comparisons except the largest comparison.

Eight trials involving 5099 participants, evaluated surgical intervention for displaced fractures. There was high-quality evidence of no clinically important difference in pain reported at 6 weeks and 8 weeks function, at one- to two-year follow-up between surgical (primarily locked plate fixation or humeral replacement) and non-surgical treatment (coping, proximal humerus) for the majority of the clinical outcomes. Humeral fractures were few and few of the included participants. There was moderate-quality evidence of little difference in quality of life at two years (and at interim follow-ups at 6 and 12 months). There was moderate quality evidence of little difference in shoulder pain.

Cochrane review: 2015

Authors' conclusions

There is high or moderate quality evidence that, compared with non-surgical treatment, surgery does not lead to a better outcome at one and two years after injury for people with displaced proximal humeral fractures involving the humeral neck and is likely to result in a greater need for subsequent surgery. The evidence does not cover the treatment of two-part humeral fractures, fractures in young people, high energy trauma, nor the less common fractures such as fracture dislocations and local splitting fractures.
JAMA: 2015

**Surgical vs Nonsurgical Treatment of Adults With Displaced Fractures of the Proximal Humerus**

The PROFHER Randomized Clinical Trial


**DESIGN, SETTING, AND PARTICIPANTS** A pragmatic, multicenter, parallel group, randomized clinical trial, the Proximal Fracture of the Humerus Evaluation by Randomization (PROFHER) trial, recruited 250 patients aged 16 years or older (mean age, 66 years [range, 24-92 years]; 192 [77%] were female, and 249 [99.6%] were white) who presented at the orthopedic departments of 32 acute UK National Health Service hospitals between September 2008 and April 2011 within 3 weeks after sustaining a displaced fracture of the proximal humerus involving the surgical neck. Patients were followed up for 2 years (up to April 2013) and 27% had complete follow-up data. The data for 231 patients (84 in surgical group and 117 in nonsurgical group) were included in the primary analysis.

PROPHER study from U.K.: 2015

**CONCLUSIONS AND RELEVANCE** Among patients with displaced proximal humeral fractures involving the surgical neck, there was no significant difference between surgical treatment compared with nonsurgical treatment in patient-reported clinical outcomes over 2 years following fracture occurrence. These results do not support the trend of increased surgery for patients with displaced fractures of the proximal humerus.

**TRIAL REGISTRATION** clinicaltrials.gov Identifier: NCT01650105


2017: Nonop vs Reverse TSR

**Nonoperative management versus reverse shoulder arthroplasty for treatment of 3- and 4-part proximal humeral fractures in older adults**

Tony A. Rolston, MD, Carlos N. Gonzales, MD, Jack M. Metz, MD, James F. Kleinman, MD, Kyle J. Aviles, MD, and N. Kansa, MD, John R. Krasnow, MD, Christopher J. Woskie, MD, John R. Talcik, MD

**METHODS:** A retrospective review was performed on all 3- and 4-part proximal humeral fractures treated with either RSA or nonoperative treatment with minimum 5-year follow-up. All patients in the nonoperative cohort were offered RSA but declined. Objective patient data were obtained from medical records. Patient-
2017: Germans find no difference

Outcomes of operative and nonoperative treatment of 3- and 4-part proximal humeral fractures in elderly: a 10-year retrospective cohort study

10 year follow up: no difference

Conclusions: In this study, we found no evidence of a difference in BHRQL, functional outcome or pain 1-10 years after operative or nonoperative treatment in patients of 65 and older with a displaced 3- or 4-part humeral fracture. Operatively treated patients showed a trend toward better social participation but also higher intervention rates.
Seems like a slam dunk in favor of not operating on these—right?

• The science says no difference between operative and nonoperative treatment
• It’s just like distal radius fracture treatment in the elderly
  – X-rays can look like crap and they can do quite well clinically
• In practice, they often get surgery anyway

Survey study suggests that reverse total shoulder arthroplasty is becoming the treatment of choice for four-part fractures of the humeral head in the elderly

Conclusions: proximal humerus fx

• The science says no difference between operative and nonoperative treatment
• It’s just like distal radius fracture treatment in the elderly
  – X-rays can look like crap and they can do quite well clinically
• In practice, they often get surgery anyway
Humeral shaft fractures:

- Open fractures
- Multi-trauma
- Vascular injury requiring repair
- Ipsilateral brachial plexus injury
- Floating elbow

Indications for Surgery:

- Open fractures
- Multi-trauma
- Vascular injury requiring repair
- Ipsilateral brachial plexus injury
- Floating elbow

Cochrane Library

2012

Surgical versus non-surgical interventions for treating humeral shaft fractures in adults (Review)

- We found 137 studies that appeared to meet our inclusion criteria. After screening we excluded all 137 studies. For 136 studies, the finding was that the comparison intervention was more effective than the control group. We identified three randomized controlled studies, two of which showed no evidence of treatment effect or benefit and one which showed a small benefit.

- There is no evidence available to suggest that any surgical intervention is superior to any other for treating humeral shaft fractures in adults. However, there is evidence to suggest that surgical interventions may be more effective than non-surgical interventions in certain circumstances.
Nonoperative treatment:

- High union rate > 90%
- High functional outcome
- Radial nerve does not require surgery unless does not recover in appropriate time

Nonoperative treatment:

Humeral shaft fractures
Gary F. Updegrave, MD; Wassim Mourad, MD; Joseph A. Abboud, MD

Humeral shaft fractures can often be successfully managed nonoperatively with splints and bracing. Radial nerve injuries are not uncommon, both from the injury as well as iatrogenic injuries from the treatment. Acceptable radiographic parameters are not well supported and do not seem to correlate with functional outcome. In certain cases, a more predictable result for alignment and union may be achieved with operative intervention. Open reduction and plate

Table I Patient and fracture characteristics more prone to nonunon

<table>
<thead>
<tr>
<th>Patient and fracture characteristics more prone to nonunion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal third fractures</td>
</tr>
<tr>
<td>Oblique pattern in the proximal third</td>
</tr>
<tr>
<td>Smoking</td>
</tr>
<tr>
<td>Female sex</td>
</tr>
<tr>
<td>Gap size at the fracture site</td>
</tr>
</tbody>
</table>
2017: JBJS

Minimally Invasive Osteosynthesis with a Bridge Plate Versus a Functional Brace for Humeral Shaft Fractures

A Randomized Controlled Trial

Fabio Torni, M.D., Ph.D., Marco Z. Segre, M.D., M.P.H., M.Sc., Hilde Mathurin, M.D., M.P.H.,

This randomized trial was performed at the Division of Orthopedic Surgery, Department of Orthopedics and Traumatology, University of São Paulo, São Paulo, Brazil. (Dr. Torni, Dr. Segre, and Dr. Mathurin) and Hospital das Clínicas da Faculdade de Medicina of the University of São Paulo (Dr. Torni, Dr. Segre).
Hard to explain why you got an infected nonunion with a radial nerve palsy for a fracture that you could have successfully treated nonoperatively if you had only read the literature on the subject.

Conclusions: humeral shaft fx

The present study demonstrated a statistically significant advantage of surgical treatment over functional bracing in terms of the self-reported DASH outcome at 6 months as well as a lower nonunion rate and less residual deformity in the coronal plane seen on radiographs after the surgery. Only the nonunion rate is likely of clinical relevance.

Results: The mean DASH score of the bridge plate group was statistically superior to that of the functional bracing group (mean scores, 10.9 and 38.0, respectively; p = 0.048) only at 6 months. The bridge plate group also had a significantly lower functional evaluation (0% versus 15%) and lower mean residual angular displacement seen on the anteroposterior radiograph (2.0° versus 33.9°; both p < 0.05). No difference between the groups was detected with regard to the SF-36 scores, pain level, Constant-Murley scores, or angular displacement seen on the lateral radiograph.

Conclusions: This trial demonstrates that, compared with functional bracing, surgical treatment with a bridge plate has a statistically significant advantage, of uncertain clinical benefit, with respect to self-reported outcome (DASH score) at 6 months, nonunion rate, and residual deformity in the coronal plane seen on radiographs.

Thank you

rjs8@columbia.edu