Clavicle Fractures: How Science Changed Practice



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Conventional Dogma

- Outcome "....generally good...."
- Displaced fractures of the clavicle "...generally do well with non-operative treatment..."
- Nonunion rate <1% (Neer -3/2239 cases)
- "Malunions of the clavicle require no treatment..."
- "The only fractures of the clavicle that do not heal are the ones that you operate on."



Identify a Problem

- Hill et al JBJS 1999
- "Closed treatment of displaced middle-third fractures of the clavicle

gives poor results"

- Patient-oriented outcom
 31% poor
- 15% nonunion
- Associated with shortening
 - > 2 cm



Clavicular malunion

- New diagnosis
- "shoulder ptosis"
- Following fractures displaced > 2 cm
- Ortho, neuro (Thoracic Oulet Syndrome), cosmetic symptoms
- Chan JSES 1999, Bosch 1999, Basamania ICSS 1999, Kuhne ICSS 1999

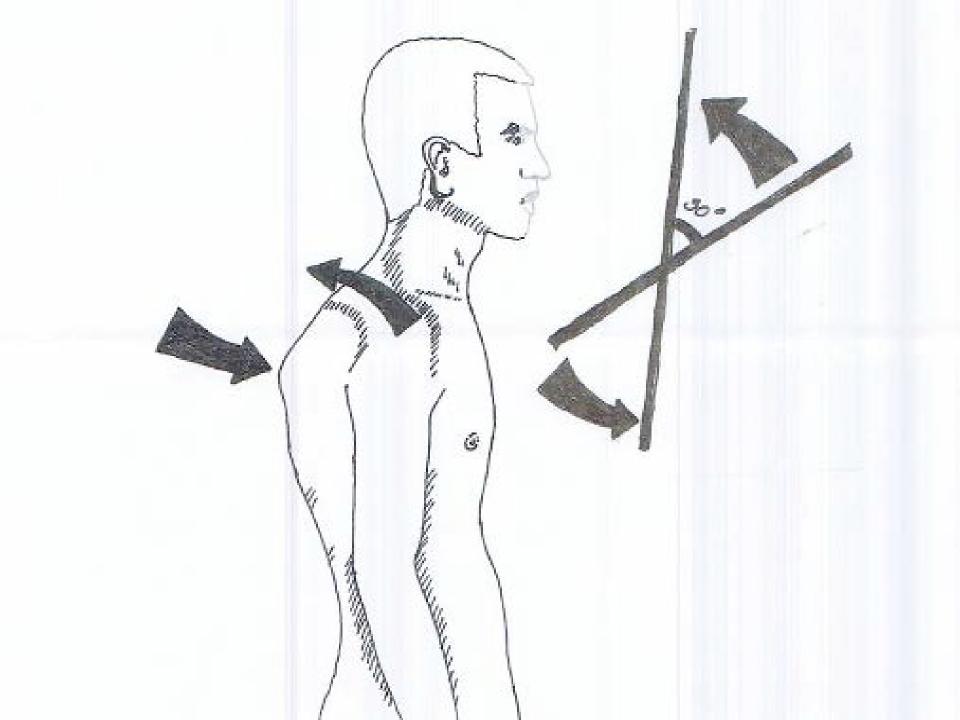




J. A. - California

• "I am a 22 year old male living in the United States. I broke my collarbone when I was 15 and surgery was not performed even though the bone were quite overlapped. And I was told by my surgeon that after 6-9 months I would be fine. Well, I'm far from that. I know things are out of place, and my shoulder is weak and painful. I tried over and over again to tell my surgeon but he just ignores me."





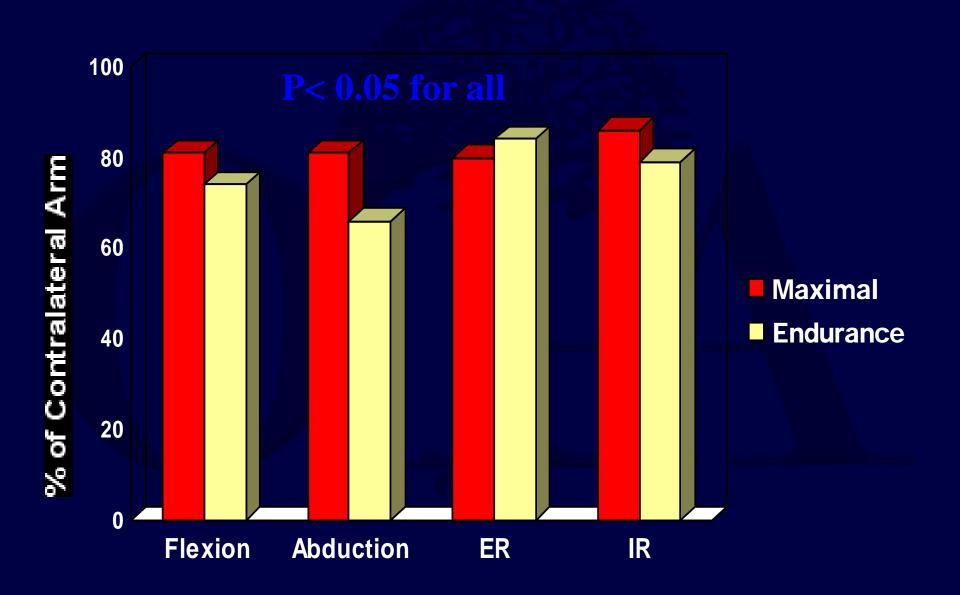
Scapular winging

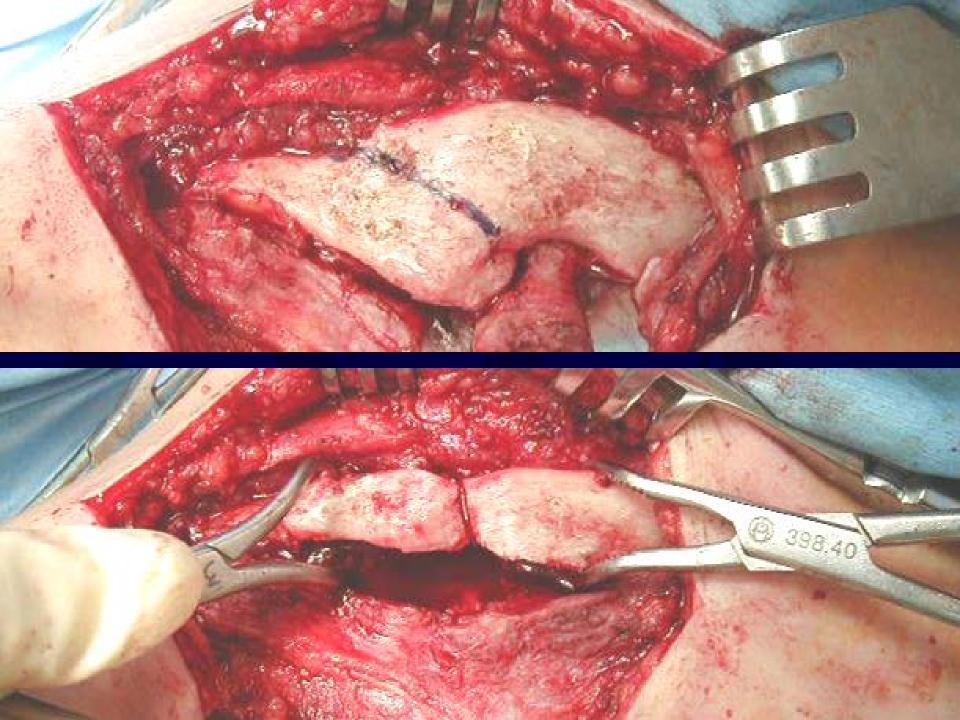
Scapular winging





Shoulder Strength





MIDSHAFT MALUNIONS OF THE CLAVICLE

BY MICHAEL D. MCKEE, MD, FRCS(C), LISA M. WILD, BSCN, AND EMIL H. SCHEMITSCH, MD, FRCS(C)

Investigation performed at the Upper Extremity Reconstructive Service, Division of Orthopaedics, Department of Surgery, St. Michael's Hospital and the University of Toronto, Toronto, Ontario, Canada

Background: The purpose of this study was to analyze the functional results of corrective osteotomy of a malunited clavicular fracture in patients with chronic pain, weakness, neurologic symptoms, and dissatisfaction with the appearance of the shoulder.

Methods: We identified fifteen patients (nine men and six women with a mean age of thirty-seven years) who had a malunion following nonoperative treatment of a displaced midshaft fracture of the clavicle. The mean time from the injury to presentation was three years (range, one to fifteen years). Outcome scores revealed major residual deficits. The mean amount of clavicular shortening was 2.9 cm (range, 1.6 to 4.0 cm). All patients underwent corrective osteotomy of the malunion through the original fracture line and internal fixation.

Results: At the time of follow-up, at a mean of twenty months (range, twelve to forty-two months) postoperatively, the osteotomy site had united in fourteen of the fifteen patients. All fourteen patients expressed satisfaction with the result. The mean DASH (Disabilities of the Arm, Shoulder and Hand) score for all fifteen patients improved from 32 points preoperatively to 12 points at the time of follow-up (p = 0.001). The mean shortening of the clavicle improved from 2.9 to 0.4 cm (p = 0.01). There was one nonunion, and two patients had elective removal of the plate.

Conclusions: Malunion following clavicular fracture may be associated with orthopaedic, neurologic, and cosmetic complications. In selected cases, corrective osteotomy results in a high degree of patient satisfaction and improves patient-based upper-extremity scores.

Level of Evidence: Therapeutic study, <u>Level IV</u> (case series [no, or historical, control group]). See Instructions to Authors for a complete description of levels of evidence.

2005 – Clavicle Fractures

• We know closed treatment has a significant failure rate (nonunion, symptomatic malunion)

 We know ORIF has a high success rate and low complication rate

• That doesn't necessarily mean that we should fix all clavicle fractures

Dangers or rushing in.....

- 1980: High rate of CVA in carotid athersclerosis
- External Carotid (EC) to Internal Carotid (IC) bypass developed
- Rapidly became "state of the art" for cerebrovascular disease
- But did it work....?
- Ethics of RCT hotly debated: "Conservative Rx not ethical"
- EC/IC Bypass Group, NEJM 1985: 14% increase in stroke in surgical group

Shoulder pain after antegrade humeral nailing

- Habernak H, Orthner E "A locking nail for fractures of the humerus" JBJS(B) 1991
- "...all cases regained full shoulder movement with no functional impairment by an average of six weeks."
- Habernak H "Letter to the editor" JBJS(B) 1998
- "This inevitably leads to damage of the cuff...

 When we reviewed the 19 active patients in 1991 we did not assess their shoulders and this should have been addressed"



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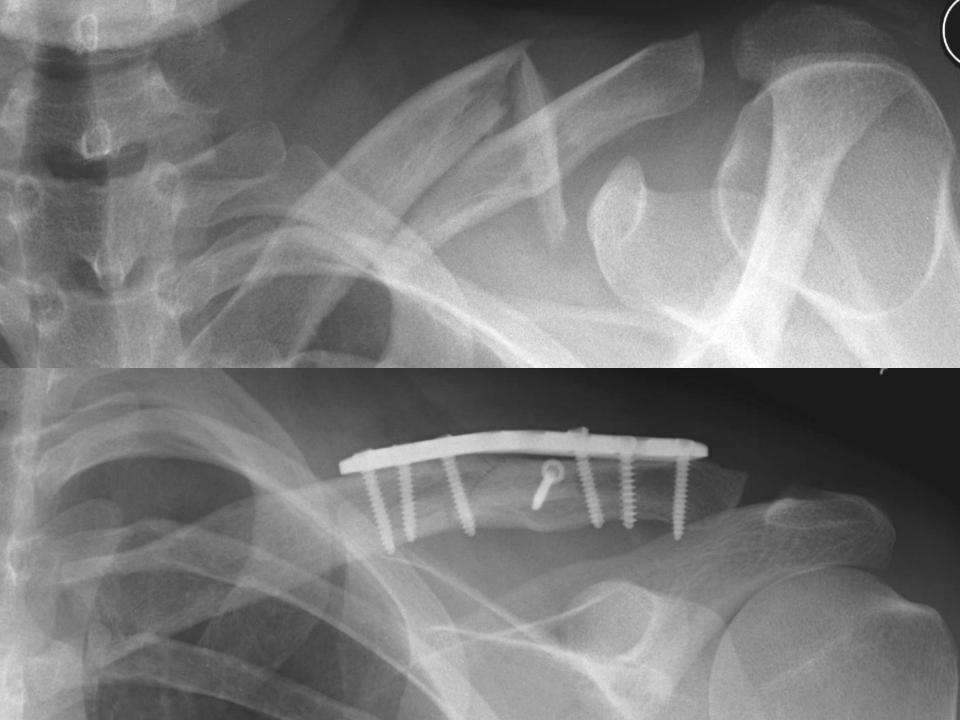
Nonoperative Treatment Compared with Plate Fixation of Displaced Midshaft Clavicular Fractures

A Multicenter, Randomized Clinical Trial

By the Canadian Orthopaedic Trauma Society







Randomized clinical trial

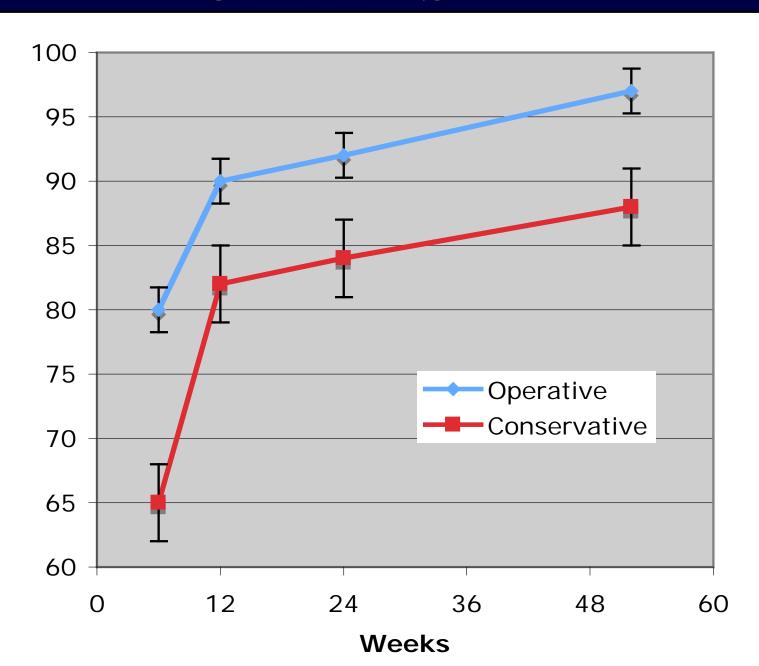
• Randomization was by sealed envelope on a 1:1 basis

• Non-operative treatment: sling

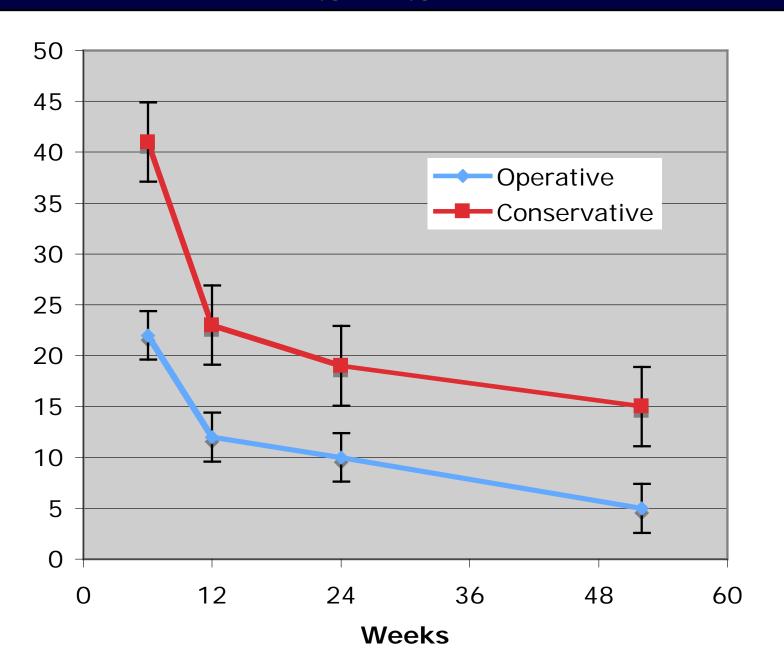
• Operative treatment: ORIF (small fragment)

• Constant, DASH and SF-36 scores were collected at 6 weeks, 3 months, 6 months, 12 months and 2 years

Constant Score



DASH Score



Reproducible Results

• The orthopaedic literature is full of reports of treatment that only work in the author's hands and for no one else.....



Operative Versus Nonoperative Care of Displaced Midshaft Clavicular Fractures: A Meta-Analysis of Randomized Clinical Trials

Robbin C. McKee, Daniel B. Whelan, MD, FRCS(C), Emil H. Schemitsch, MD, FRCS(C), and Michael D. McKee, MD, FRCS(C)

Investigation performed at St. Michael's Hospital and the University of Toronto, Toronto, Ontario, Canada

Background: Recent studies have suggested benefits following primary operative fixation of substantially displaced midshaft fractures of the clavicle. We reviewed randomized clinical trials of operative versus nonoperative treatment of these fractures, and pooled the functional outcome and complication rates to arrive at summary estimates of these outcomes.

Methods: A systematic review of the literature was performed to identify studies of randomized clinical trials comparing operative versus nonoperative care for displaced midshaft clavicular fractures.

Results: Six studies (n = 412 patients, mean Detsky score = 15.3) were included. The nonunion rate was higher in the nonoperatively treated patients (twenty-nine of 200) than it was in patients treated operatively (three of 212) (p = 0.001). The rate of symptomatic malunion was higher in the nonoperative group (seventeen of 200) than it was in the operative group (0 of 212) (p < 0.001).

Conclusions: Operative treatment provided a significantly lower rate of nonunion and symptomatic malunion and an earlier functional return compared with nonoperative treatment. However, there is little evidence at present to show that the long-term functional outcome of operative intervention is significantly superior to nonoperative care.

Level of Evidence: Therapeutic <u>Level I</u>. See Instructions for Authors for a complete description of levels of evidence.

Nonunion

	Operat	tive	Nonope	rative		Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	IV, Random, 95% C	I IV, Random, 95% CI
COTS 2007	2	62	7	49	46.0%	0.23 [0.05, 1.04]
Judd 2009	1	29	1	28	14.5%	0.97 [0.06, 14.70	1
Smekal 2009	0	30	3	30	12.6%	0.14 [0.01, 2.65]
Smith 2000	0	30	12	35	13.8%	0.05 [0.00, 0.75] +
Virtanen 2010	0	28	5	32	13.2%	0.10 [0.01, 1.79	ı] ← ■
Witzel 2007	0	35	0	33		Not estimabl	e
Total (95% CI)		214		207	100.0%	0.19 [0.07, 0.54	
Total events	3		28				
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 2.61$, $df = 4$ (P = 0.62); $I^2 = 0\%$							0.01 0.1 1 10 100
Test for overall effect:	Z = 3.14	P = 0).002)				Favours experimental Favours control

Nonunion & Symptomatic Malunion

- Nonunion:
 - Operative 4/298
 - Non-operative 53/292
 - p<0.001 (n=590)

- Symptomatic Malunion:
 - Operative 0/298
 - Non-operative 31/292
 - p<0.0001 (n=590)



84 / 292 in non-op group had a major complication • Robinson CM et al.

"Open reduction and plate fixation versus nonoperative treatment for displaced midshaft clavicular fractures: a multicenter, randomized, controlled trial." JBJS 2013 Sep 4;95(17):1576-84.

• The results of the present study do not support routine primary open reduction and plate fixation for the treatment of displaced midshaft clavicular fractures.

RCT Comparison

Factor	Canadian Orthopaedi	c Robinson et. al						
Trauma Society								
Non-op Nonunion	18%	26%						
Operative Nonunion	on 1%	1%						
Non-op Malunion	15%	10%						
Operative Malunio	on 0%	0%						
Non-op Constant	87	87						
Operative Constan	nt 97	93						
RR nonunion with	OR 94%	93%						
Plate removal	11%	14%						

31 year old male

• Fracture clavicle at work 14 months ago

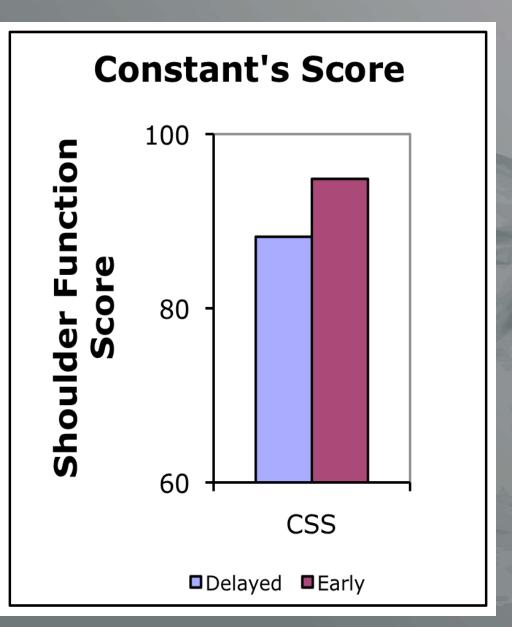
Treated with sling

Ongoing pain and weakness

Working modified duties







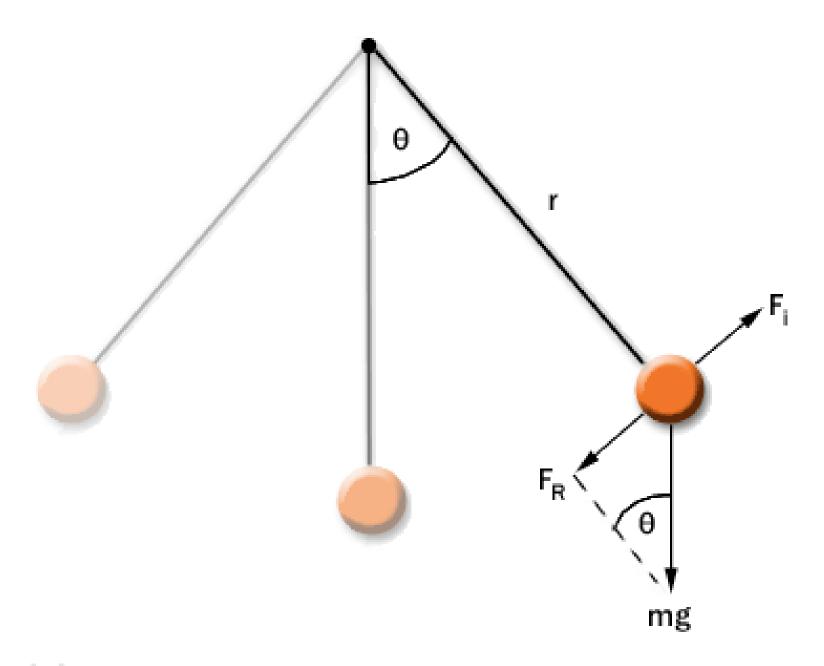
•Mean Constant Score:

Delayed: 88

Acute: 95

The difference between groups was significant (p=0.012).

Delay does matter!





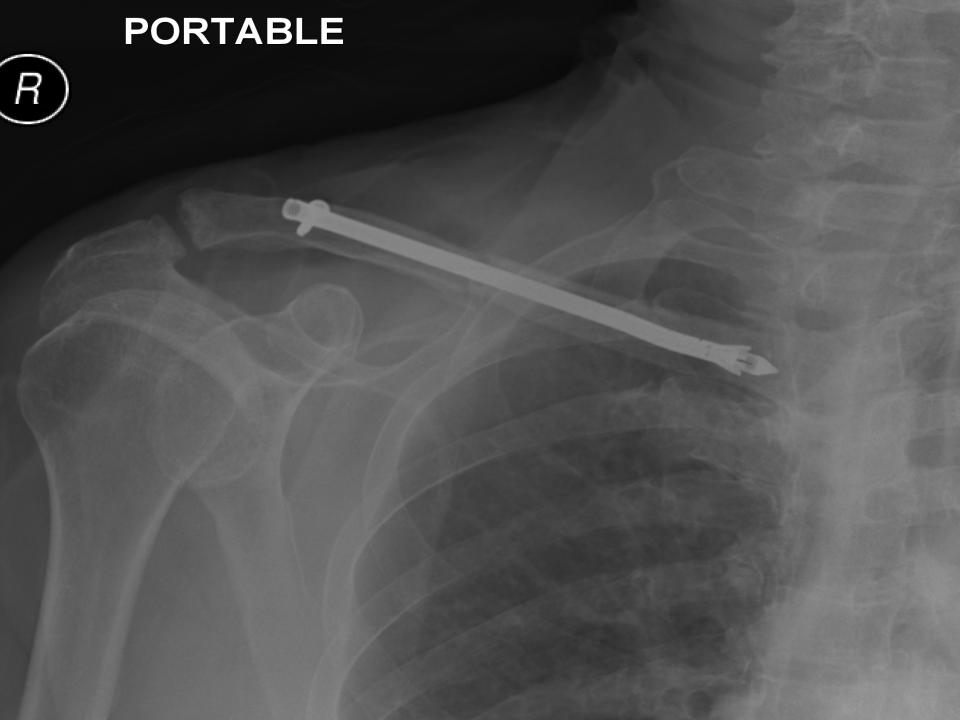
Future studies

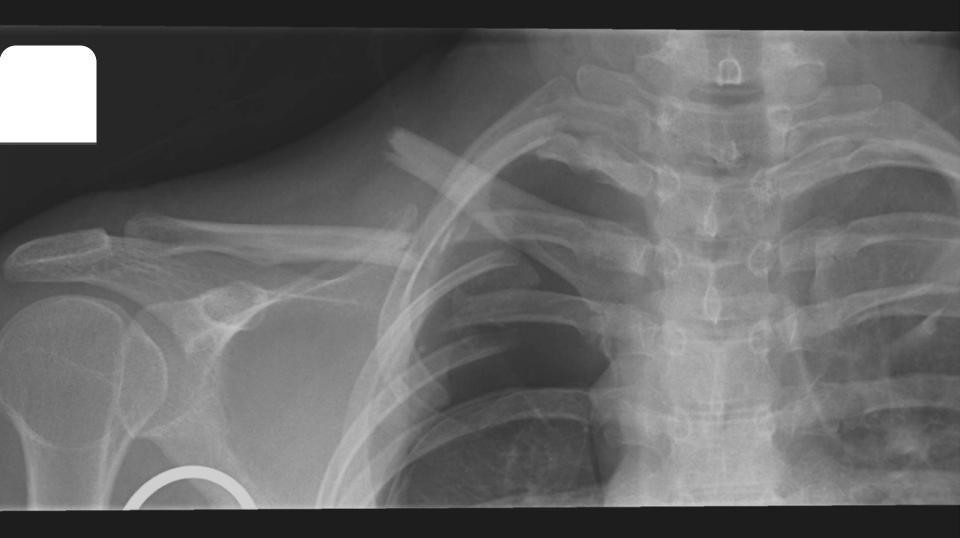
• Where do we go from here?

• Identify patients "at risk" for poor outcome

• New implants / techniques







Conclusion

- 1. Challenge dogma that you think is wrong
- 2. Accumulate evidence to support your position
- 3. RCT's to prove one treatment better than conventional Rx

- 1. Reproducible results are critical
- 2. Re-evaluate, re-define, be alert for new complications
- 3. Look to the future: things will change

For questions or comments, please send to ota@ota.org