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## Clavicle Fractures

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### Clinical scenario

- A 30-year-old left-hand-dominant male, laborer, presents with isolated intense pain in his shoulder after falling off his mountain bike.
- On examination, his left shoulder is deformed, appearing shortened and *ptotic*. It is a closed, isolated injury and his left upper extremity is neurovascularly intact (Figure 78.1).

### Top three questions

1. In patients with clavicle fractures managed nonoperatively, do displaced fractures have worse outcomes than nondisplaced fractures?
2. In patients with displaced clavicle fractures, does open reduction and internal fixation offer improved outcomes compared to nonoperative management?
3. In patients with clavicle fractures managed operatively, does intramedullary nailing result in improved outcomes compared to plating?

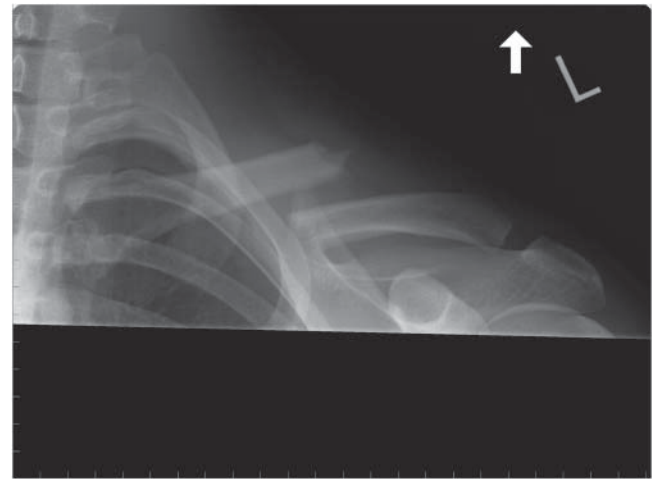
### Question 1: In patients with clavicle fractures managed nonoperatively, do displaced fractures have worse outcomes than nondisplaced fractures?

#### Rationale

In order to optimize care, it is important to identify the minority of patients who are at risk for poor outcomes with nonoperative management.

#### Clinical comment

Nonoperative management is not without risks, so physicians and patients should understand fracture and patient



**Figure 78.1** Radiograph of a 30-year-old man who fell off his mountain bike and sustained a midshaft clavicle fracture. Displacement and shortening is evident.

characteristics that negatively affect the outcome in nonoperatively treated fractures.

### Available literature and quality of the evidence

After searching the literature, nine studies were utilized to answer this question including: two level I studies and further supported with level II–IV data.

### Findings

The majority of patients with a clavicle fracture will heal uneventfully with satisfactory function with nonoperative treatment. However, a minority of patients will have ongoing sequelae from a displaced midshaft clavicle fracture as shown in a recent randomized clinical trial (RCT) reporting 23.1% nonunion with nonoperative management

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of midshaft displaced fractures.<sup>1</sup> In addition to the unexpected 15% nonunion rate reported by Hill in 1997, a 31% dissatisfaction rate, related to 25% of patients complaining of deformity and a 29% incidence of thoracic outlet syndrome, was reported. They found initial shortening >2 cm was significantly associated with nonunion and unsatisfactory results ( $p < 0.0001$ ).<sup>2</sup> McKee looked at 30 healed, displaced fractures using patient-based outcomes and strength testing. They showed 27% dissatisfaction, Constant score of 71, and a Disabilities of the Arm, Shoulder, and Hand (DASH) score of 25. There was a trend toward worse DASH scores for shortening >2 cm and there was a statistically significant inverse correlation between abduction endurance strength and shortening.<sup>3</sup> Lazarides found a 25.8% dissatisfaction rate in patients with a healed midshaft clavicle fracture, significantly associated with shortening >18 mm in males and >14 mm in females.<sup>4</sup> This phenomenon has recently been challenged by Goudie, but with an average of only 11 mm shortening and only five patients with >2 cm shortening, this study was underpowered to detect a statistical difference.<sup>5</sup>

In a systematic review, Zlowodzki reported an overall nonunion rate of 5.9% which increased to 15.1% for completely displaced fractures.<sup>6</sup> Robinson's study employing multivariate analysis found increasing fracture displacement, comminution, advancing age, and female gender all to be independent predictors of nonunion in shaft fractures.<sup>7</sup> Nowak also found that displacement, comminution, and older age were predictors for sequelae (pain and deformity) following clavicle fracture.<sup>8</sup> Murray reviewed 941 diaphyseal fractures managed nonoperatively and identified smoking (odds ratio [OR] = 3.76; 95% confidence interval [CI]: 2.39–5.89;  $p < 0.001$ ), displacement (OR = 1.17; 95% CI: 1.13–1.21;  $p < 0.001$ ), and comminution (OR = 1.75; 95% CI: 1.11–2.76;  $p = 0.015$ ) to be statistically significant risk factors for nonunion.<sup>9</sup>

### Resolution of clinical scenario

- The patient should be counseled that nonoperative management of displaced midshaft clavicle fractures results in a 15% nonunion rate and 25–30% dissatisfaction rate.
  - Major reasons for dissatisfaction: 15% nonunion, 15–20% malunion, 25% deformity, 29% thoracic outlet syndrome.
- This patient should understand this clavicle fracture has no cortical contact and has shortening which are both prognostic for poor outcome (nonunion or symptomatic malunion).
  - Poor prognostic factors include:
    - no cortical contact (displacement)
    - comminution
    - shortening >20 mm

- smoking status
- advanced age
- female gender.

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### Question 2: In patients with displaced clavicle fractures, does open reduction and internal fixation offer improved outcomes compared to nonoperative management?

#### Rationale

Multiple high-quality RCTs have suggested potential benefits to primary operative fixation of displaced midshaft clavicle fractures.

#### Clinical importance

Shared clinical decision-making between patient and provider demand an unbiased, accurate understanding and communication of the literature.

#### Available literature and quality of the evidence

After searching the literature, 11 studies were utilized to answer this question. Of these, six were level I studies including multiple high-quality RCTs.

#### Findings

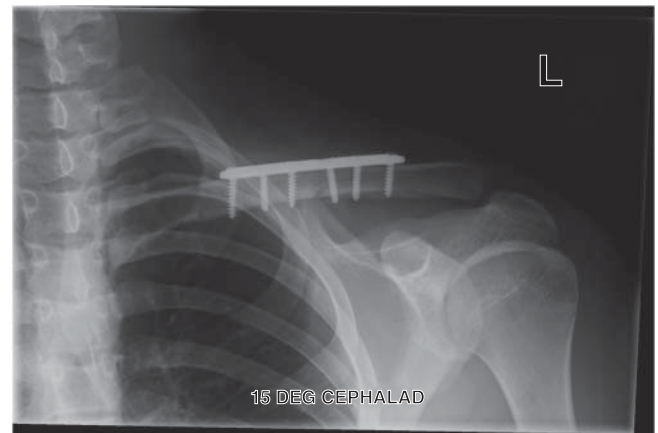
Zlowodzki et al. performed a systematic review of 2144 clavicle fractures. In a subset analysis of only displaced fractures, 460 plated fractures had a nonunion rate of 2.2% versus 15.1% for nonoperatively treated displaced fractures. They reported a nonoperative relative risk (RR) 6.9 (95% CI: 3.4–14.2) for nonunion and an absolute risk reduction (ARR) of 12.9%, with a number need to treat of 7.8 patients to avoid one nonunion for plating; relative risk reduction (RRR) of 86% (95% CI: 71–93%;  $p < 0.001$ ).<sup>6</sup> In 2007, an RCT comparing plate fixation versus nonoperative treatment for displaced midshaft clavicle fractures demonstrated statistically significant differences including a shorter time to union (16.4 vs 28.4 weeks;  $p = 0.001$ ), improved Constant and DASH scores, as well as improved patient satisfaction ( $p = 0.002$ ) and appearance ( $p = 0.001$ ) in the operative arm.<sup>10</sup> Complications for the operative group were 37% versus 63% for nonoperative treatment. The operative group's complications included hardware irritation, removal of hardware (ROH), transient brachial plexus irritations, and wound complications (4.8%). The nonoperative group had complications predominated by nonunion (7/49; 14.3%), malunion requiring corrective

surgery (9/49; 18.4%), and brachial plexus irritation. The only statistically significant difference in complications were lower nonunion (15% vs 3.2%;  $p = 0.04$ ) and malunion (22.5% vs 0%;  $p = 0.001$ ) in the operative group.<sup>10</sup> Smith and Smekal noted similar results following operative fixation of displaced midshaft clavicle fractures in two other RCTs.<sup>11, 12</sup>

In 2012, McKee et al. published a meta-analysis of nonoperative versus operative management for midshaft displaced fractures including six RCTs (412 pts) and showed an overall reduction of non- and malunions from 23 to 1.5% with fixation.<sup>13</sup> Robinson performed an RCT of 178 patients finding a significantly lower nonunion with open reduction and internal fixation (ORIF) (1.2% vs 17%;  $p = 0.007$ ) with an ARR of 15.8 for ORIF and an number needed to treat (NNT) of 6.2 to prevent one nonunion (RRR = 93%;  $p = 0.007$ ). The surgical group was more satisfied with the shoulder contour and had better DASH (3.4 vs 6.1;  $p = 0.04$ ) and Constant scores (92 vs 87.8;  $p = 0.01$ ) at all time points but this lost significance after exclusion of nonunions.<sup>14</sup> In order to better predict these nonunions and to optimize treatment choice, the same group used a retrospective review of 941 diaphyseal fractures to create a *ready reckoner* table to aid clinical decision-making in real time. Their table uses displacement, comminution, and smoking status to predict risk of nonunion. If the ready reckoner computes the risk for nonunion to be >40%, the fracture is associated with an NNT of 1.7 to prevent a single nonunion with fixation.<sup>9</sup> A meta-analysis in 2017 including 8 RCTs and 12 observational studies (1760 patients) showed lower nonunion (OR = 0.18; 95% CI: 0.10–0.33;  $p < 0.01$ ) with operative treatment. Looking only at high-quality studies, they found a lower malunion (OR = 0.26; 95% CI: 0.07–0.92), better DASH (mean difference [MD]: -2.04; 95% CI: 23.56–20.52;  $p = 0.01$ ) and Constant score (MD: 3.23 95% CI: 1.52 to 4.95;  $p < 0.01$ ), and return to work 8.6 days earlier (95% CI: -16.22 to -1.05) with fixation compared to nonoperative treatment.<sup>15</sup> While several studies cite primary fixation being more expensive than nonoperative care,<sup>14, 16</sup> these studies only include direct costs. In a retrospective review comparing 204 operatively and nonoperatively treated displaced fractures, Althausen et al. found ORIF to be \$5000 cheaper mostly as a function of less secondary lost wages from earlier return to work (8 vs 35 days).<sup>17</sup> While there is variability of such cost data in the literature, especially in meta-analysis, this internal database study may better capture the total cost of care.

### Resolution of clinical scenario

- Literature supports improved function, a lower nonunion and symptomatic malunion rate, improved cosmetic perception, and overall higher satisfaction level with operative



**Figure 78.2** The patient in the case scenario elected to have operative treatment. This radiograph was obtained during follow-up and demonstrates fixation with a precontoured clavicle plate.

versus nonoperative treatment of this displaced, shortened fracture (Figure 78.2).

- Clinical decision-making tools should be used to help understand and communicate the patient's risk for nonunion with nonoperative treatment for this patient.

### Question 3: In patients with clavicle fractures managed operatively, does intramedullary nailing result in improved outcomes compared to plating?

#### Rationale

There are a variety of fixation options available to surgeons, including intramedullary nails or pins (IMN) and plate fixation. In addition, plates can be placed on the superior or anteroinferior surface.

#### Clinical comment

Several clavicle fixation options are available. There is debate as to which method is superior and each has unique risks and benefits.

#### Available literature and quality of the evidence

After searching the literature, 14 studies were utilized to answer this question. Of these, seven were level I studies.

#### Findings

Compared to the results of plates, there is more variability in the published outcomes for IMN but larger,

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higher-quality, studies paint a more balanced picture. Ferran performed an RCT comparing IMN versus plate fixation and found no difference in functional scores (Constant score or Oxford score) but with higher hardware removal rate in the IMN group (100% vs 53%).<sup>18</sup> A similar RCT of 120 patients by Hulsmans in 2017 confirmed these same results with no difference in Quick Dash (at all time points except three months) and higher hardware removal rates in the IMN group (RR = 1.65; 95% CI: 1.24–2.19;  $p < 0.001$ ).<sup>19</sup> The same year, Funglesang published an RCT of 123 patients randomized to flexible intramedullary nail versus plate. Operative time was faster for IMN. Plate fixation showed faster functional recovery (DASH  $p < 0.001$ , and Constant score  $p < 0.001$ ) between 0 and 6 months but no difference at 12 months. Those with comminuted fractures treated with an IMN had the slowest recovery. IMN had a higher hardware removal rate.<sup>20</sup> A systematic review of 20 studies (six RCTs) reported no statistical difference in re-intervention rate (OR = 1.21; 95% CI: 0.71–2.04;  $p = 0.48$ ), Constant scores ( $p = 0.85$ ), nonunion ( $p = 0.19$ ) or infection ( $p = 0.13$ ) between plate and IMN. Plate fixation had higher major complication rate while IMN had higher removal of hardware (73% vs 38%). Re-fracture occurred more commonly after plate removal (OR = 3.42; 95% CI: 1.12–10.24;  $p = 0.03$ ).<sup>21</sup> Hussain published a systematic review and meta-analysis in *Nature* in 2016 comparing IMN versus plate fixation using seven RCTs and three quasirandomized trials showing no statistical difference in long-term function (MD:  $-0.66$ ; 95% CI:  $-2.03$  to  $0.71$ ;  $I^2 = 62\%$ ;  $p = 0.34$ ). Plating had a statistically significant twofold risk of operative complications (95% CI: 1.38–3.23;  $I^2 = 53\%$ ;  $p = 0.0006$ ) as well as prolonged operative time by 20 minutes (95% CI: 16.87–23.44;  $I^2 = 56\%$ ;  $p < 0.00001$ ) and a twofold statistically insignificant increase in treatment failure (95% CI: 0.03–5.15;  $I^2 = 0\%$ ;  $p = 0.07$ ).<sup>22</sup>

Superior plating is accepted to be biomechanically superior to anteroinferior plating.<sup>23</sup> More importantly, both options appear to have adequate efficacy clinically.<sup>24</sup> Serrano looked at the more relevant question of plate irritation in a retrospective review of 252 fixations comparing both plate positions. Superior plates were more likely to undergo secondary intervention (ROH: 5.9% anteroinferior vs 22.3% anterosuperior; OR = 4.6; 95% CI: 1.9–10.9;  $p < 0.001$ ).<sup>25</sup> Using the same economic model as Walton, secondary surgery increased the cost an incremental \$5173. They postulated that anteroinferior plating would avoid 17 additional surgeries for every 100 ORIFs and with a cost savings of \$87 000.<sup>16, 25</sup> Nourian et al. performed a meta-analysis using 34 articles to compare these techniques. They found no difference in functional score, union, malunion, or implant failure; however, superior plate had significantly higher symptomatic hardware (17% vs 8%;  $p = 0.005$ ) and significantly higher removal of hardware (11% vs 5%;  $p = 0.008$ ).<sup>24</sup> In a large national database, Naimark et al.

showed a 12.7% ROH rate within two years postoperatively. In a retrospective study of 73 plate fixations as part of the same report, they showed plate removal to be more likely in females ( $p = 0.009$ ) and with non-precontoured plates (ROH: 25.5% non-precontoured vs 12.5% precontoured;  $p = 0.27$ ) but the study was underpowered to show a statistical difference.<sup>26</sup> Those who required hardware removal had lower DASH scores, EQ-5D, and lower satisfaction.<sup>26</sup> However, a 2015 Cochrane review found the current evidence comparing clavicle operative treatment methods to be of low or very low quality. This was due to the risk of bias due to flawed methods, or such low numbers that a type I error may be possible. They support surgeon discretion in decision-making of implant choice and location: "There is very limited and low quality evidence available from RCTs regarding the effectiveness of different surgical methods of surgical fixation of fractures and nonunion of the middle third of the clavicle."<sup>27</sup>

### Resolution of clinical scenario

- When choosing between various surgical options, there is level I evidence that plate and IMN fixation are both viable options and offer similar union rates and functional outcome.
- There is level I evidence that plate fixation may offer earlier return to function, especially in comminuted fractures and that IMN fixation is associated with higher removal of hardware rates.
- Removal of hardware is associated with increased cost and inferior outcomes.

### Summary of answers

- Nonoperative management of displaced midshaft clavicle fractures results in a 15% nonunion rate and a 25–30% dissatisfaction rate.
- Factors prognostic for poor outcome (nonunion or symptomatic malunion) following nonoperative management of clavicle fractures include: no cortical contact (amount of displacement), comminution, shortening  $> 20$  mm, smoking status, advanced age, female gender.
- In patients with a displaced clavicle fracture, there is a functional benefit, lower nonunion rate, improved cosmetic perception, and overall higher satisfaction level with operative versus nonoperative treatment.
- Clinical decision-making tools should be used to help understand and communicate the patient's risk for nonunion with nonoperative treatment for this patient.
- Plate and IMN fixation are both viable options and offer similar union rates and functional outcome.
- Plate fixation may offer earlier return to function, especially in comminuted fractures.
- Precontoured plates lower the rate of hardware removal.

- IMN fixation is associated with a higher removal of hardware rates.
- Removal of hardware is associated with increased cost and inferior outcomes.

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