



Plate fixation of midshaft clavicular fractures: patient-reported outcomes and hardware-related complications

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Background: Recent studies report high hardware removal rates after plate fixation of midshaft clavicular fractures. Precontoured clavicle plates may decrease hardware-related complications while improving healing rates and patient-reported outcomes (PROs).

Methods: Using a private-payer national database, we identified 7826 patients who underwent clavicle open reduction and internal fixation (ORIF) in 2007 to 2011. Database patients were tracked for 2 years to assess hardware removal and revision fixation. In addition, we retrospectively identified 73 patients who underwent plate fixation of midshaft clavicular fractures at our institution. These patients completed the Disabilities of Arm, Shoulder and Hand (DASH) assessment, the EQ-5D (EuroQol, Rotterdam, The Netherlands) quality of life assessment, and a hardware-related outcomes survey.

Results: Among 7826 database patients, 994 (12.7%) underwent hardware removal and 78 (1%) required revision ORIF. The annual incidence of clavicle ORIF increased 61.5% between 2007 and 2011. In our institutional cohort, 56 patients (77%) were fixed with precontoured plates and 17 (23%) with standard plates. At a mean follow-up of 4.2 years, 11 patients (15%) underwent hardware removal and 1 patient (1.4%) experienced nonunion. Patients reported excellent outcomes, with average DASH of 4.0 ± 8.9 and EQ-5D of 0.89 ± 0.19 . There were no differences in PROs, hardware removal, or union rate between plate types, although our study was underpowered for these outcomes. Patients who underwent hardware removal reported lower DASH, EQ-5D, satisfaction, and shoulder function compared with patients with hardware retained. Women were more likely to undergo hardware removal in the institutional ($P = .009$) and the database ($P < .001$) cohorts.

Conclusion: Displaced midshaft clavicle fractures have high union rates with precontoured plate fixation. Women are 4 times more likely than men to have hardware removed. Patients undergoing clavicle hardware removal report worse long-term outcomes than patients with hardware retained.

Level of evidence: Level III, Retrospective Cohort Design, Treatment Study.

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Keywords: Clavicle fracture; plate fixation; precontoured plates; hardware removal; nonunion; patient-reported outcomes; national database

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Clavicular fractures are common injuries, accounting for 2.6% to 10% of all adult fractures.^{25,27} The middle third of the bone is involved in 80% of clavicular fractures. Historically, midshaft clavicular fractures were thought to almost universally heal without surgery. In the 1960s, Neer²² and Rowe³⁰ both reported a less than 1% nonunion rate with nonoperative management of midshaft clavicular fractures. Neer advocated for nonoperative management and claimed that the “most important causal factor in nonunion of fractures of the middle third has been improper open surgery.”²² This tendency toward nonoperative management of clavicular fractures, regardless of displacement, predominated for decades.^{17,28}

However, these historic studies were later criticized for heterogeneous patient populations that included pediatric patients, lack of rigorous radiographic evaluation of union, and failure to assess patient-reported outcomes (PROs). More recent literature suggests the incidence of nonunion after nonoperative treatment of displaced midshaft clavicular fractures approaches 15% or higher.^{9,18,23,28} In 2007, a randomized controlled trial compared operative and nonoperative management of displaced, midshaft clavicular fractures and found that clavicle open reduction and internal fixation (ORIF) resulted in lower nonunion rates and better functional outcome scores. Multiple studies since 2007 have investigated plate fixation vs nonoperative treatment of midshaft clavicular fractures with similar results.^{3,20,24,29,38}

The optimal implant for clavicular ORIF remains controversial. Intramedullary pins offer a fixation method that minimizes surgical dissection, scar, and hardware prominence.^{14,21} However, intramedullary pins may not be adequate to control rotation and resist bending forces that occur with shoulder elevation.^{7,26} In addition, complications from pin migration, cortical perforation, or breakage have been reported.^{6,33} Plate fixation produces low rates of implant failure and more rigid constructs compared with pins. The disadvantage of plate fixation compared with pins is the high rate of symptomatic hardware and hardware removal given the subcutaneous location and complex osseous anatomy of the clavicle.⁴ The reoperation rate after clavicle plate fixation is 18% to 25%, with isolated hardware removal accounting for most of the secondary surgeries.^{1,16}

In an attempt to minimize hardware irritation and decrease the need for plate contouring by surgeons, precontoured clavicle plates are now available from multiple manufacturers. Precontoured plates are lower profile, with beveled edges designed to decrease hardware prominence. The precontoured plates have simplified clavicle plate fixation by matching the S-shaped curvature of the clavicle and decreasing the challenge of bending a standard plate during surgery. In a study of 200 cadaveric clavicles, precontoured plates matched the S-shaped curvature in most of the specimens.¹⁰ Lastly, titanium precontoured plates have a modulus of elasticity closer to native bone than standard

stainless steel plates, theoretically reducing stress shielding. The titanium plates are strong enough to permit early rehabilitation and are biomechanically as strong as traditional stainless steel plates.^{8,34}

Whether the proposed benefits of precontoured plates are realized in clinical practice is unknown. Initial smaller series have suggested that healing rates would improve and hardware removal rates would decline with the use of precontoured clavicle plates.^{12,36} We investigated PROs and reoperation rates in patients with clavicle plate fixation in our institution and compared them to a large national private-payer database. In addition, we sought to perform a preliminary comparison of PROs, union rates, and hardware removal rates between standard and precontoured clavicle plates.

Methods

Cross-sectional cohort

Patients who underwent clavicle ORIF (Current Procedural Terminology [CPT; American Medical Association, Chicago, IL, USA] code 23515) were retrospectively queried using the private-payer component of the PearlDiver Patient Records Database (PearlDiver Technologies, Fort Wayne, IN, USA). This database is a Health Insurance Portability and Accountability Act–compliant national insurance database with a private-payer population formed from patient records of the UnitedHealth Group (Decatur, IL, USA). The database currently contains information from years 2007 through 2011 and includes more than 2.9 billion patient records from more than 25 million patients with an orthopedic International Classification of Disease, Ninth Revision (ICD-9) code or CPT code. Search results yield the number of patients in 5-year age groups, year of surgery, and gender for each CPT or ICD-9 code.³⁹⁻⁴¹

We identified all patients in the national database who underwent clavicle ORIF by CPT code 23515. These patients were tracked in the database for 2 years from their index surgery to evaluate the frequency of hardware removal (CPT 20680) and revision surgery (CPTs for clavicle ORIF and hardware removal during the same procedure). Because patients were queried by the CPT code for ORIF of clavicular fracture, the database includes plate and intramedullary fixation.

Institutional cohort

Patients at our single institution were identified using the ICD-9 code for closed fracture of the clavicular shaft (810.02) and the CPT code for open treatment of clavicular fracture, with or without internal or external fixation (CPT 23515). We included patients who had surgery from July 1, 2007, onward because this was when our institution adopted an electronic medical record.

Our inclusion criteria were patients aged 18 to 70 years old with Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association type 15-B midshaft clavicular fractures treated with ORIF with plating who had a minimum of 1 year of follow-up. Patients were excluded if they had ipsilateral limb injuries requiring surgery, open fractures, or inadequate documentation considered as no clinic notes or operative reports. With these criteria we identified

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