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Risk factors for hardware removal following operative treatment of middle- and distal-third clavicular fractures

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Background: The incidence of hardware removal (HWR) after operative fixation of clavicular fractures varies widely. Risk factors related to HWR remain incompletely understood. The aim of this study was to evaluate the incidence of and risk factors for HWR after plate fixation of middle- and distal-third clavicular fractures. We hypothesized that (1) the total HWR incidence would be <20%, (2) the HWR incidence of operatively treated distal- and middle-third clavicular fractures would not be statistically different, and (3) symptomatic implants would be the most common HWR indication.

Methods: We performed a multi-hospital retrospective study of skeletally mature patients who underwent plate fixation of middle- and distal-third clavicular fractures from November 2008 to November 2018. Data included patient demographic characteristics, mechanism of injury, operative records, hardware-related symptoms, subsequent HWR, and complications.

Results: A total of 103 patients (aged 16-75 years, 76.7% male patients) were included. Of the patients, 87 (84.5%) underwent plate fixation for midshaft clavicular fractures and 16 (15.5%) underwent plate fixation for distal-third clavicular fractures. HWR was performed in 13 patients (12.6%). A significantly higher percentage of HWR procedures were performed for distal clavicular fractures (50%) than for middle-third clavicular fractures (4.9%, $P < .0001$). An initial high-energy mechanism of injury was associated with HWR ($P = .0025$). The most common indication for HWR was symptomatic hardware (69.2%). The overall complication rate was 14.5%.

Conclusion: The overall incidence of clavicular HWR was 12.6%. A distal fracture location was associated with a significantly higher incidence of HWR. An initial high-energy mechanism of injury was a significant risk factor for HWR. The primary indication for HWR was symptomatic hardware.

Level of evidence: Level IV; Case Series; Treatment Study

Keywords: Clavicular fracture; hardware removal; middle; distal; open reduction–internal fixation; complications

The incidence of hardware removal (HWR) after operative fixation of clavicular fractures is variable and dependent on multiple reported factors, including geographic or cultural preferences, patient symptoms related to hardware, surgical complications, and method of fixation. The reported rate of removal varies from as low as 0% up to 68% in some studies, with the incidence of HWR

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for distal-third clavicular fractures on the upper end of this spectrum.[2,5,8,11,14,16,18-20,23,31,35] Clavicular fractures are common, with an incidence of approximately 64 per 100,000 persons per year,[21] accounting for 2% to 10% of all fractures in adults. The majority of clavicular fractures are sustained in the middle-third region,[20,32,35] whereas distal clavicular fractures account for 10%-30% of all clavicular fractures.[4,21,27] Orthopedic surgeons have indicated surgical treatment with increasing frequency following a study showing improved outcomes with operative treatment of displaced midshaft fractures.[6]

There are multiple fixation methods for displaced clavicular fractures. Plate and screw constructs vary and include anteroinferior plating, superior plating, and dual plating. Additional implant choices include intramedullary devices (screws, pins, or nails) and possible augmentation with suture or cortical suture-button fixation. Plate choices for midshaft and distal-third clavicular fractures include one-third tubular plates, reconstruction plates, noncontoured or precontoured plates, distally locking plates, limited-contact dynamic compression plates, and modernized plates. A recent trend toward dual plating with minifragment plates has emerged for midshaft clavicular fractures and has allowed surgeons to use 2 smaller plates, typically 2.4 or 2.7 mm in size, located anteriorly and superiorly. Dual plating reduces the prominence of the implants compared with more traditional plating systems placed superiorly in this subcutaneous location, although concern for extensive soft tissue stripping and loss of blood supply exist.[19] Distal clavicular fracture fixation remains controversial and without a gold standard.[27] Plates are commonly used, and difficulty with attaining distal fragment fixation has inspired the design of precontoured locking plates with smaller clustered screw holes to affix this small fragment. Tension-band constructs have also been described. In addition, fixation of the proximal fragment to the coracoid or acromion can be performed using a modified Weaver-Dunn procedure, hook plates, coracoid screws, suture, or suture anchors.[4,27]

There is a paucity of evidence regarding the factors that influence implant removal following middle- and distal-third clavicular fracture fixation. To our knowledge, no previous study has directly compared the HWR incidence between operatively treated middle- and distal-third clavicular fractures. Previously identified associated factors for isolated clavicular HWR include female sex,[18,24] noncontoured plating,[24,25] low body mass index (BMI),[24] and height <175 cm.[25] The rationale for HWR is most commonly for symptomatic hardware, and the symptoms most frequently involve plate prominence and discomfort[2,24,31]; however, HWR has also been reported for limited range of motion, interference with daily activity, and concern for refracture.[31] Our affiliation with an academic medical center affords an opportunity to evaluate a large series of surgically managed clavicular fractures treated in different patient care settings. The aims of this study were to (1) evaluate the incidence of postoperative HWR after plate fixation of middle- and distal-third clavicular fractures, (2) identify risk factors for HWR, and (3) characterize indications for HWR surgery. We hypothesized that (1) the total HWR incidence would be $<20\%$; (2) the incidence of distal-third and middle-third clavicular hardware would not be statistically different (null hypothesis); and (3) painful, symptomatic implants would be the most common indication for HWR.

Methods

A single-center, multi-hospital retrospective chart review was performed across 3 systems: 1 county level 1 trauma center, 1 academic teaching hospital, and 1 independent physician-led Accountable Care Organization with an ambulatory surgical center. Potential study subjects were identified from the electronic medical records via Current Procedural Terminology code 23515 for open treatment of clavicular fractures and code 20680 for removal of deep implants for a 10-year period from November 2008 to November 2018. Patients were eligible for inclusion in the study if they were skeletally mature at the time of surgery and sustained an acute, traumatic middle- or distal-third clavicular fracture that underwent subsequent open reduction–internal fixation (ORIF) with plates and screws. The exclusion criteria included skeletal immaturity, insufficient data in record, follow-up period <4 weeks, ORIF performed for nonunion or malunion, placement of additional hardware (other than plates and screws), and fracture location in the medial third of the clavicle. A total of 143 patients underwent clavicular ORIF during this 10-year period, of whom 103 were eligible for inclusion in the study (Fig. 1). The indications for middle-third clavicular fracture ORIF included midshaft fractures with >2 cm of shortening, cortical width fracture displacement $>100\%$, impending open fracture, or open fracture. Indications for distal-third clavicular fractures included displaced Neer type IIA or IIB fracture patterns,[4] impending open fracture, or open fracture. Patients were treated by 6 fellowship-trained orthopedic surgeons including 2 orthopedic traumatologists, 1 shoulder and elbow fellowship–trained orthopedic surgeon, and 3 sports medicine fellowship–trained surgeons.

The operative technique and plating choice were surgeon dependent. Wound closure occurred in layers, including deltotrapezial fascial closure, subcutaneous closure, and skin closure. Of the 6 surgeons, 2 routinely performed pants-over-vest fascial closure to provide additional soft tissue coverage over the clavicular hardware by overlapping the fascial closure.

The detailed postoperative protocol varied by surgeon; however, the most conservative postoperative protocol included sling immobilization for 6 weeks. At 2 weeks postoperatively, patients were prescribed home passive shoulder and active elbow range-of-motion exercises. Patients attended routine clinic appointments and postoperative radiographs were obtained at 6 and 12 weeks to assess fracture union and range of motion. If fracture healing was evident at 6 weeks, patients were allowed to discontinue using the sling and start active shoulder range of motion. At 12 weeks, patients started overhead motion and strengthening activities. If range of motion and fracture union were achieved by 12 weeks, patients were seen postoperatively at 1 year or, if issues arose, sooner.

Data for the 103 eligible patients were retrospectively extracted from progress notes, operative notes, and radiographs. Data

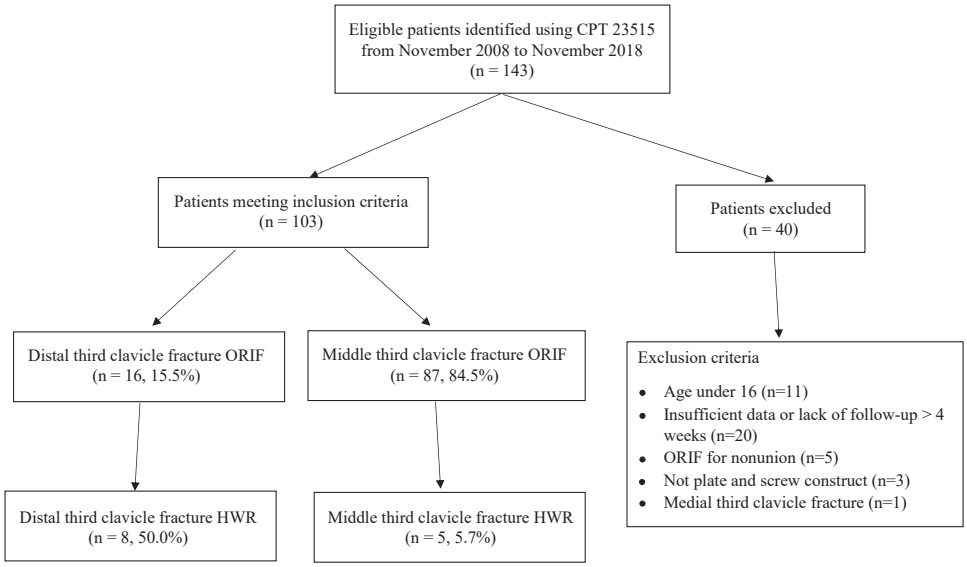

Figure 1 Patient inclusion and exclusion criteria. *CPT*, Current Procedural Terminology; *ORIF*, open reduction–internal fixation; *HWR*, hardware removal.

collected included the total number of procedures, total number of HWR procedures, time from initial surgery to implant removal, surgeon name, patient demographic characteristics (sex, age, race, BMI), laterality, fracture pattern as determined by initial radiographs, mechanism of injury, rationale documented for removal, type of practice where surgery was performed (county vs. private), anatomic plating location, operative and closure technique, incidence of subjective and objective hardware-related symptoms, and associated complications of the index and HWR procedures (including infection, implant failure, wound or scar issues, and refracture). Evidence of fracture union, malunion, or nonunion was evaluated on postoperative radiographs. The primary outcome of interest was the incidence of HWR. Secondary outcomes included evaluation of potential risk factors for HWR (patient demographic characteristics, mechanism of injury, fracture location, operative and closure technique, hardware-related symptoms, or private vs. county hospital system), the indication provided for HWR, operative complications, the incidence of malunion and nonunion, and the incidence of revision surgery other than HWR.

Statistics

Data were analyzed using GraphPad Prism 8 (version 8.1.1; GraphPad Software, San Diego, CA, USA). Descriptive statistics were calculated for all variables. Univariate analysis was performed to determine the relationship between HWR and demographic, clinical, and surgical factors. $P < .05$ was considered statistically significant.

Results

Patient characteristics

Of the 103 included patients, 87 (84.5%) underwent plate and screw fixation for a midshaft clavicular fracture and 16 (15.5%) underwent plate and screw fixation for a distal-third clavicular fracture. The mean patient age was 37.8 years (range, 16-75 years), and 79 patients were male patients (76.7%). The mean BMI was 25.6 kg/m^2 (standard deviation, 5.1 kg/m^2). The majority of patients identified as white (39.8%) or Hispanic or Latino (37.9%). Of the patients, 24 (23.3%) were treated at the public hospital whereas 79 (76.7%) were treated through one of the private systems. Implants used varied widely and appeared to vary over time (Tables I and II). The most common mechanisms of injury were falls, motor vehicle collisions, and sports injuries (Table III). There were no open fractures. The anatomic plate location was superior in 75 patients (72.8%) and anteroinferior in 1 patient (1.0%), whereas dual plating was used in 27 patients (26.2%) (Table IV, Figs. 2 and 3). For the 103 patients included in the study, the mean duration of follow-up was 190.7 days (6.3 months) and the mean time from index surgery to HWR surgery was 319.0 days (10.6 months). Notably, the public hospital patients' average follow-up period was 106.3 days (3.5 months) across all postoperative clavicular fractures. Comparatively, the private hospital patients' average follow-up period was 216.4 days (7.2 months). During the same 10-year period, 5 excluded patients did not undergo follow up and 10 excluded patients had a follow-up duration <4 weeks; had these patients been included, the average follow-up period would decrease to 117.7 days (3.9 months) across 113 patients.

Primary outcome

Of 103 patients, 13 (12.6%) underwent HWR (Table V). Among the patients who underwent distal clavicular fracture fixation, 8 of 16 (50%) subsequently underwent

Table I Middle-third hardware constructs used by year

Middle-third clavicle hardware	Year										Total
	2008	2010	2011	2012	2013	2014	2015	2016	2017	2018	
Acumed clavicle plate (Hillsboro, OR, USA)		3	2	3	7	1			1	2	19
Acumed low profile clavicle plate							4	3			7
Zimmer Biomet locking LCDCP (Warsaw, IN, USA)						1					1
Dual plating with DePuy Synthes 2.0-mm and 2.7-mm LCP (Johnson & Johnson, New Brunswick, NJ, USA)							4	5	3	6	18
Dual plating with DePuy Synthes 2.4-mm and 2.4-mm LCP									1*		1
Dual plating with DePuy Synthes 2.4-mm and 2.7-mm LCP								4*	1	2	7
Dual plating with DePuy Synthes 2.4-mm and 3.5-mm LCP								1			1
Stryker 2.7-mm LCP (Kalamazoo, MI, USA)							1				1
Stryker clavicle plate						1	2				3
Stryker locking plate (anterior)								1			1
DePuy Synthes 2.4-mm LCP								1*			1
DePuy Synthes clavicle plate					2	5	2	5	1	4	19
DePuy Synthes distal clavicle plate					1*					1	2
DePuy Synthes reconstruction plate								1			1
Plate manufacturer unclear from medical record	1*	2			1	1					5
Total	1	5	2	3	11	9	13	21	7	15	87
HWR by year	1	0	0	0	1	0	0	2	1	0	5 of 87

LCDCP, limited contact dynamic compression plate; *LCP*, locking compression plate; *HWR*, hardware removal.
* HWR.

Table II Distal-third hardware constructs used by year

Distal-third clavicle hardware	Year									Total
	2010	2011	2012	2013	2014	2015	2016	2017	2018	
Acumed distal clavicle plate				1	1					2
Acumed distal clavicle plate and coracoid screw		1*		1*						2
Acumed distal clavicle plate and TightRope							1*			1
Arthrex distal clavicle plate and suture button (Naples, FL, USA)									1	1
Arthrex distal clavicle plate and TightRope						1				1
Zimmer Biomet one-third tubular plate and suture button								1		1
Stryker distal clavicle plate							1*			1
DePuy Synthes distal clavicle plate			1*		1					2
DePuy Synthes distal clavicle plate and coracoid screw	2*	1*	1							4
Plate manufacturer unclear from medical record			1							1
Total	2	2	3	2	2	1	2	1	1	16
HWR by year	2	2	1	1	0	0	2	0	0	8 of 16

HWR, hardware removal.
* HWR.

HWR, whereas 5 of the 87 patients (5.7%) who underwent middle-third clavicular fixation underwent removal. In 11 of the 13 patients who underwent implant removal, a single superiorly placed plate was removed; the remaining 2 patients underwent removal of dual plates. Ten HWR procedures were performed electively because of symptomatic hardware, whereas the remaining 3 patients underwent reoperation for early hardware failure or refracture. In 4 of the 8 patients who underwent HWR after fixation of a distal clavicular fracture, removal of a coracoid screw was performed. Of note, 2 patients who underwent distal clavicular fixation required reoperation for coracoid screw removal only, owing to coracoid screw migration and symptomatic prominence (both of whom had superiorly placed distal clavicular plates that were retained), and another 2 patients required complete HWR inclusive of both the coracoid screw and distal clavicular plate.

Table III Initial mechanism of injury for clavicular fractures of included patients

	Patients, n	%
Mechanism of injury		
Fall*	22	21.4
Motor vehicle crash†	21	20.4
Sport-related injury*	18	17.5
Motorcycle crash†	14	13.6
Bicycling accident*	12	11.7
ATV accident†	11	10.7
Assault*	2	1.9
Automobile vs. pedestrian†	2	1.9
Blunt trauma*	1	1.0
Total	103	100.0

ATV, all-terrain vehicle.
* Moderate- or low-energy mechanism.
† High-energy mechanism.

Table IV Treatment variables for patients with operatively treated clavicular fractures

Characteristic	Patients, n	%
Fracture location		
Middle third	87	84.5
Distal third	16	15.5
Hardware location		
Superior	75	72.8
Dual	27	26.2
Anteroinferior	1	1.0
Hardware-related symptoms		
Objective (clinical examination)	22	21.4*
Pain to palpation	22	21.4
Plate prominence	13	12.6
Subjective (patient reported)	30	29.1*
Local irritation or discomfort	18	17.5
Activity related	5	4.9
Hardware removal incidence		
Middle-third HWR	5 of 87	4.9
Distal-third HWR	8 of 16	50.0
Total HWR	13 of 103	12.6

HWR, hardware removal.
* Patients presented with overlapping symptoms; thus, the percentage values will not necessarily summate to equal the overall percentage.

Secondary outcomes

A distal-third clavicular fracture location as compared with a middle-third clavicular fracture location was found to be a significant risk factor for HWR, with a 50% incidence of HWR after distal clavicular fractures and 4.9% incidence of HWR after middle-third clavicular fractures ($P < .0001$, Table VI). An initial high-energy mechanism of injury resulting in clavicular fracture was also a significant risk factor for HWR ($P = .0025$). These high-energy injury mechanisms included automobile vs. pedestrian accidents, as well as motorcycle, all-terrain vehicle, and motor vehicle accidents. Age, sex, race, BMI, plate positioning, private or county hospital setting, and wound closure method (typical wound closure compared with pants-over-vest closure) were not significant risk factors for HWR. The indications for HWR were symptomatic hardware (61.5%), activity-related pain (15.4%), hardware failure requiring removal (15.4%), and refracture (7.7%) (Table V).

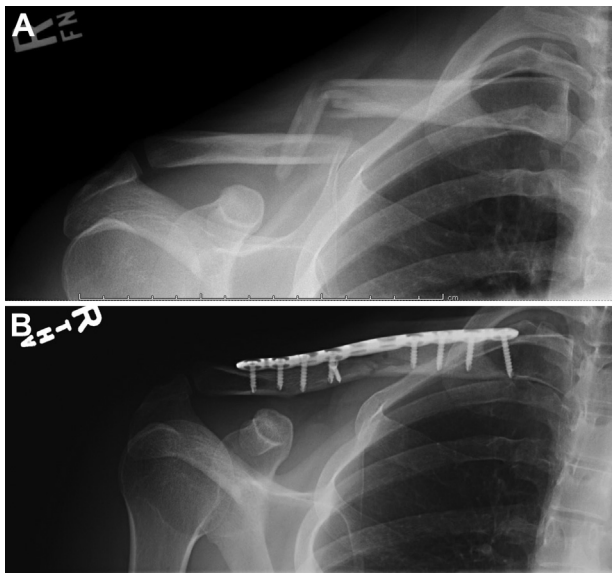

Figure 2 A 25-year-old male patient sustained a right midshaft clavicular fracture with displacement and comminution. **(A)** Preoperative radiograph. **(B)** Six-week postoperative radiograph after open reduction–internal fixation using single precontoured plate placed superiorly. *R*, right.

At final postoperative follow-up after index clavicular ORIF, 30 patients (29.1%) complained of subjective postoperative pain and 22 patients (21.4%) were found to have objective symptoms of either tenderness to palpation at the surgical site or plate prominence on physical examination (Table IV). Sixteen complications occurred during the follow-up period; 12 complications occurred after the index surgical procedure, and 4 occurred after the subsequent HWR (Table VII).

Discussion

This study aimed to evaluate the incidence of and risk factors for HWR following plate fixation of displaced middle- and distal-third clavicular fractures. Our most important findings are that a distal clavicular fracture location and an initial high-energy mechanism of injury are significantly associated with subsequent HWR. To our knowledge, the latter is a unique finding. Overall, we found a 12.6% incidence of HWR, with a 50% incidence for distal clavicular fractures and a 4.9% incidence for middle-third

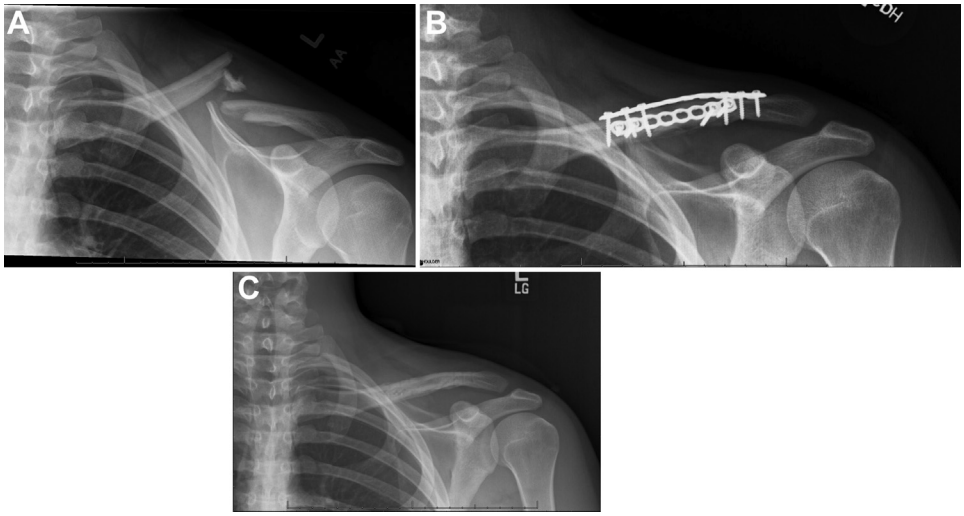

Figure 3 An 18-year-old male patient sustained a left midshaft clavicular fracture with displacement and comminution. **(A)** Preoperative radiograph. **(B)** Six-week postoperative radiograph after open reduction–internal fixation using dual 2.4-mm mini-fragment plates placed superiorly and anteriorly. **(C)** Eleven-month postoperative radiograph after implant removal for symptomatic hardware after fracture union.

clavicular fractures. The most common indication for HWR was painful and/or symptomatic implants.

Two significant risk factors were identified for implant removal after clavicular fracture ORIF. In this series including 16 patients with distal-third fractures, fixation with plates and screws resulted in a 50% rate of HWR, significantly more than the rate for the 87 patients with operatively treated midshaft fractures (5.7%), thereby rejecting the null hypothesis that the rates would be similar. Distal clavicular fractures are not as common as middle-third fractures; therefore, the literature surrounding these fixation modalities is limited, retrospective, and heterogeneous and has small sample sizes, especially for plate fixation. Furthermore, for many implants used in distal clavicular fractures, routine implant removal is recommended after fracture union.[4,27] Similarly, coracoid screws typically undergo planned HWR and have an association with screw migration or failure,[4,21] as was seen in our study. Regarding distal clavicular fixation, this study focused on hardware-related symptoms from plate fixation for Neer type II distal clavicular fractures. Recent studies have reported rates of removal between 16.2% and 25% for type II and type V distal clavicular fractures,[15,27] but we did not identify any study directly comparing the middle clavicular HWR incidence with the distal clavicular HWR incidence. Our study resulted in an overall 50% HWR rate for type II distal clavicular plate and screw fixation. This higher rate may be due in part to surgeon preference, inclusion of coracoid screw HWR, or exclusion of other hardware modalities. In addition, coracoid screws are rigid constructs associated with loosening and migration that may increase the incidence of HWR when used as part of the hardware construct for a distal clavicular fracture.

A second significant factor for HWR in our series was an initial high-energy mechanism of injury resulting in clavicular fracture. Multiple studies have reported on the mechanism of injury, but to our knowledge, the finding that higher-energy injuries are a risk factor for subsequent HWR has not been presented. High-energy mechanisms included motor vehicle, motorcycle, and all-terrain vehicle accidents, as well as automobile vs. pedestrian collisions. A possible rationale for this finding could be that soft-tissue injury occurring with a higher-energy injury may respond postoperatively with a greater amount of fracture and/or operative site sensitivity and hardware-related symptoms. Additionally, tissue quality may affect surgical wound closure given minimal soft tissue available for coverage in the peri-clavicular region.

Our overall rate of HWR was 12.6%. This is consistent with our hypothesis and consistent with the findings of other contemporary studies reporting the HWR incidence after clavicular ORIF with plates and screws. One of the largest randomized controlled trials to date reported an 8% implant removal rate related to hardware irritation within 1 year postoperatively.[6] Another recent randomized controlled trial found an elective implant removal rate of 16.7%.[35] Historically, rates of HWR after clavicular fracture fixation have varied markedly, ranging from 0% to 68%.[2,5,8,11,14,16,18-20,23,31,35] When comparing only midshaft clavicular implant removal rates—for which there is a greater body of research available—a 4.9% HWR incidence, as found in this study, represents the lower end of the reported spectrum for implant removal. Concern about high rates of secondary surgery gave impetus to the current study and our desire to understand risk factors associated with HWR.

The primary indication for HWR in a majority of our patients (61.5%) was symptomatic hardware, in essence, pain, discomfort, or irritation localized to the implant in the setting of a healed fracture. Hulsmans et al[13] found that the

Table V Patient characteristics of patients who underwent clavicular HWR

Patient no.	Age, yr	Sex	Race	BMI, kg/m^2	Mechanism of injury	Laterality	Fracture location	Plate location	Hardware-related symptoms	Hardware construct removed
1	44	M	Hispanic or Latino	31.80	Motorcycle accident	R	Middle third	Superior	Local irritation and/or discomfort: when turning neck and chewing	Plate and screws (data not available)
2	21	M	White	20.53	Sports related (football)	L	Middle third	Superior	Activity related: pain with straps (backpack) and with palpation	DePuy Synthes distal clavicle plate and screws
3	56	M	Asian	22.27	Bicycle accident	L	Middle third	Dual	Activity related: cycling	Dual plating: DePuy Synthes 2.7-mm and 2.4-mm LCP
4	57	F	White	15.80	Fall	R	Middle third	Superior	Plate prominence and local irritation and/or discomfort: hypersensitivity and peri-incisional numbness	DePuy Synthes 2.4-mm LCP
5	18	M	Hispanic or Latino	26.63	Sports related (snowboarding)	L	Middle third	Dual	Local irritation and/or discomfort: pain over superior clavicle with range of motion	Dual plating: DePuy Synthes 2.4-mm and 2.4-mm LCP
6	39	M	Declined to answer	26.54	Fall	L	Distal third	Superior with coracoid screw*	Plate prominence	4.5-mm coracoid screw (DePuy Synthes locking plate retained)
7	68	M	White	27.05	Fall	L	Distal third	Superior with coracoid screw	Plate prominence and local irritation and/or discomfort	DePuy Synthes distal clavicle plate and coracoid screw
8	55	F	Hispanic or Latino	21.63	Fall	L	Distal third	Superior with coracoid screw*	Coracoid screw failure and hardware prominence	Coracoid screw (DePuy Synthes distal clavicle plate retained)
9	41	F	White	28.49	Fall	L	Distal third	Superior	Plate prominence and local irritation and/or discomfort	DePuy Synthes distal clavicle plate
10	27	M	White	31.75	Fall	R	Distal third	Superior with coracoid screw	Reinjury and/or refracture	Acumed distal clavicle plate and coracoid screw
11	46	M	White	23.15	Fall	L	Distal third	Superior with coracoid screw	Plate prominence and local irritation and/or discomfort	Acumed distal clavicle plate (coracoid screw retained)
12	62	F	White	18.70	Fall	R	Distal third	Superior	Plate prominence and local irritation and/or discomfort	Acumed distal clavicle plate (retained Arthrex AC TightRope)
13	54	F	Black	13.15	Fall	R	Distal third	Superior	Early hardware failure and plate prominence	Stryker distal clavicle plate

HWR, hardware removal; *BMI*, body mass index; *M*, male; *R*, right; *L*, left; *LCP*, locking compression plate; *F*, female; *AC*, acromioclavicular.

* Removal of coracoid screw only.

Table VI Risk factors for clavicular hardware removal

Risk factor	*P* value
Age	.0833
Sex	.1754
BMI	.1472
Private vs. public hospital setting	.2903
Initial high-energy mechanism of injury*	.0025†
Distal-third vs. middle-third clavicular fracture	<.0001†
Single vs. dual plating	.5051
Wound closure method	>.9999

An initial high-energy mechanism of injury and a distal-third fracture location were significant risk factors for hardware removal.
BMI, body mass index.
* Table III presents specifics pertaining to high-energy mechanisms of injury.
† $P < .05$.

Table VII Complications related to clavicular surgery

Complications	Patients, n	%
Total complications after index procedure	12 of 103	11.7
Early hardware failure*	4	3.9
Hypertrophic scar or keloid	3	2.9
Minor wound dehiscence	2	1.9
Other soft tissue†	2	1.9
Refracture	1	1.0
Total complications after HWR procedure	3 of 13	23.1
Refracture	2	15.4
Superficial infection	1	7.7

HWR, hardware removal.
* This complication occurred prior to fracture union and <6 months postoperatively.
† These complications included 1 postoperative acromioclavicular separation and 1 postoperative brachial plexus injury that resolved with nonoperative modalities.

rationale for clavicular HWR was implant-related irritation in 75% of their patients whereas the remaining 25% underwent removal because of patient or surgeon preference, which is consistent with findings of our study. However, this is contrasted by the results of Robinson et al,[23] who reported that only 12% of their 86 patients underwent HWR for hardware-related complaints. Similarly, there was a high percentage of patients (29.1%) who reported symptomatic hardware but did not elect to undergo HWR. The reason for this is multifactorial yet concordant with prior studies, which have reported symptomatic clavicular hardware rates between 9% and two-thirds of patients.[13,26,31,33] Common symptoms include pain and/or sensitivity at the operative site, local prominence causing the plate to catch on straps or harnesses, incisional numbness, shoulder asymmetry, restricted range of motion, and unusual sensations with weather changes.[6,26,31,35] Patients who have symptomatic hardware but do not elect to undergo further surgery often make this choice because they fear another procedure, they are unaware that HWR is an option, or they are not significantly bothered by their symptoms.[2,31]

There was not a significant difference in the HWR incidence based on the location or type of plates used in this study. Precontoured plates have been shown to be significantly less prominent than noncontoured plates[30] while maintaining excellent biomechanical strength.[12,20] Regardless of the theoretical advantages of precontoured plates, many studies have only found non–statistically significant trends toward decreased HWR.[2,20,30] Only 1 study has demonstrated a significant difference in HWR rates with the use of precontoured plates vs. noncontoured plates (44.9% vs. 65.6%, $P < .05$).[24] Reconstruction plates have also been shown to have an elective HWR rate of 37.8% and a high reoperation rate between 6.3% and 8%, with many cases indicated for implant failure.[34] Regarding plate type, there are no clear data showing the benefit of one plate type over another. Our study was underpowered to examine the effects of precontoured vs. noncontoured plating.

The location of the plate on the clavicle is a modifiable factor that may contribute to hardware-related symptoms. Superiorly placed plating results in HWR rates between 0% and 47.9%.[3] In one of the largest studies, Naimark et al[20] found that 994 of 7826 patients (12.7%) underwent HWR after superior plating for midshaft clavicular ORIF. Anteroinferior plating was proposed with the advantage of reducing plate prominence while maintaining screw purchase, increasing biomechanical strength, and minimizing neurovascular injury.[1,3] HWR rates between 0% and 36% have been reported for midshaft clavicular fractures using anteroinferior placement.[3,7,11] However, plate location has not been shown to be a significant risk factor for HWR or implant failure.[2,17,35] On the basis of the current literature, one cannot conclude whether single superior or anteroinferior plating results in fewer HWR procedures.

Another modifiable factor is plate size. Galdi et al[10] determined that 2.7-mm reconstruction plates had a decreased rate of implant removal for midshaft clavicular fractures plated anteroinferiorly (0%) as compared with 3.5-mm plates (17%); however, this was not statistically significant, and the study was possibly underpowered. There are limited data, inclusive of those in our study, to support smaller plate sizes; however, smaller plate sizes theoretically may be less symptomatic if adequate fixation can be achieved.

Dual plating has also arisen recently as an option to minimize plate-related symptoms by decreasing plate size and placing mini-fragment plates both superiorly and anteriorly while maintaining biomechanical stability.[22,32] Studies are limited regarding HWR after dual plating, with previously reported HWR rates of 0% and 8.3%.[8,9,22] Our study did not find a difference in HWR rates for superior-only plating vs. dual-plating techniques. A recent study by Lee[17] corroborates this finding, reporting

no significant difference in implant removal rates in a military population surgically managed with either a single small-fragment plate or dual orthogonal mini-fragment plates for displaced midshaft clavicular fractures. HWR was performed in 8 of 89 patients (9%) after 3.5-mm small-fragment plating and 0 of 33 patients (0%) after dual 2.7-mm mini-fragment plating; however, the study was notably underpowered. Similar to a recently published study by DeBaun et al,[9] our study exhibited heterogeneous dual-plating techniques and did not reach sufficient power to determine whether dual plating was a separate risk factor for HWR when compared with single plating. Anecdotally, dual plating is a recent trend, with an increasing frequency of application for clavicular fractures. In this study, all dual-plating techniques were performed after 2015. Further research with larger patient populations is warranted.

Age, sex, BMI, hospital setting, and wound closure method were determined to not be significant risk factors for clavicular HWR. This finding is in contrast to the results of previous studies, in which female patients were 2 to 4 times as likely to undergo HWR,[18,20,24] and is in agreement with the results of another study, which did not find sex to be a significant risk factor.[30] It has been postulated that local irritation at the surgical site or with hardware prominence and sex differences in terms of clothing, accessories (eg, purses or bra straps), and thinner body habitus may contribute to differences in HWR between sexes. Again, in contrast to our study, Rongguang et al[24] reported that lower BMI (20.6 $\pm$ 2.7 kg/m^2 for 3.5-mm superiorly placed precontoured plates and 20.2 $\pm$ 2.9 kg/m^2 for 3.5-mm superiorly placed noncontoured plates) was a significant factor in symptomatic hardware prominence. Notably, their study was performed in a population of Chinese patients with relatively low BMI values for all patients that may not be generalizable to other populations. In our study, index fracture fixation at either a public or private hospital was not correlated with later HWR. Leroux et al[18] reported that patients who received ORIF of midshaft clavicular fractures in nonacademic hospitals were significantly more likely to undergo HWR (20.6%) than those treated in academic hospitals (15.7%). There are limited data available on wound closure after clavicular fixation. This study did not find that a pants-over-vest wound closure method was correlated with a lesser rate of HWR.

The current study had a mean time from index surgery to HWR of 319 days (10.6 months), which is similar to findings reported in other studies. Several studies have reported on the length of time from index surgery to implant removal, with a median time to HWR of about 12 months postoperatively.[13,15,18,35] One group of authors recommended that surgeons should not electively remove clavicular hardware until 1 year postoperatively.[15]

The overall complication rate was 14.5% in this study, inclusive of both the index and HWR procedures, which is similar to reported rates nearing 23%-27% for midshaft clavicular fractures[5,18,35] and 18.9%-22.2% for distal clavicular fractures after plate fixation.[21,27] In one of the largest prospective randomized controlled trials, the Canadian Orthopaedic Trauma Society reported a complication rate of 17.7% for operatively treated midshaft clavicular fractures.[6] Reoperation rates for procedures other than implant removal between 1.1%[2,18] and 10.7%[23,25,30] have been reported. Indications for reoperation other than HWR include nonunion, infection, and refracture.[23] Two revision ORIF surgical procedures were performed in our study, both indicated for hardware failure (1.9%).

We observed 3 cases of nonunion (2.9%), which all occurred in operative midshaft clavicular fractures. Notably, one of these patients was a current smoker and two of these patients were female patients. This rate is consistent with known nonunion rates reported for operative fixation of midshaft clavicular fractures of between 0.1% and 5.9%.[3,6,11,12,18-20,23,33-35] Female sex is a known risk factor for nonunion of midshaft clavicular fractures,[18] and smoking is a risk factor for nonunion in multiple types of fractures, including surgically treated clavicular fractures.[23] Reported nonunion rates across all fixation types for Neer type II distal clavicular fractures range between 1.6% and 3%.[21,27,28]

There were 2 refractures after HWR for midshaft clavicular fractures (2.3% of all midshaft ORIF cases) and 1 refracture after index distal clavicular fixation (6.3% of all distal ORIF cases) in this study. Refracture rates after HWR between 0% and 11% have been reported.[6,23,31,33] A recent study by Tsai et al[29] reported a 7.2% refracture rate after HWR for operatively managed midshaft clavicular fractures and noted that female sex and BMI $<$ 22.73 kg/m^2 were risk factors. One of our female patients who experienced refracture after HWR for a midshaft clavicular fracture was noted to have a BMI of 15.8 kg/m^2, further affirming these risk factors (patient 4 in Table V).

A single superficial infection (1.0%) occurred after HWR and resolved with oral antibiotics. Infection rates have been reported to be 2.4%-4.8% for deep infection[5,18,35] and 2.9%-4.8% for superficial wound infection and/or wound dehiscence after midshaft clavicular ORIF.[5,6,23] The infection rate after plate fixation of distal clavicular fractures has been reported to be low, between 0% and 5.6%.[15,27] However, particularly in the county hospital setting, there existed a short average follow-up period, which increased the number of operatively managed patients excluded from our study because of lack of sufficient follow-up.

Limitations

The limitations of this study include those inherent to a retrospective cohort study. Our data collection relies on the accuracy of patient records, which introduces inherent bias. Twenty patients were excluded because of insufficient data

or loss to follow-up. This represents a loss of 16% of potential study patients, which is well below the percentage common for many retrospective studies. Second, given the high rate of inadequate and short-term follow-up, which we find typical of our experience at a county level 1 trauma hospital, our sample size was lowered and we lacked sufficient power to detect smaller differences between patient groups and certain risk factors such as dual plating vs. single plating. As aforementioned, the recent trend toward lesser HWR rates with dual plating may become significant with a higher sample size.

One strength of this study is that multiple institutions and multiple surgeons were included. The study reviewed data over a 10-year period from 6 different surgeons and 3 different hospital centers; this allows for a diverse patient population, variable and evolving surgical techniques and experience, and postoperative protocols. Furthermore, a majority of the included surgeons also work with orthopedic surgery residents and fellows, which increases the heterogeneity. This may make the results of our study more generalizable to the orthopedic surgeon population that is performing clavicular ORIF.

Conclusion

The incidence of clavicular HWR was 12.6% in this study of 103 postoperative patients who underwent treatment of displaced middle-third and distal-third clavicular fractures with plate and screw fixation. Two significant risk factors were identified for subsequent HWR after clavicular plate and screw fixation, namely, a distal fracture location and an initial high-energy mechanism of injury. The primary indication for HWR in our series was painful, symptomatic hardware. These issues in conjunction with potential complications should be discussed with patients preoperatively.

Disclaimer

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