Characteristics of hardware failure in patients undergoing surgical stabilization of rib fractures: A Chest Wall Injury Society multicenter study

Babak Sarani, MD, Rebecca Allen, BA, Fredric M. Pieracci, MD, Andrew R. Doben, MD, Evert Eriksson, MD, Zachary M. Bauman, MD, Puneet Gupta, Greg Semon, MD, Patrick Greiffenstein, MD, Alistair J. Chapman, MD, Brian D. Kim, MD, Lawrence Lottenberg, MD, Scott Gardner, Silvana Marasco, MD, *and* **Tom White, MD***, Washington, District of Columbia*

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Babak Sarani, Acute Innovations, Consulting Fee, Consultant; Frederick Pieracci, DePuy Synthes, Grant, PI; Andrew Doben Zimmer, BioMet, Consulting Fee, Consultant; Greg Semon, KLS Martin, Grant, PI; Patrick Greiffenstein, Zimmer Biomet/DePuy Synthes/KLS Martin, Consulting Fee, Consultant; Alistair Chapman Synthe (Johnson & Johnson)/Cook Medical, Grants PI; Lawrence Lottenberg, Acute Innovations/Synthes Consulting Fee, Consultant; Silvano Marasco, DePuy Synthes Honorarium, Speaker; Tom White, KLS Martin/DePuy Synthes, Consulting Fees, Consultant

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BACKGROUND: Surgical stabilization of rib fractures (SSRF) is increasingly used for severe rib fractures/flail chest. There are no reports discussing mechanisms of failure of implanted hardware, its clinical presentation, or consequences. The purpose of this study was to evaluate the incidence, presenting signs, and clinical sequela of hardware failure after SSRF.

METHODS: A multicenter, retrospective study was performed by a group of surgeons with a large SSRF case volume. All cases with known hardware failure from January 1, 2010, to December 31, 2017, were included. The surgeon's experience at the time of hardware implantation, specific implant used, number of failures the surgeon had experienced with the same system, and time from implantation to hardware failure were recorded. Additionally, patient demographics, including age, comorbid conditions, and number and location of rib fractures were recorded. Symptomatology associated with hardware failure and need for explant and/or reimplantation of hardware was also recorded. Nonparametric statistical tests were used to compare cohorts.

RESULTS: Of 1,224 patients who underwent SSRF, 38 patients with 233 rib fractures and 279 fracture segments experienced hardware failure and were enrolled in the study. Twelve patients presented more than 3 months following injury. Median age was 54 years old and 34% were active smokers. One hundred forty-four plates were implanted with a median of four plates per patient. Median number of SSRF cases by each surgeon was 100 (range, 1–280). Fractures and hardware failure were most frequent in the anterolateral/lateral region. Hardware failure was mostly due to screw migration and plate fracture. Hardware failure was asymptomatic in 40% and presented as pain in 42% of cases. Fifty-five percent of the cases required explantation of hardware, and only 10% required SSRF again. There was no difference between the acute and chronic fracture cohorts.

CONCLUSION: Hardware failure after SSRF is rare and often asymptomatic. When present, it rarely requires redo SSRF. (*J Trauma Acute Care Surg.* 2019;87: 1277–1281. Copyright © 2019 Wolters Kluwer Health, Inc. All rights reserved.)

LEVEL OF EVIDENCE: Therapeutic, level V.

KEY WORDS: Surgical stabilization of rib fractures; flail chest; rib plating.

Rib fractures are the most common form of chest injury.[1] These injuries are associated with an increased risk of death due to hypoventilation and impaired pulmonary hygiene due to pain and dysfunctional chest wall physiology. Thus, control of pain and early mobility are the cornerstones of treatment of rib fractures, particularly in those with flail chest.

Over the last decade, multiple studies have demonstrated a decrease in mortality and morbidity following surgical stabilization of rib fractures (SSRF), also known as "rib plating," in those with flail chest. In response to these data, the incidence of SSRF has risen exponentially over the last several years.[2] Although presumed to be a relatively safe operation, little is known about the long-term complications of SSRF, particularly related to the implantation of permanent hardware. Prior work in this area has involved single institution reports of the incidence and management of hardware infection.[3,4] Nirula et al.[5] published a review of the literature that identified 650 complications of SSRF over 35 years, but hardware failure constituted only 1.5% of the cases. Specific complications, such as hardware migration and fracture, have not been reported. Similarly, there are no reports of the characteristics of hardware failure, such as location of failure, signs/symptoms of hardware failure, or expected clinical outcome when such failure occurs.

In 2017, a multinational group of trauma, thoracic, and orthopedic surgeons formed the Chest Wall Injury Society (CWIS) with the intent of studying the outcomes of chest wall injury and the indications, techniques, and outcomes of SSRF. Because there is no registry to examine such injuries in a granular fashion, the CWIS research committee embarked on this study as a group of subject matter experts with a large, collective case volume.

The purpose of this study was to evaluate instances of hardware failure to determine how they present, if they share any common characteristics, and their clinical sequela. We hypothesize that hardware failure following SSRF is rare and not related to any specific demographic or clinical factors.

METHODS

A multinational, retrospective study sponsored by CWIS of SSRF cases from January 1, 2010, to December 31, 2017, was undertaken. Each participating site obtained its own institutional review board approval and obtained a data use agreement with the principle investigative site. All patients who underwent SSRF and were noted to have hardware failure, defined as migration of implanted hardware or fracture of the implanted plates, were included in the study. Patients who underwent SSRF but did not have hardware failure were excluded. Use of routine postoperative imaging was at the discretion of each surgeon. Surgeon-specific factors including specialty training, number of cases performed prior to implantation of the failed hardware, and number of cases performed using the same system as failed were recorded. Patient-specific data were also recorded, including demographics in addition to number and location of rib fractures, number of plates implanted, plating system used, time to hardware failure, signs/symptoms associated with hardware failure, and the need for explantation and/or re-implantation of hardware. The CWIS consensus definitions were used to describe the location of each fracture line[6] (Fig. 1).

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From the Center for Trauma and Critical Care, Department of Surgery (B.S., R.A., P.G.), George Washington University, Washington, District of Columbia; Department of Surgery (F.M.P.), Denver General Hospital; Department of Surgery (A.R.D.), Baystate Health, Springfield, Massachusetts; Department of Surgery (E.E.), Medical University of South Carolina, Charleston, South Carolina; Department of Surgery (Z.M.B.), University of Nebraska, Omaha, Nebraska; Department of Surgery (G.S.), Wright State University, Dayton, Ohio; Department of Surgery (P.G.), Louisiana State University, New Orleans, Louisiana; Department of Surgery (A.J.C.), Spectrum Health, Grand Rapids, Michigan; Department of Surgery (B.D.K.), Mayo Clinic, Rochester, Minnesota; Department of Surgery (L.L.), Florida Atlantic University, Boca Raton, Florida; Department of Surgery (S.G., T.W.), Intermountain Health, Murray, Utah; and Department of Surgery (S.M.), Alfred Hospital, Melbourne, Australia.
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Address for reprints: Babak Sarani, MD, 2150 Pennsylvania Ave, NW, Suite 6B, Washington, DC 20037; email: bsarani@mfa.gwu.edu.

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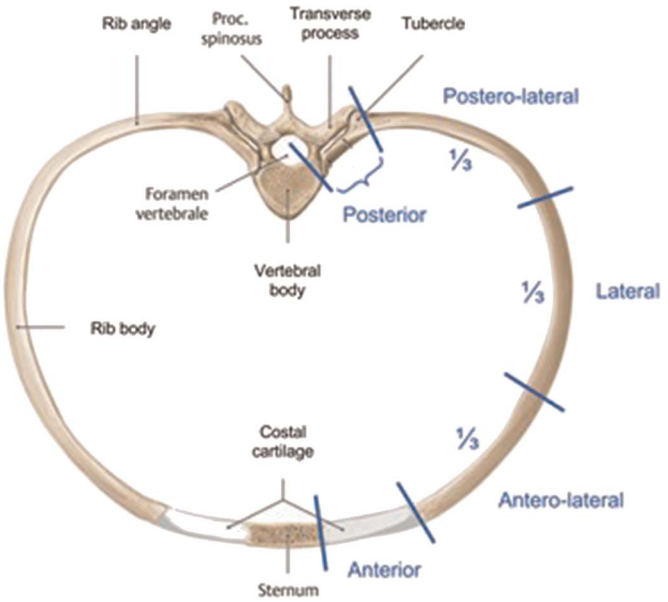

Figure 1. CWIS rib fracture location consensus definition.

Because the data had a nonparametric distribution, analyses were performed using median (25, 75 interquartile range) and χ^2 tests. Statistical significance was defined as p less than 0.05.

RESULTS

A total of 1,224 patients in 12 trauma centers underwent SSRF during the study period. From this number, 38 patients were reported as having hardware failure and constitute the study cohort. This resulted in a reported hardware failure rate 3%. In this cohort, there were 233 rib fractures involving 279 distinct fracture segments. Twelve of the fractures were repaired more than 3 months following injury, and the remainder were acute. The median number of ribs fractured per patient was 6 (4–8) and the median number of fracture segments per patient was 6 (4–9). Median patient age was 54 (45–59) years, and 71% of the patients were male. The median body mass index was 30 (26, 34) kg/m^2. Twenty nine percent of the patients never smoked, 34% were smoking at the time of SSRF, and 16% were ex-smokers. Smoking status was unknown in 21%. The median pack-years in those who smoked or were formerly smokers was 30 (16, 38). Fifty-five percent of patients had no comorbid conditions while 13% had diabetes mellitus and 32% had emphysema. No patient had dialysis-dependent renal failure. Medication use (e.g., steroids) was not collected.

All cases were performed by general/trauma surgeons except for 3, which were performed by a thoracic surgeon. No reported cases were performed by orthopedic surgeons. At the time of the procedure that resulted in hardware failure, the median number of SSRFs performed by each surgeon was 100 (18–167) with a range of 1 to 280 cases. The mean number of prior failed SSRF was 1 (0–4) with a median of 1 (0–1) failed case using the same system. By location, 13% had anterior rib fractures, 29% had anterolateral rib fractures, 42% lateral rib fractures, 58% had posterolateral rib fractures, and 21% had posterior rib fractures (Fig. 1).

A total of 144 plates were implanted resulting in a median of 4 (3–6) plates per patient. Rib plating was performed by at least one of five commercially available systems, all of which use titanium plates with locking screws. The most common plating system reported was an anterior bicortical screw location system (55%) followed by an anterior unicortical screw locking system (24%). Median time from implantation to hardware failure was 59 (10–189) days with a range of 2 to 1,327 days. Table 1 depicts the location of hardware failure by anatomic region and rib. Consistent with the most common locations where hardware was implanted, the most common areas of failure were the lateral and posterolateral regions.

The mode by which hardware failed is depicted in Table 2. There was a near equal incidence of screw migration and plate

TABLE 2. Hardware Failure Mode

Mode of Failure	Percent (%)	Number (n)
Screw migration	44.7	17
Plate migration	26.3	10
Plate fracture	47.4	18

There is no statistical association between any modality of hardware failure (χ^2).

TABLE 1. Hardware Failure by Rib Number and Location

Ribs	Anterior	Anterolateral	Lateral	Posterolateral	Posterior
1	0	0	1	0	0
2	1	0	0	0	0
3	0	0	1	1	0
4	1	0	4	4	0
5	0	1	7	4	0
6	0	0	5	2	1
7	1	1	4	1	1
8	0	0	2	3	0
9	0	0	1	5	0
10	0	0	0	2	1
Column percent (%)*	5.5	3.6	45.5	40.0	5.5
Column total (N)	3	2	25	22	3

The denominator is 55, which is the total number of implant failures in the study.

fracture, although there was no statistical difference noted between any failure mode. There was no statistically significant correlation between the modes of failure. For example, there was no correlation between screw migration and plate migration, screw migration and plate fracture, or between plate migration and plate fracture.

Forty percent of hardware failure was asymptomatic and detected in a routine chest x-ray. The most common sign of hardware failure was ongoing pain (42%) followed by persistent clicking while breathing or coughing (13%). Infection was the presenting sign of hardware failure in 8% of cases. Fifty-five percent of the cases required explant of the hardware but only 10% of the patients who underwent hardware explant required reimplantation of hardware. The majority of fractures had healed at the time of hardware removal.

There were no statistically significant differences noted in comparing patients who underwent SSRF for acute as compared with chronic nonunion/malunion fractures. Comparing the chronic to the acute cohorts, we found that the median age was 53 (34–58) versus 51 (44–58), median body mass index was 31 (24–34) versus 28 (25–32), and the median time to hardware failure was 60 (13–179) days versus 89 (12–264) days. Thirty-six percent and 30% of those in the chronic rib fracture and acute rib fracture cohorts, respectively, were actively smoking at the time of the operation. Despite not being statistically significant, there was a large difference in the absolute number of cases a surgeon had performed before the enrolled case between the cohorts (median acute fracture 28 [10–100] vs. median chronic fracture, 93 [49–135]; $p = 0.09$). There was also no difference in the modality of failure between the cohorts. Comparing those with chronic fractures to those with acute fractures, we found screw migration in 58% versus 52% ($p = 0.74$), plate migration in 33% versus 40% ($p = 0.97$), and plate fracture in 42% versus 44% ($p = 0.88$), respectively. Although there were large differences in the absolute percentage of patients who presented with various signs/symptoms of hardware failure between the cohorts, the differences did not reach statistical significance (Fig. 2).

DISCUSSION

This is the first multicenter study to examine the characteristics of hardware failure in patients undergoing SSRF. The exponential increase in the use of this operation, combined with a general publication bias against complications in surgery, led us to compile and describe this case series of hardware failure. The patients enrolled were severely injured with multi-level as well as multiple fractures per rib. As such, they are representative of patients who undergo SSRF in the trauma population.[2] Also, as expected, the surgeons involved in this study had extensive experience with SSRF. Despite this, each surgeon only had a median of 1 failed implant and the overall failure rate was only 3%, thereby suggesting that hardware failure is a rare event. Surprisingly, almost one-third of cases were performed for nonunion/malunion fractures. Such cases are significantly different both in terms of the biology of bone healing as well as the degree of difficulty of SSRF as compared with acutely injured patients. One would therefore expect a higher incidence of hardware failure in this cohort. Moreover, SSRF in this cohort is technically much more difficult than that in patients with acute fractures, and it is therefore not surprising that these patients were treated by more experienced surgeons.

A key finding of this study is that an equal number of patients who have hardware failure are asymptomatic as compared with ongoing pain. In addition, the vast majority of patients who have hardware failure do not require redo SSRF. Together, this suggests that routine postoperative imaging may not be necessary following SSRF. Patients who experience hardware failure of any consequence, for example, those with ongoing pain or clicking or those who may benefit from removal of the implant (s), will present with clinical complaints while those who have asymptomatic failure rarely require any intervention.

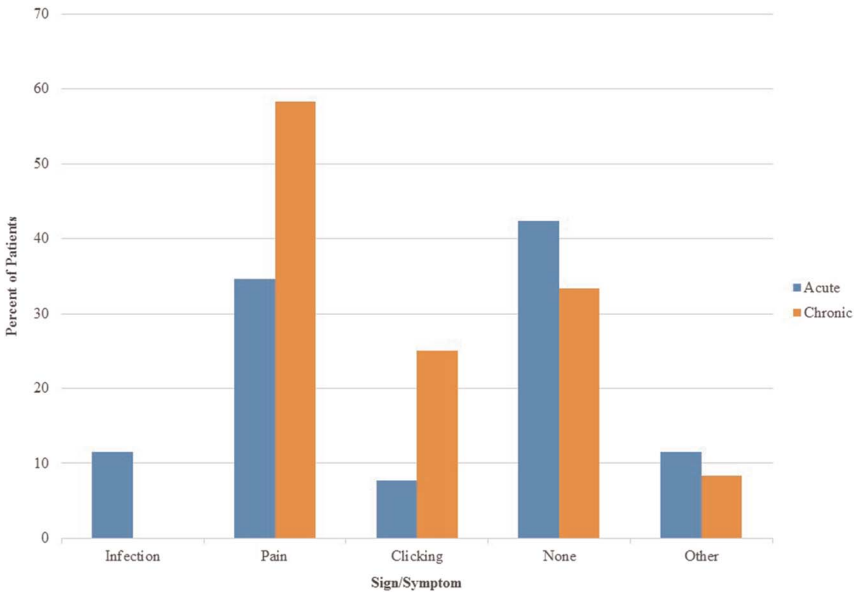

Figure 2. No statistically significant difference was noted between the groups.

Because almost 75% of reported cases were performed using only two of five commercially available systems, we were not able to compare any variables based on type of SSRF system used. Screw migration should be a rare event as all screws are designed to lock to the plate. Although not statistically significant, the finding that there were more screw migration events than plate migration events suggests that the screws were not properly inserted and secured to the plate, thus suggesting surgeon error rather than construct failure. The finding that there were an equal number of plate fractures as screw migrations is also perplexing. The most common cause of plate fracture is metal fatigue from placement of plate across a gap, resulting in the plate bearing the full stress of breathing and rib movement. Currently, it is not known how large a defect one can traverse with a plate without the risk of plate fracture becoming prohibitive. It is generally agreed upon that a defect that is less than 1 cm can be bridged and plated,[7–9] but the general principle of orthopedic repair and of SSRF is that implanted hardware is intended to facilitate healing between fractured ends rather than as a replacement for the rib itself. Given the degree of experience of the surgeons involved in this study, it may be time to reassess this teaching and forgo any gap via use of bone grafts or other matrices to support the plate. One of the biggest differences between ribs and other weight-bearing bones is that ribs must continually move, whereas extremities and the spine can be immobilized to allow for healing. Understanding the biomechanical forces on both the ribs and reconstructed matrix is of vital importance to the success of fixation.

Another key finding of this study involves the differences noted between those in the acute fracture and chronic fracture cohorts. Although these differences did not reach statistical significance, the magnitude of differences noted suggests that they may be significant given a larger sample size. As such, a larger study specifically assessing those who underwent SSRF in a delayed fashion is necessary. The patients differ from those repaired in the acute setting in many ways, including some aspects of altered fracture healing biology, which led to the nonunion in the first place. General principles of orthopedic surgery would predict that these patients will not have the same outcomes and will not necessarily have the same signs/symptoms of healing as those with acute fractures.

Our study also found that the majority of hardware failure events occurred in the lateral or posterolateral area of the rib. This is consistent with a previous study which, using computer modeling, found changes in stresses imparted on the plates during inspiration and expiration and suggested that the stresses on the plate are maximal in the lateral region.[10] Reasons that may account for this are that the ribs move maximally in this region, the serratus anterior pulls the medial rib segments anteriorly, thereby subjecting them to more stress akin to a bucket handle, and the ribs are bent in this region, thereby making contouring of the plates more difficult. The first two explanations subject the implanted hardware to inherently more repetitive stress, which can result in metal fatigue and fracture, while the last explanation may result in hardware migration due to poor fixation against the bone itself. Paradoxically, these same factors render posterolateral fractures theoretically most important to repair as compared with the relatively more stable anterior and very posterior fractures.

This study has several limitations which we acknowledge. Because there was no protocol stipulating if or when patients underwent follow-up imaging, it is very likely that the number of hardware failure cases is underreported. Second, as previously alluded to, the small sample size in comparing the acute and chronic cohorts makes a type II error likely, and larger studies evaluating the latter cohort are needed to draw meaningful conclusions. Next, there was insufficient variability in patient-specific variables to allow analysis of patient-specific risk factors for hardware failure. Since the start of this project, CWIS has created a prospective database to allow for detailed study of patients with severe chest wall injury with the hopes of addressing these limitations.

CONCLUSION

In conclusion, hardware failure after SSRF is rare and often asymptomatic. Care should be taken to ensure all hardware is implanted securely and properly using biomechanical principles. Future studies are needed to describe outcomes related to plating system used and chronicity of fracture present.

AUTHORSHIP

B.S. participated in the study design, data analysis, literature search, drafting article. F.P., A.D. participated in the data analysis, literature search, drafting article, critical revision. R.A., E.E., Z.B., P.G., G.S., P.G., A.C., B.K., L.L., and T.W. participated in the data analysis, critical revision. S.G. and S.M. participated in the data entry and data analysis. B.S. is a consultant for Acute Innovations. L.L. is a consultant for Acute Innovations, Depuy Synthes, and KLS Martin. A.R.D. is a consultant for Zimmer Biomet. F.M.P. is a consultant for Depuy Synthes and has received research funding from DePuy Synthes. P.G. is a consultant for Zimmer Biomet and Depuy Synthes. T.W. and A.J.C. are consultants for Depuy Synthes and KLS Martin. S.M. is a consultant for Depuy Synthes. B.D.K., Z.M.B., G.S., and E.E., R.A., and P.G. and S.G. do not have any conflicts of interest to disclose.

DISCLOSURE

The authors declare no funding or conflicts of interest.

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