Anthem

Medical Policy

Subject:	Internal Rib Fixation Systems		
Document#:	SURG.00120	**Publish Date:**	
Status:	Consultant Draft	**Last Review Date:**	

Description/Scope

This document addresses the treatment of rib fracture(s) using an open approach and an internal fixation system. Operative reduction and internal fixation without use of an internal fixation device is not addressed in this document.

Position Statement

Investigational and Not Medically Necessary:

The use of an internal rib fixation system is considered **investigational and not medically necessary** for all indications.

Rationale

Rib fractures are one of the most common injuries of the chest. Ribs usually fracture at the point of impact or where they are the weakest (at the posterior angle). Typically the fifth through ninth ribs are affected. Simple rib fractures can be treated with analgesia and respiratory care (to prevent complications such as pneumonia or atelectasis). Complex rib fractures or multiple rib fractures may require a more aggressive treatment plan.

Surgical stabilization of rib fractures, particularly surgery using an internal fixation system, has been studied. Currently there are a limited number of randomized clinical trials available evaluating the use of surgical fixation vs. non-surgical management for flail chest. Tanaka and colleagues (2002) reported on a randomized controlled trial of the management of individuals with a diagnosis of severe flail chest. There were 37 individuals with flail chest and acute respiratory failure who were randomly assigned to either surgery or internal pneumatic stabilization at 5 days after injury. A total of 18 individuals underwent surgical fixation and 19 individuals had respiratory management positive end expiratory pressure (PEEP) ventilation with spontaneous intermittent mandatory ventilation mode with pressure support ventilation until they reached extubation criteria. In the surgical group, 5/18 individuals had pneumonia, length of mechanical ventilation was 10.8 days, length of intensive care unit (ICU) stay was 16.5 days, 3 individuals required tracheostomy. In the medical group, 17/19 individuals had pneumonia, length of mechanical ventilation was 18.3 days, length of ICU stay was 26.8 days, 15 individuals required tracheostomy. The study is limited by a small group size and additional studies with larger groups are necessary to assess safety of the internal fixation systems.

Another randomized controlled trial was conducted by Granetzny and colleagues (2005). This study involved 40 subjects prospectively assigned to either surgical treatment or standard non-surgical care. The results indicate significantly better results in the surgical intervention vs. the control group in terms of mean days of mechanical ventilation (2 vs. 12, p=0.001), shorter ICU stay (15.6 days vs. 9.6 days, p=0.001), and mean hospital stay (23.00 days vs. 11.7 days, p=0.001). Additionally, at 2 months follow-up, subjects in the surgical group demonstrated significantly better pulmonary function test results, including % forced vital capacity (FVC) (p=0.001), total lung capacity (TLC) (p=0.001), and forced midexpiratory flow rate (FEF) 75 (p=0.001).

Marasco and others (2013) described a small randomized controlled trial involving 46 subjects with traumatic flail chest. Participants were assigned to receive surgical treatment (n=22) or standard of care with pulmonary support (n=23). While the two groups were not significantly different for most factors, the control group did undergo a higher number of orthopedic and other general surgical procedures. This, difference, however, was not statistically significant (74% vs. 48%; p=0.07). In a multivariate analysis of immediate post-operative outcomes, the control group had a higher rate on non-invasive ventilation (p=0.01), longer ICU stay (p=0.03), and higher rate of tracheostomy (p=0.04). At 3 months follow-up, 2 subjects in the operative group had persistent flail chest symptoms. This study identifies several significant benefits of surgical fixation for flail chest, including shorter ICU and non-invasive ventilation times and a lower tracheostomy rate. However, the small subject pool in this study does not allow wider generalization of these findings.

Nirula and colleagues (2006) studied the impact of operative stabilization of rib fractures on individuals with chest trauma and their subsequent dependence on a ventilator. There were 30 individuals who underwent a rib stabilization procedure and were matched with 30 control individuals who did not have surgical intervention. The primary indication for surgery was severe flail chest in the majority of the cases. The length of ICU days was similar for both groups, as was total hospital length of stay. For those individuals who had surgical rib fracture-stabilization procedures, there was a trend towards fewer total ventilation days compared to the control group (those without surgical intervention). However, the authors concluded this “did not reach statistical significance” and “long-term functional outcomes need to be assessed to ascertain the impact of this procedure.”

In 2007, Richardson and colleagues reported on 7 individuals with multiple rib fractures requiring open reduction and internal fixation. Six individuals sustained an injury following a motor vehicle accident and 1 sustained injury after falling off a horse. Five of the individuals had surgery on an average of 6 days following their injury, due to pain, respiratory failure, or mechanical ventilation requirement. One individual underwent surgery 6 weeks following the injury and another individual underwent their surgery several years after the injury due to chronic nonunion and chest pain. All 7 individuals were noted to have a thin frame and crushing chest injury with an average of 8 rib fractures. Following surgery there were no complications, infections or evidence of nonunion. While good results were noted in this study, the authors concluded that almost all chest wall fractures will heal spontaneously given enough time and “it is difficult to objectively demonstrate a benefit because the primary indication for operation is pain.”

Khandelwal and colleagues (2011) compared the intensity of pain and duration of return to normal activity in 61 individuals with rib fractures. A total of 32 individuals were treated with surgical stabilization of their rib fractures; 29 individuals were treated conventionally (without surgery). Pain was assessed using a numerical scale in numbers ranging from 0 (no pain) to 10 (worst pain). Those individuals who had a pain rating of 5 or more were treated conventionally for 10 days. Individuals were again assessed for pain on the eleventh day using the numerical scale. Only those individuals with a pain rating of 5 or more were followed. Individuals with a pain rating of 5, 6, or 7 were continued to be treated conventionally. Individuals with a pain rating of 8, 9, or 10 were chosen to have surgical stabilization of their fractured ribs. Pain was rated on days 5, 15, and 30 post-operative, and was assessed using the same numerical scale. Duration of return to normal activity was assessed by asking the participants when they were able to return to their usual daily activities. For those in the surgical group, pain was rated at 9.15 on day 5, 2.31 on day 15 and 1.12 on day 30. For those in the conventional group pain was rated at 6.25 on day 5, 5.96 on day 15 and 4.50 on day 30. For returning to normal activity, those in the surgical group had a mean of 26.62 days; the conventional group had a mean of 54.21 days. It appears that this study shows an overall reduction of pain and duration of disability compared to the conventional group, but there are several limitations to the study. The study was conducted on a small number of participants, the participants were not matched in terms of age, gender or nutritional status, and there was no standardized protocol for management of pain in the conventional group. Duration of hospital stay was not able to be assessed and more studies are required to address the limitations.

de Moya and colleagues (2011) reported on a retrospective case-control study which compared 16 individuals who underwent rib fixation to 32 individuals who didn't undergo rib fixation and were considered the control group. The primary outcome was the amount of narcotics administered during the hospital stay. The individuals who had rib fixation were noted to have a reduced need for analgesia. Morphine requirement was decreased from 110 mg preoperatively to 63 mg postoperatively, but there were no differences noted in outcomes when compared with matched controls. The authors also hypothesized that the individuals who had surgical management of their rib fractures would have fewer pulmonary complications and shorter hospital stay due to improved pain control. The authors found that there were no significant differences noted in hospital stay, intensive care unit stay, ventilation days or pneumonia rates.

Bottlang and others (2013) conducted a case series study involving 19 subjects with flail chest. They report that mean duration of mechanical ventilation was 6.4 days (range 0-37 days). Epidural analgesia was used for 15 subjects with a mean duration of 6.6 days (range 2-18 days). The mean duration of ICU stay was 7.9 days (range 1-34 days), and mean duration of hospitalization was 18.4 days (range 4-68 days). Postoperative complications included pneumonia (n=6), atelectasis (n=2), and wound infection (n=1). Three- and 6-month follow-up were obtained from 16 (84.2%) and 15 (78.9%) subjects, respectively. At 3 months, subjects were reported to have a % FVC of 84% and a % forced expiratory volume (FEV1) of 77%. These measures improved to 85% and 79% at 6 months. Return to pre-injury activities was reported for 5 subjects at 3 months and 7 subjects at 6 months. At 6 months, there were no reported hardware failures or migration. Complete healing of treated ribs was noted as well.

Slobogean and colleagues (2013) conducted a meta-analysis of studies comparing surgical fixation vs. non-operative management of flail chest. They identified 11 publications involving 753 subjects, but only 2 randomized controlled trials. They reported that surgical fixation resulted in better outcomes for all pooled analyses, including substantial decreases in ventilator days (mean 8 days, 95% confidence interval [CI], 5 to 10 days) and the odds of developing pneumonia (odds ratio [OR] 0.2, 95% CI, 0.11 to 0.32). Additional benefits included decreased ICU days (mean 5 days, 95% CI, 2 to 8 days), mortality (OR 0.31, 95% CI, 0.20 to 0.48), septicemia (OR 0.36, 95% CI, 0.19 to 0.71), tracheostomy (OR 0.06, 95% CI, 0.02 to 0.20), and chest deformity (OR 0.11, 95% CI, 0.02 to 0.60). All results were stable to basic sensitivity analysis. While these findings are promising, the authors noted that they must be viewed in the context of the pooled studies, which were mostly small and retrospective in nature. Furthermore, the two randomized studies involved only 37 and 40 subjects each. The authors commented that the current evidence addressing the various surgical methods and hardware available is not sufficient to provide any conclusions regarding comparative efficacy. They conclude that additional prospective randomized trials are still necessary.

Another meta-analysis by Leinicke and colleagues (2013) reported on nine studies which compared operative management to non-operative management in adults with flail chest. The outcomes included duration of mechanical ventilation, length of stay in the intensive care unit, length of stay in the hospital, mortality, pneumonia, and tracheostomy. While the studies overall showed reduction in the above mentioned outcomes, the surgical technique used varied among the studies and included the use of metal plates, absorbable plates, intramedullary fixation, Judet struts, and U-plates. Different surgical techniques may vary in terms of their safety and efficacy. Currently there is no standard approach to operative fixation for those individuals with flail chest. Further studies are necessary to help standardize other aspects of care that can also impact outcomes (for example, protocols which guide weaning from mechanical ventilation and sedation).

In a prospective trial by Peiracci and colleagues (2016), 35 participants with severe rib fracture received medical management compared to 35 participants with severe rib fracture who received surgical stabilization. The study design was a crossover paradigm in which the non-operative group was studied during 1 year and the operative group was studied the following year. Outcomes included respiratory failure, tracheostomy, pneumonia, days on the ventilator, length of stay, daily maximum incentive spirometer volume, requirement of narcotics, and mortality. The operative group seemed to have a more severe fracture pattern, more total fractures, and a higher incidence of flail chest compared to the non-operative group. The operative group had a lower likelihood of respiratory failure and tracheostomy and a lower duration of ventilator dependence. The daily spirometry value was higher in the operative group while the narcotic usage was comparable between the two groups. There were no reported mortalities. It should be noted that the non-operative treatment group had a significantly higher rate of neurosurgical intervention which could indicate the degree of trauma may have been higher in that group. The surgical techniques to stabilize the rib fractures were not provided for the operative group leaving no standard approach to operative fixation. The study group is too small to identify specifically which fracture patterns benefitted the most from operative intervention. There are also no long-term outcomes presented.

In the past if rib fractures required surgical intervention, the most used method was a formal thoracotomy. The addition of intraoperative thoracoscopy and computed tomography have allowed for less invasive approaches with smaller incisions and muscle-sparing techniques. Under study are minimally invasive techniques for rib fracture repair, but the benefit, durability and safety of these techniques have not been established.

Much of the current literature is limited to retrospective studies and small sample sizes. Randomized controlled trials with adequate populations to allow generalization of findings have yet to be performed. There is a paucity of evidence concerning the net benefit of operative rib stabilization versus conservative management. Further study is needed regarding the safety and efficacy of these surgical procedures.

Background/Overview

The purpose of the ribs is to protect the internal organs such as the heart and lungs. The chest wall consists of 12 pairs of ribs. Ribs one to seven connect to both the sternum in the front (anteriorly) and the spine in the back (posteriorly). Ribs 8 to 10 attach to the costal cartilage anteriorly. The lowest two ribs are "floating" and do not connect anteriorly. The first three ribs are relatively protected by the scapula, clavicle, and soft tissue. The middle ribs (numbers 4 to 10) are the most vulnerable and susceptible to injury from blunt trauma. Direct trauma to the chest wall causes most rib fractures. This can be blunt trauma such as a motor vehicle crash or penetrating trauma such as a gunshot.

Rib fractures can be associated with internal injury such as to the abdominal organs, aorta, spleen, liver or lungs. Rib fractures can be painful which can hinder breathing. Once significant accompanying injuries have been ruled out, the cornerstone of rib fracture management is pain control. Pain relief is essential to avoid complications such as pneumonia. Severe injuries can lead to mechanical ventilatory support to assist the individual in breathing.

The United States Food and Drug Administration has granted 510(k) clearance to several devices for the fixation and stabilization of rib fractures.

Definitions

Atelectasis: A collapse of all or part of the lung.

Flail chest: A condition in which at least three consecutive ribs are fractured in two or more places. Seen clinically when the paradoxical motion of an incompetent segment of chest wall is visible with respiration.

Pneumonia: An infection of the lungs which can be caused by a virus or bacteria.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

CPT	
21811	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 1-3 ribs
21812	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 4-6 ribs
21813	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 7 or more ribs

ICD-10 Procedure	
0PH104Z-0PH144Z	Insertion of internal fixation device into 1 to 2 ribs [by approach; includes codes 0PH104Z, 0PH134Z, 0PH144Z]
0PH204Z-0PH244Z	Insertion of internal fixation device into 3 or more ribs [by approach; includes codes 0PH204Z, 0PH234Z, 0PH244Z]
0PS104Z-0PS144Z	Reposition 1 to 2 ribs with internal fixation device [by approach; includes codes 0PS104Z, 0PS134Z, 0PS144Z]
0PS204Z-0PS244Z	Reposition 3 or more ribs with internal fixation device [by approach; includes codes 0PS204Z, 0PS234Z, 0PS244Z]

ICD-10 Diagnosis	
S22.31XA-S22.39XS	Fracture of one rib
S22.41XA-S22.49XS	Multiple fractures of ribs
S22.5XXA-S22.5XXS	Flail chest

References

Peer Reviewed Publications:

1. Bottlang M, Long WB, Phelan D, et al. Surgical stabilization of flail chest injuries with MatrixRIB implants: a prospective observational study. Injury. 2013; 44(2):232-238.
2. de Moya M, Bramos T, Agarwal S, et al. Pain as an indication for rib fixation: a bi-institutional pilot study. J Trauma. 2011; 71(6):1750-1754.
3. Doben AR, Eriksson EA, Denlinger CE, et al. Surgical rib fixation for flail chest deformity improves liberation from mechanical ventilation. J Crit Care. 2014; 29(1):139-143.
4. Granetzny A, Abd El-Aal M, Emam E, et al. Surgical versus conservative treatment of flail chest. Evaluation of the pulmonary status. Interact Cardiovasc Thorac Surg. 2005; 4(6):583-587.
5. Khandelwal G, Mathur RK, Shukla S, Maheshwari A. A prospective single center study to assess the impact of surgical stabilization in patients with rib fracture. Int J Surg. 2011; 9(6):478-481.
6. Leinicke JA, Elmore L, Freeman BD, Colditz GA. Operative management of rib fractures in the setting of flail chest: a systematic review and meta-analysis. Ann Surg. 2013; 258(6):914-921.
7. Majercik S, Cannon Q, Granger SR, et al. Long-term patient outcomes after surgical stabilization of rib fractures. Am J Surg. 2014; 208(1):88-92.
8. Marasco SF, Davies AR, Cooper J, et al. Prospective randomized controlled trial of operative rib fixation in traumatic flail chest. J Am Coll Surg. 2013; 216(5):924-932.
9. Middleton C, Edwards M, Lang N, Elkins J. Management and treatment of patients with fracture. Nurs Times. 2003; 99(5):30-32.
10. Nirula R, Allen B, Layman R, et al. Rib fracture stabilization in patients sustaining blunt chest injury. Am Surg. 2006; 72(4):307-309.
11. Nirula R, Diaz JJ Jr, Trunkey DD, Mayberry JC. Rib fracture repair: indications, technical issues, and future directions. World J Surg. 2009; 33(1):14-22.
12. Nirula R; Mayberry JC. Rib fracture fixation: controversies and technical challenges. Am Surg. 2010; 76(8):793-802.
13. Pieracci FM, Lin Y, Rodil M, et al. A prospective, controlled clinical evaluation of surgical stabilization of severe rib fractures. J Trauma Acute Care Surg. 2016; 80(2):187-194.
14. Richardson JD, Franklin GA, Heffley S, Seligson D. Operative fixation of chest wall fractures: an underused procedure? Am Surg. 2007; 73(6):591-596.
15. Slobogean GP, MacPherson CA, Sun T, et al. Surgical fixation vs nonoperative management of flail chest: a meta-analysis. J Am Coll Surg. 2013; 216(2):302-311.
16. Tanaka H, Yukioka T, Yamaguti Y, et al. Surgical stabilization or internal pneumatic stabilization? A prospective randomized study of management of severe flail chest patients. J Trauma. 2002; 52(4):727-732.
17. Zhang Y, Tang X, Xie H, Wang RL. Comparison of surgical fixation and nonsurgical management of flail chest and pulmonary contusion. Am J Emerg Med. 2015; 33(7):937-940.

Government Agency, Medical Society, and Other Authoritative Publications:

1. U.S. Food and Drug Administration 510(k) Premarket Notification Database. Synthes MatrixRIB Fixation System. No. K081623. Rockville, MD: FDA. September 8, 2008. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf8/K081623.pdf. Accessed on July 3, 2018.

Index

Modular RibLoc System®
Rib fracture
Synthes MatrixRIB Fixation System

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	mm/dd/yyyy	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale section.
Revised	11/02/2017	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Title change. Updated Description/Scope section.
	10/01/2017	Updated Coding section with 10/01/2017 ICD-10-PCS procedure code descriptor changes.
Reviewed	11/03/2016	MPTAC review. Updated Rationale and References sections.
Reviewed	11/05/2015	MPTAC review. Updated Rationale and References sections. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Updated Rationale and References. Updated Coding section with 01/01/2015 CPT changes; removed 0245T, 0246T, 0247T, 0248T deleted 12/31/2014.
Reviewed	11/14/2013	MPTAC review. Updated Rationale and References.
Reviewed	11/08/2012	MPTAC review. Updated Description/Scope, Rationale, Background/Overview, References and Index.
Reviewed	11/17/2011	MPTAC review. Updated Rationale and References.
	02/17/2011	Updated Rationale and References.
New	11/18/2010	MPTAC review. Initial document development.