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Clinical Policy Bulletin:
Internal Fixation of Rib Fracture

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Policy

Aetna considers the use of the following internal rib fixation systems in the treatment of rib fractures experimental and investigational because of insufficient evidence of effectiveness in the peer-reviewed literature:

MatrixRIB fixation system

RibLoc Rib Fracture Plating System

See also CPB 0582 - Titanium Rib.

Background

Most injuries to the chest wall do not result in long-term respiratory dysfunction and operative indications for chest wall injuries are rare. Recent studies have explored the option of internal fixation of rib fracture for treatment of complex rib fractures, including flail chest, open fracture, symptomatic nonunion, and thoracotomy for other indications (Lafferty et al, 2011). Flail chest is diagnosed when multiple, consecutive ribs are fractured in two or more places, creating an incompetent region of the chest wall (Slater et al, 2001).

A number of small scale studies have evaluated the use of internal fixation of rib fractures. Lardinois et al (2001) prospectively evaluated chest wall integrity and pulmonary function following operative stabilization of flail chest. They followed 66 patients with antero-lateral flail chest. Forty-seven percent of patients were able to be extubated immediately following the procedure and 85 % within 7 days post-operatively. Pulmonary function testing and clinical assessment were performed 6 months post-operatively. The results showed that the 30-day mortality was at 11 % and chest wall complains were noted in 6 of 57 patients, requiring removal of all plates and screws in 3 of those patients. Six month follow-up results also showed a significant difference between predicted and recorded vital capacity (p = 0.04) and forced expiratory volume (p = 0.001). The investigators concluded that antero

http://qawww.aetna.com/cpb/medical/data/800_899/0822_draft.html

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-lateral flail chest injuries accompanied by respiratory insufficiency, particularly when stabilized early, may be cost effective in that they reduce days on mechanical ventilation and restriction-related working incapacity.

Tanaka et al (2002) conducted a prospective randomized trial of 37 severe flail chest patients requiring mechanical ventilation, comparing the relative clinical efficacy of surgical stabilization (S group) and internal pneumatic stabilization (I group). The authors reported that “the S group showed a shorter ventilatory period (10.8 +/- 3.4 days) than the I group (18.3 +/- 7.4 days) (p < 0.05), shorter intensive care unit stay (S group, 16.5 +/- 7.4 days; I group, 26.8 +/- 13.2 days; p < 0.05), and lower incidence of pneumonia (S group, 24 %; I group, 77 %; p < 0.05). Percent forced vital capacity was higher in the S group at 1 month and thereafter (p < 0.05).” Although the findings of this study are encouraging, the relatively small sample size and the specificity of the inclusion criteria must be taken into account when attempting to generalize these findings.

Nirula et al (2006) conducted a matched case-control study to evaluate the impact of operative stabilization of rib fractures due to trauma. Thirty patients undergoing rib stabilization were matched with 30 controls and followed for length of intensive care unit stay (controls, 14.1 +/- 2.7 vs cases, 12.1 +/- 1.2, p = 0.51), total hospital stay (controls, 21.1 +/- 3.9 vs cases, 18.8 +/- 1.8, p = 0.59), total ventilator days (cases, 6.5 +/- 1.3 days versus controls, 11.2 +/- 2.6 days, p = 0.12), and ventilator days post-stabilization (cases, 2.9 +/- 0.6 days versus controls, 9.4 +/- 2.7 days, p = 0.02). The investigators concluded that rib fracture fixation may reduce ventilator requirements in trauma patients with severe thoracic injuries, but long-term functional outcomes need to be assessed to ascertain the impact of this procedure.

Richardson et al (2007) performed open reduction and internal fixation on 7 patients using titanium plates and screws. The investigators reported that “there was one death in the sternal fracture group in a patient who was ventilator-dependent preoperatively and extubated himself in the early postoperative period. Otherwise, the results were excellent, with no complications occurring in this group.” However, there are limitations to the degree to which findings can be extrapolated given the sample size of 7 patients.

Campbell et al (2009) reported on open reduction and internal fixation using Inion OTPS wraps for treatment of rib fractures for 32 Parkinson’s disease patients with osteoporotic thoracolumbar compression fracture. Would infection occurred in 19 % of patients, chest wall stiffness in 60 %, dyspnea at rest in 20 %, and nonunion of fracture occurred in 1 patient. The authors reported patient satisfaction with the procedure was at 100 % and that the procedure allowed for excellent stabilization of the ribs in both ambulatory and ventilated patients. However, it should be noted that there was a small sample size and relatively high complication rate, although this patient population was one with significant co-morbidity.

Mayberry et al (2009) conducted a survey of members of the Eastern Association for the Surgery of Trauma, the Orthopedic Trauma Association, and thoracic surgeons affiliated with teaching hospitals in the United States and received surveys from 238 trauma surgeons (TRS), 97 orthopedic trauma surgeons (OTS) and 70 thoracic surgeons (THS). Although 82 % of TRS, 66 % of OTS, and 71 % of THS thought that rib fracture repair was indicated in selected patients, only 26
% of surgeons reported that they had performed or assisted on a chest wall fracture repair, whereas 22 % of surgeons were familiar with published randomized trials of the surgical repair of flail chest. Mayberry et al (2009) concluded that “the published literature on surgical repair is sparse and unfamiliar to most surgeons. Barriers to surgical repair of rib and sternal fracture include a lack of expertise among TRS, lack of research of optimal techniques, and a dearth of randomized trials.”

Marasco et al (2009) had conducted a pilot study of operative fixation of fractured ribs in 13 flail chest patients, requiring on average 4 ribs fixed. Positive results were achieved in all patients with the flail chest stabilized and paradoxical chest wall movement eliminated. Based on the findings of this pilot study, a prospective randomized trial is currently underway. Marasco et al (2010) explored the operative stabilization of rib fracture in 13 patients who had 58 ribs fixed with absorbable prostheses, of which 10 rib fixations failed. The investigators observed that stresses on the plate differed between inspiration and expiration, with greater stress on the screws on the posterior part of the broken rib, and separation of the plate from the rib seemed more likely to occur at this site.

In September of 2008 the Food and Drug Administration granted 510K clearance to Synthes (West Chester, PA) for the Synthes MatrixRIB Fixation System for the fixation and stabilization of rib fractures, fusions and osteotomies of normal and osteoporotic bone (FDA, 2008). The Synthes MatrixRIB Fixation System is indicated for the fixation and stabilization of rib fractures, fusions and osteotomies of normal and osteoporotic bone. The system consists of bone plates, intramedullary (IM) splints and screws. All plates, IM splints and screws are manufactured from titanium alloy.

The current practice management guideline for pulmonary contusion - flail chest, issued by the Eastern Association for the Surgery of Trauma, states that surgical fixation may be considered in severe unilateral flail chest or in patients requiring mechanical ventilation when thoracotomy is otherwise required (Simon et al, 2006). However, this guideline is listed as a Level 3 recommendation, indicating that “the recommendation is supported by available data but adequate scientific evidence is lacking ... This type of recommendation is useful for educational purposes and in guiding future clinical research”.

Bottlang et al (2013) stated that surgical stabilization of flail chest injury with generic osteosynthesis implants remains challenging. A novel implant system comprising anatomic rib plates and intramedullary splints may improve surgical stabilization of flail chest injuries. In an observational study, these investigators evaluated the early clinical experience with this novel implant system to document if it can simplify the surgical procedure while providing reliable stabilization. A total of 20 consecutive patients who underwent stabilization of flail chest injury with anatomic plates and intramedullary splints were prospectively enrolled at 2 Level I trauma centers. Data collection included patient demographics, injury characterization, surgical procedure details and post-operative recovery. Follow-up was performed at 3 and 6 months to assess pulmonary function, durability of implants and fixation and patient health. Patients had an Injury Severity Score of 28 ± 10, a chest Abbreviated Injury Score of 4.2 ± 0.4 and 8.5 ± 2.9 fractured ribs. Surgical stabilization was achieved on average with 5 plates and 1 splint. Intra-
operative contouring was required in 14% of plates. Post-operative duration of ventilation was 6.4 ± 8.6 days. Total hospitalization was 15 ± 10 days. At 3 months, patients had regained 84% of their expected forced vital capacity (% functional vital capacity [FVC]). At 6 months, 7 of 15 patients who completed follow-up had returned to work; there was no mortality. Among the 91 rib plates, 15 splints and 605 screws in this study there was no hard-ware failure and no loss of initial fixation. There was one incidence of wound infection; implants were removed in 1 patient after fractures had healed. The authors concluded that anatomic plates eliminated the need for extensive intra-operative plate contouring. Intramedullary rib splints provided a less-invasive fixation alternative for single, non-comminuted fractures. These early clinical results indicated that the novel implant system provided reliable fixation and accommodated the wide range of fractures encountered in flail chest injury. These early findings from a small observational study need to be validated by well-designed studies.

The RibLoc Rib Fracture Plating System (ACUTE Innovations, LLC; Hillsboro, OR) was cleared by the FDA through the 510 (k) process in January 2012; it is indicated to stabilize and provide fixation for fractures, fusions, and osteotomies of the ribs, and for reconstructions of the chest wall and sternum. RibLoc Rib Fracture Plating System consists of plates and screws for fractures, fusions, and osteotomies. The plates are pre-contoured to minimize bending that is done intra-operatively. Instrumentation is supplied with the implants to aid in the insertion of the plates and screws. All plates and screws are manufactured from titanium or titanium alloy. Large-scale, well-designed studies of this system need to be completed to evaluate the evidence-base for use of this system.

Messing et al (2014) presented a review on the role of open reduction and internal fixation of flail chest injuries. A 37-year old woman involved in a motorcycle crash sustained comminuted rib fractures on her right 3rd through 12th ribs. On post-injury day 2, the patient's 5th through 9th ribs were surgically reduced and plated. Later that same day, the patient was successfully weaned from mechanical ventilation and experienced a rapid improvement in incentive spirometry volumes. The authors concluded that further studies are needed to definitively determine the benefits of rib plating versus conventional treatment.

Fabricant et al (2014) performed a prospective clinical trial of resection with or without plate fixation for symptomatic rib fracture nonunion 3 or more months post-injury with 6-month post-operative follow-up. The McGill Pain Questionnaire (MPQ) and RAND 36 Health Survey were administered and activity level (sedentary, ambulatory, moderately active, vigorous), functional status (disabled, non-physical labor, physical labor), and work status (employed, unemployed, retired, student) were queried pre- and post-operatively. A total of 24 patients 4 to 197 months (median of 16 months) post-injury underwent surgical intervention for 1 to 4 rib fracture nonunions (median of 2 nonunions). Evidence of intercostal nerve entrapment was present in 9 patients (38%). MPQ Present Pain Intensity and Pain Rating Index and RAND 36 Physical Functioning, Role Physical, Social Functioning, Role Social, Bodily Pain, Vitality, Mental Health, and General Health were significantly improved at 6 months compared with study entry (p < 0.05). Activity levels significantly improved (p < 0.0001) but functional and work status did not change; 24-hour morphine equivalent dosage of opioids at study entry was
20.3 ± 30.8 (mean ± standard deviation) and at study completion was 9.4 ± 17.5 (p = 0.054). Complications included 1 wound infection, 2 partial screw back-outs, and 1 chest wall hernia at 1 year after resection of adjacent nonunions with significant gaps repaired with absorbable plates. The authors concluded that surgical intervention for rib fracture nonunion may improve chronic pain and disability but without change in functional or work status. Resection of adjacent nonunions with significant gaps may lead to chest wall hernia.

Majercik et al (2014) noted that there has been increased interest in surgical stabilization of rib fractures (SSRF). It is difficult to define long-term benefits of the procedure. This is a descriptive study of patient outcomes after SSRF. Patients who had undergone SSRF between April 2010 and August 2012 at a Level I trauma center were identified. Data were collected from the medical records. A telephone survey asking about pain, satisfaction, and employment was administered to patients after hospital discharge. A total of 101 patients met inclusion criteria; 50 % patients completed the survey. Indications for SSRF included flail chest, displaced fractures, pain, and inability to wean from mechanical ventilation. Pain was gone at 5.4 ± 1.1 weeks post-discharge. Satisfaction with SSRF on a scale of 1 to 10 was 9.2 ± .2; and 90 % of employed patients returned to the same work at 8.5 ± 2.1 weeks. The authors concluded that SSRF patients were satisfied and were able to return to normal activity with few limitations. Moreover, they stated that a prospective study using modern rib fixation technology is needed to further define benefits. A drawback of this study was that only 50 % of patients completed the survey; thus the findings may have been skewed.

An UpToDate review on “Inpatient management of traumatic rib fractures” (Bulger, 2014) states that “Rib fracture stabilization -- Rib fracture fixation has traditionally required an open thoracotomy for adequate exposure. Several plate types and plate fixation methods have been used, but the search for the optimal material and fixation method continues. Rib fracture fixation is complicated by the anatomy of the human rib. Rib thickness ranges from 8 to 12 mm with a very thin cortex. As a result, it does not hold cortical screws well. In addition, the rib tends to fracture in a spiral pattern or in many small fragments (i.e., comminuted), which complicate repair. Entrapment of the intercostal nerve either as a result of the injury or due to repair can lead to chronic postoperative rib pain. One approach to rib fracture fixation uses malleable plates attached to the anterior surface of the rib (image 1). However, fixation of these plates can be problematic. Another method of fixation uses wire cerclage (i.e., wrapped around the rib) but this can be complicated by wire breakage and plate dislodgement. In addition, circumferential fixation of the rib with a permanent material can potentially impinge the intercostal nerve, causing chronic pain which may require removal of the plates. For this reason, when cerclage is necessary (i.e., comminuted fracture), absorbable sutures should be used. As an alternative, screws can be used to hold the plates in place, but their use is often limited by cortical thickness. Novel techniques for rib fracture fixation include the use of contoured rib plates, absorbable plates, intramedullary rods, U-plates fixed with screws placed over the top of the rib minimizing the risk to the intercostal nerve, and application of osteogenic protein at the fracture site”.

Wiese et al (2014) reported the experience with the Stratos system in 2 surgical centers for the management of 2 types of rib fractures: (i) flail chest and (ii)
multiple dislocated rib fractures with significant chest wall deformity. From January 2009 to May 2012, a total of 94 consecutive patients were included. Selected indications were extended antero-lateral flail chest (n = 68) and dislocated painful rib fractures (n = 26). The open reduction internal fixation (ORIF) system consists of flexible titanium rib clamps and connecting plates. The post-operative course was assessed. Clinical and functional outcomes were evaluated at 6 months. Functional assessment consisted of measurement of the FVC and magnetic resonance imaging (MRI) examination with determination of the radiological vital capacity (rVC) in patients with a flail chest. The median operation time and length of hospital stay were 122 mins and 19 days, respectively, in patients with a flail chest, and 67 mins and 11 days, respectively, in patients with dislocated painful rib fractures. The morbidity rate was 6.4 % and the overall 30-day mortality rate was 1.1 %. Clinical evaluation and pulmonary function testing at 6 months revealed no deformity of the chest wall, symmetrical shoulder girdle mobility in 88 % and a feeling of stiffness on the operated side in 19 % of the patients operated for a flail chest. Median ratio of FVC was 88 %, not suggesting any restriction after stabilization. Magnetic resonance imaging was performed in 53 % (36 of 68) of the patients with a flail chest. The analysis of the rVC showed, on average, no clinically relevant restriction related to the operation, with a mean rVC of the operated relative to the non-operated side of 92 % (95 % confidence interval [CI]: 83 to 100). Stabilization of more than 4 ribs was associated with a lower median rVC than stabilization of 4 or less ribs. The authors concluded that these findings suggested that stabilization of the chest wall with this screwless rib fixation device can be performed with a low morbidity and lead to early restoration of chest wall integrity and respiratory pump function, without clinically relevant functional restriction. Owing to the simplicity of the fixation technique, indications for stabilization can be safely enlarged to selected patients with dislocated and painful rib fractures. The findings of this small study (only 26 patients with rib fractures) need to be validated by well-designed studies.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes not covered for indications listed in the CPB:

0245T
0246T
0247T
0248T

ICD-9 codes not covered for indications listed in the CPB:

807.00 - Fracture of rib(s) closed
807.09

807.10 - Fracture of rib(s) open
807.19

Other ICD-9 codes related to the CPB:
738.3 Acquired deformity of chest and rib
756.3 Other anomalies of ribs and sternum

The above policy is based on the following references:


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