Value Analysis Brief: Operative Fixation for Flail Chest
Abstract

• **Background:** Flail chest is a life-threatening injury typically treated with supportive ventilation and analgesia. Some evidence now suggests rib fixation can improve patient outcomes. The purpose of this brief is to summarize the clinical and economic value of operative fixation for treatment of flail chest based on current evidence.

• **Methods:** Informed by comparative, peer-reviewed literature published after 1990 on clinical and economic outcomes after operative fixation of flail chest or rib fracture. Both MEDLINE and EMBASE databases were queried.

• **Results:** Seven manuscripts compared rib fixation vs. non-operative management of rib fractures. Analysis of the data showed patients treated with rib fixation were 60% less likely to die, 70% less likely to get infection/pneumonia, on average received 6 fewer days of ventilation, and on average were in the ICU for 8 fewer days compared to non-operative management. Assessment of hospital economic data also demonstrated favorable results for rib fixation over non-operative management.

• **Limitations:** Though data were pooled via meta analysis to increase statistical power, most included studies were small. Furthermore, only two of the seven comparative studies were prospective in design. Retrospective comparative studies, particularly those with non-concurrent controls, are subject to risk and indication biases. All comparative outcomes were short-term in nature.
This value analysis brief summarizes the clinical and economic value of operative fixation for treatment of flail chest.

The contents of this value analysis brief were informed by:

- Comparative, peer-reviewed literature published after 1990 on clinical and economic outcomes after operative fixation of flail chest or rib fracture. Both MEDLINE and EMBASE databases were queried.

Where possible, data from multiple studies were pooled using random effects meta analysis.
Flail chest is associated with significant mortality and morbidity.

- Commonly defined as unilateral fractures of at least 3 consecutive ribs, each with 2 or more fractures.¹
  - The flail segment moves paradoxically (outward with expiration and inward with inspiration), contributing to respiratory compromise.
- Occurs in 5-13% of patients with chest wall trauma, most commonly resulting from motor vehicle accidents²
- Mortality between 10 – 20%³

Flail chest is associated with significant mortality and morbidity (cont.)

- Patients with flail chest commonly have multiple, non-thoracic injuries, including traumatic brain injury.¹

- Respiratory compromise in patients with flail chest frequently warrants mechanical ventilation (MV), particularly in the presence of concomitant pulmonary contusion.¹

- Impaired pulmonary function and/or prolonged mechanical ventilation can increase risk for potentially fatal complications, including
  - pneumonia,
  - sepsis, and
  - atelectasis.²

1. Wanek 2004
Patients with flail chest are reported to suffer from long-term pain and disability.

The following have been observed after long-term follow up of patients with flail chest:

- persistent chest wall pain\textsuperscript{1,2},
- chest wall deformity\textsuperscript{2},
- dyspnea on exertion\textsuperscript{1}, and
- prolonged disability.\textsuperscript{1}

2. Simon 2012
The clinical burden of flail chest is associated with significant economic impact.

- In the US, patients with flail chest are in the hospital an average of 15 days, predominantly in the intensive care setting.¹
  - Costs per incremental ICU day without MV = $3,902²
  - Costs per incremental ICU day with MV = $4,945²

- More than 30% of patients require additional care in post-acute settings.¹

- Indirect, societal costs result from inability to work or reduced workplace productivity.

¹ Healthcare Cost and Utilization Project. 2010. Hospital discharges with International Classification of Diseases, Clinical Modification, 9th Revision (ICD-9-CM) for flail chest (807.4) as a primary diagnosis.
² Dasta JF, McLaughlin TP, Mody SH, Piech CT. Daily cost of an intensive care unit day: The contribution of mechanical ventilation. Critical Care Medicine [Internet]. 2005 Jun;33(6):1266–71. NOTE: updated from $US 2005 to $US 2013 using a 1.28 inflation multiplier from the Medical Care Component of the CPI-U. NOTE: Data from table 7 for 3+ days, trauma patients.
Surgical fixation has been adopted for a select subset of patients with flail chest.

- According to guidelines from the Eastern Association for the Surgery of Trauma (EAST):¹
  
  “Surgical fixation may be considered in cases of severe flail chest failing to wean from the ventilator or when thoracotomy is required for other reasons.”

- The UK’s National Institute for Health and Clinical Excellence (NICE) has concluded the following:²
  
  “Current evidence on insertion of metal rib reinforcements to stabilise a flail chest wall is limited in quantity but consistently shows efficacy. In addition, there are no major safety concerns in the context of patients who have had severe trauma with impaired pulmonary function.”

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1. Simon 2012  
Surgical fixation has been adopted for a select subset of patients with flail chest (cont.)

- Lafferty and colleagues offer additional considerations for operative fixation of flail chest, including:
  
  - Failure to wean from ventilator;
  
  - Paradoxical movement visualized during weaning;
  
  - The extent of pulmonary contusion; and
  
  - No substantial brain injury.

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Two prospective and five retrospective studies compared outcomes between fixation and nonoperative management of flail chest.

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Study design</th>
<th>Country</th>
<th>Sample Size</th>
<th>Fixation Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ahmed (1995)¹</td>
<td>Retrospective</td>
<td>UAE</td>
<td>64</td>
<td>K-wires</td>
</tr>
<tr>
<td>Balci (2004)²</td>
<td>Retrospective</td>
<td>Turkey</td>
<td>64</td>
<td>Suture and traction</td>
</tr>
<tr>
<td>Granetzny (2005)³</td>
<td>Prospective, randomized</td>
<td>Germany</td>
<td>40</td>
<td>K-wires or steel wire</td>
</tr>
<tr>
<td>Nirula (2006)⁴</td>
<td>Retrospective</td>
<td>USA</td>
<td>60</td>
<td>Adkin struts</td>
</tr>
<tr>
<td>Solberg (2009)⁵</td>
<td>Retrospective</td>
<td>USA</td>
<td>16</td>
<td>Titanium plates</td>
</tr>
<tr>
<td>Tanaka (2002)⁶</td>
<td>Prospective, randomized</td>
<td>Japan</td>
<td>37</td>
<td>Judet struts</td>
</tr>
<tr>
<td>Voggenreiter (1998)⁷</td>
<td>Retrospective</td>
<td>Germany</td>
<td>42</td>
<td>Rib clamp or pelvic reconstruction plate</td>
</tr>
</tbody>
</table>

Patients who received operative fixation for flail chest were approximately 60% less likely to die from sustained injuries than patients treated nonoperatively.

### Meta analysis of Relative Risk of Death, Fixation versus No fixation for Flail Chest

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Fixation Events</th>
<th>No Fixation Events</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ahmed 1995</td>
<td>2</td>
<td>11</td>
<td>0.27 [0.06, 1.10]</td>
</tr>
<tr>
<td>Balci 2004</td>
<td>3</td>
<td>10</td>
<td>0.41 [0.12, 1.35]</td>
</tr>
<tr>
<td>Granetzny 2005</td>
<td>2</td>
<td>3</td>
<td>0.67 [0.12, 3.57]</td>
</tr>
<tr>
<td>Voggenreiter 1998</td>
<td>3</td>
<td>8</td>
<td>0.41 [0.13, 1.34]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>93</strong></td>
<td><strong>117</strong></td>
<td><strong>0.40 [0.21, 0.78]</strong></td>
</tr>
</tbody>
</table>

Heterogeneity: $\tau^2 = 0.00$; $\chi^2 = 0.68$, df = 3 ($P = 0.88$); $I^2 = 0\%$

Test for overall effect: $Z = 2.68$ ($P = 0.007$)
Chest infection or pneumonia were approximately 70% less likely to occur among patients who received operative fixation.

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Fixation Events</th>
<th>Fixation Total</th>
<th>No Fixation Events</th>
<th>No Fixation Total</th>
<th>Weight</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ahmed 1995</td>
<td>4</td>
<td>26</td>
<td>19</td>
<td>38</td>
<td>27.1%</td>
<td>0.31 [0.12, 0.80]</td>
<td></td>
</tr>
<tr>
<td>Balci 2004</td>
<td>0</td>
<td>27</td>
<td>8</td>
<td>37</td>
<td>3.1%</td>
<td>0.08 [0.00, 1.33]</td>
<td></td>
</tr>
<tr>
<td>Granetzny 2005</td>
<td>2</td>
<td>20</td>
<td>10</td>
<td>20</td>
<td>12.9%</td>
<td>0.20 [0.05, 0.80]</td>
<td></td>
</tr>
<tr>
<td>Solberg 2009</td>
<td>0</td>
<td>9</td>
<td>3</td>
<td>7</td>
<td>3.1%</td>
<td>0.11 [0.01, 1.91]</td>
<td></td>
</tr>
<tr>
<td>Tanaka 2002</td>
<td>4</td>
<td>18</td>
<td>17</td>
<td>19</td>
<td>32.1%</td>
<td>0.25 [0.10, 0.60]</td>
<td></td>
</tr>
<tr>
<td>Voggenreiter 1998</td>
<td>4</td>
<td>20</td>
<td>7</td>
<td>22</td>
<td>21.7%</td>
<td>0.63 [0.22, 1.83]</td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>120</td>
<td>143</td>
<td></td>
<td></td>
<td>100.0%</td>
<td>0.29 [0.18, 0.48]</td>
<td></td>
</tr>
</tbody>
</table>

Total events 14 64

Heterogeneity: \( \tau^2 = 0.00; \ Chi^2 = 3.78, df = 5 (P = 0.58); I^2 = 0\%

Test for overall effect: \( Z = 4.81 (P < 0.00001) \)
On average, patients who received operative fixation for flail chest received 6 fewer days of mechanical ventilation compared to patients treated nonoperatively.

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Fixation</th>
<th>No Fixation</th>
<th>Mean Difference IV, Random, 95% CI [days]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean [days]</td>
<td>SD [days]</td>
<td>Total</td>
</tr>
<tr>
<td>Balci 2004</td>
<td>3.1</td>
<td>1.8</td>
<td>27</td>
</tr>
<tr>
<td>Nirula 2006</td>
<td>6.5</td>
<td>1.3</td>
<td>30</td>
</tr>
<tr>
<td>Solberg 2009</td>
<td>1.9</td>
<td>1.1</td>
<td>9</td>
</tr>
<tr>
<td>Tanaka 2002</td>
<td>10.8</td>
<td>3.4</td>
<td>18</td>
</tr>
<tr>
<td>Voggenreiter 1998</td>
<td>18.65</td>
<td>24.34</td>
<td>20</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td></td>
<td></td>
<td>104</td>
</tr>
<tr>
<td>Heterogeneity:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$\tau^2 = 3.11$</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$\chi^2 = 11.32$, df = 4 (P = 0.02); $I^2 = 65%$</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: $Z = 5.37$ (P &lt; 0.00001)</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Meta analysis of Ventilator Days, Fixation versus No fixation for Flail Chest
On average, patients who received operative fixation for flail chest were in the ICU for 8 fewer days than those who received nonoperative care.

### Meta analysis of ICU Days, Fixation versus No fixation for Flail Chest

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Fixation</th>
<th>No Fixation</th>
<th>Mean Difference</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean [days]</td>
<td>SD [days]</td>
<td>Total</td>
<td>Mean [days]</td>
</tr>
<tr>
<td>Nirula 2006</td>
<td>12.1</td>
<td>2.7</td>
<td>30</td>
<td>14.1</td>
</tr>
<tr>
<td>Solberg 2009</td>
<td>5.4</td>
<td>1.5</td>
<td>9</td>
<td>21</td>
</tr>
<tr>
<td>Tanaka 2002</td>
<td>16.5</td>
<td>7.4</td>
<td>18</td>
<td>26.8</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>57</td>
<td>56</td>
<td>100.0%</td>
<td>-8.24 [-16.60, 0.12]</td>
</tr>
</tbody>
</table>

Heterogeneity: $\text{Tau}^2 = 43.44$; $\text{Chi}^2 = 11.93$, df = 2 ($P = 0.003$); $I^2 = 83$

Test for overall effect: $Z = 1.93$ ($P = 0.05$)
Two studies from the meta analysis, as well as one publication on the cost of ICU days, permitted estimation of the potential economic impact of fixation for flail chest on US hospitals.

- Mean days in the ICU (with and without mechanical ventilation) were calculated for patients with and without fixation from Nirula (2006) and Solberg (2009).

<table>
<thead>
<tr>
<th>Author (year)</th>
<th>Mean ICU days, without MV</th>
<th>Mean ICU days, with MV</th>
<th>Sample Size</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fixation</td>
<td>No fixation</td>
<td>Fixation</td>
</tr>
<tr>
<td>Nirula (2006)</td>
<td>5.6</td>
<td>2.9</td>
<td>6.5</td>
</tr>
<tr>
<td>Solberg (2009)</td>
<td>3.5</td>
<td>7.7</td>
<td>1.9</td>
</tr>
<tr>
<td>Mean days, weighted average</td>
<td>5.1</td>
<td>3.8</td>
<td>5.4</td>
</tr>
</tbody>
</table>

- Using an inflation factor from the Medical Care Component of the Consumer Price Index for Urban Consumers (CPI-U), $US 2013 costs for ICU days were estimated from Dasta (2005): $3,902/day without mechanical ventilation and $4,945 with mechanical ventilation.

- Implant costs for patients undergoing fixation were estimated from manufacturer list prices\(^1\), as well as a recent study on operative fixation of flail chest.\(^2\)

- Estimated operating room costs ($25/minute x 171 minutes) were derived per-minute charges in the operating room updated to $2013 using the Medical Care Component of the CPI-U\(^3\), as well as on mean operating room time for rib fixation.\(^2\)

Operative fixation may reduce hospital costs for management for flail chest by approximately 17% due to reductions in ICU and mechanical ventilation days.

Abstract

• Introduction and Methods
• Burden of Flail Chest
• Role of Fixation in the Care Pathway

Results

• Mortality
• Infection/Pneumonia
• Ventilator Dependence
• Total ICU days

Economics

About MatrixRIB

Limitations

*Weighted mean days in ICU with mechanical ventilation (MV) from Nirula (2006) and Solberg (2009) = 5.4 with fixation vs. 11.6 without fixation; weighted mean days in ICU without MV = 5.1 days with fixation vs. 3.8 days without fixation. ICU and MV Costs derived from Dasta (2005) and updated to $US 2013 using the Medical Care Component of the Consumer Price Index. ICU costs without MV = $3,902 and with MV = $4,945. Implant costs and mean OR time of 171 minutes based on 2013 list prices of MatrixRIB and utilization data from Bottlang M, Long WB, Phelan D, Fielder D, Madey SM. Surgical stabilization of flail chest injuries with MatrixRIB implants: A prospective observational study. Injury [Internet]. Elsevier Ltd; 2013 Mar;44(2):232–8.

OR costs estimated to be $25 per minute: derived from operating room charges of $62/minute updated to $US 2013 using the Medical Care Component of CPI-U and converted to costs using national average cost-to-charge ratio of 0.30, informed by the following data sources: Shiplett RD. A study of time-dependent operating room fees and how to save $100,000 by using time-saving products. American Journal of Cosmetic Surgery 2005; 22 (25-34) and Dalton K, Freeman S, Bragg A. Refining cost to charge ratios for calculating APC and MS-DRG relative payment weights. RTI International. CMS Contract No. HHS5-500-2005-0029I. July 2008.

NOTE: Costs and hospital length of stay vary by individual hospitals. As such, the above results may not be applicable to your institution.
From payer and societal perspectives, operative fixation may be cost-effective relative to nonoperative management of flail chest.

- An economic model showed operative fixation for flail chest to be less costly and offer quality-of-life benefits relative to nonoperative management:
  - US Medicare costs were predicted to be ($17,162 vs. $22,537, for operative and nonoperative management of flail chest, respectively).
  - Operative fixation also offered quality-of-life benefits relative to nonoperative management.

- Tanaka et al. (2002) also reported lower medical costs for Japanese public health insurance for patients who received operative fixation relative to those who received nonoperative management ($13,455 vs. $23,423, p < 0.05).

NOTE: Costs and hospital length of stay vary across individual hospitals, payers, and countries. As such, the above results may not be locally applicable.
MatrixRIB System

- Abstract
- Introduction and Methods
- Burden of Flail Chest
- Role of Fixation in the Care Pathway
- Results
  - Mortality
  - Infection/Pneumonia
  - Ventilator Dependence
  - Total ICU days
  - Economics
- About MatrixRIB
- Limitations
The MatrixRIB Fixation System was designed to provide stable fixation of normal and osteoporotic ribs.

- Pre-contoured titanium alloy locking low-profile 1.5mm plates with 2.9mm locking screws
  - Plates precontoured to fit average rib shape, which minimizes intraoperative bending
  - Plate stiffness similar to cadaveric osteoporotic rib*, allows for flexibility of the rib cage
  - Plates long enough to fixate multiple and comminuted/oblique fractures
  - Anterior plating technique minimizes disruption of intercostal soft tissues

- Intramedullary splints enable minimally invasive approach

- Specialized instrumentation

* Data on file in DePuySynthes test report MT08-481. Mechanical test results are not necessarily indicative of clinical performance.

NOTE: The MatrixRIB System was not the fixation device used in any of the previously referenced clinical studies. Please refer to the MatrixRIB technique guide and package insert for full indications, contraindications, instructions for use, warnings and/or precautions.
The safety and efficacy of MatrixRIB for treatment of flail chest was evaluated in a 6-month prospective, single-arm study.

- Twenty consecutive patients seen between 2009 and 2011 received operative fixation with MatrixRIB for flail chest.\(^1\)
  - Patients had average (SD) Injury Severity Score of 28 (10) and 8.5 (2.9) fractures.
  - An average of 6.2 ribs were stabilized per patient, using an average of 4.8 plates and .8 splints.

<table>
<thead>
<tr>
<th>Surgical stabilization of flail chest injuries with MatrixRIB implants: A prospective observational study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of postoperative mechanical ventilation, mean (range)</td>
</tr>
<tr>
<td>Length of stay in the ICU, mean (range)</td>
</tr>
<tr>
<td>Overall hospital length of stay, mean (range)</td>
</tr>
<tr>
<td>Pneumonia, number (%) of patients</td>
</tr>
<tr>
<td>Atelectasis, number (%) of patients</td>
</tr>
<tr>
<td>Wound infection requiring hardware removal, number (%) of patients</td>
</tr>
<tr>
<td>Improvement in FVC and FEV1 at six months, mean*</td>
</tr>
<tr>
<td>Return to pre-injury activity at six months, n (%)*</td>
</tr>
</tbody>
</table>

*15 patients available for follow up assessment at six months

Limitations of the evaluated studies

• Though data were pooled via meta analysis to increase statistical power, most included studies were small.

• Only two of the 7 comparative studies were prospective in design.
  
  — Retrospective comparative studies, particularly those with non-concurrent controls, are subject to risk and indication biases.

• Neither patients nor assessors were blinded in any of the studies, introducing several forms of bias.

• All comparative outcomes were short-term in nature.