NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of insertion of metal rib reinforcements to stabilise a flail chest wall

The condition in which multiple rib fractures allow a segment of the rib cage to move independently from the main chest wall is called a flail chest. The effect compromises breathing and may be life-threatening.

In this procedure, metal (usually titanium) is used to stabilise the 'flail' segment of chest wall. This procedure aims to improve lung function and reduce the length of critical care and hospital stay.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in May 2010.

Procedure name

• Insertion of metal rib reinforcements to stabilise a flail chest wall

Specialty societies

- Society for Cardiothoracic Surgery in Great Britain and Ireland
- British Thoracic Society
- The Intensive Care Society.

Description

Indications and current treatment

Chest wall injury is common following significant blunt trauma (for example, motor vehicle accidents). It varies in severity from minor bruising or an isolated rib fracture to severe crush injuries of both hemithoraces leading to respiratory compromise.

A flail chest occurs when a segment of the thoracic cage is separated from the rest of the chest wall. It has been defined in a variety of ways but at least 2 fractures per rib in at least 2 ribs are needed to produce a flail segment. A flail chest will cause paradoxical movement of a segment of the chest wall – indrawing on inspiration and moving outwards on expiration –and this segment of chest wall fails to contribute to lung expansion. Large flail segments may extend bilaterally or involve the sternum, and may compromise respiration sufficiently to require mechanical ventilation.

Management of chest wall injury is directed towards protecting the underlying lung, preventing infection and achieving adequate oxygenation and ventilation. In the least severe cases analgesia is used at a level to allow normal inspiration and coughing without respiratory depression. This may be achieved with patient-controlled analgesia machines, oral pain medications or indwelling epidural catheters. Intubation and positive pressure ventilation are used for patients who are unable to maintain adequate oxygenation. Suction may be necessary to remove mucus or secretions from the airways to prevent atelectasis.

Surgical stabilisation with metal rib reinforcements aims to allow earlier weaning from mechanical ventilation, reduce acute complications and avoid chronic pain sometimes associated with permanent malformation of the chest wall. Kirschner wire may be used on its own, but this method of rib stabilisation is not covered by this guidance.

What the procedure involves

With the patient under general anaesthesia, an incision is made over the fractured ribs to be treated, and the fractured ribs are reduced manually. Ribs are stabilised using struts or metal plates and fixed with screws or intramedullary wire. Fractured ribs from T4 to T10 are usually fixed when involved, but ribs between T1 and T3 are not routinely fixed because of the risk of injury to the subclavian vessels. Ribs at T11 and T12 are rarely involved in significant paradoxical movement. A continuous subcutaneous drainage tube may be inserted after the ribs have been stabilised. Patients may receive ventilator support. The metal plates and screws are usually inserted on a permanent basis.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to insertion of metal rib reinforcements to stabilise a flail chest wall. Searches were conducted of the following databases, covering the period from their commencement to 21 January 2010, and updated 24 May 2010: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies.
	Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study.
	Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with flail chest.
Intervention/test	Insertion of metal rib reinforcements.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

Table 1	Inclusion	criteria for	identification	of relevant studies
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List of studies included in the overview

This overview is based on 225 patients from 1 randomised controlled trial $(RCT)^1$, 2 non-randomised controlled trials^{2,3} and 4 case series^{4,5,6,7}.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A. Studies where only k-wire was used to stabilise the ribs have been excluded from this overview.

Table 2 Summary of key efficacy and safety findings on insertion of metal rib reinforcements to stabilise a flail chest wall

Study details	Key efficacy findings		Key safety findings	Comments		
Tanaka H (2002) ¹	Number of patients analysed: 37 (18 vs 19)				Not reported	Follow-up issues:
RCT		Surgical group (n = 18)	Internal group (n = 19)	p value		No loss to follow-up.
Japan	Length of mechanical	10.8 ± 3.4	18.3 ± 7.4	< 0.05		Study design issues:
Recruitment period: 1992–1998	ventilation (days)			_		Patients randomised
Study population: patients with flail chest who required mechanical ventilation (presence of hypoxia and/or	Length of TICU stay (days)	16.5 ± 7.4	26.8 ± 13.2	< 0.05		5 days after injury according to a
hypercarbia under 40% inspired oxygen inhalation,	Tracheostomy at day 7	0%	26.3% (5/19)	NS		randomisation chart
presence of airway obstruction or repeated atelectasis).	Tracheostomy at day 21	16.7% (3/18)	78.9% (15/19)	< 0.05		(unclear if this method is
n = 37 (18 vs 19)	% FVC at baseline	44%	42%	NS		satisfactory).
	% FVC at 1 month	70%	53%	< 0.05		
Age: surgical group: 43 years (mean), internal group: 46	% FVC at 3 months	85%	65%	< 0.05		Study population issues:
years (mean)	% FVC at 6 months	95%	78%	< 0.05		No significant difference
Sex: surgical group: 66.7% (12/18) male, internal group:	% FVC at 12 months	96%	80%	< 0.05		in group demographics
73.7% (14/19) male	Chest tightness at 12 months*	33.3% (6/18)	84.2% (16/19)	< 0.05		at baseline including age, sex, number of
Patient selection criteria: patients excluded if they were under 14 years and did not require mechanical	Thoracic cage pain at 12 months*	38.9% (7/18)	89.5% (17/19)	< 0.05		fractures, site of flail segment, tube
ventilation; had fractures of fewer than 6 ribs; did not develop acute respiratory failure; had severe closed	Dyspnea on effort at 12 months*	27.8% (5/18)	63.2% (12/19)	< 0.05	 thoracotomy PaO₂/FiO₂ a Mean value contusion so similar in bo 	thoracotomy and PaO ₂ /FiO ₂ at admission
head injury (head Abbreviated Injury Scale score >3 with unconsciousness) and/or spinal injury; had chronic pre-	% in full time employment at 6 months	61.1% (11/18)	5.3% (1/19)	< 0.01		Mean value of lung contusion score was
existing heart, pulmonary and/or renal disease.	% in full time employment at 12 months	88.9% (16/18)	63.2% (12/19)	NS		similar in both group. Surgical group: 2.0 ± 0.9
Technique: surgical stabilisation using Judet struts within 14 days of injury plus internal pneumatic stabilisation vs internal pneumatic stabilisation only. All patients on ventilator support until they reached extubation criteria (absence of hypoxia, stable haemodynamics and consciousness, respiratory rates > 25 breaths/min, spontaneous tidal volume >12 mL/kg and no obstruction of airway).	*reported by patient in quest FVC data read by IP analyst <u>Pneumonia</u> Pneumonia at day 7: Surgical group: 5.6% (1/18) Internal group: 15.8% (3/19)	from graph, there		internal group: 2.0 ± 0.8		
Follow-up: 12 months	Pneumonia at day 21:					
Conflict of interest/source of funding: not reported	Surgical group: 22.2% (4/18) Internal group:89.5% (17/19)					

Study details	Key efficacy findings		Key safety findings	Comments		
Voggenreiter G (1998) ²	Number of patients analysed: 42 (20 vs 22)		Mortality: Group 1: no deaths Group 2: 30% (3/10) of patients. 2 patients died	Follow-up issues:Loss to follow-up not		
Non-randomised comparative study Germany		Mean length of ventilator support (days)	from massive haemorrhage and 1 patients died septic multiorgan failure. Group 3: 38.9% (7/18) of patients. 4 patients	reported. Study design issues:		
Recruitment period: 1988–1994 Study population: patients with flail chest	Group 1: Surgical group without PC (n = 10)	6.5 ± 7.0*	died from head injury, 1 patient died from ARDS, 1 patient died from severe haemorrhage and 1 patient died from multiple organ failure.	Retrospective study		
with and without PC n = 42 (20 vs 22) Age: surgical group without PC: 52.2 years	Group 2: Surgical group with PC (n = 10)	30.8 ± 33.7	Group 4: 1 patient died from head injury. Sepsis:			
(mean), surgical group with PC: 50.4 years (mean), conservative group without PC: 44.2 years (mean and conservative group	Group 3: Conservative group without PC (n = 18)	26.7 ± 29.0	Group 1: 0 patients. Group 2: 30% (3/10) of patients. Group 3: 55.6% (10/18) of patients. Group 4: 1 patient.			
with PC: 47.8 years (mean) Sex: not reported	Group 4: Conservative group with PC (n = 4)	29.3 ± 22.5				
Patient selection criteria: indications for surgical stabilisation: flail chest with thoracotomy, flail chest without pulmonary contusion and severe head injury but with respiratory insufficiency, paradoxical movement of chest wall in weaning period from the respirator or severe deformity of chest wall (stove-in chest).	*p < 0.02 compared with <u>Pneumonia with further</u> Group 1: 1 patient Group 2: 40% (4/10) of Group 3: 27.8% (5/18) of Group 4: 50% (2/4) of p	disturbance of gas exchan patients of patients:	<u>ge</u> :			
Technique: surgical stabilisation using reconstruction plates or isoelastic rip clamps vs no surgical stabilisation (not otherwise described)						
Follow-up: not reported						
Conflict of interest/source of funding: not reported						

Study details	Key efficacy findings	Key safety findings	Comments
Study details Paris F (1975) ³ Non randomised comparative study Spain Recruitment period: 1969–1974 Study population: patients with severe flail chest	Key efficacy findings Not reported	Key safety findings Number of patients analysed: 29 (11 vs 10 vs 4 vs 4) Mortality: IPPR only: 73% (8/11). All patients in this group had multiple injuries and were deemed unsuitable for surgical stabilisation: 5 had brain injuries and 4 were in severe shock on admission. No other details relating to reason for deaths are given. IPPR + surgical stabilisation: 40% (4/10). All	Comments Follow-up issues: • Length and loss to follow-up is unclear.
n = 29 (11 IPPR vs 10 IPPR + surgical stabilisation vs 4 surgical stabilisation only vs 4 thoracotomy + surgical stabilisation) Age: not reported		patients in this group had multiple injuries. Two patients died in a coma from associated brain damage (the paradoxical movement of the chest wall had been relieved by the surgical stabilisation in both cases), 1 patient died due to ulcerative oesophagotracheal fistual and sepsis due to prolonged IPPR; and 1 patient died from an irreversible cardiac arrest at the time of anaesthesia induction.	
Sex: not reported Patient selection criteria: not reported Technique: intermittent positive pressure respiration [IPPR] vs IPPR+ surgical stabilisation using stainless steel struts vs surgical stabilisation only using stainless steel struts vs exploratory thoracotomy + surgical stabilisation using stainless steel struts. Follow-up: not reported Conflict of interest/source of funding: not reported		Surgical stabilisation only: 0% (0/4). None of these patients had multiple injuries. Thoracotomy + surgical stabilisation: 25% (1/4). One patient died from abdominal lesions.	

Study details	Key efficacy findings		Key safety findings	Comments
Lardinois D (2001) ⁴	Number of patients analysed: 66		30-day mortality: 10.6% (7/66) of patients. 4 patients died from ARDS and multiorgan failure due to	Follow-up issues:Loss to follow-up at
Case series Switzerland		Outcome (n = 66)	persistent pneumonia. These patients had delayed surgical stabilisation after 3 weeks of mechanical ventilation and failed to achieve adequate stabilisation	6 months: 3.4% (2/59) of surviving patients.
Recruitment period: 1990–1999	Median postoperative intubation time	2.1 days	of chest wall. 1 patient died from cerebral haemorrhage, 1 patient from infarction and 1 patient	Study design issues: Prospective study
Study population: patients with anterolateral flail chest (\geq 4 ribs fractured at \geq 2 sites)	Mean length of ICU stay	6.8 days	from refractory arrhythmia subsequent to a severe cardiac contusion.	
n = 66	Median length of hospital stay	17.4 days	Timing of these deaths is not reported.	Study population
Age: 52.6 years (mean)	Pulmonary function at 6	months	Complications during hospital stay: 18.2% (12/66) Of these:	 Associated haemothorax in 94% (62/66) of patients and pneumothorax
Sex: 84.8% (56/66) male		Outcome (n = 50)	Atelectasis and pneumonia of the ipsilateral lung 7.6% (5/66). Pneumonia successfully investigated and	
Patient selection criteria: see above	% normal	52% (26/50)	treated by bronchoscopy, mini-tracheotomy and antibiotics	in 86.4% (57/66) of patients identified by
Technique: surgical stabilisation using reconstruction plates and cancellous screws within	% with obstruction pattern	22% (11/50)	Acalculous cholecystitis: 4.5% (3/66) treated by cholecystectomy	chest X-ray at baseline. CT scan
median time of 2.8 days after admission.	% with restriction pattern (total lung	10%* (5/50)	Myocardial infarction: 3% (2/66) treated successfully with fibrinolysis	indicated 80.3% (53/66) had associated lung
Follow-up: 6 months	capacity <85% predicted)		Wound infections: 3% (2/66) at 10 and 13 days which required reoperation and debridement. Healing	contusion.
Conflict of interest/source of funding: not reported	% with obstruction and restriction pattern	16% (8/50)	achieved with drainage and antibiotics. Timing of complications is not reported unless	
	*all patients working full time without complaint		otherwise stated. Complications reported at follow-up:	
			Attenuated sensitivity of anterior chest wall: 7% (4/57).	
	No chest wall deformity of any surviving patients at follow-up.		Persistent pain at operative site: 10.5% (6/57). This improved in 3 patients after complete removal of plates and screws.	

Key efficacy findings		tudy details
Outcome (n = 23) 3.9 days 7.8 days n all patients at adiological up: 95.2%	Number of patients analy Mean postoperative intubation time Mean length of ICU stay Chest wall symmetrical in follow-up confirmed by ra evaluation. Return to work at follow- (20/21).	tudy details outon W (1997) ⁵ ase series witzerland ecruitment period: 1990–1996 tudy population: patients with flail chest = 23 ge: 52.2 years (mean) ex: 91.3% (21/23) male atient selection criteria: flail chest with respiratory sufficiency not responding to peridural analgesia in atients who did not require prolonged intubation
23) days days atients at jical .2% activity all or	(n = 3.9 c 7.8 c n all pa adiolog up: 95 ports a nest wa	(n =Mean postoperative intubation time3.9 cMean length of ICU stay7.8 cChest wall symmetrical in all pa follow-up confirmed by radiolog evaluation.Return to work at follow-up: 95.

Study details	Key efficacy findings	Key safety findings	Comments
Menard A (1983) ⁶	Number of patients analysed: 13	Number of patients analysed: 18	Follow-up issues:Loss to follow-up not reported.
Case series		Mortality: 27.8% (5/18). 1 patient died from	
_	<u>Timing of extubation (n = 13):</u>	cardiac arrest at the end of the procedure; 1	Study design issues:
France	Within 24 hours of procedure: 3 patients	patient died of respiratory failure with fever 24 hours after the procedure; 1 patient died of	Unclear if prospective or
Recruitment period: 1973–1979	Within first 8 days: 2 patients	gastrointestinal haemorrhage due to carcinoid	retrospective study.
	During third week: 7 patients	tumour of the duodenum on day 5; 1 died from	Study population issues:
Study population: patients with flail chest	At 68 days: 1 patient	diffuse bronchoalveolitis on day 11; and 1 patient	7 patients had intercostal
n = 18	Describer and a second sector of a sector of	committed suicide on day 15.	drainage for haemothorax,
11 = 16	Bronchopneumonia: 2 patients (both required reintubation).	Complications:	associated with pneumothorax in
Age: 48 years (mean)	(both required reintubation).	Septicaemia from a urinary tract infection caused	3 patients.Timing of procedure: 4 patients
Sex: 83.3% (15/18) male		by Pseudomonas aeruginosa: 1 patient	had procedure within 24 hours
		(extubation delayed)	because of associated ruptured
Patient selection criteria: indications for surgical		Regressive atelectasis: 2 patients.	spleen in 1 patient and open
stabilisation: pronounced paradoxical movement and /or fracture severely displaced (9 patients), painful		Diffuse bronchoalveolitis: 1 patient. Pleurisy (with a serohematic effusion) after	chest wound in 3 patients. 13
but unimportant paradoxical movement with		removal of intercostal tube: 1 patient (improved	patients had the procedure within the first week after injury and
imminent respiratory failure (2 patients), chronic		after repetitive intercostal drainage).	1 patient had the procedure at
bronchitis making prolonged ventilation undesirable		Persistent pulmonary infection: 2 patients	day 13 when the results of
(1 patient), surgeon proposed stabilisation while		(extubation delayed).	ventilation alone were
performing other procedures on patient (6 patients).		Transient wound infections at incision site: 2 patients (in 1 case intramedullary Kirschner	unsatisfactory.
Technique: surgical stabilisation using Judet struts.		wire had migrated and had to be removed).	
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Follow-up: not reported		Timing and treatment of complications not	
Conflict of interest/source of funding: not reported		reported.	
connict or interest/source of funding. not reported			

Study details	Key efficacy findings	Key safety findings	Comments
Hellberg K (1981) ⁷	Number of patients analysed: 10	Mortality: 30% (3 /10) of patients died. 1 patient died at day 20 from brain damage, sepsis and	Follow-up issues:
Case series	10	congestive heart failure; 1 patient died from	Loss to follow-up not reported.
	Surviving patients ventilated for	sepsis 2 days after pneumonectomy for	Study design issues:
Germany	5.4 days (mean) after the procedure.	empyema and lung abscess; and 1 patient died 4 days after the procedure (an autopsy of this	 Unclear if prospective or retrospective study.
Recruitment period: 1979–1981		patient indicated ischaemic heart disease with an old carotis interna occlusion with cerebral	Study population issues:
Study population: patients with flail chest		oedema).	 2 patients had type A chest flail
n = 10		Complications:	(anterior with uni-or bilateral fractures in the costochondral
Age: 17 66 years (range)		Myocardial infarction at 3 weeks: 1 patient	area), 3 patients had type B
Age: 17–66 years (range) Sex: 80% (8/10) male		(further course was uncomplicated).	(lateral) chest flail with segmenta
			serial fractures, 4 patients had type B chest flail with serial rib
Patient selection criteria: see above			fractures and 1 patient had a
Technique: surgical stabilisation using dynamic compression plates and screws			dislodged sternum fracture which led to respiratory insufficiency
Follow-up: not reported			
Conflict of interest/source of funding: not reported			

Efficacy

Lung function

A randomised controlled trial (RCT) of 37 patients (18 surgical stabilisation vs 19 internal pneumatic stabilisation) reported a significantly higher mean percentage of forced vital capacity (%FVC) at 12 months in the surgical group in comparison to the internal pneumatic compression group (96% vs 80%, p < 0.05) (%FVC values were read from graph by the IP analyst and are therefore approximate)¹.

A case series of 66 patients reported that 52% (26/50) of patients had a normal pulmonary function at 6-month follow- up^4 .

Length of postoperative ventilation

The RCT of 37 patients reported a significantly shorter mean period of mechanical ventilation in the surgical group in comparison to the internal pneumatic compression group (10.8 days vs 18.3 days, p < 0.05)¹.

A non-randomised comparative study of 42 patients (20 surgical stabilisation vs 22 no surgical stabilisation) reported a significantly shorter mean period of mechanical ventilation for patients without pulmonary contusion in the surgical group (n = 10) compared with patients with pulmonary contusion in the surgical group (n = 10) and patients without pulmonary contusion in the non-surgical group (n = 18) (6.5 days, 30.8 days and 26.7 days respectively, p < 0.02)².

The case series of 66 patients reported a median length of postoperative intubation of 2.1 days⁴. A case series of 23 patients reported a mean length of postoperative intubation of 3.9 days⁵. A case series of 10 patients reported a mean length of mechanical ventilation of 5.4 days in surviving patients⁷.

<u>Pneumonia</u>

The RCT of 37 patients reported a significantly lower proportion of patients with pneumonia at day 21 in the surgical group in comparison to the internal pneumatic compression group (22% [4/18] vs 89% [17/19], p < 0.05). Timing and treatment of pneumonia is not reported¹.

The non-randomised comparative study of 42 patients (20 surgical stabilisation vs 22 conservative treatment) reported 1 patient with pneumonia in patients without pulmonary contusion in the surgical group (n = 10), 4 patients with pneumonia in patients with pulmonary contusion in the surgical group (n = 10), 5 patients with pneumonia in patients without pulmonary contusion in the conservative group (n = 18) and 2 patients with pneumonia in patients

The case series of 66 patients reported 8% (5/66) of patients with atelectasis and pneumonia of the ipsilateral lung during their hospital stay. Pneumonia was investigated and treated successfully with bronchoscopy, mini-tracheotomy and antibiotics⁴.

A case series of 18 patients reported 2 patients with bronchopneumonia, both required re-intubation. Timing and treatment of bronchopneumonia is not reported⁶.

Length of stay in intensive care unit (ICU)

The RCT of 37 patients reported a significantly shorter mean length of stay in critical care in the surgical group in comparison to the internal pneumatic compression group (16.5 days vs 26.8 days, p < 0.05)¹.

The case series of 66 and 23 patients reported a mean length of stay in ICU of 6.8 days and 7.8 days respectively^{4,5}.

Return to employment

The RCT of 37 patients reported a significantly higher percentage of patients who had returned to full-time employment at 6 months in the surgical group in comparison to the internal pneumatic compression group (61% [11/18] vs 5% [1/19], p < 0.01)¹.

The case series of 23 patients reported that 95% (20/21) of surviving patients had returned to work at a mean follow-up of 28 months⁵.

Safety

Mortality

The non-randomised comparative study of 42 patients (20 surgical stabilisation vs 22 conservative treatment) reported no deaths in patients without pulmonary contusion in the surgical group (n = 10), 3 deaths (2 due to massive haemorrhage and 1 to septic multiorgan failure) in patients with pulmonary contusion in the surgical group (n = 10), 7 deaths (4 due to head injury, 1 to ARDS, 1 to severe haemorrhage and 1 to multiple organ failure) in patients without pulmonary contusion in the conservative group (n = 18) and 1 death (due to head injury) in patients with pulmonary contusion in the conservative group (n = 4). Timing of each death is not reported².

A non-randomised comparative study of 29 patients (11 IPPR vs 10 IPPR plus surgical stabilisation vs 4 surgical stabilisation only vs 4 thoracotomy plus surgical stabilisation) reported 73% (8/11) of patient in the IPPR only group died (length of follow-up and cause of death is not reported). 40% (4/10) of patients in the IPPR plus surgical stabilisation group died. In this group 2 patients died in a coma from associated brain damage (the paradoxical movement of the chest wall

IP overview: Insertion of metal rib reinforcements to stabilise a flail chest wall Page 12 of 26 had been relieved by the surgical stabilisation in both cases), 1 patient died due to ulcerative oesophagotracheal fistual and sepsis due to prolonged IPPR; and 1 patient died from an irreversible cardiac arrest at the time of anaesthesia induction. None of the 4 patients in the surgical stabilisation only group died. One of the 4 patients in the thoracotomy plus surgical stabilisation group died from abdominal lesions³.

The case series of 66 patients reported a mortality rate of 10.6% (7/66) at 30 days. Four patients died from adult respiratory distress syndrome (ARDS) and multiorgan failure due to persistent pneumonia. These patients had delayed surgical stabilisation after 3 weeks of mechanical ventilation failed to achieve adequate stabilisation of chest wall. One patient died from cerebral haemorrhage, 1 patient from infarction and 1 patient from refractory arrhythmia after a severe cardiac contusion⁴.

The case series of 23 patients reported a 30-day mortality rate of 9% (2/23). One patient died from refractory arrhythmia after heart contusion and 1 patient from ARDS and multiorgan failure due to persistent ipsilateral pneumonia and empyema. The latter patient had undergone delayed stabilisation after 3 weeks of mechanical ventilation had failed to consolidate the chest wall⁵.

The case series of 18 patients reported a mortality rate of 28% (5/18). One patient died from cardiac arrest at the end of the procedure. One patient died of respiratory failure with fever 24 hours after the procedure. One patient died of gastrointestinal haemorrhage due to carcinoid tumour of the duodenum on day 5. One died from diffuse bronchoalveolitis on day 11 and one patient committed suicide on day 15^6 .

The case series of 10 patients reported a mortality rate of 30% (3/10). One patient died at day 20 from brain damage, sepsis and congestive heart failure. One patient died from sepsis 2 days after pneumonectomy for empyema and lung abscess. One patient died 4 days after the procedure. An autopsy of this patient indicated ischaemic heart disease with an old carotis interna occlusion with cerebral oedema⁷.

<u>Sepsis</u>

The non-randomised comparative study of 42 patients (20 surgical stabilisation vs 22 conservative treatment) reported no patients with sepsis in patients without pulmonary contusion in the surgical group (n = 10), 3 patients with sepsis in patients with pulmonary contusion in the surgical group (n = 10), 10 patients with sepsis in patients without pulmonary contusion in the conservative group (n = 18) and 1 patient with sepsis in patients with pulmonary contusion in the conservative group (n = 4). Timing and treatment of sepsis is not reported².

The case series of 18 patients reported 1 patient with septicaemia from a urinary tract infection. Timing and treatment of septicaemia is not reported⁶.

IP overview: Insertion of metal rib reinforcements to stabilise a flail chest wall Page 13 of 26

Pain or discomfort requiring removal of metal plates

The case series of 66 patients reported that 11% (6/57) of patients had persistent pain at the operative site at 6-month follow-up. This improved in 3 patients after complete removal of stabilisation plates and screws⁴.

The case series of 23 patients reported that 24% (5/21) of patients had prolonged pain and discomfort at the stabilisation site at 3 months. This improved in 2 patients after complete removal of stabilisation plates and screws at 6 months⁵.

Validity and generalisability of the studies

- One RCT on this topic.
- Four of the included studies are more than 10 years old.
- A variety of different metal plates were used in the included studies, which may lead to differences in results.
- Studies that only use metal wire to stabilise flail chest were excluded.

Existing assessments of this procedure

The Eastern Association for the Surgery of Trauma in the United States published a practice management guideline for 'pulmonary contusion – flail chest' in June 2006. The guideline recommended that surgical fixation may be considered in severe unilateral flail chest or in patients requiring mechanical ventilation when thoracotomy is otherwise required⁸.

Related NICE guidance

There is currently no NICE guidance related to this procedure.

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr Eric Lim (British Thoracic Society), Mr John Edwards and Mr Sion Barnard (Society for Cardiothoracic Surgeons of Great Britain and Northern Ireland)

 One adviser performs the procedure regularly; one had performed it at least once and one has never performed this procedure or taken part in referral for this condition.

- Two advisers consider this to be a minor variation on an existing procedure and one adviser considers it to be a novel procedure with uncertain efficacy and safety.
- The comparators are standard stabilisation using suture fixation and conservative treatment (including ventilation, tracheostomy and analgesics).
- Two of the advisers state that fewer than 10% of specialists are engaged in this area of work.
- Theoretical adverse events: migration of metalwork, fracture of stabiliser, lung injury from stabiliser, screw loosening or separation and allergy.
- Anecdotal adverse events: fracture of the stabiliser, infection of metalwork.
- Efficacy outcomes: survival, length of ventilation, length of ICU stay, length of hospital stay, postoperative spirometry, long-term stabilisation of chest wall, pain, patient satisfaction and return to work.
- One adviser states that this procedure should be performed by or in conjunction with cardiothoracic surgeons, with or without support from trauma and orthopaedics (depending on the technique and familiarity of the cardiothoracic team).

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme were unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

• Future study: 'MatrixRIB implants for surgical stabilisation of flail chest injuries: a registry' (NCT00810251). The study started in December 2008 and aimed to enroll 20 patients and be completed in March 2010. The MatrixRIB system is the first implant system that has been specifically designed for fixation of flail chest injuries. Inclusion criteria: patients aged 21 to 80 years with monolateral or bilateral flail chest injury and paradoxical motion of the chest wall, whereby a flail chest is defined by 3 or more consecutive ribs broken in at least 2 locations. Patients' functional outcome to be assessed up to the standard follow-up visit 3 months after surgery.

References

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- 4. Lardinois D, Krueger T, Dusmet M et al. (2001) Pulmonary function testing after operative stabilisation of the chest wall for flail chest. European Journal of Cardio-Thoracic Surgery 20:496–501.
- 5. Mouton W, Lardinois D, Furrer M et al. (1997) Long-term follow-up of patients with operative stabilisation of a flail chest. Thoracic & Cardiovascular Surgeon 45:242–244.
- 6. Menard A, Testart J, Philippe JM et al. (1983) Treatment of flail chest with Judet's struts. J Thorac.Cardiovasc.Surg 86:300–305.
- 7. Hellberg K, de Vivie ER, Fuchs K et al. (1981) Stabilization of flail chest by compression osteosynthesis--experimental and clinical results. Thoracic & Cardiovascular Surgeon 29:275–281.
- Simon B, Ebert J, Bokhari F et al. (2006) Practice management guideline for "pulmonary contusion - flail chest". Charleston (SC): Eastern Association for the Surgery of Trauma (EAST) 1–74.

Appendix A: Additional papers on insertion of metal rib reinforcements to stabilise a flail chest wall

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up (FU)	Direction of conclusions	Reasons for non- inclusion in table 2
Teng J-P, Cheng YG., Ni D. et al. (2009) Outcomes of traumatic flail chest treated by operative fixation versus conservative approach. [Chinese]. Journal of Shanghai Jiaotong University (Medical Science) 29 (12):1495– 1498.	Non-randomised comparative study n = 60 (32 vs 28) Follow-up = 6 months	Mean time of hospital stay, ICU stay and mechanical ventilation was significantly shorter, and prevalence of chest wall deformity, pulmonary infection, pulmonary atelectasis and respiratory failure were significantly lower in operation group than those in non-operation group (p < 0.05). Inspiratory capacity, forced vital capacity, forced expiratory volume in one second, peak expiratory flow, total lung capacity and maximal midexpiratory flow were significantly higher in operation group (P < 0.05).	Only abstract available in English
Borrelly J, Aazami MH. (2005) New insights into the pathophysiology of flail segment: the implications of anterior serratus muscle in parietal failure. European Journal of Cardio-Thoracic Surgery 28:742-749.	Case series n = 127 FU = not reported (NR)	Hospital mortality: 8% when sliding staples struts used. 4 patients developed wound suppuration (treated with antibiotics)	Mainly using sliding staples struts
Di FD, Benetti D, Benvenuti M et al. (1995) [Surgical stabilization of post-traumatic flail chest. Our experience with 116 cases treated]. [Italian]. Minerva Chirurgica 50:227-233.	Case series n = 116 FU=NR	Judet struts, metal plates and wire used. Mortality: 20.6%	Only abstract in English
Galan G, Penalver JC, Paris F et al. (1992) Blunt chest injuries in 1696 patients. European Journal of Cardio-Thoracic Surgery 6:284-287.	Case series n = 29 flail chest (part of larger case series of 1696 chest injuries)	Stainless steel struts used. Mortality: 24% (7/29)	Larger studies in table 2 Procedures done in 1970s
Paris F, Tarazona V, Blasco E et al. (1975) Surgical stabilization of traumatic flail chest.	FU = NR Case series n = 18	3 different types of stainless steel struts and wire sutures used.	Larger studies in table 2

Article	Number of patients/follow-up (FU)	Direction of conclusions	Reasons for non- inclusion in table 2
Thorax 30:521-527.	FU = NR	Mortality: 28% (5/18)	Old study
Article	Number of patients/follow-up	Direction of conclusions	Reasons for non- inclusion in table 2
Reber P, Ris H-B, Inderbitzi R et al. (1993) Osteosynthesis of the injured chest wall: Use of the AO (Arbeitsgemeinschaft fur Osteosynthese) technique. Scandinavian Journal of Thoracic and Cardiovascular Surgery 27:137-142.	Case series n = 12 FU = 11 months (mean)	1 patient died from massive cardiac contusion. Mean intubation time: 3.7 days Mean time in intensive care: 7.3 days Mean length total hospitalisation: 31.5 days Airway infection: 38% 1 patient complained of stiffness in chest wall at 6 months and plates were	reported in Mouton 1997 in Table 2.
Salhiyyah K, Tilkerides , Davies M et al. (2009) Surgical stabilisation of posterolateral flail chest:normalisation of lung function. Abstract from Annual meeting of Society for Cardiothoracic Surgery in Great Britain and Ireland pg 142	Case series n = 7 FU = 3 months	removed. UK study Mean FEV1 at 3 months: 97% Mean FVC at 3 months: 99% Postoperative ventilation time: 3 hours (mean) Mean length ITU stay: 2 days Mean length hospital stay: 18 days Complications: Cellulitis: 1 patient Deep wound infection: 1 patient Elective tracheostomy: 1 patient Sputum retention: 1 patient At 3 months the 3 patients in employment preoperatively had returned to work	Larger studies in table 2 Conference abstract
Sanchez-Lloret J, Letang E, Mateu M et al. (1982) Indications and surgical treatment of the traumatic flail chest syndrome. An original technique. Thorac.Cardiovasc.Surg 30:294-297.	Case series n = 7 treated with surgical stabilisation (part of larger case series of 18 flail chest injuries) FU = NR	Stainless steel extraperiostal rib plaques designed by one of the authors used. Mortality: 0% and no complications. Mean hospital stay: 23.5 days compared to 29.4 days for those who did not receive surgical stabilisation.	Larger studies in table 2

Article	Number of patients/follow-up (FU)	Direction of conclusions	Reasons for non- inclusion in table 2
Engel C, Krieg JC, Madey SM et al. (2005) Operative chest wall fixation with osteosynthesis plates. Journal of Trauma-Injury Infection & Critical Care 58:181-186	Case report n = 3 FU = 1 year, 10 months and 6 months	Case 1: pelvic reconstruction plates contoured to chest wall and fixed with screws. Patient able to return to full-time employment 4 months after injury. Prominent hardware irritated the patient and was removed 6 months later. Case 2: mandibular plates fixed with locking head screws. Patient returned to full shift work 6 months after injury. Case 3: titanium plates fixed with cortical locking screws. Patient returned to full-time employment within 14 days. Prominent hardware along clavicle removed at 1 year although rib plates not removed.	Larger studies in table 2
Oyarzun JR, Bush AP, McCormick JR et al. (1998) Use of 3.5-mm acetabular reconstruction plates for internal fixation of flail chest injuries. Annals of Thoracic Surgery 65:1471-1474.	Case series n = 2 flail chest (plus 3 after elective chest wall reconstruction) FU = 3 and 8 years	Reconstruction plates fixed with cortical screws. Technique successful.	Larger studies in table 2
Thomas AN, Blaisdell FW, Lewis FR, Jr. et al. (1978) Operative stabilization for flail chest after blunt trauma. Journal of Thoracic & Cardiovascular Surgery 75:793-801.	Case report n = 2 (of a series of 4 patients) FU = 6 years and 20 days,	Case 1:Jergesen orthopaedic plates contoured to chest wall and fixed with wire. Mechanical ventilation fro 24 hours. No respiratory symptoms or chest pain at 6 years Case 2: Bilateral rub strutting performed. Patient died at day 20 from acute myocardial infarction, severe diffuse coronary artery disease ad ARDS.	Larger studies in table 2 Old study
Slater MS, Mayberry JC, Trunkey DD. (2001) Operative stabilization of a	Case report n = 1	Stabilisation with reconstruction plates and steel wire carried out 6	Larger studies in table 2

Article	Number of patients/follow-up (FU)	Direction of conclusions	Reasons for non- inclusion in table 2
flail chest six years after injury. Annals of Thoracic Surgery 72:600-601.	FU = 18 months	years after injury. After 18 months the patient was working full time with a significant improvement in dyspnea and pain free	

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non- inclusion in table 2
Haasler GB. (1990) Open fixation of flail chest after blunt trauma. Annals of Thoracic Surgery 49:993-995.	Case report n = 1 FU = 1 year	Struts and stainless steel wires used. Vital capacity 85% predicted and forced expiratory volume 115% of predicted at follow-up.	Larger studies in table 2
Cacchione RN, Richardson JD, Seligson D. (2000) Painful nonunion of multiple rib fractures managed by operative stabilization. Journal of Trauma - Injury, Infection and Critical Care 48:319- 321.	Case report n = 1 FU = 6 months	Stabilisation with reconstruction ribbon plates fixed with screws conducted 2 years after injury. Patient in minimal pain with improved shortness of breath and complete rib union at follow-up.	Larger studies in table 2
Landreneau RJ, Hinson JM, Jr., Hazelrigg SR et al. (1991) Strut fixation of an extensive flail chest. Annals of Thoracic Surgery 51:473-475.	Case report n = 1 FU = 7 weeks	Road arches and orthopaedic external fixation devices used. Apparatus removed 7 weeks after insertion under mild sedation and patient's rehab progressed to independence at home with minimal support.	Larger studies in table 2
Dunlop RL, Tiong W, Veerasingam D et al. (2010) Novel use of hand fracture fixation plates in the surgical stabilisation of flail chest. Journal of Plastic, Reconstructive & Aesthetic Surgery: JPRAS 63:e51–e53.	Case report n= 1 FU = 4 weeks	36 year old male with eight rib flail segment following a compression injury. Patient underwent surgical fixation using hand fracture fixation plates from the Leibinger mini-plate system 7 days after injury. Patient discharged on day 19 following uneventful wound healing and reported minimal residual pain or movement of flail segment and had excellent shoulder mobility at 4 weeks.	Larger studies in table 2
Carbognani P, Cattelani L, Bellini G et al. (2000) A technical proposal for the complex flail chest. Annals of Thoracic Surgery 70:342-343.	Case report n = 1 FU = 15 days	50 cm steel bar moulded to chest wall and fixed with non-absorbable stitches and stabilised with Judet devices. Patient discharged at 15 days.	Larger studies in table 2

Appendix B: Related NICE guidance for insertion of metal rib reinforcements to stabilise a flail chest wall

There is currently no NICE guidance related to this procedure.

Appendix C: Literature search for insertion of metal rib reinforcements to stabilise a flail chest wall

Database	Date searched	Version/files
Cochrane Database of	24/05/2010	May 2010
Systematic Reviews – CDSR		
(Cochrane Library)		
Database of Abstracts of	24/05/2010	-
Reviews of Effects – DARE		
(CRD website)		
HTA database (CRD website)	24/05/2010	-
Cochrane Central Database of	24/05/2010	May 2010
Controlled Trials – CENTRAL		
(Cochrane Library)		
MEDLINE (Ovid)	24/05/2010	1950 to May Week 2 2010
MEDLINE In-Process (Ovid)	24/05/2010	May 21, 2010
EMBASE (Ovid)	24/05/2010	1980 to 2010 Week 20
CINAHL (NLH Search 2.0)	24/05/2010	-
BLIC (Dialog DataStar)	19/01/2010	-
Zetoc	24/05/2010	-

Websites	Date searched	Title, year and link
NICE ('published' and 'in development' guidance)	21/01/2010	Related: <u>IPG310: Placement of pectus bar for</u> <u>pectus excavatum (Nuss procedure)</u> <u>(August 2009)</u>
Notification and specialist advisors papers	21/01/2010	No additional information found
FDA (MAUDE database)	21/01/2010	Summary of safety and probable benefit: Prosthetic Rib Synthes Vertical Expandable Prosthetic Titanium Rib (VEPTR)
ASERNIP	21/01/2010	Management of chest trauma
ANZHSN	21/01/2010	No information found
Cochrane reviews (CDSR)	21/01/2010	No information found
National Institute for Health Research Clinical Research	21/01/2010	No information found

Notwork Coordinating Contro (NILLD		
Network Coordinating Centre (NIHR CRN CC) Portfolio Database		
Current Controlled Trials <i>meta</i> Register of Controlled Trials - <i>m</i> RCT	21/01/2010	No additional information found
Clinicaltrials.gov	21/01/2010	MatrixRIB Implants for Surgical Stabilization of Flail Chest Injuries: A Registry (NCT00810251)Trial of Operative Fixation of Fractured Ribs in Patients With Flail Chest (NCT00298259)Clinical Study of the U-Plate Fracture Repair System to Treat Rib Fractures (NCT00556543)
		Evaluation of the RibLoc ™ Device in the Treatment of Pain and Disability for Chronic, Non- healing Rib Fracture (NCT00774618)
Conference websites	21/01/2010	Surgical Stablisation Of Posterolateral Flail Chest: Normalisation of Lung Function. Salhiyyah, K. et al. Annual Meeting Society for Cardiothoracic Surgery in Great Britain and Ireland, March 2009, Abstract 107
General internet search	21/01/2010	<u>Flail Chest (eMedicine) 2009</u> <u>Surgical stabilization of severe flail</u> <u>chest. Casali, C. et al, CTSNet, 2005.</u>

MEDLINE search strategy

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	Flail Chest/
2	(flail adj3 chest).tw.
3	Rib Fractures/
4	(multi* adj3 rib* adj3 fract*).tw.

IP overview: Insertion of metal rib reinforcements to stabilise a flail chest wall Page 25 of 26

5	(paradox* adj3 chest* adj3 wall*).tw.
6	or/1-5
7	Bone Plates/
8	Bone Screws/
9	Bone Wires/
10	Bone Nails/
11	Titanium/
12	(metal* adj3 (plate* or screw* or nail* or clip* or ribbon* or bar* or bridge* or implant*)).tw.
13	Thoracic Surgical Procedures/
14	Reconstructive Surgical Procedures/
15	Fracture Fixation/
16	((surg* or fract* or rib* or thora*) adj3 (stabili* or reconstruct* or support* or reinforce* or fix* or repair* or manage* or insert*)).tw.
17	or/7-16
18	6 and 17
19	Animals/ not Humans/
20	18 not 19