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ORIGINAL ARTICLE

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Functional results after chest wall stabilization with a new screwless fixation device

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Abstract

OBJECTIVES: This is the experience with the Stratos system in two surgical centres for the management of two types of rib fractures: flail chest and multiple dislocated rib fractures with significant chest wall deformity.

METHODS: From January 2009 to May 2012, 94 consecutive patients were included. Selected indications were extended anterolateral 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 postoperative course was assessed. Clinical and functional outcomes were evaluated at 6 months. Functional assessment consisted of measurement of the functional vital capacity (FVC) and magnetic resonance imaging (MRI) examination with determination of the radiological vital capacity (rVC) in patients with a flail chest.

RESULTS: The median operation time and length of hospital stay were 122 min and 19 days, respectively, in patients with a flail chest, and 67 min 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. MRI 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: 83, 100). Stabilization of more than four ribs was associated with a lower median rVC than stabilization of four or less ribs.

CONCLUSIONS: Our results suggest 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.

Keywords: Chest wall • Trauma • Surgery techniques • Outcome • Imaging

INTRODUCTION

Blunt chest wall trauma is commonly associated with rib fractures [1–3]. The number of consecutive fractured ribs has been found to be an independent marker of injury severity, resulting in increased morbidity and mortality, particularly in the elderly [1, 4, 5]. Flail chest injuries are observed in about 10% of chest wall trauma and are associated with a high mortality rate of 10–36%, partly due to the high incidence of associated life-threatening extrathoracic injuries, but also because of pneumonia and sepsis related to prolonged intubation [1–6]. Surgical management of a flail chest is still controversial and there are no large adequate prospective randomized trials comparing conservative and surgical management [1, 4, 7]. However, several studies and reports have clearly indicated that operative chest wall stabilization for a flail chest in highly selected patients leads to a shorter duration of ventilation support and, consequently, to a reduced morbidity due to prolonged mechanical ventilation, considerably less infections and septicaemia as well as to a shorter intensive care unit (ICU) stay [8–10]. Moreover, stabilization does not seem to be associated with restriction of pulmonary function [4, 11]. A review of nine published studies, regarding a more recent indication for chest wall stabilization in patients without a flail chest, but with consecutive dislocated and painful rib fractures, suggested that open reduction internal fixation (ORIF) of isolated multiple rib fractures improves outcome in terms of pain reduction, respiratory function, quality of life and allows a shorter recovery period [12]. Patients with anterolateral dislocations are particularly prone to develop late restriction and pseudarthrosis, leading to partial or complete functional incapacity [4, 6, 7]. The incidence of pseudarthrosis is certainly under-reported and the consequences are underestimated [1, 13, 14]. To prevent short- and long-term morbidity of multiple dislocated painful rib fractures, several centres have initiated stabilization procedures in selected patients [12, 15–17]. The present study was designed to first assess the feasibility and the complication rate of chest wall stabilization using a new screwless rib fixation device (Stratos™, MedXpert, Heitersheim, Germany) for several indications in selected patients in two centres. The second intention of the study was to assess the functional lung capacity and the mobility of the chest wall after ORIF in the subgroup of patients with a flail chest. The ethics committees of both hospitals provided approval for this study. This was an investigator-initiated study with funding support from MedXpert, Germany.

PATIENTS AND METHODS

Patients

From January 2009 to May 2012, 94 selected patients underwent chest wall stabilization using the new screwless fixation device from Stratos™ (Strasbourg Thoracic Osteosynthesis System, MedXpert) in two thoracic centres, the POVISA Hospital of Vigo, Spain (50 patients) and the University Hospital of Basel, Switzerland (44 patients). Patients with an indication for surgical fixation could be divided into those with extended flail chest (68 of 94, 72%) and those without a flail chest (26 of 94, 28%). In patients with a flail chest, indications were as follows: non-intubated patients with respiratory failure despite continuous epidural analgesia and aggressive clearance of bronchial secretions (n = 16, 24%); patients with an extended anterolateral flail chest and progressive dislocation of the fractured ribs (n = 27, 40%); intubated patients who did not require prolonged intubation in the absence of severe pulmonary contusion or cerebral injuries, in order to reduce the use of mechanical ventilation when the patient failed to wean (n = 19, 28%); and patients who required a thoracotomy or thoracoscopy due to associated extended haemothorax (n = 6, 9%). The group of patients without a flail chest consisted of multiple severe dislocated and therapy-refractory painful rib fractures, particularly in young athletic patients or in old patients living alone and requiring a prompt recovery.

Twenty patients were women (21%) and 74 were men (79%), with a mean age at operation of 55 years, ranging from 22 to 88 years. Fifty-five patients (59%) had motor vehicle accidents, 20 patients (21%) were injured at work or during sports activities, and 19 patients (20%) fell at home. Associated injuries were observed in 72 patients (77%) and consisted of orthopaedic lesions, head injuries and abdominal lesions. Of the 68 patients with a flail chest, 20 (29%) were intubated before or upon admission, due to respiratory insufficiency, associated cerebral injuries or hypovolemic shock. Chest trauma was unilateral in 97% (91 of 94 patients) and bilateral in 3% of the patients (3 of 94 patients). In patients with a flail chest, the median number of fractured ribs was 8, ranging from 6 to 11.

Surgical technique and postoperative follow-up

The new screwless Stratos device consists of flexible titanium rib clips and connecting bars [16]. Because of the excellent pliability of titanium, the rib clips and connecting bars can easily and precisely be adapted to the shape of the ribs. The implants will rebound minimally after bending so that the material can be anchored tightly to the chest wall and resist against loosening. In the case of a flail chest, one complete implant consists of two rib clips that are either straight or angular (22.5° or 45° types) and a connecting bar to overbridge the unstable segment. The three different angulations of the rib clips can be adapted to any anatomical situation by means of bending instruments and cover a maximum range of −12° up to 57° (Fig. 1A). Dislocated rib fractures can also be stabilized by simple rib clips without connecting bars (Fig. 1B). Several straight or angled forceps can be used to shape and fixate the titanium implants onto the ribs. The same system can be used for reconstruction of the chest wall after partial resection and for correction of sternal deformities. In patients with a flail chest, ORIF was performed through an extended lateral approach. In patients without a flail chest, the skin incision was shorter and made just over the fractures. Through this single incision, it was possible to stabilize up to five ribs. Care was taken to avoid increasing injury of the contused soft tissue. The serratus anterior muscle was dissected and divided at its insertion on the chest wall in patients with a flail chest or divided within its fibres in patients with dislocated rib fractures. This technique provided a good exposure of the consecutive fractured ribs without causing extensive muscle damage. Care was

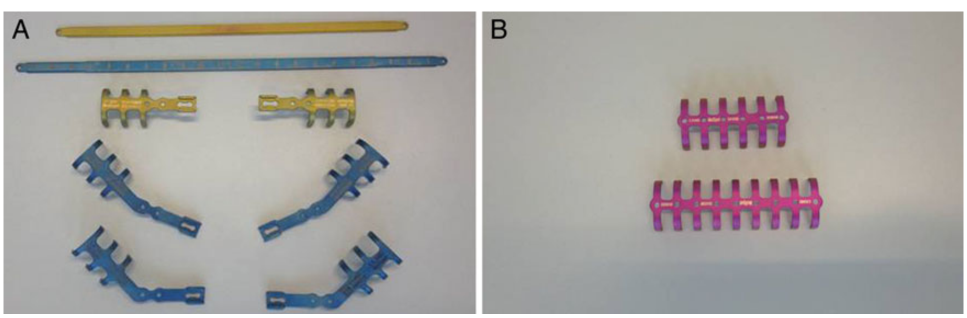

Figure 1: (**A**) The new screwless Stratos device consists of flexible titanium rib clips and connecting bars. This system is used for chest wall stabilization in patients with a flail chest. (**B**) Simple rib clips without connecting bars can be fixed to the ribs by grasping in patients with dislocated painful fractures.

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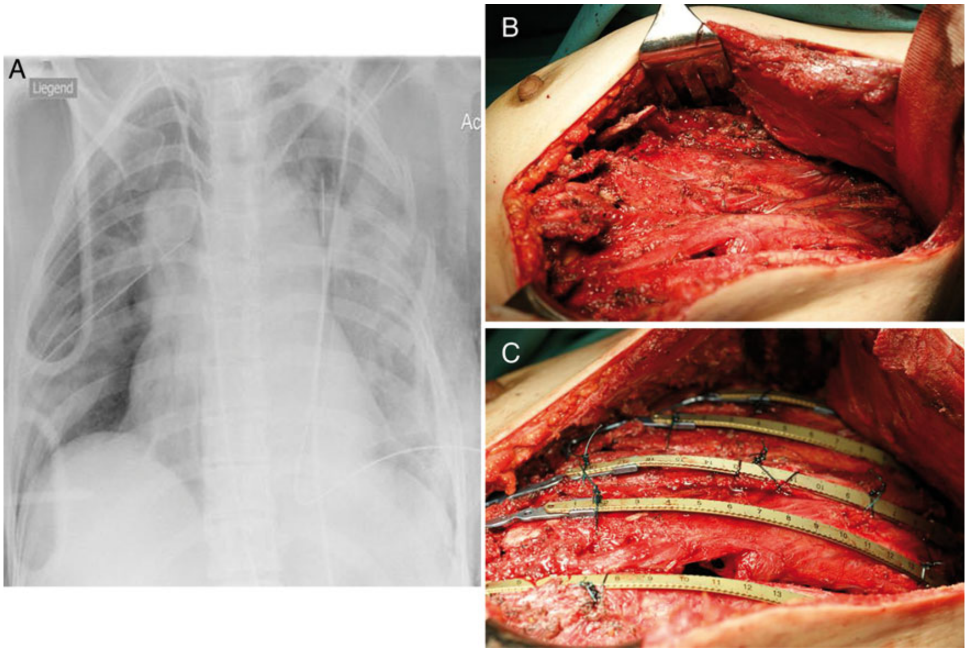

Figure 2: (**A**) Chest X-ray after a severe blunt chest trauma showing bilateral dislocated rib fractures and a left haemothorax. An extended flail chest was diagnosed on the left side. (**B**) Intraoperative situs with severe dislocated rib fractures and impaction of the unstable segment. (**C**) Left chest wall after stabilization showing the rib clips and the connecting bars. The chest wall is well-shaped, avoiding postoperative restriction.

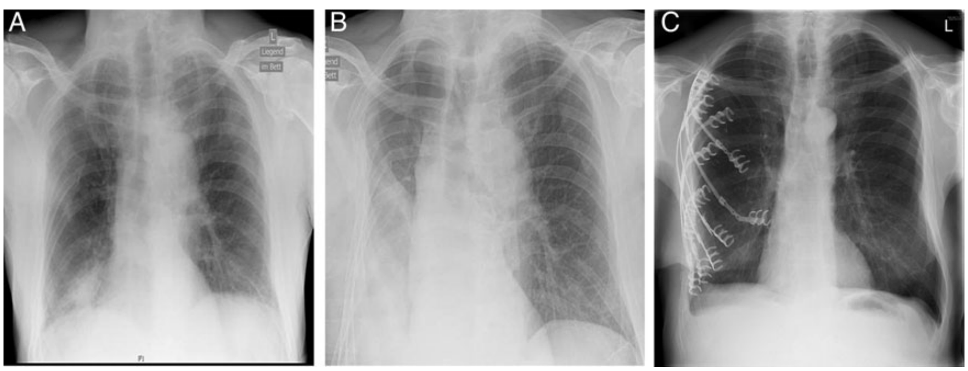

Figure 3: (**A**) Chest X-ray with dislocated rib fractures on the right side. The patient received analgesia with epidural catheter and was transferred to the normal ward. (**B**) Progressive shrinkage with reduction of the volume of the right hemithorax. The patient developed acute respiratory insufficiency. He was transferred to the intensive care unit and was intubated. (**C**) Chest X-ray after ORIF showing a well-shaped right hemithorax.

taken not to strip the periostium from the ribs and to prevent injury of the intercostal neurovascular bundle at the inferior margin of the rib. In patients with a flail chest, rib clips were first fixed medially and dorsally to the unstable segment. A connecting bar was then shaped and fixed to the rib clips while the lung was ventilated by the use of high tidal volumes in order to prevent operation-related restriction. The unstable part of the rib was fixed to the connecting bar by the use of a resorbable thread of Vicryl® (Ethicon) (Figs 2 and 3). In patients without a flail chest, only titanium rib clips were used without connecting bars. The fractures were reduced and stabilized with a minimum of three clips on each side of the fracture line (Fig. 4). Only the most dislocated ribs were stabilized. The first two ribs were not operated to avoid injury of the subclavian vessels and the brachial plexus.

The postoperative course of all patients was prospectively assessed. For all patients, key data consisting of the number of stabilized ribs, operation time, duration of postoperative intubation, length of hospital stay, morbidity and mortality were recorded. At 6 months following surgery, patients were clinically examined. The clinical evaluation included a subjective assessment of residual pain or discomfort of the chest wall and shoulder girdle, and was followed by an examination of the chest wall and shoulder girdle function. Functionality of the stabilized chest was assessed by lung function tests and by a dynamic magnetic resonance imaging (MRI) examination. MRI was only considered in the group of 68 patients with flail chest.

Six-month pulmonary function testing

We used functional vital capacity (FVC) in the evaluation of a possible postoperative restriction. A restriction was noted if the measured FVC was <80% of the predicted value [18].

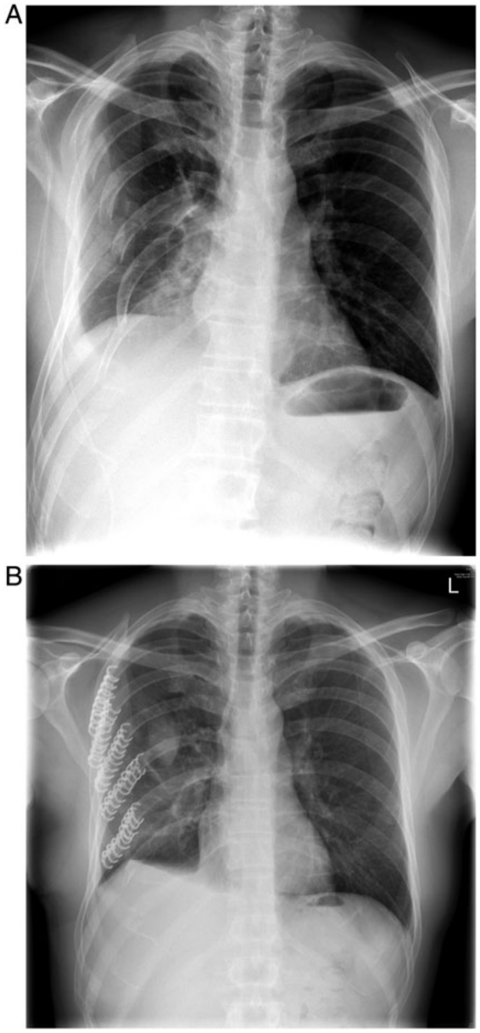

Figure 4: (**A**) Vehicle accident with dislocated rib fractures 4 → 11 on the right side. Despite analgesia with epidural catheter, the patient was unable to move and to cough. (**B**) Chest X-ray after stabilization using simple rib clips. The patient was discharged from the hospital 6 days after the operation.

Six-month magnetic resonance imaging examination

MRI exams were performed with a magnetic flux density of 1.5 T. A half-Fourier acquisition single-shot turbo spin echo sequence was acquired in the axial and coronal plane at inspiration and expiration with a slice thickness of 10 mm and no inter-slice gap covering the entire thorax. All MRI findings were centrally interpreted at the University Hospital of Basel by two experienced radiologists familiar with thoracic examinations. The endpoint of this analysis was the measured radiological vital capacity (rVC) on the operated side relative to the target rVC on the operated side. We derived the target rVC from the non-operated side by measuring the total volume of each side of the lung during maximal inspiration [radiological total lung capacity (rTLC)] and during maximal expiration [radiological residual volume (rRV)]. The difference between rTLC and rRV was defined as the rVC (Fig. 5). Measurements were performed by manual tracing of the lung contour on each slice, for the right and left lung and by automatic calculation of the volume based on these measurements. The comparison of both sides was performed under the assumption that, in a healthy adult, the distribution of the total lung volume [18] and of the rVC is 55% on the right side and 45% on the left side. In addition, we assumed that the stabilization of one side of the chest wall does not influence the mobility of the other side 6 months after surgery, when post-taumatic recovery is assumed to be established.

The following patients were excluded from the analysis: patients with no consent and lost to follow-up, claustrophobia, pregnancy, immobility and bilateral chest wall stabilization and contraindications for MRI like metallic implants, pacemaker and old types of tattoo.

Statistical analyses

To assess the rVC of the operated compared with the non-operated side, we calculated a two-sided 95% confidence interval (CI) for the mean rVC of the operated side relative to its target value (derived from the non-operated side) (rVC %). We also report results of a sensitivity analysis with logarithm-transformed rVC % to achieve a better approximation to normality. The resulting CI on the logarithmic scale was then transformed back to the original units, resulting in a CI for the geometric mean.

In an additional analysis, we describe functional results for patients with four or less stabilized ribs and for those with more than four stabilized ribs.

We used R version 3.1.0 (R Foundation for Statistical Computing, Vienna, Austria) and the R add-on package *lattice* version 0.20–29 for our analyses and for graphics.

RESULTS

Baseline and procedure characteristics of the 33 patients with a flail chest and unilateral chest wall stabilization, included in the analysis of the rVC %, and of the 35 patients with a flail chest but no MRI or bilateral chest wall stabilization, excluded from this analysis, are provided in Table 1. In the 68 patients who underwent stabilization for a flail chest, the median time from admission to stabilization of the chest wall was 3.4 days (range, 0–17 days). The median operation time in this group was 122 min, ranging from 70 to 205 min, and the median length of hospital stay was 19 days, with a range of 4–84 days. In the 26 patients who underwent stabilization for persistent dislocated and painful rib fractures, the median operation time was 47 min, ranging from 28 to 95 min, and the median length of hospital stay was 11 days, with a range of 3–74 days. The overall 30-day mortality rate was 1.1%. The patient who died underwent stabilization for a flail chest. The mortality rate in this group was 1.5% (1 of 68 patients). The patient who died was a 76-year old polytrauma patient who had undergone stabilization for a flail chest. Several operations were required, which prolonged the intubation period and delayed operative stabilization. Postoperative complications were observed in 6 patients, all of whom were in the flail chest group (6/68, 9%). These complications included pneumonia of the ipsilateral lung in 4 patients and wound infection in 2 patients. All 4 patients with postoperative pneumonia recovered after treatment combining bronchoscopic removal of secretion and antibiotics. In the 2 patients with infection, partial removal of the ORIF material was required 9 and 12 days after chest wall stabilization. These patients were diabetics and underwent a severe trauma with extended contusion of overlying soft tissue. Fortunately, the extent of the infection in the chest wall was well localized and only partial

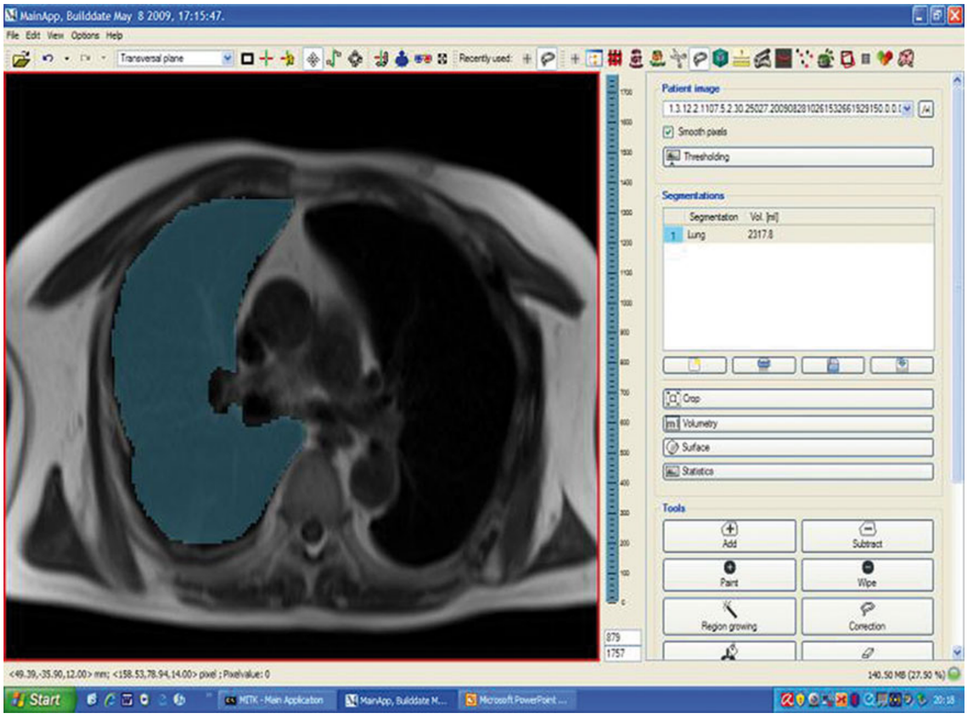

Figure 5: MRI examination: primary endpoint consisting of determination of the radiological vital capacity on the operated right side (difference between radiological total lung capacity and radiological residual volume).

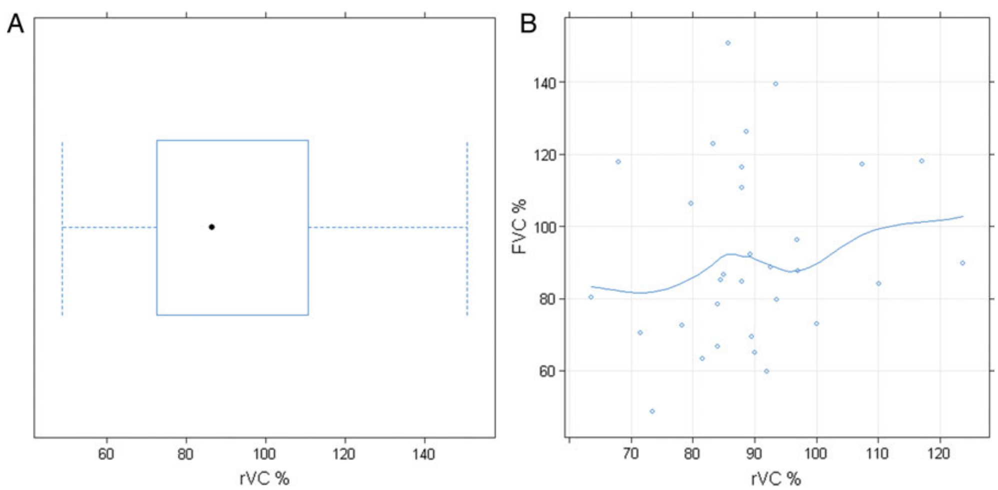

Figure 6: (**A**) Radiological vital capacity (rVC) of the operated side relative to its target value as derived from the non-operated side (rVC %) (n = 33). (**B**) Radiological vital capacity of the operated side relative to its target value as derived from the non-operated side (rVC %) against the ratio of the forced vital capacity (FVC %) for patients with a flail chest included in the main analysis and with an FVC % measurement available (n = 31). The smooth curve is a local average found using the default loess smoother in the R add-on package *lattice* version 0.20–29.

removal of the material was required, assuring further stability. Healing was achieved with drainage and antibiotics.

The six-month follow-up for clinical evaluation and pulmonary function testing was obtained in 75 of 93 surviving patients (81%), including 56 patients with a flail chest and 19 patients with dislocated and painful rib fractures. Nineteen patients were lost to follow-up or did not consent to further evaluation. In our clinical set-up, we did not observe any delayed fracture healing, including the 2 patients who had wound infections. We did not notice any mechanical fatigue of the ORIF material and we only partially removed the ORIF material in 2 cases of local wound infection. Attenuated sensitivity of the anterior chest wall was noted in 9% of the patients (8/93), all of whom initially suffered from a flail chest. Thirteen patients reported feeling persistent pain and rigidness on the operated side following surgery. All these patients had been operated for a flail chest (13 of 67, 19%). Shoulder girdle function

Table 1: Baseline and procedure characteristics of patients with a flail chest and those with painful and dislocated rib fractures

	Flail chest		Painful and dislocated rib fractures
	MRI and unilateral chest wall stabilization (n = 33)	No MRI or bilateral chest wall stabilization (n = 35)	No MRI foreseen (n = 26)
Baseline characteristics			
Study centre, n (%)			
Basel, Switzerland	19 (58)	14 (40)	11 (42)
Vigo, Spain	14 (42)	21 (60)	15 (58)
Median age (IQR), years	57 (45, 68)	52 (44, 67)	52 (47, 68)
Female gender, n (%)	5 (15)	8 (23)	7 (27)
Side, n (%)			
Left	11 (33)	16 (46)	11 (42)
Right	22 (67)	16 (46)	15 (58)
Both sides	0 (0)	3 (9)	0 (0)
Trauma, n (%)			
Fall	14 (42)	6 (17)	10 (38)
Traffic	18 (55)	26 (74)	11 (42)
Other	1 (3)	3 (9)	5 (19)
Median number of fractured ribs (IQR)	8 (6, 10)	8 (7, 12)	6 (5, 10)
Preoperative mechanical ventilation, n (%)	13 (39)	20 (57)	5 (19)
Procedure characteristics			
Median number of stabilized ribs (IQR)	4 (3, 5)	4 (4, 7)	4 (2, 5)
Median length of hospital stay[a] (IQR), days	17 (10, 29)	22 (16, 33)	11 (7, 20)
30-day mortality, n (%)	0 (0)	1 (3)	0 (0)

Patients with a flail chest were further subdivided into patients with MRI and unilateral chest wall stabilization and those with no MRI or bilateral chest wall stabilization.
MRI: magnetic resonance imaging; IQR: interquartile range.
[a]Available in 32 (97%), 33 (94%) and 26 (100%) patients with MRI and unilateral chest wall stabilization, with no MRI or bilateral chest wall stabilization and painful dislocated rib fractures, respectively.

was symmetrical in 66 patients (88%), whereas in 9 patients abduction of the ipsilateral shoulder was limited to 90°. These patients also had associated injuries of the ipsilateral shoulder girdle. Chest wall deformity was observed in none of the patients. Radiological evaluation at follow-up showed no dislocation of the material in any of the patients. Pulmonary function testing 6 months following surgery revealed a median ratio of the FVC of 88% [interquartile range (IQR): 79, 95; range, 61, 124], suggesting that ORIF was not associated with postoperative restriction in the majority of patients.

Six-month magnetic resonance imaging results

Of the 68 patients who underwent chest wall stabilization for a flail chest, 36 patients (53%) underwent MRI. Thirty-two patients were initially excluded due to the criteria mentioned above and did not undergo MRI. Three additional patients who underwent MRI were excluded from the main analysis due to bilateral chest wall stabilization. Overall, there were no apparent differences between patients with a flail chest included in the main analysis and those excluded from this analysis (Table 1).

The MRI showed no paradoxical chest wall movement. The analysis of the rVC of the operated side relative to its target value as derived from the non-operated side (measurement and comparison of the lung volume on both sides) yielded a median of 87% (IQR: 73, 111) (Fig. 6). The mean rVC % was 92% (95% CI: 83, 100).

The sensitivity analysis with logarithmic transformation of the rVC % yielded results comparable with those from the main analysis, with a geometric mean rVC of the operated side relative to its target value as derived from the non-operated side of 89% (95% CI: 81, 97).

In an additional analysis, we assessed the rVC % separately for patients with stabilization of up to four ribs (n = 22) versus those with stabilization of more than four ribs (n = 11). We found a higher median rVC % in patients with stabilization of up to four ribs compared with those with stabilization of more than four ribs [88% (IQR: 79, 110) vs 80% (IQR: 71, 98)].

Correlation between magnetic resonance imaging and pulmonary function

Finally, a scatter plot of the rVC of the operated side relative to its target value as derived from the non-operated side against the ratio of the FVC revealed a modest correlation, with a Spearman rank correlation coefficient of 0.21 (Fig. 6B).

DISCUSSION

The goals of surgical chest wall stabilization are a preservation of chest wall mechanics and lung function [19]. ORIF might theoretically lead to a rigidity of the chest wall. However, it has been shown that chest wall stabilization with reconstruction plates does not lead to impaired postoperative pulmonary function [4]. These results are confirmed in our study with the Stratos™ material. Lung function tests analysing the FVC at 6 months following surgery revealed no restriction, not only in the whole series of patients, but also in the subgroup of 56 patients who suffered from more severe chest wall injuries and extended flail chest [median FVC: 86% (IQR: 79, 93; range, 61, 124)]. Studies indicate that both FVC and total lung capacity (TLC) measurements are equally suitable for evaluation of pulmonary restriction [18]. In this study, we have chosen the FVC since spirometry is easier to perform during follow-up.

Our aim was to investigate the functional results following stabilization in greater detail than with simple lung function testing. The reason for this additional analysis is that patients who undergo rib stabilization often describe a feeling of heaviness, comparable with wearing a corset, on the operated side. MRI examination was performed in a subgroup of 33 patients with extended injury of the thorax and a severe flail chest. The analysis of the rVC of the operated side in comparison with the non-operated side seems to exclude a clinically relevant restriction due to stabilization.

A further analysis was then performed to evaluate if the number of stabilized ribs is associated with the mobility of the chest wall. In our series, the median number of stabilized ribs was 4. This number was arbitrarily chosen as a threshold for this evaluation. The measurement of rVC % showed a potential tendency to restriction in the subgroup of 11 patients with more than four stabilized ribs with a median rVC % of 80 compared with 88% in the subgroup of patients with four or less stabilized ribs. In the 13 patients presenting with a feeling of rigidity on the operated side, there was no difference in the number of stabilized ribs. Although this analysis was purely descriptive and the subgroups were small, these results are an important suggestion that stabilization of all fractured ribs is not necessary to obtain a good lung capacity and that ORIF of a large number of ribs might lead to a relative functional stiffness of the chest wall [1, 20, 21]. However, patient discomfort seems to be rather caused by the severity of the trauma than by the operation itself. This observation was already mentioned in previous studies, revealing that the feeling of stiffness was frequently encountered in patients with severe thoracic injuries who did not undergo stabilization [4]. In this respect, we do not advise the removal of the fixation device when patients complain of residual chest wall discomfort.

This study shows that the use of the Stratos™ device in two centres with extensive experience is practicable and associated with a very low complication and morbidity rate. In our study, we had no dislocation of the material. An important point is the possibility to obtain a stable ORIF without devascularizing the pericostal structures. In 2 patients, partial removal of the ORIF material was required 9 and 12 days after chest wall stabilization due to infection. These patients were diabetics and underwent a severe trauma with extensive soft-tissue contusion. Fortunately, the extent of the infection to the chest wall was well localized and only partial removal of the material was required, assuring further stability. The in-hospital mortality rate of the entire series of patients was 1.1%. The patient who died suffered from an extended flail chest. The mortality in this group was 1 of 68 (1.5%) patients, which is relatively low compared with other reports (up to 12% after stabilization) [1, 4, 8, 21]. We are aware that the population of patients included in this study is relatively heterogeneous and consists not only of patients with a flail chest. We agree that therapy for rib fractures should be conservative in most cases; of note, out of about 300–400 patients annually treated in our hospital for serial rib fractures, there were approximately 80 patients with a flail chest and only a small percentage of patients were stabilized by ORIF, but we think that indications for stabilization should not be restricted to selected patients with an unstable chest wall. Severe dislocated and painful rib fractures are frequently accompanied by a significant limitation of functional capacity and are often associated with an incapacity to work and social impairments [12, 15]. In addition, young athletes could benefit from early chest wall stabilization, since this form of operative therapy could allow them to continue training as soon as possible following surgery. Furthermore, older patients with a good quality of life, who are living alone could also benefit from early stabilization, since they often need to recover as rapidly as possible, so that they can continue to be active and independent. The low morbidity observed with the Stratos™ material in our study might justify the use of this system for such 'lesser-known' indications for chest wall stabilization.

We are planning a randomized controlled study to evaluate if rib stabilization for dislocated painful fractures with the Stratos™ system is associated with less analgesia, a faster recovery and an earlier return to normal activities than conservative therapy.

In conclusion, our study shows that chest wall stabilization with the screwless fixation device Stratos™ can be performed easily, safely and in a manner that conserves tissue. The same device not only allows stabilization of an extended flail chest, but also of severe dislocated or painful rib fractures. In patients with a flail chest, our results suggest that chest wall stabilization with this device does, on average, not lead to impaired postoperative pulmonary function or to a functional restriction as measured by MRI. ORIF of all fractured ribs is most likely not necessary to obtain good cosmetic and functional results. Mobility of the chest wall might be reduced after stabilization of a high (>4) number of ribs. These results reinforce our opinion that surgical chest wall stabilization has a place in the multimodal therapy for a flail chest. If we consider that operative stabilization may provide better cosmetic results and considerable savings due to a reduction in the use of ICU and general hospital resources when compared with conservative therapy in selected cases, while preserving pulmonary function and quality of life, chest wall stabilization might be underutilized [22].

Conflict of interest: none declared.

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