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Sternal closure with titanium plate fixation — a paradigm shift in preventing mediastinitis☆

Jai Raman[a,*], David H. Song[a], Gil Bolotin[b], Valluvan Jeevanandam[b]

[a]*Department of Surgery, Sections of Plastic and Reconstructive Surgery, University of Chicago, MC 5040, 5841 South Maryland Ave, Chicago, IL 60637, USA*
[b]*Department of Cardiothoracic Surgery, University of Chicago, USA*

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Abstract

Sternal instability predisposes to post-operative mediastinitis. Biomechanical studies have shown the superiority of rigid plate fixation over wire circlage in sternal healing. We studied rigid plate fixation for sternotomies in high-risk patients. High-risk patients were identified as those having three or more historically established risk factors for post-operative mediastinitis, such as COPD, re-operative surgery, renal failure, diabetes, steroid use, obesity, existing infection, and immunosuppression. Three hundred and twenty high-risk patients had prophylactic rigid plate fixation (Group S) between July 2000 and Jan 2005. The control group (Group C) comprised 215 patients with similar risk profiles that were not plated during 2000 and 2001. Average age, male-female ratio, risk factors and type of procedures were similar in both groups. Follow up ranged from 4 to 200 weeks. There were 12 peri-operative deaths (3.75%) in group S and 8.6% (18 patients) in group C. There were no instances of deep mediastinitis in group S. Group C had mediastinitis in 28 (13%, $P<0.05$), requiring high dose antibiotics and plastic surgical intervention. Sternal fixation with titanium plates is an effective way of ensuring sternal immobility thereby reducing the substrate for bony infections. Application of this technique in high-risk patients prevents mediastinitis.

Keywords: Sternum; Plating; Rigid fixation; Mediastinitis

1. Introduction

Sternotomies are the most frequently performed osteotomies worldwide. Traditionally, cardiothoracic surgeons have been trained to close or approximate the sternum with wire circlage. Despite improvements in the understanding of the principles of rigid fixation with plates, these changes have not been applied to sternal closure, widely. Based on biomechanical studies in a bone analog model, plates and screws were adapted for use in sternal closure. Infectious complications leading to post-sternotomy mediastinitis are extremely morbid and the mortality rate can be as high as 15% [1]. Methods for preventing post-sternotomy mediastinitis have included prophylactic measures including antibiotic therapy and various means of skin closure. Few have focused on rigid osseous fixation as a means for preventing infection despite experimental evidence to support it [2].

Since Julian reintroduced Milton's (1897) operation of median sternotomy in 1957 [3], numerous methods for sternal osteosynthesis have been described. Despite evidence of the superiority of rigid plate osteosynthesis, the current standard for sternal closure remains circlage wire fixation. Due to the proven merits of increased stability and decreased incidence of non-union, mal-union and infection, the principles of rigid fixation have caused paradigm shifts away from wire fixation of bone, in other areas. Circlage fixation under normal physiologic loads can prove to be inadequate, leading to separation [4]. Bacterial contamination in the face of sternal instability can then progress to deep sternal wound infections and mediastinitis. Effective rigid osteosynthesis of the sternum may prevent post-sternotomy mediastinitis from occurring by affording stability, promoting primary healing of the sternum.

We adopted this technique of rigid plate fixation, by modifying plates that were used in mandibular fixation.

We had earlier reported on our preliminary experience with the use of titanium plate fixation of the sternum [5]. We now report on our evolving experience in this area.

2. Patients and methods

A system of plates and screws were developed for specific use in the sternum by the W Lorenz Corp (Jacksonville, Florida), called the Sternalock system. The screws that were initially developed required pre-drilling of the bone and were bi-cortical. These were eventually changed to mono-cortical, self-tapping screws.

Between July 2000 and January 2005, 320 patients underwent internal fixation of the sternum with the Sternalock

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*Corresponding author. Tel.: +1-773 702 2500; fax: +1-773 702 4187.
E-mail address: jraman1@uchicago.edu (J. Raman).

system. This system of plating was applied in patients that were considered high-risk based on previously described risk criteria for deep sternal wound infection.

Pre-operative risk factors included

- Diabetes mellitus
- Chronic Obstructive Pulmonary Disease (C.O.P.D)
- Obesity (BMI >30)
- Renal failure
- Chronic steroid use
- Concurrent infection and acquired or iatrogenic immunosuppression.
- Immunosuppression
- Redo sternotomy

Intra-operative risk factors included

- Off mid-line sternotomies,
- osteoporosis,
- long cardio-pulmonary bypass runs (of >2 h),
- transverse fractures of the sternum.

If three or more of there factors were present, the patient's sternum was internally fixed with plates and screws that were part of the Sternalock system. Cardiac surgeons selected all patients and rigid plate fixation was applied immediately after the cardiac procedure.

2.1. Surgical technique

Care is taken to ensure a midline sternotomy. The pre-sternal pectoral muscle tissue is dissected off the anterior table of the body of the sternum. One figure-of-eight wire is placed in the manubrium and one in the region of the xiphi-sternum. The sternal halves are carefully aligned and approximated with a combination of the wires and bone reducing forceps placed in the 2nd and 5th intercostal spaces. The plates are then seated in such a way that they straddle the sternal halves. The plates are then secured into the bone with the appropriate self-tapping screws.

As the procedure and comfort level with plating evolved, plates were secured to the body of the sternum, while figure-of-eight wires were placed in the manubrium and xiphi-sternum. Fig. 1 is a photograph of a plated sternum.

Patients were followed up clinically and their sternal wounds assessed both during their hospital stay and in the outpatient follow-up setting. Patients were followed by the cardiac surgical team and managed irrespective of the sternal closure. Criteria for discharge and routine follow-up care did not vary. Successful sternal closure was defined by physical exam devoid of instability, pain, wound healing complications and radiographs showing unchanged location of hardware for a minimum of 8 weeks.

For purposes of comparison, patients that underwent plate fixation were classified in Group S and compared to a similar group of patients ($n=215$) that underwent standard wire closure in 2000 and 2001, selected on the basis of their risk profiles. These patients were classified as Group C.

A biostatistician using SAS software performed the statistical analysis. Fisher's exact test was used to assess statistical significance and a P-value of <0.05 was considered significant.

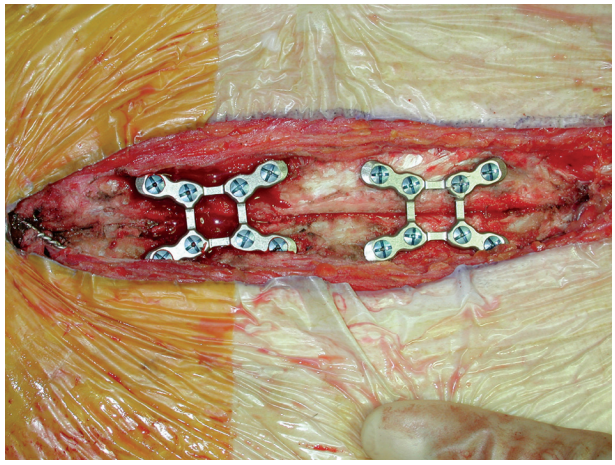

Fig. 1. Plated sternum.

3. Results

Patients were followed up between 4 and 200 weeks. Patients referred to us from other centers were discharged with a specific note about the sternal plates and the need for us to be contacted if there was a problem with the plates (specifically if the plates needed to be removed or the sternum reopened).

Demographic characteristics, risk factors and operative procedures were similar in the two groups.

During the same study period, analysis of a similar cohort of high-risk patients in Group C had mediastinitis, in 28 as defined by deep sternal wound cultures and systemic sepsis (13%, $P<0.05$). This required high dose antibiotics and plastic surgical intervention. Mortality of 8.6% (18 patients) was noticed in Group C. The age, gender, risk factor distribution was very similar to the study group. All of these patients required surgical debridement, sternectomies and pectoral muscle flap closure. Of the 18 deaths in Group C, two were attributed to post-sternotomy mediastinitis. The total number of adult cardiac procedures during the control study period was 671 and the total incidence of post-sternotomy mediastinitis was 4.2%.

There was no mediastinitis in the study group (Fisher's exact test, $P=0.0002$).

There were five instances of sterile sternal dehiscence (1.5%) in the presence of sternal plates. None of these patients had evidence of infection by wound culture. The first patient had very strong bone and the plating system was an early version with small screws that ripped out of the sternum. The second patient was also a very muscular patient in whom the screws seemed to rip out. Both these patients had intractable post-operative coughing. The other three patients were elderly diabetics with significant osteoporosis. The screws were not able to find proper purchase in their very soft bone. Alternative strategies are being developed for this select but high-risk population.

A log-rank test was not used because of the relatively small number of patients in the study group and the disparate nature of the groups.

4. Discussion

Few proven measures have been developed for the prevention of mediastinitis. This is despite many strides that have been made in the management of post-sternotomy mediastinitis. Existing modalities focus on adjunct methods to prevent bacterial contamination from both the surgical team and the patient [6]. Focusing on a more stable and successful technique of sternal osteosynthesis in an effort to prevent complications has been cited. Most revolve around a different pattern of wire circlage or various non-rigid methods of closure [7]. Rigid plate fixation of the sternum, although not new, has not been widely used as the optimal method of sternal osteosynthesis for various reasons.

Some of these include added time and expense, the difficulty of emergent re-entry and the availability of a simple and effective plating system. One obstacle for the acceptance of rigid plate fixation to the sternum has been the logistics of drilling into the sternum. This has been circumvented by developing a system of self-tapping screws. The screws are selected based on sternal thickness and we have switched to mono-cortical screws. This means securing the anterior table of the sternum after lining it up appropriately.

A second obstacle has been the issue of emergent re-entry into the mediastinum for hemorrhage. The SternaLock® plates are specifically designed to be cut in the middle with standard wire cutters found in any re-entry tray. Salvage of the closure can then be performed with new plates and without re-drilling by exchanging the 2.4 mm screws for 2.7 mm emergency screws. These plates are made of titanium and do not interfere with magnetic resonance imaging. They are clearly radio-opaque and readily visible on X-ray imaging.

A third obstacle to wide acceptance has been the cost of hardware placement and the additional time it takes to implant hardware. While the implants are more expensive than wires, the time taken to implant them is now less than wiring. At our institution, the average additional hospital charge for patients suffering from post-sternotomy mediastinitis is just over $500,000. Prevention of post-sternotomy complications not only can be fiscally sound, but more importantly it can potentially decrease morbidity and mortality associated with this complication. The cost of the plates ranges from $700 to approximately $900 depending on the number of plates and screws used.

Efficient plating systems for many other bones abound, a plating system specifically designed for the sternum was first described by us in 2003. Previous attempts at rigid plate fixation of the sternum had employed mandibular reconstruction plates or fracture mini-plates with some success, but issues of emergent re-entry and accurate precision placement were not addressed [8]. Furthermore, fashioning mandibular reconstruction plates for the sternum was cumbersome as each plate had to be cut specifically for each region of the sternum.

The benefits of rigid plate osteosynthesis have caused paradigm shifts away from wire fixation for orthopedic and plastic surgeons over 20 years ago. More recently, neurosurgeons have adopted plate fixation of bone flaps in the past five years. Cardiac surgeons are the only surgeons who continue to fix bone with wire-circlage. Ironically, cardiac surgeons perform the sternotomy, which is the most common osteotomy worldwide. Yet, as a group we have not adopted the state-of-the-art techniques in stabilizing this osteotomy. In the setting of a surgically created osteotomy or fracture treatment, a failure rate even below 5% might be considered unacceptable but may be tolerated by the patients. However, in the setting of the sternotomy, this failure rate may have devastating complications such as non-union, persistent pain and deep sternal wound infection.

Complications of median sternotomy have been reported ever since the early and widespread adoption of this common technique [9]. Sternal stability has always been regarded as essential for normal healing of these wounds. There was a report from our unit in 1994, on the use of rigid internal fixation in post-operative mediastinitis, with bony union being achieved in over 90% of patients [9]. Others have used plates to provide a template for more rigid fixation [10] in sternal dehiscence. Cyano-acrylate glue has been used in mediastinitis even with the risk of toxicity in an attempt at improving sternal stability [11]. Negri and co-workers evaluated a new technique using thermo-reactive clips that seemed to improve the rate of wound infection but did not eliminate it [12]. Our approach was to use the best existing techniques of osteotomy closure and adapting them to the sternal situation. As we grew more familiar with the technique of rigid plate fixation, we made modifications. We found that using a figure-of-eight wire in the manubrium and the xiphi-sternum assisted in approximation of the bone along with the reducing forceps. We found this combination approach to be cost-effective and efficient. Therefore, many of the patients received two wires and two plates.

Based on our early success in a high-risk population with a historically high rate of complications, we embraced the concept of rigid plate fixation. This report highlights the fact that rigid plate fixation can dramatically reduce sternal wound infection if used prophylactically in high-risk patients. While it may not eliminate sternal deshiscence completely, it can provide a way to ensure secure closure in a variety of patients that are at increased risk of wound infections and poor healing.

Summary: A safe, and effective technique for rigid plate fixation of the sternum is outlined. Experience with this technique of rigid sternal osteosynthesis has shown a dramatic reduction in wound infections associated with sternotomies in high-risk patients.

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