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Rigid Fixation for the Prevention and Treatment of Sternal Complications

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Background: Most surgical specialties working with bone have transitioned from wire fixation to more stable plate and screw fixation. Rigid plate fixation results in more rapid bony healing with decreased rates of nonunion, malunion, and infection. Despite sternotomies being the most frequently performed osteotomy, cerclage wire fixation remains the standard technique of closure. This study reviews our 5-year experience with rigid fixation at the University of California Davis Medical Center.

Materials and Methods: A retrospective review of patients who underwent rigid sternal fixation between January 2006 and December 2012 at UC Davis Medical Center was performed. Demographic factors, indications for surgery, and risk factors for postoperative complications including mediastinitis and nonunion were reviewed. The type of fixation system was recorded. Outcomes assessed included dehiscence, deep and superficial infections, sternal instability, and need for reoperation.

Results: Fifty-seven rigid sternal fixations were performed (M/F, 37:20; average age, 54 years; range, 16–79 years). Indications for operation included prophylaxis against mediastinitis (61.4%), sternal nonunion (24.6%), sternal fractures (7.0%), and pectus deformities (7.0%). Of the rigid fixation systems used, 87.3% used SternaLock, 12.7% used Talon, 1.8% Lactosorb, and 1.8% Flexigrip. Thirty-five patients were plated for prophylaxis against mediastinitis. In the prophylactic group, the average number of risk factors per patient was 3.92, indicating very high-risk patients. Fourteen patients were plated for sternal nonunion. The average number of risk factors in the nonunion group was 1.57. Other less common indications for rigid sternal stabilization included sternal fracture (4 patients) and pectus deformity (4 patients). Eight patients had a pectoralis flaps performed at the time of their sternal fixation, 7 for soft tissue coverage of plates and 1 for coverage of a contaminated wound bed. All patients went on to heal their sternums without evidence of mediastinitis.

Conclusions: Rigid sternal fixation is a natural extension of principles learned from bone stabilization in other parts of the body. It can be used for rigid bony fixation of osteotomies performed after median sternotomy as well as in sternal reconstructions for traumatic fractures, nonunions, and pectus deformities. Rigid sternal fixation can be used safely and effectively in the prophylaxis against the development of mediastinitis in addition to the treatment of sternal nonunion or malunion in high-risk patients.

Key Words: sternal plating, mediastinitis, sternum, reconstruction, rigid fixation

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S ternal fractures result from either iatrogenic or traumatic insults. As the most common osteotomy, or "surgical fracture," the median sternotomy is the standard approach for open-heart operations. The accepted current technique for closure of this osteotomy is stainless

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steel wire cerclage. Although this closure method is satisfactory in many patients, it is complicated by bony nonunion and infection in 0.4% to 5.1% of all cardiac procedures¹ and up to 14.8% to 16% in high-risk patients.^{2,3}

The evidence regarding the benefits of sternal plating as a primary or secondary method of sternal closure is robust. Multiple biomechanical studies in both cadavers and sternal models have shown the superior stability with rigid plate fixation over traditional wire cerclage.^{4,5} Clinical research has supported these findings showing associated benefits such as a decrease in mediastinitis, and a relief of painful sternal nonunion after median sternotomy or trauma^{6,7} and superior bony healing⁸ when compared to wire fixation. This literature suggests an expanding role for rigid fixation in the treatment of median sternotomies and other causes of sternal separation.

This article reviews our experience with sternal fixation. We report on our current indications for rigid sternal fixation and settings we deem helpful in obtaining reliable sternal healing.

METHODS

A retrospective analysis of operative and clinic records was performed on patients who had rigid sternal fixation between January 2006 and December 2012 at a single academic medical center. Demographic factors collected included age, sex, body mass index, smoking history, concurrent steroid use, and previous radiation therapy to the chest. Medical comorbidities were also reviewed including coronary artery disease, diabetes mellitus, chronic obstructive pulmonary disease, and chronic kidney disease. Preoperative diagnosis and indication for sternal fixation was also recorded. Intraoperative measures examined included fixation system used, whether the sternal reconstruction was a primary or subsequent reconstruction, use of pectoralis flaps, time on coronary bypass pump, use of intra-aortic balloon pump, and bilateral internal mammary artery harvest. Outcomes were analyzed for complications including pneumothorax, wound dehiscence, need for reoperation, infection, removal of hardware, and instability at 3 months postoperative.

RESULTS

Fifty-seven rigid sternal fixations were performed (M/F, 37:20; average age, 54 years; range, 16-79 years) at UC Davis Medical Center between the years of 2006 and 2012 (Table 1).

Indications for sternal fixation were then evaluated. Thirty-five patients were rigidly stabilized as a prophylactic measure against the development of mediastinitis (Table 2). The mean age was 57.6 years (range, 29–79 years). A variety of sternal fixation systems were used, most common were Biomet's SternaLock (88.6%) and Talon, produced by KLS Martin (8.6%). Preoperative risk factors evaluated included obesity (65.7%), diabetes mellitus (51.4%), end-stage renal disease (17.1%), chronic obstructive pulmonary disease (8.6%), steroid use (8.6%), and radiation therapy (8.6%). Intraoperative risk factors included long pump times more than 2 hours (85.0%) and bilateral harvest of the intramammary arteries (11.4%). The average number of preoperative risk factors was 3.03, intraoperative 0.97, and total 4.1, indicating very high-risk patients in this indication group.

Of the 35 patients plated prophylactically, 26 (74.3%) had no complications (Table 3). Complications seen in this group included

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TABLE 1. Patient Information

| | Value |
|--------------------------------|-------|
| Female/male | 20:35 |
| Age, y | |
| Mean | 54 |
| Range | 16–79 |
| Mean BMI | 32.58 |
| Mean BMI, female | 30.38 |
| Mean BMI, male | 36.43 |
| BMI indicates body mass index. | |

sterile soft tissue dehiscence (8.6%), sternal nonunion (2.9%), and infection (14.3%). Most of these infections were superficial, and only the 2 (5.7%) most serious required hardware removal. Importantly, there were no cases of mediastinitis. Twelve of the 14 of patients achieved bony healing. One patient was unstable at 1 month postoperative but was then lost to follow-up, and another patient died from her underlying illness before bony healing was assessed. Other complications seen in this group included sterile soft tissue dehiscence (21.4%).

Fourteen patients underwent rigid fixation after sternal nonunion (Table 4). The mean age for this indication group was 50.8 years (range, 18–75 years). Two systems were used, namely, SternaLock (71.4%) and Talon (28.6%). Risk factors for sternal nonunion were evaluated. Risk factors included obesity (57.1%), diabetes mellitus (35.7%), end-stage renal disease (21.4%), chronic obstructive pulmonary disease (14.3%), and concurrent steroid use (7.1%). The average number of risk factors per patient in this group was 1.57.

Four patients were plated for sternal fractures. The average age of patients was 51.5 years (range, 30–61 years). Three patients had fractures secondary to blunt trauma, and 1 patient was plated after a

| TABLE 2. | Prophylaxis (35 Patients) | |
|----------|---------------------------|--|
| | | |

| | Value (%) |
|----------------------------------------|-----------|
| Male/female | 21:15 |
| Age, y | |
| Mean | 57.6 |
| Range | 29-79 |
| Plate type | |
| Sternalock (Biomet) | 31 (88.6) |
| Talon (KLS Martin) | 3 (8.6) |
| Flexigrip (Praesidia) | 1 (2.9) |
| Preoperative risk factors | |
| BMI, >30 kg/m ² | 23 (65.7) |
| Diabetes mellitus | 18 (51.4) |
| End-stage renal disease | 6 (17.1) |
| Chronic obstructive pulmonary disease | 3 (8.6) |
| Steroid use | 3 (8.6) |
| Radiation therapy | 3 (8.6) |
| Intraoperative risk factors | |
| On-pump time, >2 h | 30 (85.0) |
| Bilateral intramammary artery harvest | 4 (11.4) |
| Average number of risk factors/patient | |
| Preoperative | 3.03 |
| Intraoperative | 0.97 |
| Total risk factors | 3.92 |

| Indication (No. Patients) | Outcome | n (%) |
|------------------------------|---------------------------------------|-----------|
| Prophylaxis (35) | No complications | 26 (74.3) |
| | Sterile soft tissue dehiscence | 3 (8.6) |
| | Sternal bone outcome | |
| | Healed | 34 (97.1) |
| | Sternal nonunion and instability | 1 (2.9) |
| | Infection | 5 (14.3) |
| | Hardware removal | 2 (5.7) |
| | Mediastinitis | 0 (0.0) |
| Nonunion (14) | No complications | 10 (71.4) |
| | Sterile soft tissue dehiscence | 3 (21.4) |
| | Sternal bone outcome | |
| | Healed | 12 (85.7) |
| | Lost to follow-up <3 mo postoperative | 1 (7.1) |
| | Died | 1 (7.1) |
| Trauma (4) | No complications | 3 (75.0) |
| | Loose screws | 1 (25.0) |
| Pectus deformity (4) | No complications | 4 (100.0 |

transverse sternal fracture occurred during a redo sternotomy. All patients were plated immediately after trauma with the SternaLock plating system. All 4 patients went on to clinically heal their sterna, with no pain or sternal instability elicited with palpation. At time of data analysis, 1 patient was scheduled for reoperation due to loose screws.

Four patients were plated for pectus deformity, 2 with a diagnosis of pectus excavatum and 2 with pectus carinatum. Two patients were rigidly fixed as a primary reconstructive procedure, and 2 patients were plated after failed reconstructions done elsewhere. One of the primary repairs used Lactosorb (Biomet) plates, whereas the other 3 patients were rigidly fixed with SternaLock plates. There were no postoperative complications within this indication group. All patients went on to heal their sterna by clinical benchmarks, meaning no sternal instability or pain was present at 3 months postoperatively.

Eight (14.0%) patients had a pectoralis major flap procedure performed at the time of their sternal stabilization procedure. The mean age was 53.5 years (range, 39–64 years). Indications for the flap

TABLE 4. Nonunion (14 Patients)

| | Value (%) |
|----------------------------------------|-----------|
| Male/female | 10:4 |
| Age, y | |
| Mean | 50.8 |
| Range | 18-75 |
| Plate type | |
| Sternalock (Biomet) | 10 (71.4) |
| Talon (KLS Martin) | 4 (28.6) |
| Preoperative risk factors | |
| BMI, $>30 \text{ kg/m}^2$ | 8 (57.1) |
| Diabetes mellitus | 5 (35.7) |
| End-stage renal disease | 3 (21.4) |
| Chronic obstructive pulmonary disease | 2 (14.3) |
| Steroid use | 1 (7.1) |
| Average number of risk factors/patient | 1.57 |

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procedure included soft tissue coverage of the plates (7 patients) and coverage of a contaminated wound bed (1 patient). All 8 patients had pectoralis flaps during a redo procedure after the primary sternal reconstruction had failed.

DISCUSSION

Despite the growing body of evidence regarding the benefits of rigid sternal fixation, resistance to primary sternal plating still exists in both iatrogenic and traumatic cases. Some reasons for this include the relative rarity of nonunion and mediastinitis, addition of time to an already lengthy cardiac procedure, concern over the cost of plating systems, and the need for possible emergent reentry to the chest cavity.

A growing body of literature has supported the use of rigid sternal fixation as a means of preventing mediastinitis in high-risk patients and treating postoperative mediastinitis through faster bony healing. In 2 retrospective reviews of high-risk sternotomy patients, defined as patients having 3 or more risk factors for the development of mediastinitis, use of primary rigid sternal fixation was noted to have significantly lower rates of postoperative mediastinitis in patients who were plated prophylactically compared to 14.8% in the wired patients of Song et al² and 16% in the patients of Kuo et al³ treated with any modified wire technique intended to provide greater stability compared to the standard cerclage techniques. Despite our prophylaxis patients having an average of almost 4 risk factors, we were still able to eliminate mediastinitis as a complication.

The mortality and economic benefits of reducing or preventing the development of postoperative mediastinitis are clear and significant. Although the incidence of mediastinitis after median sternotomy is just 1% to 5%, the mortality estimates from this complication range from 10% to 47%^{1,3} with 10-year follow-up data showing that these patients have a mortality rate double that of patients without mediastinitis.⁹ The economic burden of these infections is 2.8 times that of patients with uncomplicated hospital stays,³ whereas other literature estimated the additional cost of each case at approximately half a million dollars.² A recent study by Kuo et al³ noted that despite the higher upfront cost of the plating system, the total cost of caring for patients treated with rigid fixation was less than those treated with modified wire techniques as the wired group had higher rates of complications including the development of mediastinitis. In addition, when complications did occur in plated patients they were more minor, with the cost of caring for each complication significantly less in the plated patients (\$1057) compared to the wired patients (\$51,083). These economic considerations have never been more important as mediastinitis is now classified as a "never event" by Medicare, meaning the expenses associated with mediastinitis will no longer be reimbursed.

Existence of a contaminated wound bed or loss of soft tissue can necessitate use of myocutaneous or fasciocutaneous flaps for coverage. We found pectoralis major flaps to be an important tool for sternal reconstructions, with 14.0% of our patients receiving a flap as part of their surgery. The most common indications for flap use were for coverage of a contaminated wound bed, and creation of sufficient soft tissue to cover the hardware. Soft tissue deficits can be present with sternal reconstructions for any indication. A frequent cause of soft tissue loss was removal during debridement. In one circumstance, the soft tissue deficit was due to an expanded sternal surface area after reconstruction for pectus carinatum.

Sternal nonunion, or instability in the absence of infection, is a rare complication of median sternotomy and traumatic sternal fractures. Sternal nonunion may increase postoperative pain and the area between the nonhealed segments may serve as a fertile ground for infection. Cerclage wiring, regardless of technique used, allows for some movement under normal physiologic loads. In vitro studies and animal models have shown a superior rate of osseous healing with plate fixation when compared to wires. Synthetic and cadaveric models demonstrate significantly increased stability with plate fixation under mechanical load. In vivo, multiple studies have demonstrated the use of sternal plating for treatment of sternal nonunion, including a recent multicenter international prospective randomized controlled trial by Raman et al,⁸ which showed a significant sternal healing advantage with rigid fixation as opposed to wire cerclage at 3 and 6 months postoperatively. At 6 months, sternal union was seen in 70% of plated patients, compared with 24% of cerclage patients. In our study, 85.7% of patients had achieved a clinically stable sternum by their 3-month postoperative appointment and no patients were found to be unstable, meaning they had no pain or sternal instability at follow-up. We did have 1 patient who was unstable at 20 days postoperatively who was then lost to follow-up and 1 patient who died before her sternal stability was assessed.

Traumatic sternal fractures are seen most commonly with motor vehicle crashes, with rates of 3% to 8% in blunt trauma patients. Most of these fractures are treated conservatively, with indications of operative fixation including chronic nonunion, sternal instability, displaced fracture, and severe pain inhibiting respiration. Currently, consensus does not exist on the optimal surgery for traumatic sternal fractures. A 2011 review by Harston and Roberts9 showed that in practice, whether these fractures were fixated internally with wires or with plates, all sternal fractures included in the review went on to heal. The literature on sternal fractures emphasizes the importance of fracture stabilization to decrease the pain resulting from the movement of mobile fracture segments with respiration and to accelerate healing.⁵ We first reviewed our experience with the use of rigid fixation in the treatment of traumatic sternal fractures in a 2011 case report.¹⁰ Both patients in this prior study had sternal fractures because of blunt anterior chest wall trauma. Since that time, our experience has expanded from solely blunt trauma patients to also include patients with sternal fractures occurring intraoperatively. Our additional experience with this indication has continued to show excellent outcomes from rigid fixation, with no major complications seen and all patients achieving bony healing.

With the exception of external braces, the treatment of pectus deformities is surgical and involves bars or osteotomies to contour the sternum. Previously, we reported on a case of failed pectus excavatum repair, where sternal plating was performed after Nuss bar erosion.¹¹

Since the time of that case report, we have plated 3 more patients for pectus deformity, both as the primary reconstructive procedure, and as part of a reoperative procedure after the primary reconstruction failed. In the youngest patient (16 years old), we preformed a primary reconstruction; we used Lactosorb (Biomet) resorbable plates as opposed to the titanium plates and screws used in the other 3 reconstructions. Absorbable plates are standard of care in pediatric craniofacial reconstructions due to the risk of nonresorbable plates becoming intracranial with skull growth. Although there are no reported cases of titanium plates or wires becoming intrathoracic after sternal reconstruction in a pediatric patient, this phenomenon poses an interesting theoretical risk. Although our patient was compliant with regard to sternal precautions in the postoperative period and went onto heal without incident, we did have concerns whether the absorbable plates would have sufficient strength during the resorbing process to allow for proper healing. More data and experience with this technology applied to the sternum are needed before these plates become more widely adopted; however, they remain an attractive option for reconstruction of pectus and other sternal deformities in our pediatric patients.

CONCLUSIONS

Rigid sternal fixation is a natural extension of principles learned from bone stabilization in other parts of the body. It can be used safely and effectively for rigid bony fixation of osteotomies performed after median sternotomy as well as sternal reconstructions for traumatic fractures, nonunions, and pectus deformities. We believe rigid plate fixation is preferable to wire cerclage in certain settings, including prophylaxis against the development of mediastinitis as well as for the treatment of sternal nonunion in patients deemed high risk for these complications.

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