Sternal Closure With Rigid Plate Fixation Versus Wire Closure: A Randomized Controlled Multicenter Trial

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Background. **Rigid bone fixation is the standard of care for all bone reconstructions except that after sternotomy. Sternal reconstruction after median sternotomy using rigid fixation with plates may improve bone healing and reduce pain when compared with wire cerclage.**

Methods. **One-hundred forty patients at six centers who were determined preoperatively to be at high risk for sternal wound complications were randomly assigned to sternal closure with rigid plate fixation (n = 70) or wire cerclage (n = 70). Sternal healing was evaluated at 3 or 6 months by a core laboratory using computed tomography. Pain and function were evaluated at postoperative day 3 through discharge, 3 weeks, 6 weeks, 3 months, and 6 months.**

Results. **Sternal healing was superior in rigid plate fixation patients at both 3 and 6 months. Mean computed tomography scores in the rigid plate fixation and wire cerclage groups at 3 months were 1.7 ± 1.1 and 0.9 ± 0.8 ($p = 0.003$). At 6 months, the scores were 3.2 ± 1.6 and 2.2 ± 1.1, respectively ($p = 0.01$). At 6 months, 70% of rigid plate fixation patients had achieved sternal union, compared with 24% of conventional wire cerclage patients ($p = 0.003$). Pain scores and narcotic usage were lower in rigid plate fixation patients. Significant differences in pain scores were observed at 3 weeks for total pain ($p = 0.020$) and pain with coughing ($p = 0.0084$) or sneezing ($p = 0.030$). Complication rates were similar in both groups.**

Conclusions. **Sternal reconstruction using rigid fixation with plates improved bone healing and reduced early postoperative pain compared with wire cerclage.**

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Sternotomy, or surgical fracture of the sternum, is one of the most common osteotomies in surgery. Unlike fractures in which rigid fixation of bone segments is used routinely to improve stability and bone union, wire cerclage remains the primary median sternotomy closure technique for most cardiac surgeons.

Mechanical studies show that rigid fixation of the sternum using plates and screws results in mechanical properties superior to those of wire closure [1-3]. Studies also suggest that this mechanical benefit may translate into improved clinical outcomes [4-9]. The objective of this study was to determine whether sternal reconstruction using rigid fixation with plates results in improved bone healing and patient function and less postoperative pain than wire cerclage for patients at high risk for sternal wound complications after median sternotomy.

Material and Methods

Study Design

This prospective, randomized, controlled multicenter trial evaluated clinical and radiographic outcomes in patients with two or more risk factors for sternal wound complications. Patients were randomly assigned to sternal closure with rigid plate fixation (RPF) using SternaLock Plates (Biomet Microfixation, Jacksonville, FL) or conventional wire cerclage (CWC). A total of 140 patients enrolled at six centers in the United States and Europe from November 2008 to May 2010. Institutional Review Board and Institutional Ethics Committee approval was obtained from all sites. Patient consent for study participation and collection of a computed tomography (CT) scan was obtained before enrollment. This study was sponsored by Biomet Microfixation (registered as NCT00819286 on clinicaltrials.gov).

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Inclusion criteria were the presence of two or more risk factors for sternal wound complications. Risk factors identified preoperatively included diabetes mellitus, chronic obstructive pulmonary disease, obesity (body mass index >30 kg/m^2), renal failure, chronic steroid use, immunosuppression, repeat sternotomy, osteoporosis, concurrent infection, and neurologic dysfunction affecting ambulation [10-12]. Risk factors identified intraoperatively included off-midline sternotomies, bilateral internal mammary artery harvest, cardiopulmonary bypass of more than 2 hours' duration, and transverse sternal fracture [12, 13]. Exclusion criteria included nonstandard sternotomies, sternotomies that reduced the bony margin to less than 2 mm, emergent or salvage procedures, New York Heart Association class IV heart failure, delayed sternal closure, or preoperative administration of narcotics.

The RPF was performed using one "L" plate at the manubrium and two "X" plates on the sternal body, according to a described technique [6]. Sternal thickness was measured to select the appropriate screw length to engage the posterior cortex. The CWC was performed using simple, single parasternal wires. One no. 6 stainless steel sternotomy suture was used for every 10 kg of patient weight, with at least seven wires. Patients in both groups received two transsternal wires at the manubrium and one parasternal wire at the xyphoid.

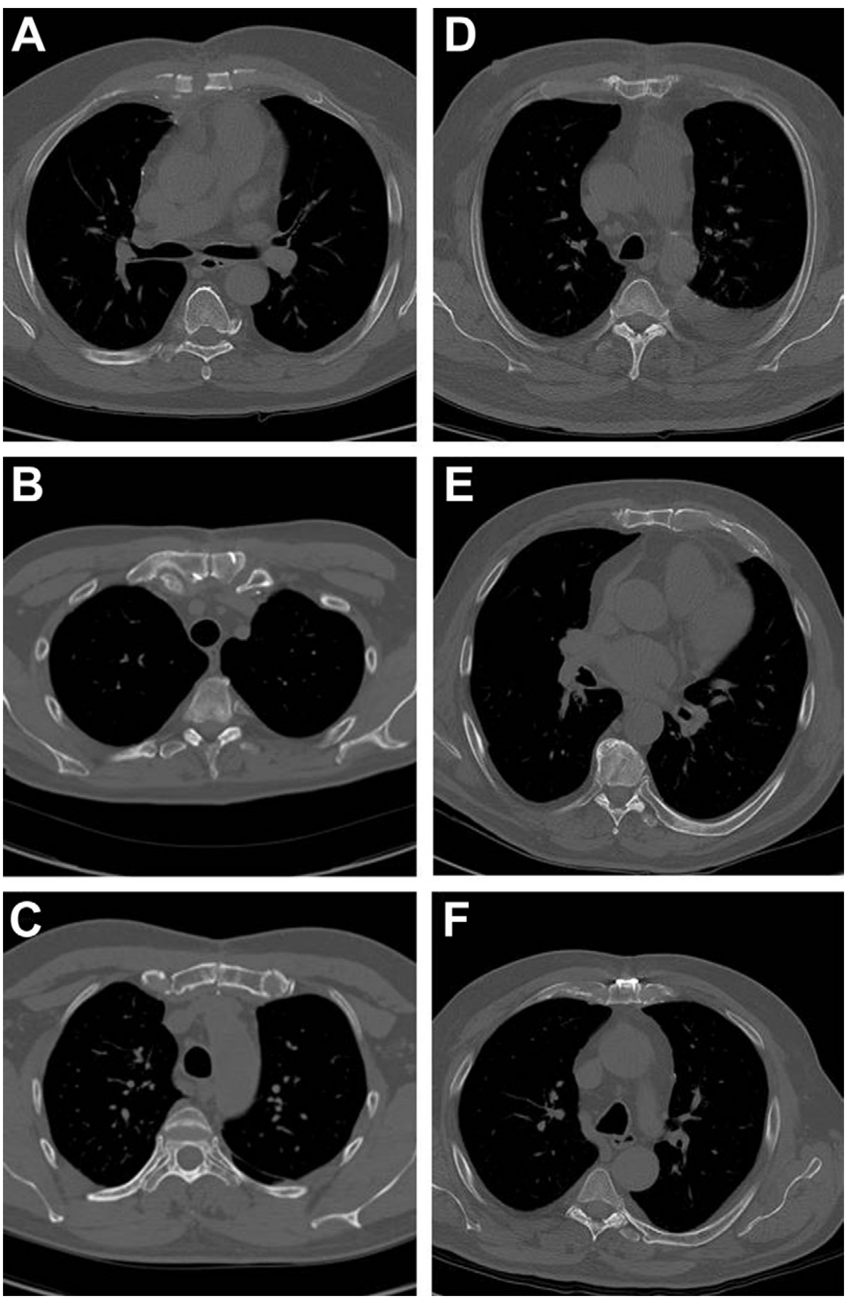

Fig 1. Axial computed tomography scan images representative of each score on 6-point scale. Each score was defined as follows: (A) 0 = no sign of healing (clear lack of healing, nonunion, sternal separation); (B) 1 = minimal healing (sternal separation, lack of bridging bone); (C) 2 = mild healing (sternal separation with hazy, immature bone formation); (D) 3 = moderate healing (partial bridging bone indicative of sternal stability); (E) 4 = partial synthesis (significant bridging bone); and (F) 5 = complete synthesis (complete bridging bone).

Table 1. Patient Enrollment and Clinical Follow-Up

	Subject Count at Follow-Up Visit				
Follow-Up	Discharge	3 Weeks	6 Weeks	3 Months	6 Months
Enrolled	140	140	140	140	140
Death (cumulative)	3	4	7	9	9
Revision (cumulative)[a]	12	14	15	18	18
Available for clinical follow-up[b]	125	122	118	113	113
Lost to follow-up	9	14	13	5	12
Actual follow-up[c]	116	108	105	108	101
Percent follow-up[d]	93	89	89	96	90

[a] Emergent reentries and resternotomies in which patient could not be reclosed per protocol. [b] Number enrolled minus deaths and revisions. [c] Patients with some clinical efficacy data. [d] Actual/available.

Treatment Group and CT Scan Randomization

Patients were randomly assigned to sternal closure with RPF or CWC using simple balanced randomization (1:1 ratio) at each site. In addition to treatment group randomization, patients were randomly assigned (1:1 ratio) to receive a CT scan at 3 or 6 months. Randomization envelopes containing treatment group and CT scan time point allocation were provided to each site. The sponsor maintained a master randomization list. Randomization envelopes were opened intraoperatively at sternal closure to blind the investigator to the method of closure during the procedure and minimize the potential for bias.

Patient Follow-Up and Outcome Measures

Patients were evaluated for sternal union using CT, postoperative sternal pain using a visual analog scale [14], and functional outcomes using the Heart Surgery Symptom Index [15]. Evaluators were blinded to the method of sternal closure.

The CT scans at 3 or 6 months were used to assess sternal bone healing. A preliminary analysis of CT scans from patients with plates or wires was conducted by cardiothoracic surgeons and thoracic and musculoskeletal radiologists to develop the scanning protocol and scoring algorithm. Standard CT methods specifying parameters such as slice thickness, acquisition, spatial resolution, field of view, state of respiration, gantry tilt, algorithm, pitch, and file type were defined in the protocol and provided to each site and radiology facility. All CT scans were read by two independent radiologists in a core radiology laboratory using methodology validated for interobserver and intraobserver agreement. Axial slices were analyzed at five locations along the sternum (manubrium, top of the aortic arch, aortopulmonary window, main pulmonary arteries, and aortic root) using a 6-point quantitative scale (0 = no sign of healing, 1 = minimal healing, 2 = mild healing, 3 = moderate healing, 4 = partial synthesis, 5 = complete synthesis) (Figure 1). A mean score was assigned to each patient with a CT scan on the basis of an average of consensus scores for the sternal locations. Sternal union, a binary outcome, was defined as a mean score of 3 or greater. A score of 3 was the threshold for radiographic healing based on the observation of partial bridging bone, which indicates sternal stability and healing. This threshold was established by the radiologist and cardiothoracic surgeons.

Patients independently recorded pain scores using a 10-cm visual analog scale [14]. Patients rated sternal pain at rest and with coughing, sneezing, and general movement. A total activity pain score was derived as the sum of each subscale. Pain scores were determined preoperatively and postoperatively on days 3 to 10, discharge, 3 and 6 weeks, and 3 and 6 months. Postoperative opioid analgesic usage in the hospital was evaluated by converting to equivalent morphine units to allow comparison of groups [16]. Functional outcomes were evaluated using a 21-question version of the Heart Surgery Symptom Index, a disease-specific outcome measure for patients undergoing coronary artery bypass graft surgery [15].

Statistical Analysis

Continuous baseline variables were compared using an independent two-sample pooled *t* test. Comparisons of categorical baseline variables were performed using Fisher's exact test, which was also used to compare proportions of subjects with adverse events. Primary outcome measures of sternal union, pain, and function were tested for noninferiority and superiority. Confidence bounds were computed using exact (Clopper-

Table 2. Patient Enrollment and Radiographic Follow-Up

	Subject Count at Follow-Up Visit	
Enrollment and Follow-Up	3 Months	6 Months
Randomly assigned to CT scan	71	69
Deaths	6	3
Revisions[a]	9	9
Available for radiographic follow-up[b]	56	57
Lost to follow-up	4	8
Actual follow-up[c]	52	49
Percent follow-up[d]	93	86

[a] Emergent reentries and resternotomies in which patient could not be reclosed per protocol. [b] Number randomly assigned to computed tomography (CT) scan minus deaths and revisions. [c] Patients with CT scan data. [d] Actual/available.

Table 3. Patient Demographics and Risk Factors

Characteristics	RPF	CWC	*p* Value
Age, years, mean ± SD	66.3 ± 9.8	64.0 ± 8.9	0.14
Male	73	74	1.0
Body mass index, kg/m^2, mean ± SD	31.8 ± 5.5	31.8 ± 4.6	0.98
Body mass index >30	64	70	0.59
Diabetes mellitus	69	61	0.48
Renal failure	27	27	1.0
COPD	21	27	0.55
Repeated sternotomy	14	14	1.0
Osteoporosis	6	9	0.74
Immunosuppression therapy	4	3	1.0
Chronic steroid use	1	0	1.0
CPB >2 hours' duration	46	46	1.0
BITA harvest	13	17	0.64
Transverse sternal fracture	3	3	1.0
Off-midline sternotomy	6	0	0.12

Data presented as percent, unless otherwise indicated.

BITA = bilateral internal mammary artery; COPD = chronic obstructive pulmonary disease; CPB = cardiopulmonary bypass time; CWC = conventional wire cerclage; RPF = rigid plate fixation.

Pearson) methods for the binary sternal union outcome and simple *t* test methods for the means of continuous outcomes. There was no adjustment for covariates or correction for multiple comparisons.

Results

One hundred and forty patients enrolled; 70 received RPF, and 70 received CWC. Clinical and radiographic follow-up are presented in Tables 1 and 2. Patients were well matched in terms of demographics and risk factors for sternal wound complications (Table 3). Mean number of risk factors was 2.7 ± 0.9 in RPF patients and 2.8 ± 0.9 in CWC patients. Isolated coronary artery bypass graft surgery was performed in 53.2% of patients; isolated valve replacements in 19.1%; and combination coronary artery bypass graft/valve procedures in 24.1%. Mean number of bypass grafts was 3.0 ± 1.3. Mean hospital stay was 13.3 ± 9.8 days for RPF patients and 10.7 ± 6.3 days for CWC patients ($p = 0.80$).

Validation of CT scan methodology indicated a high level of observer agreement. Kappa statistics for intraobserver variability were 0.61 to 0.88 over five sites analyzed by the two independent radiologists, indicating substantial to almost perfect agreement. For the interobserver variability, the kappa statistics were 0.73 to 0.93, which also indicates substantial to almost perfect agreement. Thus, the methodology is repeatable and reproducible, with low variability among reads.

The primary endpoint, CT evaluation of sternal healing, demonstrated that RPF patients had greater healing than CWC patients at both 3 and 6 months (Table 4, Figs 2 and 3). At 3 months, mean CT scores in the RPF group and CWC group were 1.7 ± 1.1 and 0.9 ± 0.8, respectively ($p = 0.003$). At 6 months, mean CT scores in the same groups were 3.2 ± 1.6 and 2.2 ± 1.1, respectively ($p = 0.01$).

Evidence of sternal union at 3 months was limited in both groups. At 3 months, 15% of RPF patients had evidence of sternal union, compared with 0% of CWC patients ($p = 0.11$). By 6 months, 70% of RPF patients had sternal union, compared with 24% of CWC patients ($p = 0.003$).

Evaluation of postoperative pain scores and narcotic usage indicated less pain in RPF patients than in CWC patients (Table 5). In the hospital, pain scores in RPF patients were as much as 25% lower than in CWC patients, and postoperative narcotic usage was also reduced by more than 25% during this period (220.3 ± 243.8 mg versus 306.1 ± 572.2 mg; $p = 0.277$). The greatest differences in pain scores were seen in the first 6 weeks after surgery and were greatest with coughing or sneezing. Over the 6-month follow-up, pain scores began to approach baseline for both groups. Heart Surgery Symptom Index questions about the sternal incision showed similar trends as visual analog scale pain scores.

Table 4. Sternal Union Rates in Rigid Plate Fixation and Conventional Wire Cerclage Patients and Percentage of Sites Evaluated, and Computed Tomography Scores at 3 and 6 Months[a]

CT Scans	No. of Patients	Mean CT Scan Score	% Patients With Sternal Union (Mean Score ≥ 3)	% Sites With CT Scan Score					
				0	1	2	3	4	5
Three-month CT scans									
Rigid plate fixation	27	1.7 ± 1.1	15	22.2	27.4	21.5	16.3	10.4	2.2
Conventional wire cerclage	25	0.9 ± 0.8	0	40.0	37.6	16.8	4.8	0.8	0.0
p Value		0.003	0.11	0.002	0.086	0.558	0.004	0.001	0.248
Six-month CT scans									
Rigid plate fixation	23	3.2 ± 1.6	70	15.7	7.0	4.3	17.4	24.3	31.3
Conventional wire cerclage	26	2.2 ± 1.1	24	16.9	18.5	18.5	27.7	12.3	6.2
p Value		0.01	0.003	0.863	0.008	1.0	0.067	0.019	<0.001

[a] A score of 0 = no healing, 5 = complete union.

CT = computed tomography.

Fig 2. Representative computed tomography scans for (A) rigid plate fixation patients and (B) conventional wire cerclage patients at 3 months. Axial images are from patients with computed tomography scores representative of mean values for their respective group.

Complication rates were similar in both groups. Nine subjects (6 RPF and 3 CWC) died (p = 0.49). There were 18 revision surgeries (11 RPF and 7 CWC; p = 0.466), including 5 emergent reentries in each group (p = 1.0). Reasons included bleeding (n = 3 RPF and n = 2 CWC), redo operation (n = 1 in each group), constrictive pericarditis (n = 1 RPF), pulmonary artery embolectomy (n = 1 CWC), and ascending aortic dissection (n = 1 CWC). No deaths or emergent reentries were related to use of plates or wires. Wound complication rates were similar in both groups (p = 0.282). Six patients had plates removed 7 to 82 days postoperatively for screw backout (n = 1), pull through (n = 1), sternal wound infection (2 deep and 1 superficial), and elective removal for a noninfected wound sinus (n = 1). Three patients received a sternal rewire. In 2 cases, hardware was removed and no additional wires or plates were placed, because the underlying sternum seemed healed. One case resulted in a pectoralis muscle flap. Two CWC patients had sternal wires removed 12 to 110 days postoperatively owing to deep sternal wound infections. Both

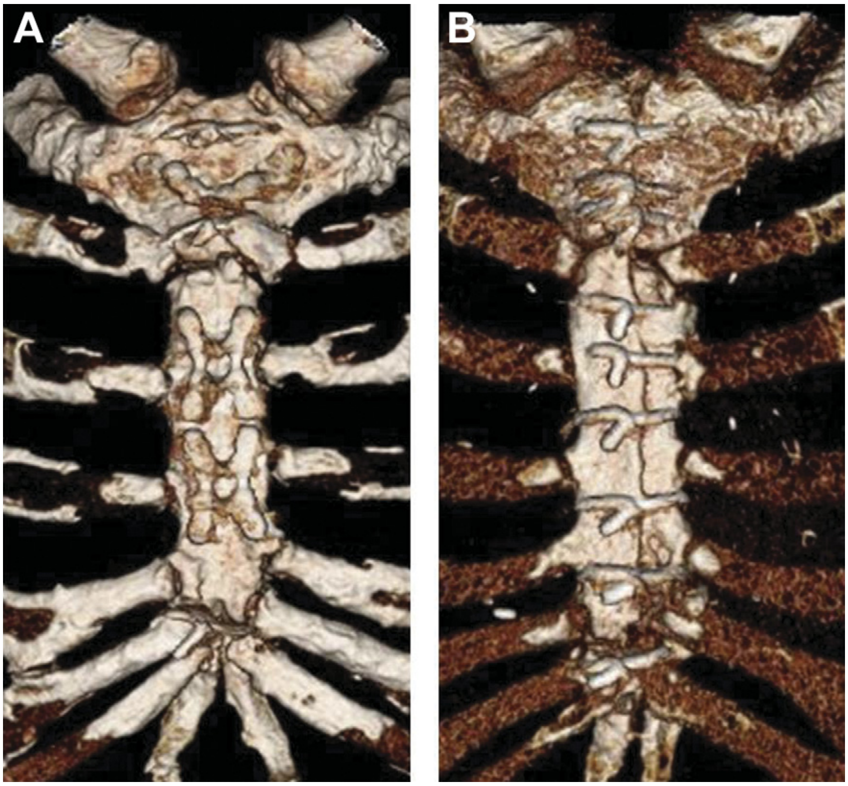

Fig 3. Representative computed tomography scans for (A) rigid plate fixation patients and (B) conventional wire cerclage patients at 6 months. Three-dimensional scan reconstructions are from patients with computed tomography scores representative of mean values for their respective group. Rigid plate fixation patient on left had mean score of 4.0, and conventional wire cerclage patient on right had mean score of 2.2.

patients underwent multiple revision surgeries and ultimately received a pectoralis muscle flap.

Comment

Despite the adoption of rigid fixation in other specialties, sternal closure is still typically performed using wires, the standard method for more than 50 years [17]. Many factors may contribute to this, such as relatively low rates of sternal wound complications, cost, and training. Now, a prospective, randomized multicenter trial has demonstrated that the mechanical benefits of RPF result in superior bone healing to that of simple parasternal wires. In addition, RPF patients had less

Table 5. Comparisons of Postoperative Sternal Pain After Sternal Closure With Rigid Plate Fixation or Conventional Wire Cerclage

Postoperative Sternal Pain	Period	RPF (Mean ± SD)	CWC (Mean ± SD)	% Difference Between CWC and RPF Patients	*p* Value
Pain with coughing	Day 3	4.6 ± 1.8 (n = 36)	4.7 ± 2.2 (n = 41)	2.1	0.83
	Day 4	3.5 ± 2.2 (n = 41)	4.7 ± 2.5 (n = 48)	25.1	0.021
	Day 7	3.1 ± 1.8 (n = 45)	3.6 ± 1.9 (n = 39)	14.9	0.18
	Discharge	2.3 ± 1.3 (n = 56)	3.0 ± 2.0 (n = 58)	20.9	0.046
	3 weeks	2.3 ± 1.2 (n = 51)	3.1 ± 1.9 (n = 55)	26.2	0.0084
	6 weeks	2.3 ± 1.7 (n = 49)	2.7 ± 1.8 (n = 56)	15.1	0.24
	3 months	1.9 ± 1.1 (n = 51)	2.0 ± 1.3 (n = 55)	6.5	0.59
	6 months	1.9 ± 1.2 (n = 45)	1.9 ± 1.3 (n = 56)	1.6	0.91
Pain with sneezing	Day 3	4.1 ± 2.0 (n = 31)	3.9 ± 2.1 (n = 36)	−5.4	0.68
	Day 4	3.3 ± 2.2 (n = 35)	3.8 ± 2.3 (n = 43)	12.0	0.38
	Day 7	3.0 ± 1.7 (n = 42)	3.3 ± 1.9 (n = 36)	10.2	0.41
	Discharge	2.4 ± 1.3 (n = 48)	2.8 ± 2.0 (n = 54)	14.9	0.22
	3 weeks	2.4 ± 1.5 (n = 48)	3.1 ± 1.8 (n = 54)	23.4	0.03
	6 weeks	2.3 ± 1.7 (n = 48)	2.7 ± 1.9 (n = 55)	12.8	0.29
	3 months	1.8 ± 1.0 (n = 51)	2.1 ± 1.3 (n = 55)	17.1	0.12
	6 months	1.8 ± 0.8 (n = 45)	1.9 ± 1.3 (n = 56)	8.3	0.47

CWC = conventional wire cerclage; RPF = rigid plate fixation.

pain and narcotic usage in the early postoperative period.

All wiring techniques allow movement and separation of sternal halves under normal physiologic loads. As a result, standard wiring techniques have been modified to increase the stability of sternal closure. Despite these modifications, mechanical studies show that they result in more movement and sternal separation than single or double parasternal wires. Furthermore, these reinforced wiring techniques have similar clinical outcomes to those of standard single wires [18]. The application of rigid fixation to the sternum has been shown to increase strength and stability and result in earlier union than CWC in primates [19].

In this study, CT scans demonstrated better sternal bone healing with RPF than CWC at 3 and 6 months. Notably, neither group had a high rate of sternal union at 3 months, regardless of the method of closure. This finding is significant and, for the first time, provides prospective randomized data evaluating the time course of sternal healing. In this complex group of patients, the limited sternal healing seen at 3 months runs counter to the traditional teaching to release patients to activity 6 weeks after surgery. While a soft callous or fibrous tissue may add stability after a sternotomy at 6 weeks, limited mineralization and mature bone healing were seen at 3 months. Most patients with RPF had sternal union by 6 months, supporting the hypothesis that improved mechanical stability translates into improved healing.

Sternal nonunion and movement may also increase pain [20], which can affect recovery, respiratory function, mobility, and activity [21-23]. In this study, early postoperative pain scores and narcotic usage were roughly 25% lower in RPF patients with all triggers for chest pain in the poststernotomy setting, a finding supported by a recent study [24].

This study enrolled patients at high risk for sternal wound complications and, as such, the complication rates in both groups were commensurate with the study population and other published rates [2, 5, 7, 25]. The overall reported rates of revision and deep sternal wound infection at 30 days are roughly 5% and 0.5% to 1%, respectively; however, these rates are known to increase with many risk factors in this study [11]. Enrolled patients had, on average, nearly three risk factors, including obesity, diabetes, chronic obstructive pulmonary disease, and renal failure. Patients were followed for 6 months. Although complication rates in this study were similar in both groups ($p = 0.282$), there were more reoperations for sternal wound complications in RPF patients. Evaluation of CT scans for wire patients revealed wire pull through; however, this was not always associated with a revision procedure. The RPF patients in whom screw backout, pull through, or sternal wound infections were observed had 10-mm or 12-mm screw lengths where the mean weight was 105 kg. This finding suggests that the screws were inappropriately selected and would not have achieved bicortical purchase. Successful plate fixation in cancellous bone requires screws to engage both cortices. In addition, a new generation of the plating system has been developed with locking screws to prevent backout.

This study adds to the growing body of literature evaluating rigid fixation of the sternum [4-9, 26]. Randomly assigning patients to a CT scan at 3 or 6 months limited the ability to assess the correlation between bone healing and pain scores or complications. The single CT scan per patient was designed to minimize exposure to mediastinal radiation. This analysis demonstrated a clear difference in sternal healing between groups and upended notions that the sternum heals completely within 6 weeks after sternotomy. Radiologists and patients were not blinded to treatment group allocation; however, steps were taken to minimize bias. The high level of interobserver and intraobserver agreement for CT scan reads, administration of questionnaires to patients by research staff blinded to treatment group, and reduced narcotic usage combined with lower pain scores support the minimization of bias. This study also used a simple wiring technique using parasternal wires, based on their frequency of use in sternal closure and superior mechanical performance compared with reinforced wiring techniques. In addition, the impact of reduced pain on activity or quality of life was not evaluated. These limitations represent opportunities for future studies.

In summary, this study demonstrated that RPF of the sternum significantly improved sternal healing and caused less postoperative pain than CWC.

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A candidate applying for admission to the certifying examination must fulfill all the requirements of the Board in force at the time the application is received.

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