Rigid Plate Fixation Versus Wire Cerclage: Patient-Reported and Economic Outcomes From a Randomized Trial

Keith B. Allen, MD, Vinod H. Thourani, MD, Yoshifumi Naka, MD, PhD, Kendra J. Grubb, MD, John Grehan, MD, PhD, Nirav Patel, MD, T. Sloane Guy, MD, Kevin Landolfo, MD, Marc Gerdisch, MD, Mark Bonnell, MD, and David J. Cohen, MD, MS

Department of Cardiothoracic Surgery, Saint Luke's Mid America Heart Institute, Kansas City, Missouri; Division of Cardiothoracic Surgery, Department of Surgery, Emory University School of Medicine, Atlanta, Georgia; Division of Cardiothoracic Surgery, Department of Surgery, Columbia University Medical Center, New York, New York; Department of Cardiovascular and Thoracic Surgery, University of Louisville, Louisville, Kentucky; Department of Cardiothoracic Surgery, Allina Health, St. Paul, Minnesota; Department of Cardiothoracic Surgery, Lenox Hill Hospital, New York, New York; Department of Cardiothoracic Surgery, Temple University, Philadelphia, Pennsylvania; Department of Cardiothoracic Surgery, Mayo Clinic, Jacksonville, Florida; Department of Cardiothoracic Surgery, Franciscan St. Francis Health, Indianapolis, Indiana; Department of Cardiothoracic Surgery, University of Toledo, Toledo, Ohio; and Department of Cardiology, Saint Luke's Mid America Heart Institute, Kansas City, Missouri

Background. **In a multicenter randomized trial, sternal closure after cardiac operations using rigid plate fixation (RPF) compared with wire cerclage (WC) resulted in improved sternal healing, reduced sternal complications, and was cost neutral at 6 months. Additional secondary end points are presented from this trial.**

Methods. **Twelve United States centers randomized 236 patients to RPF (n = 116) or WC (n = 120). Patient-reported outcomes measures, including pain, function, and quality of life scores, were assessed through 6 months and correlated to computed tomography–derived sternal healing scores using logistic regression. Cost analysis through 90 days was performed to mimic bundled care models.**

Results. **All patient-reported outcomes measures were numerically better in RPF patients than in WC patients at all assessments. RPF resulted in more patients reporting no sternal pain after coughing at 3 weeks (41.1% vs 19.6%; $p = 0.001$) and 6 weeks (54.5% vs 35.1%; $p = 0.005$) and at rest at 6 weeks (74.1% vs 58.8%; $p = 0.02$) and 3 months (87.6% vs 75.9%; $p = 0.03$) compared with WC. Better sternal healing scores correlated to having no sternal pain at rest (odds ratio, 1.6; 95% confidence interval, 1.2 to 2.2; $p = 0.002$) and after coughing (odds ratio, 1.6; 95% confidence interval, 1.2 to 2.2; $p = 0.0007$). RPF resulted in improvements in the 36-Item Short Form Health Survey quality of life scores at 3 weeks (53.5 ± 8.7 vs 50.5 ± 10.4; $p = 0.03$), 6 weeks (45.3 ± 8.4 vs 42.7 ± 8.4; $p = 0.03$), and 6 months (56.4 ± 6.8 vs 53.9 ± 9.0; $p = 0.04$) compared with WC. Through 90 days, RPF compared with WC was $1,888 less (95% confidence interval, –$8,889 to $4,273; $p = 0.52$).**

Conclusions. **In patients undergoing sternal closure after median sternotomy, RPF compared with WC resulted in reduced sternal pain, improved upper extremity function, and similar total 90-day costs.**

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The cornerstone in managing osteotomies/fractures to prevent nonunion, reduce complications, and improve patient outcomes is rigid fixation. Although most disciplines use rigid fixation, most cardiac surgeons continue to use wire cerclage (WC) for sternotomy closure. Wires are effective at sternal approximation but do not provide rigid fixation and are inadequate at preventing sternal movement after the operation [1–6]. Although studies have shown that rigid plate fixation (RPF) improves sternal stability and healing and reduces sternal complication rates compared with WC [7–12], adoption of RPF by cardiac surgeons has been limited by the perception that outcomes with WC are adequate and their initial cost is low compared with RPF. As reimbursement models evolve to value quality balanced by cost beyond 30 days, economically dominant innovations, such as RPF, that improve outcomes out to 90 or 180 days without increasing cost should become more appealing [8, 13].

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Address correspondence to Dr Allen, 4320 Wornall Rd, Medical Plaza II, Ste 50, Kansas City, MO 64111; email: kallen2340@aol.com.

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Abbreviations and Acronyms

BIMA = bilateral internal mammary artery
CABG = coronary artery bypass grafting
CI = confidence interval
CT = computed tomography
PROM = patient-reported outcome measure
QOL = quality of life
RPF = rigid plate fixation
SF-36 = 36-Item Short Form Health Survey
UEF = upper extremity function
UEFI = upper extremity functional index
WC = wire cerclage

In a prospective, randomized trial, we recently reported that sternal closure with RPF compared with WC resulted in improved sternal healing ($p = 0.0007$) and reduced sternal complications ($p = 0.03$) while also being cost neutral ($p = 0.6$) through 6 months of follow-up [8]. In this report we describe secondary end points from this study, including pain, upper extremity function (UEF), and quality of life (QOL) scores through 6 months and their correlation to sternal healing as evaluated by computed tomography (CT). In an effort to mimic anticipated bundled care models, we also examined health care-related costs through 90 days.

Patients and Methods

Study Design

This prospective, randomized, single-blinded, multicenter trial enrolled 236 patients undergoing elective cardiac operations at 12 United States centers between March 2013 and June 2015 [8]. Institutional Review Board approval was obtained from participating institutions along with informed consent from each patient. This study was sponsored by Zimmer Biomet (Jacksonville, FL) and registered on clinicaltrials.gov (NCT01783483).

The study design and methods were previously reported [8]. Briefly, patients undergoing an elective cardiac operation through a median sternotomy who were admitted to the hospital within 24 hours of the operation were eligible for enrollment. Exclusion criteria included a body mass index of 40 kg/m^2 or higher, severe chronic obstructive pulmonary disease, active infection, New York Heart Association Functional Classification IV heart failure, dialysis-dependent renal failure, chronic steroid/narcotics use, the use of nonresorbable hemostatic agents (bone wax), or any intraoperative condition that would require or preclude the use of WC or RPF, such as poor bone quality, bleeding, surgical complications, or off-midline sternotomies. Exclusion criteria were selected to reduce variability in nonsternal postoperative complication costs and expand upon a previously evaluated patient population comparing RPF to WC [7]. Patients were randomized intraoperatively at the time of sternal closure to RPF or WC in a 1:1 ratio. Patients were blinded to the method of sternal closure, with blinding efficacy assessed at each follow-up interval.

Sternotomy Closure Technique

The technique for RPF (SternaLock Blu; Zimmer Biomet, Jacksonville, FL) was previously reported [7, 8, 14]. Briefly, RPF involved reduction of the sternal halves with 3 wires, followed by 1 sternal plate on the manubrium and 2 plates on the sternal body. Self-drilling cancellous screws of appropriate length to engage the anterior and posterior sternal cortex were selected and locked into the plates (Fig 1A–C). In patients randomized to WC, a minimum of 6 wires was prespecified; however, the wiring configuration was according to surgeon preference (Fig 1D–F).

Outcome Measures and Follow-up Schedule

The primary study end point, which was previously reported, was sternal healing based on blinded radiologic core laboratory evaluation of computed CT at 6 months [8]. Secondary end points, which are reported here, include patient-reported outcome measures (PROMs), including pain, QOL scores, and UEF, along with assessment of 90-day health care-related costs by a health economics core laboratory.

Postoperative sternal pain was evaluated daily during the index hospital admission and at 3 weeks, 6 weeks, 3 months, and 6 months using a 10-point numerical rating pain scale. Pain intensity was evaluated first at rest then after forced coughing and ranked from 0 to 10 (0 representing no pain and 10 representing the worst possible pain imaginable). All centers used a standardized, prespecified postoperative pain protocol for both arms of the study, which included patient-controlled analgesics, followed by oral hydrocodone/acetaminophen.

QOL was evaluated at baseline, discharge, 3 weeks, 6 weeks, 3 months, and 6 months using the 36-Item Short Form Health Survey (SF-36) questionnaire (SF-36 v2, QualityMetric, Lincoln, RI). The SF-36 measures functional status and well-being from the patient's perspective and includes two summary scores: (1) a physical component score (PCS), which measures physical functioning, bodily pain, general health, and limitations due to physical problems, and (2) a mental component score (MCS), which measures limitations due to emotional problems, social functioning, vitality, and mental health. The scores are scaled such that amongst the United States population, the mean is 50 with an SD of 10 (higher scores indicate better status).

UEF was assessed at baseline, 3 weeks, 6 weeks, 3 months, and 6 months using the UEF index (UEFI). The UEFI is a validated 20-item questionnaire used for quantifying UEF in performing normal daily activities in patients with musculoskeletal problems [15]. Respondents use a 5-point scale (0 to 4) to rate their difficulty in performing upper extremity activities, with lower scores representing greater difficulty.

Assessment of Bone Healing

The primary end point of this study, sternal healing at 6 months, was determined by a radiology core laboratory (University of Chicago, Chicago, IL) using CT scans and a validated method that has been described previously

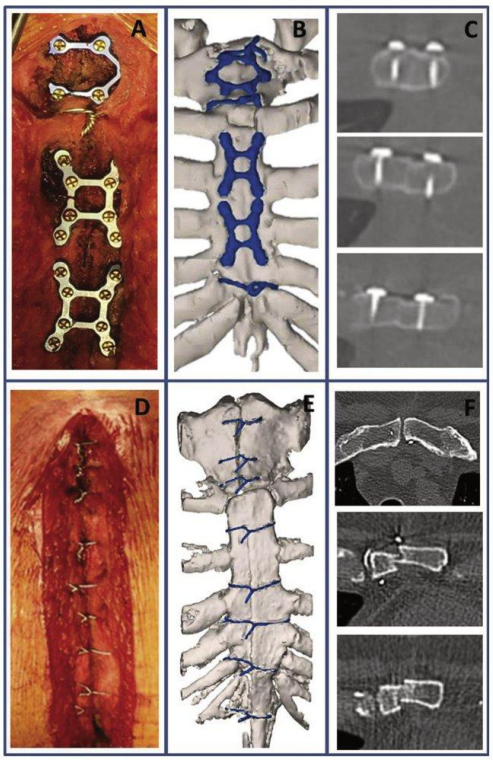


Fig 1. Intraoperative images of (A) rigid plate fixation and (D) wire cerclage, along with (B and E) three-dimensional computed tomography scan reconstructions and (C and F) corresponding axial slices used to assess sternal healing at 6 months.

(Figs 1C, 1F) [7, 8, 16]. Briefly, a core laboratory radiologist selected 5 axial CT slices from anatomic locations defined a priori. To preserve blinding, the core laboratory radiologist attempted to select CT slices that did not reveal which method of closure was used. Two additional radiologists then independently scored each location using a 6-point scale (greater scores represent greater healing).

Economic Analysis

A health economic core laboratory (Saint Luke's Mid America Heart Institute) performed the economic analysis using methods similar to those applied to drug-eluting coronary stents and transcatheter vs surgical aortic valve replacement [17–19]. As described previously, medical resource use and hospital billing data were collected for all patients starting from the time of randomization (sternal closure) through 6 months of follow-up [8]. Charges were converted to costs using hospital- and department-specific cost-to-charge ratios from each hospital's Medicare cost report. Sites also collected data on rehabilitation facility/nursing home stays and outpatient resource use (emergency department visits, physician, and allied health provider visits) for which costs were assigned based on the Medicare fee schedule. To mimic bundled care models that typically reimburse providers over a 90-day global period, we restricted the cost analysis for this report to the first 90 days of follow-up.

Table 1. Patient Demographics

Variables[a]	Rigid Plate Fixation (n = 114)	Wire Cerclage (n = 118)	*p* Value
Demographics			
Age, y	65.3 ± 13.0	65.7 ± 11.4	0.78
Male	86 (74.1)	91 (75.8)	0.76
Height, cm	172.2 ± 9.8	172.7 ± 9.9	0.65
Weight, kg	85.6 ± 17.6	88.2 ± 16.5	0.23
Body mass index, kg/m^2	28.8 ± 4.7	29.4 ± 4.6	0.28
White race	103 (88.8)	103 (85.7)	0.48
Hypertension	86 (74.1)	83 (69.2)	0.40
Peripheral artery disease	12 (10.3)	5 (4.2)	0.07
Cerebrovascular disease	10 (8.6)	7 (5.8)	0.41
Risk factors for sternal complications			
Diabetes	35 (30.2)	44 (36.7)	0.29
Body mass index ≥33 kg/m^2	26 (22.4)	29 (24.2)	0.75
Chronic lung disease	22 (19.0)	22 (18.3)	0.58
Current tobacco use	14 (12.1)	10 (8.3)	0.34
Renal failure	0 (0)	2 (1.7)	0.16
BIMA	7 (6.0)	4 (3.4)	0.37
Previous sternotomy	8 (6.9)	5 (4.2)	0.36
Intraoperative variables			
Isolated CABG	56 (48.3)	57 (47.9)	0.95
Isolated valve	33 (28.5)	33 (27.7)	0.90
CABG and valve	25 (21.6)	28 (23.5)	0.72
Bypass grafts, No.	2.7 ± 1.1	2.9 ± 1.1	0.45
Operative time, h	5.6 ± 1.8	5.6 ± 1.4	0.98
Sternal closure time, min	18.9 ± 9.0	16.3 ± 9.3	0.03

[a] Continuous data are expressed as mean ± SD and categoric data as number (%).

BIMA = bilateral internal mammary artery; CABG = coronary artery bypass grafting.

Statistical Analysis

Statistical analyses were on an intent-to-treat basis and prespecified in the statistical plan of the protocol. Continuous data, including scores for PROMs, were summarized and compared using *t* tests and are presented as a mean ± SD. Categoric data, including complication rates and the percentage of patients without sternal pain or functional limitations, were compared using two-sided Fisher exact tests and are summarized as a number (%).

Table 2. Patient Follow-Up and Blinding

Follow-Up Interval[a]	Rigid Plate Fixation % (n/N)	Wire Cerclage % (n/N)	Overall % (n/N)	Patient Blinding Maintained % (n/N)
3 weeks	97 (111/114)	93 (110/118)	95 (221/232)	83 (179/215)
6 weeks	97 (110/114)	98 (116/118)	97 (226/232)	82 (185/226)
3 months	90 (103/114)	92 (108/117)	91 (211/231)	80 (171/213)
6 months	90 (102/114)	86 (101/117)	88 (203/231)	77 (152/198)

[a] Patient follow-up excludes deaths. A total of 3 patients died in the rigid plate fixation group, and 2 patients died in the wire cerclage group.

We previously reported that RPF resulted in better sternal healing scores at 3 (2.6 ± 1.1 vs 1.8 ± 1.0; $p < 0.0001$) and 6 months (3.8 ± 1.0 vs 3.3 ± 1.1; $p = 0.0007$) compared with WC [8]. To determine the potential effect of sternal healing on PROMs, the relationship between the mean CT scan sternal healing score and postoperative sternal pain was evaluated using logistic regression. The independent variable in both models was the CT sternal healing score at 6 months. One model had the dependent variable "pain at rest" and the other had the dependent variable "pain after coughing." A patient reporting a score of 0 was classified as having "no pain," and a patient with a pain score of 1 to 10 was classified as having "pain."

Total cost from the time of sternal closure through 90-day follow-up is described as mean values and was compared using nonparametric bootstrapping (1,000 replicates), a standard technique for comparing non-normally distributed variables where inference on mean differences is desired [20]. For patients with incomplete 3-month follow-up, measures of resource utilization and cost were imputed for the missing time period based on their daily rates during the immediately previous time period.

Results

There were 236 patients randomized to RPF (n = 116) or WC (n = 120). Patient demographics, risk factors for sternal complications, and intraoperative variables (Table 1) were similar between groups and previously reported [8]. Sternal closure in WC patients was achieved with a mean of 7.7 $\pm$ 0.8 wires/patient, with single wires used in 48.3% (58 of 120) of patients, double wires in 25.0% (30 of 120), figure of 8 in 18.3% (22 of 120), and a combination of configurations in 8.3% (10 of 120). Follow-up and the efficacy of subject blinding are summarized in Table 2.

Patient-reported pain scores at rest and after forced coughing are summarized in Figure 2. Pain scores at rest and after forced coughing were numerically lower (ie, less pain) with RPF than with WC at each follow-up assessment. More patients in the RPF group reported no sternal pain at rest at 6 weeks ($p = 0.02$) and 3 months ($p = 0.03$) and

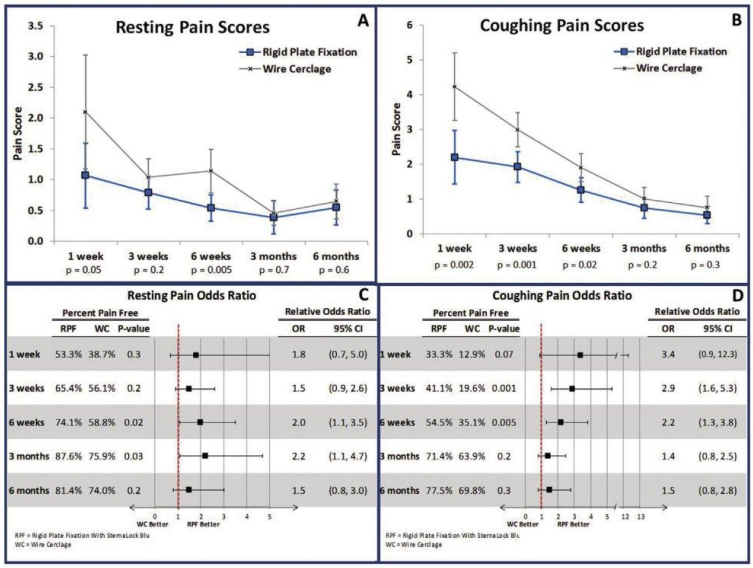


Fig 2. Pain scores (A) at rest and (B) with coughing. Mean data are shown with the SD (range bars). The percentage of patients who reported having no sternal pain (C) at rest and (D) with coughing is shown. The squares show the odds ratios (ORs) and the horizontal lines indicate the 95% confidence interval (CIs).

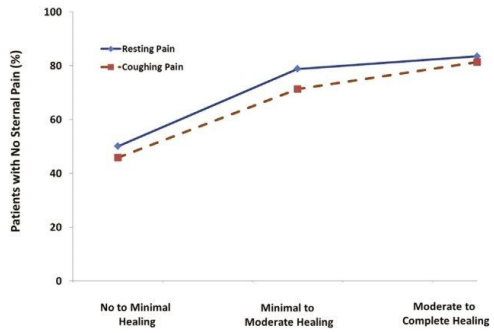


Fig 3. The percentage of patients who were pain free as a function of sternal healing is shown. Computed tomography scores were aggregated to represent no to minimal healing (scores from 0 to 2), minimal to moderate healing (2 to 4), and moderate to complete healing (4 to 5).

no sternal pain after forced coughing at 3 weeks ($p = 0.001$) and 6 weeks ($p = 0.005$) compared with WC patients. Logistic regression analysis demonstrated a significant correlation between sternal healing and postoperative pain (Fig 3). For each unit of increase in the patient's CT scan healing score, the odds of being pain free increased by 60% at rest (odds ratio, 1.6; 95% confidence interval, 1.2 to 2.2; $p = 0.002$) and after forced coughing (odds ratio, 1.6; 95% confidence interval, 1.2 to 2.2; $p = 0.0007$).

SF-36 QOL scores are summarized in Figure 4. QOL PCS and MCS scores were numerically higher (ie, better) with RPF at all follow-up assessments, with significant differences in favor of RPF for the PCS at 6 weeks (mean difference, 2.6 points; $p = 0.03$) and for the MCS at 3 weeks (mean difference, 3.0 points; $p = 0.03$) and 6 months (mean difference, 2.5 points; $p = 0.04$).

Patient-reported outcomes involving UEF are summarized in Figure 5. Mean scores on the UEFI were numerically better after RPF than after WC at all measured assessments; however, the differences were only statistically significant at 6 weeks (67.6 ± 14.5 vs 62.0 ± 17.1; $p = 0.02$). In contrast, the probability of a patient reporting no difficulty with UEF was significantly better with RPF at all follow-up times (Fig 5B).

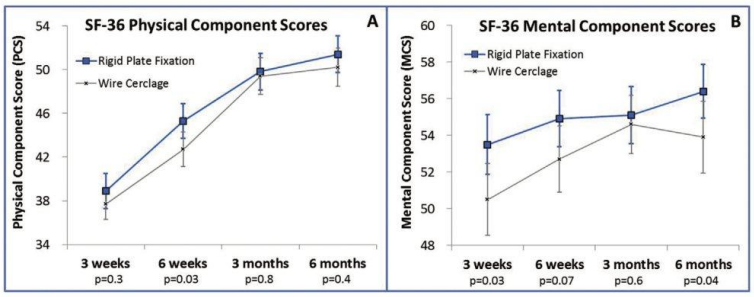
The results of the economic analysis using a 90-day global model are summarized in Table 3. As previously reported, index hospitalization costs were approximately $2,800/patient higher ($p = 0.11$) with RPF than with WC, a difference driven primarily by the cost of the sternal closure system [8]. After discharge through 90 days, health care costs were approximately $4,500/patient lower in the RPF group than in the WC group ($p = 0.06$). The cost reduction was driven by trends toward fewer sternal complications (0% [0 of 116] vs 4.2% [5 of 120]; $p = 0.06$), fewer readmissions (12.9% [15 of 116] vs 20.8% [25 of 120]; $p = 0.1$), and fewer days in rehabilitation hospitals and skilled nursing facilities (312 days vs 520 days; $p = 0.2$). In addition, there was a trend over 90 days toward fewer days in the hospital after RPF compared with WC (mean 6.6 ± 3.4 vs 7.9 ± 8.0; $p = 0.1$).

These key cost offsets resulted in reductions of $2,297/patient related to sternal complications ($p < 0.001$), $1,462/patient from reduced readmissions costs ($p = 0.3$), and $992/patient from reduced outpatient resource utilization ($p = 0.5$). When these "downstream" cost offsets were combined with the higher up-front cost of RPF, total 90-day costs were $1,888 less in RPF patients compared with WC patients ($29,179 vs $31,067; 95% confidence interval, –$8,889 to $4,273; $p = 0.52$). Additional analyses using generalized linear models with a gamma distribution and log link demonstrated that 90-day costs differences were stable with regards to study site.

Comment

In a multicenter, randomized trial, sternotomy closure with RPF resulted in significantly better sternal healing by CT, fewer sternal complications, and no additional cost compared with WC through 6 months after the operation [8]. Secondary end points from this randomized controlled trial reported here demonstrated that RPF also reduced postoperative pain, improved UEF, and improved QOL scores at several time points during the 6-month follow-up period. When health care costs were analyzed post hoc through 90 days of follow-up (designed to mimic proposed bundle payment models), these important patient benefits were achieved with no additional cost and a trend toward cost savings.

Fig 4. (A) Physical and (B) mental component quality of life scores on the 36-Item Short Form Health Survey (SF-36; QualityMetric, Lincoln, RI).



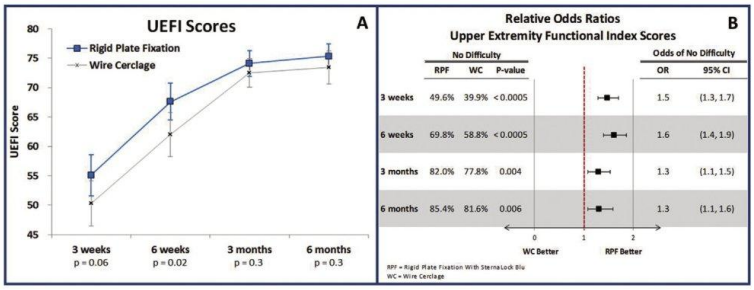


Fig 5. (A) Upper extremity functional index (UEFI) scores, presented as means and SD (range bars). (B) Relative odds of patients reporting no difficulty with using their upper extremities. The squares indicate the odds ratio (ORs) and the horizontal lines indicate the 95% confidence intervals (CIs).

Sternal stability is a key factor in optimizing recovery after a median sternotomy. Sternal movement and separation occur shortly after sternotomy closure with wires alone [5, 21]. An analysis of sternal separation using ultrasound after WC showed sternal separation approaching 2 mm on postoperative day 1 [21]. Similarly, CT scan assessment at 10 days postoperatively showed that sternal separation in WC patients was significantly greater than in RPF patients [5]. Separation in both studies occurred laterally and anteriorly/posteriorly and was enough to limit or prevent bone healing [21]. Finally, previous studies have shown that patients closed with WC have not achieved sternal healing by 3 months; and even at 6 months, fewer than half of patients have CT evidence of sternal union [7, 22].

Through 90 days of follow-up, RPF compared with WC demonstrated a trend toward fewer overall sternal complications, which included deep and superficial sternal wound infection (0% [0 of 116] vs 4.2% [5 of 120]; $p = 0.06$). As previously reported, when this follow-up was extended to 6 months, RPF compared with WC resulted in significantly fewer sternal complications (0% [0 of 116] vs 5% [6 of 120]; $p = 0.03$) and a trend toward fewer sternal wound infections (0% [0 of 116] vs 4.2% [5 of 120]; $p = 0.06$), with 50% of sternal complications occurring beyond the traditionally reported 30-day period [8].

Although sternal complications are of unquestioned clinical relevance, PROMs, such as the ability to resume normal activities after the operation and postoperative pain, are increasingly scrutinized by payors. RPF provides early and better sternal stability than WC, which leads to significant improvements in PROMs independently of bone healing. These improvements were seen during the first 3 months after the operation, when the number of patients with complete sternal healing is still limited (41% of RPF patients vs 16% of WC patients; $p < 0.0001$) [8], suggesting that the immediate postoperative stability provided by RPF plays an important role in mitigating sternal pain and improving UEF. These differences in PROMs were identified in a study in which patients were blinded to the type of sternal closure and in which identical postoperative pain management protocols and instructions were used, which strongly suggests that these improvements resulted from the treatment itself rather than from bias on the part of patients or their physicians.

In recent years, there has been increasing interest in episode payment models for cardiac operations, whereby hospitals are responsible for the cost over longer time periods. In 2015, Congress passed the Medicare Access and Children's Health Insurance Program Reauthorization Act and established alternative payment models and the Merit-based Incentive Payment System. Under these models and the proposed 90-day bundle for isolated coronary artery bypass grafting, hospitals that meet quality and cost targets would benefit financially, whereas those that fail would be penalized [23]. Under such payment models, the use of RPF would be highly favored given the improvements in clinical outcomes that were achieved without an increase in 90-day or 6-month cost.

Important lessons can be learned from early participants in bundled payment models. Engelman [13] noted that incorporating protocols or treatments that reduce readmissions and effectively reduce postacute disposition to extended care facilities were the two biggest variables in affecting a positive margin in their bundle. The use of RPF in this trial resulted in a trend toward reducing readmission rates and less time spent in rehabilitation hospitals and skilled nursing facilities. Despite the recent

Table 3. Index Hospitalization, Follow-Up, and Aggregate 90-Day Global Costs

Variable	RPF Costs/Patient Mean ± SD, $	WC Costs/Patient Mean ± SD, $	RPF – WC Difference $ (95% CI)	Bootstrap p Value
Index hospitalization costs	23,437 ± 12,421	20,574 ± 14,102	2,863 (–681 to 6,103)	0.11
Total follow-up costs	5,742 ± 15,148	10,493 ± 24,625	–4,751 (–10,289 to 312)	0.06
Total 3-month costs	29,179 ± 21,016	31,067 ± 28,562	–1,888 (–8,889 to 4,273)	0.52

CI = confidence interval; RPF = rigid plate fixation; WC = wire cerclage.

discussion on repealing the Affordable Care Act and rethinking implementation of episode payment models, payors will continue to push for physician and hospital payment based on transparent performance metrics tied to patient-reported outcomes. Innovations in care, such as RPF, can only be successful if supported by economic models that demonstrate cost effectiveness in conjunction with improved clinical and patient reported outcomes, as demonstrated in this randomized controlled trial.

Limitations of this study include a sample size designed to prove the primary end point of improved sternal healing but not secondary end points. Sample size calculations for patient-reported pain, however, indicated that the number of patients enrolled was appropriate to detect the differences reported here. Although this study, like most randomized controlled trials, was not sufficiently powered for some of the secondary end points, the improvements in these outcomes, which were consistently seen at each time point with RPF compared with WC, are supportive. These secondary end points, however, could be evaluated in larger, future studies to validate them and determine their generalizability. An additional limitation was the occurrence of patient unblinding during follow-up, which could influence PROMs for the small number of unblinded patients.

In conclusion, this prospective, randomized, multicenter trial found sternotomy closure using RPF compared with WC resulted in improved PROMs, improved sternal healing by CT and fewer sternal complications while remaining cost neutral at 3 and 6 months of follow–up [8]. Economically dominant technology, such as RPF, that improves outcomes without increasing costs will become increasingly important as the focus of health care shifts from the index admission/30-day period to a global episodic payment model.

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