Randomized, multicenter trial comparing sternotomy closure with rigid plate fixation to wire cerclage

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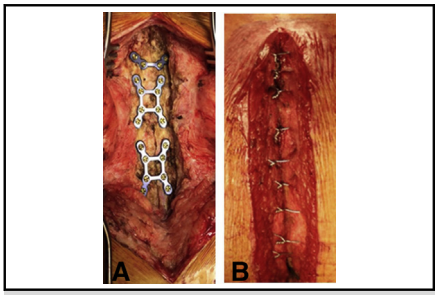
ABSTRACT

Objective: To evaluate sternal healing, complications, and costs after sternotomy closure with rigid plate fixation or wire cerclage.

Methods: This prospective, single-blinded, multicenter trial randomized 236 patients at 12 US centers at the time of sternal closure to either rigid plate fixation (n = 116) or wire cerclage (n = 120). The primary endpoint, sternal healing at 6 months, was evaluated by a core laboratory using computed tomography and a 6-point scale (greater scores represent greater healing). Secondary endpoints included sternal complications and costs from the time of sternal closure through 6 months.

Results: Rigid plate fixation resulted in better sternal healing scores at 3 (2.6 ± 1.1 vs 1.8 ± 1.0; $P < .0001$) and 6 months (3.8 ± 1.0 vs 3.3 ± 1.1; $P = .0007$) and greater sternal union rates at 3 (41% [42/103] vs 16% [16/102]; $P < .0001$) and 6 months (80% [81/101] vs 67% [67/100]; $P = .03$) compared with wire cerclage. There were fewer sternal complications through 6 months with rigid plate fixation (0% [0/116] vs 5% [6/120]; $P = .03$) and a trend towards fewer sternal wound infections (0% [0/116] vs 4.2% [5/120]; $P = .06$) compared with wire cerclage. Although rigid plate fixation was associated with a trend toward greater index hospitalization costs ($23,437 vs $20,574; $P = .11$), 6-month follow-up costs tended to be lower ($9002 vs $13,511; $P = .14$). As a result, total costs from randomization through 6 months were similar between groups ($32,439 vs $34,085; $P = .61$).

Conclusions: Sternotomy closure with rigid plate fixation resulted in significantly better sternal healing, fewer sternal complications, and no additional cost compared with wire cerclage at 6 months after surgery. (J Thorac Cardiovasc Surg 2017;153:888-96)



Intraoperative photograph of rigid plate fixation (A) and wire cerclage (B) patient.

Central Message

Sternal closure with rigid plate fixation resulted in improved sternal healing, fewer sternal complications, and no additional cost at 6 months compared with wire cerclage.

Perspective

In a prospective, randomized, single-blinded, multi-center trial, sternotomy closure using rigid plate fixation (RPF) compared with wire resulted in improved sternal healing and fewer sternal complications with no additional health care–related costs at 6 months. Although the benefits of RPF are well established, this is the first randomized controlled trial that correlates RPF with improved sternal healing and outcomes.

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Median sternotomy is the most common osteotomy and is performed in more than 500,000 patients/year in the United States alone.[1] Although most surgical disciplines involved in the management of fractures and osteotomies adhere to the principles of approximation, compression, and stabilization of the bone using rigid fixation, the vast

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Abbreviations and Acronyms

BMI = body mass index
CI = confidence interval
CT = computed tomography
DSWI = deep sternal wound infection
OR = odds ratio
RCT = randomized controlled trial
RPF = rigid plate fixation
STS = Society of Thoracic Surgeons
WC = wire cerclage

Scanning this QR code will take you to a video and appendix for the article.

majority of cardiac surgeons continue to use wire cerclage (WC) for sternotomy closure because of the perceived low rate of sternal wound complications and the low cost of wires.

Although wires are effective at sternal approximation, they do not provide rigid fixation, nor do they adequately prevent sternal movement and separation.[2,3] Mechanical studies have demonstrated that rigid plate fixation (RPF) of the sternum results in superior mechanical properties compared with WC, and in nonrandomized trials RPF has been reported to improve clinical outcomes.[4-10] Although deep sternal wound infection (DSWIs) are reported to occur at a <1% rate, recent reports suggest sternal complications occur with a greater frequency, ranging from 0.7% to 11.1%, and represent significant clinical and economic events that might be mitigated by modifying sternal closure techniques.[11-18]

In a randomized trial comparing WC with a previous generation of the RPF system used in the current study, Raman and colleagues[19] demonstrated that the mechanical benefit of RPF translated into better sternal healing as measured by computed tomography (CT) and that postoperative pain was improved. The impact of improved sternal healing with RPF on other clinically significant endpoints and an analysis of health care–related costs after sternal closure with RPF, however, have not been reported previously. The objective of this study was to evaluate sternal healing, sternal complications, and health care–related costs after sternotomy closure with RPF or WC in a prospective, randomized, single-blinded, multicenter trial. This study hypothesized RPF leads to superior sternal healing via CT at 3 and 6 months.

METHODS

Study Design

This prospective, randomized, single-blinded, multicenter trial enrolled 236 patients undergoing elective cardiac surgery at 12 US centers between March 2013 and June 2015 (Appendix E1). Institutional review board approval was obtained at each site, and informed consent was obtained from each patient before enrollment. This study was sponsored by Zimmer Biomet, Jacksonville, Fla, and registered at clinicaltrials.gov (NCT01783483). Inclusion criteria included patients ≥18 years of age undergoing elective cardiac surgery via a median sternotomy who were admitted to the hospital within 24 hours of surgery. Preoperative exclusion criteria included patients with a body mass index (BMI) ≥40, severe chronic obstructive pulmonary disease as defined by the Society of Thoracic Surgeons (STS), an active infection, New York Heart Association class IV heart failure, dialysis-dependent renal failure, and chronic steroid or narcotics use. Some of these were excluded to reduce variability in costs from nonsternal-related postoperative complications, whereas others had already been evaluated in a previous, multicenter randomized controlled trial (RCT) in which the authors evaluated RPF.[19] Intraoperative exclusion criteria included the use of nonresorbable hemostatic agents or any intraoperative condition that would preclude the use of either WC or RPF (poor bone quality, off-midline sternotomies, bleeding, surgical complications, etc).

Patients meeting pre- and intraoperative enrollment criteria were randomized to either RPF (SternaLock Blu, Zimmer Biomet, Jacksonville, Fla) or WC (Figure 1) at the completion of the cardiac surgical procedure and immediately before sternal closure. Patients were randomized in a 1:1 ratio with a schedule generated by the sponsor. Randomization was stratified by site with a fixed block size of 6. Sites were blinded to the randomization scheme, and no site was to enroll >25% of the total population. Patients were blinded to the method of sternal closure. St Luke's Mid America Heart Institute (Kansas City, Mo) served as the coordinating center for the study.

Sternotomy Closure Technique

For patients randomized to RPF, a prespecified technique that has been described previously was used (Video 1).[9,19] In summary, sternal thickness was measured at anticipated plate locations to select the appropriate screw lengths needed to engage the posterior sternal cortex. Three sternal wires were used to reduce the sternal halves, muscle/fascia was elevated off the sternum at the location of plate placement, and plates were contoured as needed. One plate was placed on the manubrium, 2 "X" plates were positioned on the sternal body, and self-drilling screws were placed and fully locked into the plates. Should emergent re-entry be required, cuttable cross sections of the sternal plates spanning the sternotomy can be cut with standard wire cutters, or in redo sternotomies, the screws may be backed out and the plates removed. The technique for sternal closure with WC was prespecified to require a minimum of 6 stainless-steel wires (either single or double stranded) but was otherwise per institutional/surgeon preference to allow for various wiring configurations. Closure technique of the suprasternal soft tissue and skin was at the surgeon's discretion. Sternal closure time was recorded and included the time to prepare, approximate, and fixate the sternal halves.

Outcome Measures and Follow-up Schedule

The primary endpoint of the study, sternal healing at 6 months, was determined by independent radiologists at a core laboratory (University of Chicago, Chicago, Ill) using CT scans and a validated method that has been described previously and shown to have a high level of inter- and intraobserver agreement.[20] To summarize, 5 axial CT slices from a priori–defined anatomic locations were selected by one core laboratory radiologist for evaluation. 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