Zippering up after a median sternotomy: Are we at the end of the wire?

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The median sternotomy represents one of the most commonly performed osteotomies in surgery.¹ Most cardiac surgeons reapproximate the sternum with wire cerclage (WC), whereas rigid plate fixation (RPF) is typically used in other surgical specialties.² The perceived advantages of WC include familiarity, ease of use, speed, and low complication rate. The most devastating complications of sternal closure are mediastinitis and deep sternal wound infection, estimated to occur in approximately 1% of sternotomies.³⁻⁵

In this study, Allen and colleagues⁶ randomly allocated 236 patients to either RPF (n = 116) or WC (n = 120). The primary outcome was sternal healing at 6 months, as evaluated by computed topography on a 6-point scale, a previously validated scoring system.^{7,8} Secondary outcomes included sternal complications and costs from time of sternal closure to 6 months. Allen and colleagues⁶ are to be commended on conducting a well-designed study; patients were effectively randomized, and baseline demographics were equal in both groups. Furthermore, although surgeons were not blinded to the allocated treatment, the patients were. Importantly, all scans were read centrally by radiologists blinded to the treatment assignment—the selected computed tomographic slices for review were chosen as representative but with minimal evidence of the method of sternal closure. Allen and colleagues⁶ also prospectively collected costing data to perform a cost comparison between the 2 study arms.

Patients in the RPF group had better sternal healing scores at both 3 months (2.6 ± 1.1 vs 1.8 ± 1.0 ; $P < .0001$) and 6 months (3.8 ± 1.0 vs 3.3 ± 1.1 ; $P = .0007$) of follow-up. Furthermore, sternal union rates (defined as sternal healing score ≥ 3) were higher at 3 months (41% [42/103] vs 16% [16/102]; $P < .0001$) and 6 months (80% [81/101] vs 67% [67/100]; $P = .03$). There were also fewer sternal complications requiring readmission in the RPF group (0% [0/116] vs 5% [6/120]; $P = .03$). It is also important to note that there were no sternal infections in the RPF arm, suggesting that by achieving

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Central Message

Rigid plate fixation showed improved rates of sternal union at 3 and 6 months and significantly fewer sternal complications than seen with wire cerclage without a significant difference in costs.

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more rigid immobilization, infectious complications may be reduced as well (the expected sternal infection rates in the 2 arms were not reported). Finally, index hospitalization and costs at 6 months were not significantly different between groups; the increased early costs in the RPF group were offset by reduced costs in follow-up.

Still, there are some limitations to this study. First, there is reduced generalizability, because the study excluded patients with anticipated wound healing problems such as those with severe chronic obstructive pulmonary disorder and morbid obesity (body mass index >40 kg/m²).⁹ Although 461 patients were screened, only 236 patients were randomly assigned in the intent to treat analysis; 190 were not eligible for the study on the basis of inclusion and exclusion criteria, and 35 patients were excluded after informed consent was obtained (19 preoperatively and 16 intraoperatively). Furthermore, the specified primary outcome was a surrogate measurement, sternal union rates at 3 and 6 months. The clinical significance of the outcome is unclear, although Allen and colleagues⁶ will be publishing quality of life and functional index results separately. The inclusion of a cost analysis that was conducted by an expert health economist highlights the importance of financial considerations in the adoption of new health technologies. Allen and colleagues⁶ chose to assess costs between the 2 groups with diagnosis-related group billing data, a well-validated method for cost assessment. Costs were not

measured until time of sternal closure and excluded the index cost of the operation itself, which is more accurate to assess the costs of the closure methods; however, exclusion of the index procedure will limit overall generalizability of the cost comparison. Other rigid fixation systems exist.^{10,11} It is unknown whether the results of this study represent a class effect or whether the results of the study are strictly limited to this device. There are only 2 randomized trials in the literature examining RPF, a previous study from this manufacturer with an earlier generation closure system and this current study.^{6,7}

Again, Allen and colleagues⁶ are to be congratulated for highlighting such an important and relevant issue in cardiac surgery. Medicare has deemed deep sternal wound infection to be a “never event,” and this study shows potential benefit in reducing sternal complications. This highlights the need for a larger and more inclusive trial to determine which patients will benefit the most from RPF. Furthermore, a formalized cost-utility analysis, the criterion standard for many national decision making agencies, is warranted to determine the true cost-effectiveness of rigid fixation compared with WC.¹² A cost-utility analysis can incorporate the values and preferences of the patient along with changes in quality of life between the 2 study arms to calculate a common measure of cost-effectiveness, allowing for comparison across health care interventions. If further trials can prove that RPF is superior to WC in clinically relevant outcomes and in a cost-effective manner, there will be a paradigm shift in the way we ‘zip’ our patients up.

References

1. Mozaffarian D, Benjamin EJ, Go AS, Arnett DK, Blaha MJ, Cushman M, et al. American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2015 update: a report from the American Heart Association. *Circulation*. 2015;131:e29-322. Errata in: *Circulation*. 2016;133:e417. *Circulation*. 2015;131:e535.
2. Uhthoff HK, Poitras P, Backman DS. Internal plate fixation of fractures: short history and recent developments. *J Orthop Sci*. 2006;11:118-26.
3. El Oakley RM, Wright JE. Postoperative mediastinitis: classification and management. *Ann Thorac Surg*. 1996;61:1030-6.
4. De Feo M, Renzulli A, Ismeno G, Gregorio R, Della Corte A, Utili R, et al. Variables predicting adverse outcome in patients with deep sternal wound infection. *Ann Thorac Surg*. 2001;71:324-31.
5. Benedetto U, Altman DG, Gerry S, Gray A, Lees B, Pawlaczyk R, et al; Arterial Revascularization Trial investigators. Pedicled and skeletonized single and bilateral internal thoracic artery grafts and the incidence of sternal wound complications: insights from the Arterial Revascularization Trial. *J Thorac Cardiovasc Surg*. 2016;152:270-6.
6. Allen KB, Thourani VH, Naka Y, Grubb KJ, Grehan J, Patel N, et al. Randomized, multicenter trial comparing sternotomy closure with rigid plate fixation to wire cerclage. *J Thorac Cardiovasc Surg*. 2017;153:888-96.
7. Raman J, Lehmann S, Zehr K, De Guzman BJ, Aklog L, Garrett HE, et al. Sternal closure with rigid plate fixation versus wire closure: a randomized controlled multicenter trial. *Ann Thorac Surg*. 2012;94:1854-61.
8. Stacy GS, Ahmed O, Richardson A, Hatcher BM, MacMahon H, Raman J. Evaluation of sternal bone healing with computed tomography and a quantitative scoring algorithm. *Open Med Imaging J*. 2014;8:29-35.
9. Song DH, Lohman RF, Renucci JD, Jeevanandam V, Raman J. Primary sternal plating in high-risk patients prevents mediastinitis. *Eur J Cardiothorac Surg*. 2004;26:367-72.
10. Schulman NH. Trans-sternal titanium fixation bars: an initial experience with 28 patients. *Ann Plast Surg*. 2012;69:429-30.
11. Fawzy H, Osei-Tutu K, Errett L, Latter D, Bonneau D, Musgrave M, Mahoney J. Sternal plate fixation for sternal wound reconstruction: initial experience (retrospective study). *J Cardiothorac Surg*. 2011;6:63.
12. Canadian Agency for Drugs and Technologies in Health. *Guidelines for the economic evaluation of health technologies: Canada*. 3rd ed. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2006.