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CABLE TIES FOR CHEST CLOSURE: ZIPFIX OR ZIPFAIL?

To the Editor:

We read with great interest the randomized clinical trial (RCT) conducted by Marasco and colleagues comparing ZIPFIX (DePuy Synthes CMF, West Chester, Pa), a polymer cable tie system, with traditional wire cerclage in primary sternal closure after cardiac surgery in 118 patients.¹ The authors reported no difference in postoperative pain (the primary outcome) despite more movement on ultrasonographic examination (the secondary outcome) in the ZipFix group. The authors conclude that ZIPFIX provides a reliable closure without any demonstrable benefit compared with wires.

The results of this study are strikingly different from those published by Nezafati and colleagues in *Heart, Lung & Circulation*.² In a RCT of 326 patients randomized to ZIPFIX or wire cerclage, the authors reported improved pain scores with ZIPFIX. More impressive, the authors reported a significant reduction in sternal dehiscence (0 in the ZIPFIX group and 5 in the wire group; $P < .001$). Can Marasco and colleagues provide any insight into the heterogeneity in the results of these 2 studies? Is it simply a problem of sample size or was there a difference in closure technique, generational differences in the ZIPFIX closure device, or some other factor that resulted in divergent results.

Drawing conclusions from this study alone would suggest that ZIPFIX is a dominated strategy in health economics speak—the use of ZIPFIX comes at a higher cost to the traditional treatment strategy of wires without providing any additional benefit. In fact, although the authors conclude that ZIPFIX might provide a reliable closure, their ultrasonographic outcome suggests otherwise because there was more movement compared with wire cerclage. An RCT comparing rigid plate fixation

with wire cerclage showed improved sternal healing and lower rates of sternal complications with plates,³ highlighting that adhering to the basic principles of fracture management, reapproximation, stabilization, and immobilization, remains key to optimal bone healing. Perhaps understanding how this study differs than the results of the published literature might shed light on how ZIPFIX might be used to improve sternal healing after median sternotomy.

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POLYMER CABLE TIE CLOSURE OF THE STERNUM: IS IT AN ACCEPTABLE FIX?

Reply to the Editor:

It was enlightening to read the insightful letter to the Editor by Tam and Fremes¹ regarding the randomized, controlled trial (RCT) conducted by Marasco and colleagues² to compare ZIPFIX ties (DePuy Synthes, West Chester, Pa) with traditional wire cerclage for primary sternal closure. The investigators reported no difference in postoperative pain between the 2 groups (primary outcome). Follow-up ultrasonography, however, showed more movement in the ZIPFIX group, suggesting sternal instability. Notably, ultrasonographic follow-up in this study was incomplete, and ultrasonographically documented sternal dehiscence was not the primary outcome.

Another recent RCT, conducted by Nezafati and colleagues³ and published in *Heart, Lung and Circulation*, also compared ZIPFIX with wire cerclage and found remarkably different results. Those investigators reported that the patients who underwent ZIPFIX fixation had lower pain scores ($P < .001$) and significantly less sternal

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dehiscence. In contrast, Marasco and colleagues² found more ultrasonographically documented sternal instability in the ZIPFIX arm than in the wire cerclage arm. This raises the question of why the results are so divergent between the 2 studies, as Tam and Freme¹ point out.

There can be no single, simple answer. Although both studies were randomized, they were not similarly designed. The primary outcome of the RCT of Marasco and colleagues² was pain only, whereas in the study of Nezafati and colleagues,³ the primary outcomes were infection, dehiscence, and pain. Notably, the report of Nezafati and colleagues³ is unclear about the details of the technique used for wire cerclage (eg, number and size of wires, number of twists), any of which could affect outcomes. Furthermore, neither study followed a standardized protocol to detect malunion or dehiscence. Nezafati and colleagues³ relied solely on clinical detection of sternal click on physical examination; use of this criterion by itself could have missed a lot of malunions in either group. Although Marasco and colleagues² used ultrasonography to evaluate sternal instability, a more robust imaging modality such as computed tomography could have been more sensitive in detecting malunion. Furthermore, neither study included high-risk patients.

It is also important to point out that wire cerclage cannot be defined loosely in such comparisons. To compare wire cerclage with other modalities, we first need to standardize wire cerclage according to the available evidence. Through the years, various configurations of wire closure—simple, parasternal, transsternal, alternating, figure-of-eight, and others—have been studied, with varying results, and each technique has its firm adherents. There is thus no clear consensus regarding the best wire closure technique.⁴

Bioengineering studies in various synthetic and cadaveric models have shown that rigid sternal fixation with plates, based on orthopedic principles, provides better results than wire cerclage. A recent RCT⁵ and a recent meta-analysis⁶ have validated these findings in the clinical setting. These findings raise the question of whether there is any value in comparing sternal plates with ZIPFIX ties in the face of better results with rigid plate fixation.

In summary, both studies cited by Tam and Freme¹ suffer from reporting, attrition, detection, and selection biases. I completely agree with them that a better-planned

RCT might help us determine what role, if any, sternal ZIPFIX should have in chest closure.

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TO ZIP OR WIRE: AN ONGOING DEBATE

Reply to the Editor:

We thank Drs Tam and Freme for their interest in our ZipFix sternal closure randomized controlled trial¹ and for alerting us to a very similar trial published at the same time in *Heart, Lung and Circulation*.² As they point out, on first glance, the results appear somewhat divergent between the 2 trials, despite similar study designs. However, closer inspection of the study protocols offers some explanation as to the varied results seen.

In the study by Nezafati and colleagues,² a single surgeon performed all the sternotomies and sternal closures. This is a strength of that study because it obviously reduces any variability between operators. In contrast, we had 3 surgeons performing sternal closure, which inherently introduces some variability.

The assessment of pain between groups was analyzed differently between the 2 studies, but the results are not that dissimilar. Both studies used a Visual Analogue Scale of 0 to 10 to assess pain, and in both studies, pain decreased over time as would be expected. In our study, these assessments were made by research staff blinded to the treatment arms, and pain was measured at days 1 and 3 postoperatively, the day of discharge, and 4 weeks postoperatively. Analysis of variance was performed, and the multivariable