Author has nothing to disclose with regard to commercial support.

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 Frenes¹ 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 Frenes¹ 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.

Shuab Omer, MD

Division of Cardiothoracic Surgery

Baylor College of Medicine

Michael E DeBakey VA Medical Center

Houston, Tex

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TO ZIP OR WIRE: AN ONGOING DEBATE

Reply to the Editor:

We thank Drs Tam and Frenes 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

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model was fitted using main effects for treatment and time and an interaction between treatment and time to determine if pain scores behaved differently. Although overall postoperative pain levels were lower in the ZipFix group, this result was not statistically significant (median [interquartile range] 1 [0-3] vs 2 [0-4], $P = .10$). When a per protocol sensitivity analysis was performed, patients who received ZipFix did have significantly lower overall pain levels (median [interquartile range] 0 [0-3] vs 2 [0-4], $P = .03$), although there were no significant post hoc differences between groups at any time point.

In the study by Nezafati and colleagues,² the surgeon performed the assessments of pain postoperatively and at the follow-up visits. This part of the study protocol has an inherent risk of allowing bias to creep into the assessments. The patient's pain was reported as being measured when coughing and as the current, least, and worst pain experienced in the previous 24 hours. However, it is not exactly clear as to what was then recorded. Furthermore, the pain scores were analyzed at each time point using a t test, rather than a repeated-measures analysis of variance; thus, the statistical treatment of the results is incorrect. It is possible that the results would have been similar to those of our study if the statistical analysis was performed differently. Nezafati and colleagues² have not reported any analgesia use between groups, which ideally should have been addressed as part of the overall pain assessment.

Our use of ultrasound to assess sternal movement at 4 weeks postoperatively has been shown to have high interobserver and intraobserver reliability.³ Assessments were performed by a physiotherapist skilled in this assessment and blinded to the treatment arms. In contrast, the assessment of sternal dehiscence in the study by Nezafati and

colleagues² was by clinical examination only, and presumably again performed by the nonblinded surgeon.

The use of ultrasound to examine the sternal separation quantifies the distance apart of the cut edges of the orthotomy and as such measures the amount of sternal micromotion associated with the various upper limb and truncal movements, cough, and deep inspiration. At 4 weeks postoperatively, we do not expect there to be any bony bridging, and thus the assessment measures the rigidity of the sternal closure. This is not the same as dehiscence, and it is not a surrogate for dehiscence. We performed ultrasound examination because we thought there could be an association between sternal movement and postoperative pain. Neither study was powered to show differences in sternal infection rates.

Although the 2 studies had methodological differences accounting for somewhat divergent findings, more careful scrutiny of the studies shows remarkably similar results.

Silvana F. Marasco, MBBS (Hons), MSurg, PhD, FRACS^{a,b}

Louise Fuller, BAppSc, MAPA^c

Adam Zimmet, MBBS, FRACS^a

David McGiffin, MBBS, FRACS^{a,b}

^aCJOB Cardiothoracic Surgery Department

^cPhysiotherapy Department

The Alfred Hospital

Melbourne, Victoria, Australia

^bDepartment of Surgery

The Alfred Hospital

Monash University

Melbourne, Victoria, Australia

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