Author has nothing to disclose with regard to commercial support.

Nonrandomized database analysis cannot be considered superior to randomized, controlled trials because of the inherent bias in patient selection. As practicing surgeons, we all would agree that on most occasions we can identify an unsuitable candidate for MS and quite rightly proceed with FS. This will therefore lead to selection bias in such analyses.

The MiniStern Trial does not conclude that MS approach is inferior to FS for aortic valve replacement. Our conclusion is solely that although patient satisfaction is high among the MS group, we failed to demonstrate a reduction in hospital stay in the UK National Health Service practice after aortic valve replacement performed through MS relative to FS (Figure 1). Therefore, although we are a group of surgeons enthusiastic about minimal access cardiac surgery, we failed to provide objective evidence to claim superiority of the MS approach relative to the FS approach for performing aortic valve replacement.

Once again, I thank Drs Mori and Geirsson for their comments on our article.

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MINIMALLY INVASIVE CARDIAC SURGERY PRESENTS CHALLENGES FOR DESIGN OF RANDOMIZED

CLINICAL TRIALS

Reply to the Editor:

Cardiac surgery can provide excellent outcomes when performed through a conventional sternotomy. Nevertheless, the burden of sternotomy on functional recovery can last for weeks or even months. Efforts to accelerate recovery after sternal entry are warranted.^{1,2} Novel approaches that improve early sternal fixation^{1,3} have been shown to accelerate functional recovery. Minimizing or avoiding sternotomy by using minimally invasive approaches is another option that has gained clinical momentum and wide acceptance. The evidence for such approaches in comparison with conventional sternotomy, however, may be disproportionate to the growing adoption and

enthusiasm amongst surgeons and patients alike. The recent randomized study by Nair and colleagues⁴ is an important addition to the literature.

As mentioned in Fedak's accompanying editorial,⁵ perspectives on this recent study are predicted to be mixed, and the lack of observed benefits will be debated by enthusiasts and late adopters. In their letter, Mori and Geirsson provide a perspective. They stress the importance of surgical expertise in conducting minimally invasive cardiac surgery. They underscore the tight relationship between clinical outcomes and the experience of the expert operator. To support their argument, they provide a hypothetical figure depicting the expertise scale and 2 surgical techniques. We agree that there should be a positive correlation between a surgeon's experience and clinical outcomes. Watching a trainee's skills evolve with time is all the proof one needs to support this claim. We can also safely presume that experience and outcomes are enhanced by surgical volumes for individual surgeons and even programs.

Despite this relationship, validating new procedures still requires academic rigor and equipoise. Although operator experience may influence the results of a clinical trial, randomization should be capable of limiting the magnitude of such factors. We argue that the vast majority of experienced cardiac surgeons are so highly skilled that they can perform technical procedures with such consistency and high quality that technical skill would not present an independent variable predictive of functional recovery after cardiac surgery. In addition, if a surgical procedure is so technically complex that an experienced cardiac surgeon is unable to achieve reproducible and consistently high-quality outcomes, then we must question how much impact such an innovation may have once generalized to the wider community.

Furthermore, being pragmatic, can we ever really measure and determine an individual surgeon's experience and underlying skill as it may relate to a specific clinical outcome? It has been said that we cannot manage what we cannot measure. We agree that robust study design in surgical trials must make efforts to account for operator experience and skills to provide a meaningful comparison. The best compromise may be the use of expertise-based trial designs that allow random assignment to operators in each arm with sufficient experience and expertise.⁶

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References

1. Fedak PW, Kieser TM, Maitland AM, Holland M, Kasatkin A, Leblanc P, et al. Adhesive-enhanced sternal closure to improve postoperative functional recovery: a pilot, randomized controlled trial. *Ann Thorac Surg.* 2011;92:1444-50.
2. Fedak PW, Kolb E, Borsato G, Frohlich DE, Kasatkin A, Narine K, et al. Kryptonite bone cement prevents pathologic sternal displacement. *Ann Thorac Surg.* 2010;90:979-85.
3. 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.
4. Nair SK, Sudarshan CD, Thorpe BS, Singh J, Pillay T, Catarino P, et al. Mini-Stern trial: a randomized trial comparing mini-sternotomy to full median sternotomy for aortic valve replacement. *J Thorac Cardiovasc Surg.* 2018;156:2124-32.e31.
5. Fedak PW. Make sternotomy great again. *J Thorac Cardiovasc Surg.* 2018;156:2133-4.
6. Devereaux PJ, Bhandari M, Clarke M, Montori VM, Cook DJ, Yusuf S, et al. Need for expertise based randomised controlled trials. *BMJ.* 2005;330:88.

<https://doi.org/10.1016/j.jtcvs.2019.01.039>