



Sternal closure: wiring or not wiring?

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Deep sternal wound infection, is one of the most dangerous and life-threatening complication in cardiac surgery. It is one of the most expensive complications with a 3-fold increase in overall costs (1). Despite advances in prevention and treatment strategies, incidence remains high ranging between 0.25% and 5% (2,3) Wound infections may result from contamination during surgery, both from the patient and the surgeon (4). In this setting, despite patient related risk factors like diabetes, obesity, COPD, etc., are often unmodifiable, many preventive measures have been demonstrated effective in reducing the incidence of wound infections. The principles of prevention are recently stated in an expert consensus paper that highlighted the importance of a multifactorial approach with several recommendations that include preoperative screening for carriage of multi-resistant organisms (e.g., Methicillin Resistant *Staphylococcus Aureus*), glycemic control, antimicrobial prophylaxis, preoperative skin preparation and accurate surgical technique with particular attention to the sternal closure (Bosco). Since the past decades, accurate sternal fixation has been demonstrated to significantly reduce the incidence of wound dehiscence enhancing the role of the surgical approach (5).

Rigid plate fixation (RPF) has been proved to be biomechanically superior to wire cerclage (WC) in sternal osteo-synthesis. In fact, experimental studies, both *in vitro* and in human cadavers, showed significant greater stiffness and less lateral displacement of the sterna closed with RPF respect to the standard wire closure (6-8). Despite these evidences, the use of WC for sternal closure has remained the standard in cardiac surgery till today and RPF has not yet gained a widespread use. Many advantages have

been recognized to the WC. It is an acceptable, well-validated, and established elastic fixation. It is easy to perform, requires a short learning curve and is effective and adaptable in all type of sternal configurations even in case of sternal deformity. Finally, sternal cerclage is easy to remove quickly, without specialized instrumentation, in every clinical condition as emergency, elective redo surgery or late device complications. On the other hand, RPF is more complex in terms of implantation technique, learning curve, and requires longer time of implantation in respect to the traditional wires. Rigid plate systems are produced in different models, characterized by different designs and different procedural technique, with the detriment of standardization and uniformity of results of these devices. In fact, in a recent study, high and unexpected incidence of postoperative wound infections was observed after implantation of a RPF system. Authors hypothesized that hardware design and the presence of large screws could be responsible of the failure (9).

Allen and co-authors (10) investigated, with a randomized multicenter trial of 12 cardiac centers, a total of 236 patients undergoing elective cardiac surgery (ranging from 1 to 38 patients per center) in a time period of about 27 months. During this period 461 patients were screened for eligibility. However, 461 patients represent a small percentage of all comers considering the time frame of the study period and the large number of centers involved. Furthermore, patients enrolled did not represent a high-risk population for wound dehiscence. Mean age was 65 years, the great majority, about 75%, underwent a single cardiac procedure, and the use of bilateral internal mammary artery was no more than 6%. Patients with severe obesity, use of steroids

and chronic pulmonary disease were excluded. Despite these selection criteria, the operating surgeon excluded 16 additional patients intra-operatively. Use of bone wax, or other intraoperative conditions as poor bone quality or off-midline sternotomy were all judged as parameters that made the patient unfit for randomization. A German study, based on a questionnaire about topics in sternal closure that included 79 cardiac centers, evidenced that intraoperative evidence of poor bone quality in terms of osteoporosis, fractured sternum, and obesity were the most frequently cited risk factors for sternal instability (11). In our opinion the exclusion from the study protocol of patients with poor bone quality, with severe obesity, or with other risk factors for sternal complications weaken the results. These high-risk conditions should particularly be considered in a study that aims to evaluate an improved sternal closure system. These issues have already been pointed out in an editorial commentary to the same study that evidenced some limitations in terms of reduced generalizability of this treatment. The exclusion of patients with anticipated wound healing problems such as those with severe chronic obstructive pulmonary disorder and morbid obesity (body mass index $>40 \text{ kg/m}^2$) were also considered an important drawback of the study (12).

As described in the manuscript, sternal closure was performed in the same fashion in all centers involved in the study for the RPF arm, but in the WC arm, the only recommendation of the study protocol was to use a minimum of six wires, and various configurations have been performed on the basis of the surgeon preference (single or double stranded). Authors recommended a minimum of six wires, but it is known that the use of more than six wires (a minimum of seven wires), in particular at the lower part of sternum, actually reduces the incidence of deep wound infections (5). This consideration underlines the importance to perform an accurate and effective WC closure. Certainly, sternal closure is one of the most important preventive measures to reduce the incidence of deep sternal wound dehiscence, but little or nothing is reported about the other preventive measures for wound complications observed per each center involved (13). These aspects reduce the uniformity of treatment over the study population.

Authors concluded that patients treated with the RPF system had significantly better sternal healing at 3 and 6 months, and fewer sternal complications at 6-month follow-up. Sternal healing have been defined by a CT scan union score (14). It represents an interesting imaging evaluation composed by different levels. Despite it is a

validated approach to evaluate the progression of sternal healing, it takes in consideration steps that are undetectable by clinical examination and do not match with a respective clinical status of the sternal wound healing. In other words, this score have an unclear impact on the patient clinical conditions, in terms of functional capacity, quality of life and pain (12). Finally, it is noteworthy that CT scan union score definitely differs from the evidence of sternal instability or deep sternal wound dehiscence. In this setting, the sternal union rates, appears to be a secondary outcome in respect to deep sternal wound dehiscence. In fact, as stated in methods section, sternal union was defined as a mean CT scan score of at least 3 (10). Despite the plate fixation arm achieved a significantly better union score at 3 months follow-up, the mean score was less than 3 in both groups (2.6 ± 1.1 vs. 1.8 ± 1 RPF vs. WC group respectively). This result evidenced that neither the RPF nor the WC group achieved a complete sternal union 3 months after surgery. At 6 months follow-up both groups evidenced a complete sternal union healing. In fact, both groups achieved a CT scan score higher than 3 (3.8 ± 1.0 vs. 3.3 ± 1.1 , RPF vs. WC group respectively). The higher value of CT scan score observed in the RPF group, despite statistically significant both at 3 and 6 months does not correlate with any clinical significant difference between the two groups in terms of wound complications. It is remarkable that differences between the two study groups in terms of CT scan score appeared significant both at 3 and 6 months follow-up, without any significantly differences in terms of sternal complications between the two groups during the same time-frame follow-up.

The meaning of CT scan union score appears linked to the physiological healing process of the sternal bone, but its clinical role appears unclear and far from the real patients condition. All patients were discharged from the hospital at both follow-up time (3 and 6 months), independently from CT scan score. Only patients with clinical wound complications have been readmitted to the hospital for surgical wound treatment. Thus, sternal healing score definitely represents a secondary outcome that cannot be used as an alternative outcome parameter to sternal instability. Difference between sternal stability and sternal instability is the main clinical results that influence patient quality of life, functional capacity and the eventual type of treatment.

It is remarkable that authors have analyzed together, in the statistical section, deep sternal wound infection with superficial wound infection and late wires removal for pain. These complications represent grossly different clinical

conditions, in terms of etiology, clinical outcome, treatment and prognosis. In our opinion these complications should be analyzed separately. Despite this methodological approach no significant differences were evident in the comparison between the two groups. Only a favorable trend for rigid system in terms of wound complications at 6 months has been observed.

In our experience, over more than 5,000 consecutive sternotomies closed with WC, incidence of deep sternal wound infections was 0.8%. Mediastinitis mortality rate was 2%. Septic shock at the moment of wound diagnosis was the only cause of wound related mortality. All patients were successfully reclosed with WC and pectoralis muscle advancement flaps after negative pressure wound treatment period (15).

Sternal wound dehiscence remains a multifactorial complication (16). A stable sternal closure has an important role in sternal healing along with other preventative measures.

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