In Vitro Comparison of Wire and Plate Fixation for Midline Sternotomies

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Background. **The incidence of severe sternal wound complications in high-risk cardiac patients presents a significant need for more stabile sternal fixation techniques after median sternotomy procedures. Rigid metal plates, a potential alternative to wire fixation, are thought to promote faster sternal healing by reducing motion at the wound site. The goal of this study was to compare the stability provided by commercially available sternal plates with standard wires using an in vitro model.**

Methods. **Lateral distraction tests were conducted on bisected polyurethane sternal models fixed with either a standard 7 wire configuration (n = 5) or a 3 plate configuration (n = 3). To assure controlled loading, the sternal models were attached to a computer-controlled test machine by a novel tethering system that distributes the total force (180N) equally to eight locations on the sternum. Stability was defined as the ability to restrict sternal separation at seven locations along the midline quantified using digital image analysis.**

Results. **Our results indicate that rigid plate fixation significantly reduced lateral motion relative to wire fixation. The lower sternal region most noticeably benefited from plate fixation as the splaying observed for wire fixation was reduced.**

Conclusions. **Under these loading conditions, plating increased stability at the midline compared to wires; this increased stability may facilitate the recovery of high-risk patients undergoing cardiac operation. To enhance in vitro testing methods, future studies should incorporate additional in vivo loading conditions applied to the sternum. Alternate plating configurations should also be examined to further increase stability.**

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Median sternotomy, a procedure required for cardiac access during open heart surgery such as cardiac valve replacement and coronary bypass surgery, is associated with complications in 0.7 to 1.5% of all cases, and a high mortality rate [1]. These complications include dehiscence, mediastinitis, osteomyelitis, and chronic sternal instability [2, 3] and have been attributed to the inability of traditional parasternal stainless steel wires to prevent excessive motion between the sternal halves, which delays bony union during sternal healing [4]. Stabile fixation is particularly crucial in the growing "high risk" population with severe risk factors, such as obesity, diabetes, smoking, hemodynamic instability, and steroid use, who are prone to suffer complications [5, 6]. Together, these observations indicate that there is a clear need to develop more stabile fixation methods.

A number of alternatives to stainless steel cerclage wires have been studied in recent years including stainless steel bands and side plates to reduce wire pull through [7–11] and rigid fixation plates [12–14]. In craniofacial and orthopedic applications, where similar morbidity and complications including infection, delayed healing, and nonunion are observed with wire fixation, adoption of rigid plate fixation has been near universal [15, 16]. In fact, preliminary clinical studies indicate that rigid plate fixation improves sternal healing over wire fixation [4, 13, 14, 17]. However, cardiothoracic surgeons have been reluctant to adopt rigid plate fixation of the sternum because of concerns including drilling near the heart and bypass conduits, the added time and expense of plates, and the difficulty of reentry to the chest cavity in emergency situations [17]. A recent study by Song and colleagues [17] addressed these concerns by examining commercially available titanium plates specifically designed for sternal fixation (see discussion in Ref 17). In their study, plating reduced mediastinitis in high-risk patients. Since the number and placement of plates on the sternum was based on intuition rather than mechanical measurements, and no mechanical analysis of stability was performed, it is unclear if the plating configuration used in the study provided maximum stability with a minimal number of plates. For widespread acceptance of rigid plate fixation, systematic biomechanical studies must be conducted to determine simple and mechanically sound plating configurations for the sternum [21].

This paper describes the first in a series of systematic

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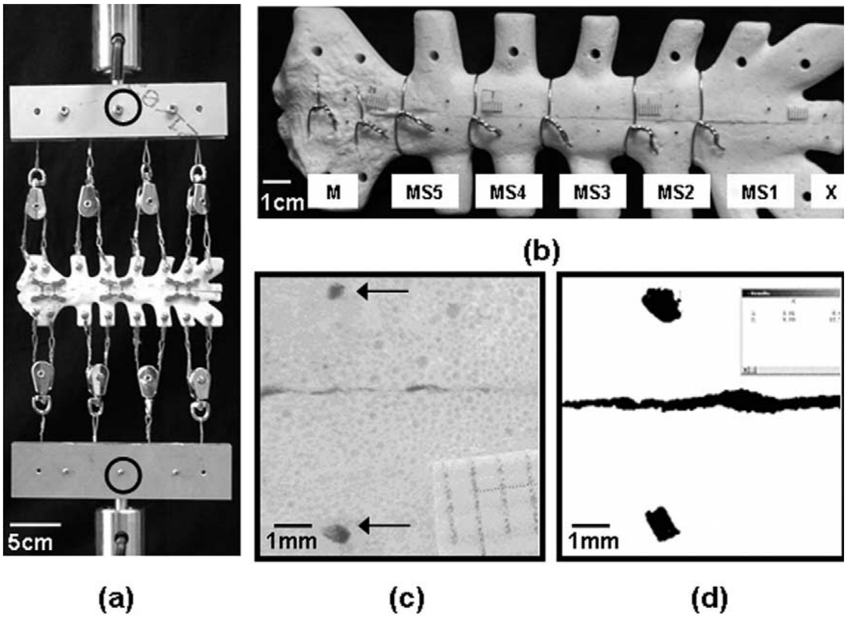

Fig 1. (a) Tethering system consisting of multiple low-friction pivots (circled*) and pulleys, which provides equal lateral force to each point of attachment on the polyurethane sternal model. The clamps are attached to a computer-controlled uniaxial testing machine. (b) Close-up view of sternal model with 7S (seven simple straight wires) wire configuration showing the placement of graphite markers at the manubrium (*M*), midsternum 1, 2, 3, 4, and 5 (*MS1–5*), and xiphoid (*X*) as well as a scale marker. (c) High magnification picture of one marker pair. (d) The image from (c) is thresholded for determination of the centroid of each marker and subsequent calculation of sternal separation using image analysis software.*

biomechanical studies analyzing the stability of rigid plate fixation for closure of median sternotomy. The overall hypothesis of this project is that improving the mechanical stability of sternal fixation through optimal plate usage will further enhance the rate of sternal healing and decrease the occurrence of complications associated with median sternotomy. To begin testing this hypothesis, this study describes a quantitative comparison of the mechanical stability of sternal models reapproximated using a standard wire configuration and a standard plate configuration using a computer-controlled in vitro test system.

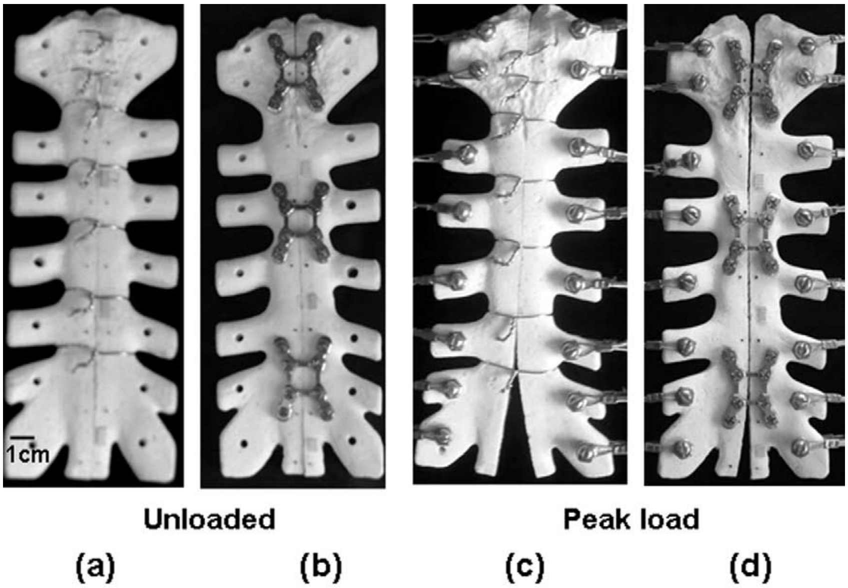

Fig 2. Visual comparison of wire (a),(c) and plate (b),(d) sternal fixation in the unloaded state (a),(b) and at 180N (c) and 360N (d) lateral load. For better visualization, the separation in the plate-fixed model is shown at a higher force; it was not possible to test wire-fixed models above 180N due to risk of wires pulling through the bone model.

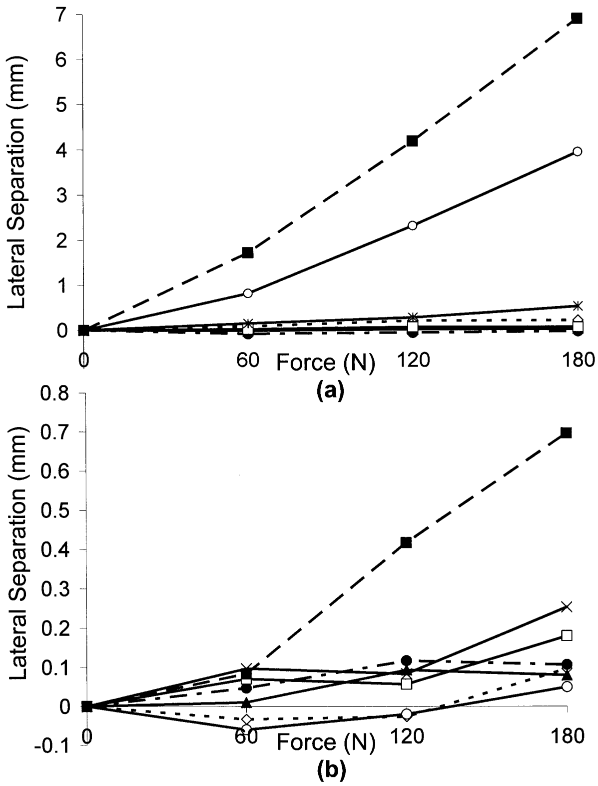

Fig 3. Average lateral separation at each of the seven marker locations as a function of total lateral forced applied for (a) wire-fixed (n = 5) and (b) plate-fixed (n = 3) sternal models. Note that different scales are used in (a) and (b) and that negative "separations" can occur (see Comment). The regions (M. . . X) are defined in Figure 1b. Standard deviations (SD) are omitted to avoid crowding; mean and SD values are available in Tables 1 and 2. ◇ = M (manubrium); ● = MS5 (midsternum five); ▲ = MS4; □ = MS3; × = MS2; ○ = MS1; ■ = X (xiphoid).

Material and Methods

To compare the stability of wire and plate fixation, we developed a test apparatus to provide controlled lateral forces to the sternum and utilized synthetic sternal models to reduce specimen-to-specimen variability. Stability of fixation was defined in terms of the resistance to sternal separation and was determined at multiple points along the sternum. As a first step towards complete biomechanical characterization of sternal fixation, basic wire and plate configurations were compared.

Specimen Preparation

Commercially available sternum-shaped polyurethane bone models with a density of 20 lb/ft^3 and elastic modulus of 5.5 MPa (Sawbones, Pacific Research Laboratories, Vashon, WA) were bisected using standard midline sternotomy techniques and either plated using titanium sternal plates (SternaLock Plates, Walter Lorenz Surgical, Jacksonville, FL) or wired using stainless steel wires (Ethicon Inc, Somerville, NJ) by a surgeon at the University of Massachusetts Medical Center (author NF). Our plate configuration consisted of three X ("3X") plates spaced evenly down the sternum, as seen in Figure 1a. This configuration was considered the most basic arrangement of plates that would be used clinically and is not necessarily an optimal configuration of rigid metal plates. The wired samples were fixated using the standard 7S wire configuration (7 simple straight wires). Five sternal models were configured with wires and three sternal models were configured with plates. A greater number of wired samples were used as we expected relatively high variability in this group.

Mechanical Testing

Each wire-fixed or plate-fixed sternal model was attached by the rib struts to a screw driven testing system with a 5,000N (1,124 lb) load cell (± 5N accuracy, MTS Syntac with QTest/5 Software; MTS, Minneapolis, MN) using a custom tethering system (Fig 1a). To apply the distraction force over the length of the entire sternum in a controlled manner, we developed a tethering device consisting of a series of low friction pulleys and pivots. In this system, the total force is distributed equally to eight individual tethers and applied to all rib struts orthogonal to the midline of the sternum. This loading state is not meant to mimic the in vivo load distribution but rather to provide reproducible, quantifiable loads to the sternum.

The sternal models were pulled laterally at 0.212 mm/s. In preliminary tests, forces exceeding 200N caused the cerclage wires to cut into, and in some cases fracture, the model sterna; thus, the maximum load was limited to 180N for this study. At increments of 60N the separation of the sternum was measured as described below.

Quantification of Stability of Fixation

Stability was quantified by measuring the amount of separation between the two halves of the sternum using digital image analysis. Small graphite chips, used as

Table 1. Average Separation ± Standard Deviations at Each of the Seven Marker Locations for a 7S Wire Configuration (n = 5)

Force (N)/Location	Lateral Separation (mm) Mean ± Standard Deviation						
	M	MS5	MS4	MS3	MS2	MS1	X
60	0.08 ± 0.50	−0.08 ± 0.23	−0.02 ± 0.11	0.02 ± 0.10	0.15 ± 0.17	0.82 ± 0.48	1.72 ± 0.71
120	0.21 ± 0.46	−0.05 ± 0.19	0.02 ± 0.08	0.07 ± 0.07	0.28 ± 0.23	2.32 ± 0.58	4.19 ± 1.13
180	0.22 ± 0.52	−0.02 ± 0.23	0.03 ± 0.12	0.07 ± 0.14	0.53 ± 0.46	3.95 ± 1.78	6.91 ± 3.43

M = manubrium; MS1–5 = midsternum one to midsternum five; 7S = seven simple straight wires; X = xiphoid.

Table 2. Average Separation ± Standard Deviations at Each of the Seven Marker Locations for 3X Plates Spaced Evenly Down the Sternum (n = 3)

Force (N)/Location	Lateral Separation (mm) Mean ± Standard Deviation						
	M	MS5	MS4	MS3	MS2	MS	X
60	−0.03 ± 0.04	0.05 ± 0.06	0.01 ± 0.05	0.07 ± 0.03	0.10 ± 0.13	−0.06 ± 0.34	0.08 ± 0.35
120	−0.03 ± 0.07	0.12 ± 0.17	0.09 ± 0.15	0.06 ± 0.09	0.08 ± 0.07	−0.02 ± 0.30	0.42 ± 0.28
180	0.10 ± 0.11	0.11 ± 0.14	0.08 ± 0.13	0.18 ± 0.12	0.25 ± 0.16	0.05 ± 0.54	0.70 ± 0.58

M = manubrium; MS1–5 = midsternum one to midsternum 5; 3X = three X-shaped plates; X = xiphoid.

fiducial markers (~ 0.5 mm diameter, Fig 1b), were affixed in pairs on opposite sides of the sternal model halves at seven different locations using cyanoacrylate adhesive. A series of high resolution pictures was taken at each force increment using a digital camera (5.0 mega pixel Coolpix 5700; Nikon, Melville, NY). Marker locations at the manubrium (M), the proximal to distal midsternum (MS1, MS2, MS3, MS4, MS5), and the xiphoid (X) (Fig 1B) were determined using image analysis software (Scion Image; Scion Corporation, Fredrick, MD) by calculating their centroids after thresholding (Figs 1c and 1d). Scale markers were used to convert pixels to millimeters; the resolution of the digital images was 12 μm/pixel.

Based on previous studies [12], we also calculated the structural stiffness at each location for each sample (ie, slope of the force-displacement curve). However, we have not included these data since, due to the linearity of the force-displacement curves, this parameter does not provide any supplementary information in addition to the separation data presented herein.

Statistical Analysis

Overall differences in stability between the wire and plate configurations were determined using multivariate analysis of variance (MANOVA, SPSS 12.0; SPSS Inc, Chicago, IL) to compare the sternal separations at each location at the peak force (180N). A level of p less than 0.05 was considered significant. The MANOVA was necessary to compare the fixation types while accounting for the fact that the locations along the sternum are spatially related and thus are not independent. To determine differences at specific locations between the fixation configurations, post hoc analysis was performed using the Tukey HSD (honestly significantly different) test.

Results

Overall, the plated sternal models experienced much lower separations in all areas compared with the wired sternal models, most noticeably in the lower sternal region. Of equal importance, the stability at different locations varied considerably despite the uniformity of the loading distribution. The difference between fixation configurations can be visually observed by comparing the separation of the wire-fixed and plate-fixed sternal models when loaded (Fig 2). These differences are confirmed by the quantitative data in Figure 3 and Tables 1 and 2. Statistical comparison of the standard 7S wire configuration with a 3X plate configuration showed significant differences in separation at 180N at the X and MS1 locations.

Tests conducted to determine the level of force that the model sterna could withstand before failure when fixed with each method showed that plated models were capable of withstanding twice the magnitude of force (~ 400N) as the wired models (~ 200N). Additionally, the plated models fractured at the rib struts where they were attached to the tethering system and not the screws. In contrast, the wired models failed due to wire pull-through and not the attachment method. Since this study focused on subfailure behavior, all subsequent tests were conducted with a peak load of 180N for comparability between fixation methods.

A more noticeable variation in stability was found along the length of the sternal models for the wire configuration than for the plate configuration. However, for both fixation methods the xiphoid region proved to be susceptible to large separations (Fig 3), and the separations in the M, MS5, MS4, MS3, and MS2 locations remained relatively low at all forces (Tables 1 and 2). The largest difference between fixation methods was in the lower sternal region. In the case of wires (Fig 3a), the lower sternal region (X and MS1 marker locations) experienced average sternal separations greater than 4 mm, whereas the remaining locations separated less than 1 mm. For plates, the separations at all regions were below 2 mm (Table 2). As a result of this disparity, the variation in mean separation along the length of the sternum of the plated sample data (0.08 to 0.70 mm) was lower than that of the wired group (-0.02 to 6.9 mm). The variability at each measurement location was also relatively high (eg, greater than 45% coefficient of variation in all locations for wire-fixed samples) despite the fact that polyurethane models were used and two additional wire-fixed samples were tested (Table 1). Interestingly, we observed negative separation values at the MS5 location for the wired models (Table 1) and the M and MS1 locations of the plated models (Table 2), possibly due to bending effects (see Comment).

Comment

It is generally accepted in the orthopedic literature that limiting relative motion between broken segments of bone is beneficial for rapid boney healing [18]. Thus, compared to stainless steel wires, rigid plates have great potential to improve the stability of sternal reapproximation and thus healing [4, 17]. The goal of this study was to quantitatively compare the mechanical stability provided by commercially available sternal plates with standard wires using an in vitro model of sternal fixation.

Rigid plates provide significantly more stable fixation than wires, especially in the xiphoid region. The average separations in the lower sternal regions (X and MS1 locations) of wire-fixed sternal models are ten to fifteen times greater than the separations observed at the other five locations (Fig 2c) and much larger than observed in the plated samples (Fig 2d). Splaying at the xiphoid coincides with clinical observations and is a concern with the wiring technique. This phenomenon is most likely due to the lack of wire support directly in the area of the lower sternum. Dasika and colleagues [19] demonstrate in vitro that reinforcing the xiphoid region of sternal models with additional wires reduces these large separations; however in clinical practice, the lower sternum represents a difficult area of fixation as there is transition to a cartilaginous region with variable degrees of parasternal calcification. Although it may appear "unfair" to compare wired and plated configurations where the plate is situated further towards the xiphoid than the lowest wire, we chose to compare two standard fixation techniques, as each would be clinically performed.

In vivo, the sternum is loaded by a complex combination of tensile, shear, and compressive forces acting in multiple directions. Therefore, many loading paradigms including lateral [7, 9, 20], transverse, shear [21], and bending [12] have been utilized in in vitro studies to assess the mechanical stability of various sternal fixation methods. In cadaver studies, McGregor and colleagues [21] found that lateral distraction provides the most sensitive measure of the efficacy of fixation since bone-on-bone frictional forces do not have to be overcome in this direction. Based on this finding, they have developed efficient in vitro test methods to avoid the variability and expense inherent in cadaveric testing [19, 20].

Furthermore, in their cadaver studies, the authors [21] had the insight to measure the sternal separation at multiple locations. They observed substantial variation in the distraction along the length of the sternum, most notably large separations in the xiphoid region. These results were the first to demonstrate that the location where one measures sternal separation is critical in determining the effectiveness of a fixation method. This point is also clearly demonstrated by the fact that the difference in stability between the fixation methods in our study was not significantly different in the upper sternal region (M, MS5, MS4, and MS3 locations), whereas it was overwhelmingly different in the lower region (Fig 3). Previous studies comparing the stability of fixation between plates and wires [12] were limited because they only measured stability in one location. McGregor and colleagues [21] attribute the nonuniform separations to anatomic factors such as variable bone thickness and stabilizing structures (eg, clavicle); however, uneven distribution of loading along the sternum inherent in their method could also have contributed to the nonuniform separation. In their cadaver tests, the sternum was loaded at only three locations along its length (second, fourth, and sixth ribs) and, although the total force was known, the distribution of load between the three tethers was neither controlled nor quantified. To enable proper interpretation of the nonuniform separations along the sternum in our testing method, we applied a known distribution of forces along the length of the sternum. In contrast, the loads applied to sternal models in most in vitro systems are spread over multiple ribs by potting them in epoxy and/or clamping them [9, 12, 19, 20], yet the load distribution remains unknown.

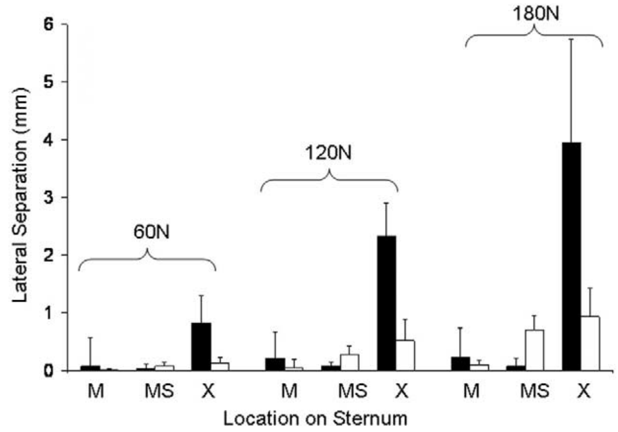

*Fig 4. Comparison of current data (■) for wire-fixed specimens attached by 8 equally-loaded tethers with data from a previous study (Trumble and colleagues [20], □), where four tethers were attached to rigid plates that sandwiched the rib struts. Note that the loading method has a large effect on the sternal separations at different locations along the sternum. The separation shown at 180N from the previous study [20] was obtained by linear interpolation. (*M = *manubrium;* MS = *midsternum;* X = *xiphoid.)*

In addition to the separation of the sternum being nonuniform, we observed negative sternal "separation" at the manubrium and the midsternum regions in multiple samples (Fig 3, Tables 1 and 2). This nonintuitive inward motion (only outward forces were applied) appears to be the result of flexure of the sternum that results from the wires and screws acting as pivots. It is important to note that although the negative separations were sufficiently large to be detected by our image analysis, bending was not visible to the naked eye and the deflections were relatively small (0.01–0.1mm) in comparison with the separations at the X and MS1 locations (> 3 mm).

To demonstrate the impact of the particular load distribution applied to the sternum during in vitro testing, our data from wire-fixed models at 60N, 120N, and 180N are graphed with analogous data from Trumble and colleagues [20] in Figure 4. In the previous study, the ribs are sandwiched between rigid plates (2 sets per side) and attached to the loading mechanism by 4 tethers (2 per set of plates). The "manubrium", "midsternum," and "xiphoid" locations correspond with MS1, MS3, and M locations defined herein, and the separations for 120N are linearly interpolated from the published data. The difference between the two data sets at the manubrium is minimal at all three loads (< 1 mm); however, the separations measured in the present study are considerably smaller at the midsternum and larger and at the xiphoid for all loading levels. These differences are most likely due to greater loading in the center of the sternum in the previous study relative to the loading of our models, although the true force distribution from the previous study cannot be calculated due to the linkage mechanisms. While these data demonstrate that the distribution of loading chosen for in vitro testing is critical, the actual in vivo forces at different points along the sternum are unknown, thus it is unclear which method provides more physiologically relevant data.

While cadaver sterna represent an ideal model for in vitro studies in terms of anatomy and material properties, they are not ideal for systematic mechanical studies due to high variability and high cost. To reduce specimen-to-specimen variability and cost, polyurethane models were used in this study; these sternal models exhibit mechanical behavior similar to cadaver sterna [20, 22, 23] and have been used extensively in previous studies [9, 19]. With biological variability eliminated from the testing, the substantial variation in stability due to small differences in tension and torque is clearly evident. In this study, and generally in clinical practice, the tension of the wires and the torque in the screws are not controlled. These results highlight the possibility that even small differences in the way a fixation device is applied can lead to substantial differences in stability and demonstrate the importance of standardizing clinical fixation protocols.

Clearly, the quasistatic loading methods described in this study are not sufficient to simulate demanding physiologic conditions such as chronic coughing secondary to emphysema or respiratory congestion, and vertical or transverse shear loading [9]. Furthermore, the homogenous nature of the polyurethane models does not simulate the bicortical structure of sternal bone or the cartilaginous xiphoid, making them unable to withstand large mechanical loads applied during coughing or predict the effects of wire and screw pull-through. Future studies should utilize multiple sternal models and test protocols including a more robust laminated polyurethane model exposed to multiple loading directions and repetitive cyclic loading [6, 9, 24].

This report is the first in a series of systematic studies examining the stability of rigid plate fixation for the closure of median sternotomy. The results of this study demonstrate that a simple 3 plate fixation configuration significantly reduces sternal separation in comparison to standard 7 wire fixation, particularly splaying at the xiphoid. It is important to note that the methods used in this study are meant to gauge the relative stability of each closure method, not to approximate actual clinical conditions. Such in vitro testing systems are highly desirable because they allow for uniform, inexpensive, rapid, and consistent mechanical comparisons of different closure methods that are not possible in vivo. We found that the local stability of the fixated sternum is dependent upon the placement of plates and wires, the loading distribution applied to the sternum, and the measurement locations. These findings highlight the need for more detailed analysis of the mechanics of sternal fixation. The in vitro testing system described in this study represents an important, yet incremental step toward developing a comprehensive biomechanical model system for effectively evaluating sternal closure techniques. Further studies are necessary for determining optimal plate configurations to reduce wound healing complications in a variety of patient populations.

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INVITED COMMENTARY

The report by Pai and colleagues [1] documents significantly reduced lateral motion using wire fixation in a polyurethane bone model. This and other previously published biomechanical studies of median sternotomy closure suggest that standardized nonbiologic sternal analogues are inexpensive and obviate the variability of bone density, size, thickness, shape, and geometry common among biologic specimens. It should be noted, however, that only detailed biomechanical comparisons between human cadaveric and bone analogue sterna can show whether the manufactured material adequately replicates all features of the biologic tissues. Well-supported conclusions about one or the other method's superiority have not yet been established.

The authors have not discussed in much detail the results of an earlier *in vivo* trial comparing cerclage wires and compression plates in skeletally mature baboons. The study showed that rigid fixation resulted in earlier osseous union at 4 weeks, and no clinical difference between the treatment groups at 8 weeks [2]. The results of this and several clinical studies [3–5] suggest that the plates provide greater inherent stability. The limited study enrollment, short follow-up, and variability in internal fixation methods preclude definitive conclusions about their superiority over more established wire closure methods, however [6].

Pai and colleagues [1] observed that plates provided more stable fixation in the xiphoid region, where the largest separation typically occurs [7]. It remains unclear whether plates positioned at the xiphoid process provide equivalent support in living patients, in whom the region is primarily cartilaginous.

The authors' conclusions are based entirely on biomechanical analysis of static traction forces; it is uncertain whether their model would respond differently if tested under repetitive loads. The forces used in the Pai study ruptured sternal union at 200–400 N (Newtons). These findings are not consistent with the results of available human cadaveric trials. A German median sternotomy study using increasing traction found that wires cut through the bones at forces between 390 and 490 N [8]; a more recent trial using repetitive cycling loads found that even at 800 N, the wires did not typically cut through or fracture sterna [6].

Pai and colleagues [1] show that sternal plating provides a more stable union than cerclage wires in polyurethane sterna models stressed by a static traction. Future studies comparing the biomechanical behavior of the plates in biologic and non-biologic sterna, and using repetitive cycling loads that more closely approximate breathing and coughing, can be expected to authoritatively establish the best models for biomechanically testing this and other median sternotomy closure techniques.

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