

A Mechanical Study of Rigid Plate Configurations for Sternal Fixation

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Abstract—Rigid metal plates are a promising alternative to wires for reapproximating the sternum after open-heart surgery due to their potential ability to reduce motion at the wound site and thereby reduce the likelihood of post-operative healing complications. Despite initial clinical success, the use of plates has been limited, in part, by insufficient knowledge about their most effective placement. This study compares the ability of five plate configurations to provide stable closure by limiting sternal separation. Commercially available x-shaped and box-shaped plates were used and combinations of parameters (plate type, location, and number of plates) were investigated *in vitro*. Lateral distraction tests using controlled, uniform loading were conducted on 15 synthetic sterna and the distractions between separated sternum halves were measured at seven locations. Distractions at the xiphoid, a critical region clinically, varied widely from 0.03 ± 0.53 mm to 4.24 ± 1.26 mm depending on all three plate parameters. Of the configurations tested, three x-shaped plates and one box-shaped plate resisted sternal separation most effectively. These results provide the first comparison of plate configurations for stabilizing a sternotomy. However, basic mechanical analyses indicate that sternal loading *in vivo* is non-uniform; future studies will need to accurately quantify *in vivo* loading to improve *in vitro* test methods.

Keywords—Sternum, Biomechanics, Wound closure device, Forces.

ABBREVIATIONS

M	manubrium (graphite marker measurement location)
MS1	midsternum one (graphite marker measurement location)

MS2	midsternum two (graphite marker measurement location)
MS3	midsternum three (graphite marker measurement location)
MS4	midsternum four (graphite marker measurement location)
MS5	midsternum five (graphite marker measurement location)
X	xiphoid (graphite marker measurement location)
7S	seven simple straight wires, used in this study as the standard wire configuration
3X	three “X”-shaped plates spaced evenly down the sternum
3XO	similar to 3X only the third plate was placed towards the xiphoid
4X	four “X”-shaped plates spaced evenly down the sternum
2X-1Box	similar to 3XO only the third “X”-shaped plate was replaced with a Box-plate
3X-1Box	similar to 4X only the fourth “X”-shaped plate was replaced with a Box-plate

INTRODUCTION

Median sternotomy requires the sternum to be reapproximated with a closure device following the cardiac procedure. Stainless steel wires are the most common fixation method; however, the wires’ tendency to cut into bone allows substantial motion between the reapproximated segments.¹⁹ This motion is believed to contribute to complications including sternal separation, poor sternal healing, and dehiscence in 0.7–1.5% of the 686,000 cases performed in the US every year.^{1,22} Sternal dehiscence may cause discomfort, mediastinitis, osteomyelitis, and chronic sternal instability.⁹

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Rigid plating has become the standard of care for reapproximating fractured bones^{3,7,16} because of its ability to minimize fibrocartilage formation by reducing relative motion between bone fragments.⁴ Although motion at the fracture site may be beneficial to healing,⁵ the magnitude of acceptable motion is considerably small (<0.2 mm), and contrary evidence shows that motion may delay healing.² Consequently, similar fixation plates have been proposed for sternal reapproximation^{10,17,19} and have been used successfully in a limited number of clinical cases.^{12,20,21} Despite initial clinical success, cardiac surgeons have been slow to adopt rigid plates for sternal fixation due, in part, to a lack of information about how these plates should be used.²¹ We recently demonstrated *in vitro* that three plates spaced evenly along the sternum are sufficient to secure the sternum more effectively than standard wire fixation.¹⁸ However, we also observed relatively large distractions in the lower sternum (xiphoid region) with this simple plate configuration. Motion in this clinically susceptible region indicates that a more stable plating configuration may be beneficial, yet no studies have been conducted to determine optimal placement of plates. Presently, surgeons must rely on intuition and experience when choosing the type of plate to use, where to place the plates on the sternum, and the number of plates needed for each patient. Hence, a rational plating configuration based on systematic mechanical testing and analysis would be a valuable tool.

Our overall goal is to determine plating configurations that provide maximal stability along the entire length of the sternum with a minimum number of plates and screws to reduce cost, operative time and surgical complications. Towards this goal, this study compares the stability afforded by five clinically relevant configurations using two types of commercially available plates. Basic analyses of the distribution of loading along the sternum and the mechanics of plate fixation are also presented.

MATERIALS AND METHODS

Choice of Plating Configurations

Five plating configurations (Fig. 1) were chosen to investigate the effects of location, number, and type of plates on the stability of fixation along the entire length of the midline of the sternum. Based on input from the surgeons on our team, we chose to use no more than four plates to limit cost and operation time. Furthermore, we limited our study to two types of commercially available plates (X and Box SternaLock plates, courtesy of W. Lorenz Surgical, Jacksonville, FL). Placement of the plates was restricted to areas that, in human sterna,

would typically have adequately solid bone (minimal cartilage) to assure sufficient screw purchase.

The first configuration, three X-plates spaced evenly along the sternum (3X), was considered the basic configuration in this study because it utilizes a small number of plates of a single type. We recently demonstrated that at low lateral forces (<180 N), this configuration provides more stability than standard wire fixation.¹⁸ The second configuration is a variation of 3X whereby one of the three plates is moved as far down the xiphoid as possible without entering the cartilaginous region (3XO). As high distractions at the xiphoid are a clinical concern, placing a plate in this region was considered a logical way of reducing the observed distractions. The third configuration consisted of four X-plates spaced evenly down the sternum (4X) and was chosen to examine the effect of increasing the number of plates. The fourth configuration (2X-1Box) is similar to 3XO except the lower X-plate is replaced with a Box-plate to investigate the effect of using the more compact Box-plate near the xiphoid. The fifth configuration is a variation of 2X-1Box where an extra X-plate was added to examine the effect of increasing the plated surface area (3X-1Box).

Experimental Testing System

The stability afforded by each configuration was determined using methods described in detail previously.¹⁸ Briefly, sternum-shaped polyurethane bone models (Model 1025-2, 20 pcf (0.32 g/cm³ density), Sawbones, Pacific Research Laboratories, Vashon, WA) were bisected using a bone saw and plates were screwed in place using a template to assure reproducible placement. Each of the five configurations was tested on three separate model sterna ($n = 3$) using our custom fixture (Fig. 2). A screw-driven testing system equipped with a 5000 N (± 5 N) load cell was used to load the specimens laterally at a rate of 0.21 mm/s (MTS Syntac with QTest/5 Software, MTS, Minneapolis, MN). Eight tethers were used to distribute the force along each side as evenly as possible given the geometry of the sternum. Equal tether forces were achieved using a series of low-friction pivots and pulleys (Fig. 3a). Frictional forces in the pulleys was measured to be ± 2.5 N, and slight non-parallelism of the tethers ($<10^\circ$) resulted in less than 2% difference in lateral forces at the attachment points (e.g., the maximum angle in Fig. 2a is 8.1° ; the cosine of this angle is 0.99 resulting in 1% lower force perpendicular to the sternum).

Small graphite chips were affixed in pairs on opposite sides of the bisected sterna at seven different locations along the sternum to serve as markers for determining distraction between the sternal halves

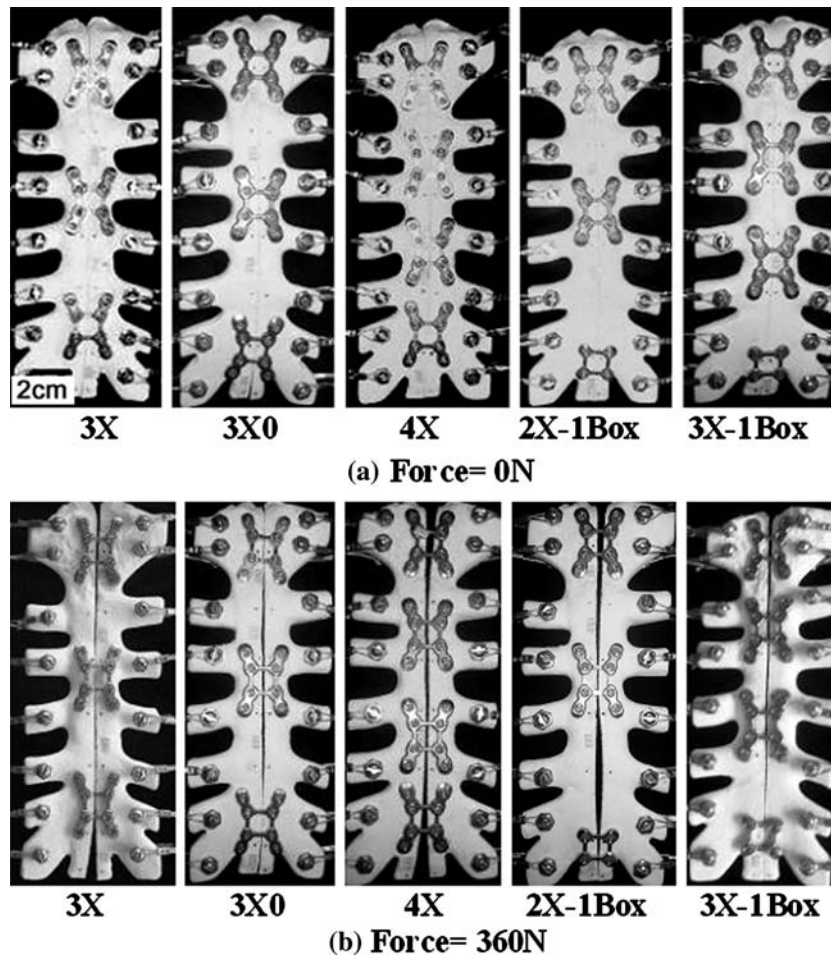


FIGURE 1. Photographs of plate configurations used in this study with naming convention: (a) unloaded at 0 N and (b) at maximum load of 360 N. These photographs are for illustrating the plate configurations and the separation of the model halves at peak load; the images used for distraction measurements were taken at a higher magnification.

(Fig. 2b). At 60 N increments of force up to 360 N the force was held constant (~ 10 s), and a series of high resolution images was taken using a digital camera (Coolpix 5700, Nikon, Melville, NY) to determine the marker positions. These images were then thresholded, and the centroid of each graphite marker was determined using image analysis software (Scion Image, Scion Corporation, Fredrick, MD) (Fig. 2c, d). Scale markers in each image were used to calibrate pixels to millimeters; at the magnification used in this study, the resolution of the digital images was $12 \mu\text{m}/\text{pixel}$. The distraction at each location was calculated as the difference in the distance between the markers from the unloaded state and each loaded state.

Estimation of the Distribution of Loading along the Sternal Midline

To estimate the force distribution in our system, we created a finite element (FE) model of the polyurethane model. First, the surface of the sternal model was

digitized using five planar scans, each having a point cloud density of 0.2 mm by 0.2 mm , using a 3D laser scanner with an accuracy of $\pm 0.05 \text{ mm}$ (LPX-600, Roland DGA Corp, Irvine, CA) (Fig. 3b). The scans were registered and merged into a “water-tight” polygonal model (EZ Studio, Roland DGA Corp, Irvine, CA) and smoothed and translated into IGES surfaces using RapidForm 2006 software (Rapidform Inc. San Jose, CA). The IGES model was then imported into ABAQUS CAE (ABAQUS Inc., Providence, RI) and meshed. The polyurethane material was approximated as linear elastic with an elastic modulus of 267 MPa and Poisson’s ratio of 0.3 per manufacturer’s published values. Lateral 45 N loads were applied to the outer surface of each bolt hole to simulate the experimental setup. The central plane of the bisected sternum was pinned in the direction of force and stress was measured at the nodes on that surface. The stresses on the center plane were binned along the length (x-direction) of the specimen in 1 mm wide bins using MATLAB (Mathworks, Natick, MA).

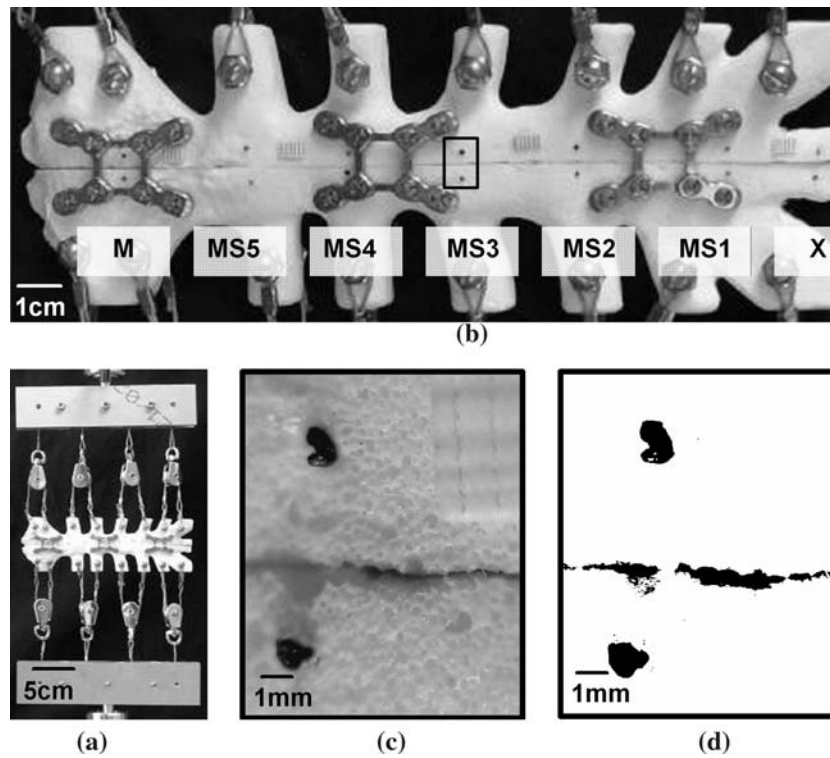


FIGURE 2. Experimental set-up showing model system to measure distraction. (a) Tethering system used to conduct uniaxial tensile tests on the model sternum for all five plate configurations. (b) Close up view of sternal model showing a 3X plate configuration. Seven graphite markers can be seen placed in pairs across the two sternum halves at the Manubrium (M), Mid Sternum 1, 2, 3, 4, and 5 (MS1–5) and Xiphoid (X) as well as a scale marker. Note that one pair is indicated by an enclosing square frame. (c) Close up screen shot of one graphite marker pair. (d) Thresholded screen shot used to measure distractions (difference in y-coordinates of the centroids of each marker pair) at each of the seven locations.

Integrating the bins through the depth (sternal thickness, z-direction) of the specimen yielded the force per length. The length of the sternum was then normalized to one. Integrating along the length yields 360 N, the total applied force in the model.

For a rough comparison with our loading distribution, we estimated the force distribution at the midline of human sternum by measuring the cortical bone thickness along the midline of three cadaver sternum, i.e., the force per length was assumed to be proportional to the cortical bone thickness at a given location. For this approximation we assume that the cortical shell bears the majority of the load and bone forms in proportion to loading (demineralizes when not loaded and increases mineralization when loaded).¹⁴ The sternum (two female, one male, age 77–89, embalmed) were bisected using standard surgical technique, images were taken using a 6.3 mega pixel digital camera (Canon Digital EOS, Japan) with 10 $\mu\text{m}/\text{pixel}$ resolution at the given magnification, and the bone density was quantified using image analysis software (Scion Image). Integrating the density through the depth (sternal thickness) of the specimen yielded the force per length. The length of the sternum was then normalized to one and the arbitrary density values adjusted such

that integrating along the length resulted in 360 N (the total applied force in the *in vitro* experiment).

Statistical Analysis

Distraction between the two halves of the sternum at each of the seven marker locations at the maximum load (360 N) was used to determine “stability” of each configuration (i.e., lower distraction indicates higher stability). The distractions were compared for each of the five plate configurations (factor 1) at each of the seven measurement locations (factor 2) using a Two-Way Analysis of Variance (MANOVA, SigmaStat 3.1, Systat Software Inc., Richmond, CA). This analysis accounts for the spatial component inherent in making multiple measurements along the length of a given specimen. A p -value of <0.05 indicated significant differences between groups. Specific differences were determined by *post hoc* analysis using the Tukey HSD.

RESULTS

A comparison of the distractions between the individual plate configurations showed noticeable differences in deformation magnitudes and patterns;

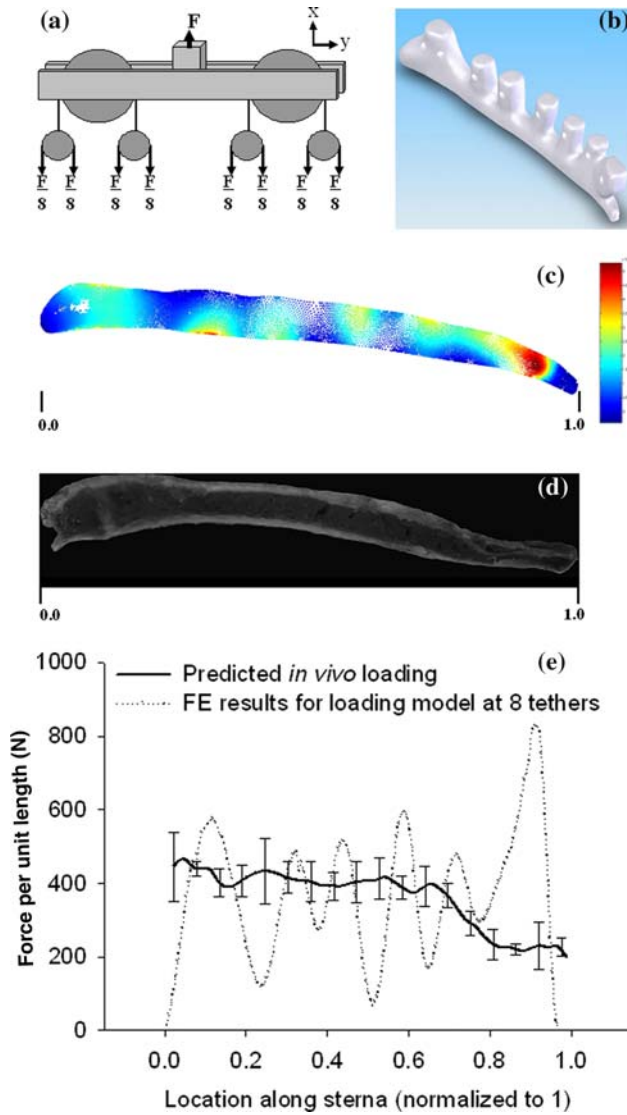


FIGURE 3. (a) Schematic of tethering system showing pulley method for obtaining equal force in each tether. (b) Laser scan of homogeneous polyurethane sternal model input into finite element (FE) software for stress analysis. Note the holes where the tethers attach to the model. (c) Distribution of stress in the lateral direction along center plane of polyurethane model loaded with eight tethers obtained by FE analysis. Scale goes from 0 MPa (blue) to 0.5 MPa (red). (d) Longitudinal cross-section of a human cadaver sternum showing thicker cortical region in manubrium, on left, relative to thinner xiphoid on right. (e) Estimated distributions of force along the sternal midline based on the cortical bone densities of three cadaver sterna (solid line \pm SD, $n = 3$) and an FE analysis based on the *in vitro* loading applied to polyurethane model (dotted line, see text for details). The area under each curve is 360 N (total peak force applied in the *in vitro* testing).

while the detailed data and statistical analysis are shown in Fig. 4 and Table 1, here we focus on highlighting the important trends. Distractions with the standard 3X configuration were generally low across

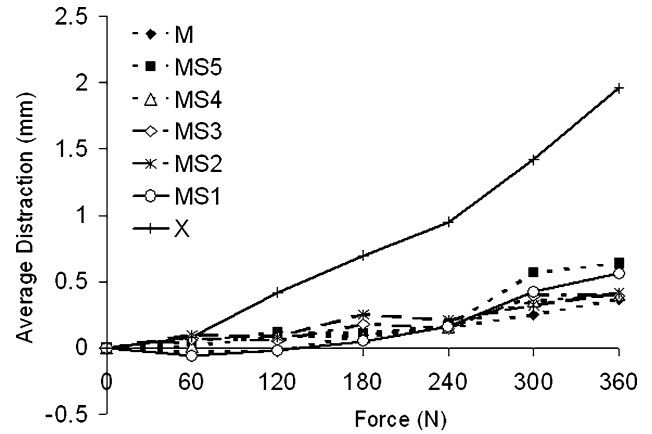


FIGURE 4. Average distraction as a function of force for three sternal models plated with the 3X configuration. The distractions at the xiphoid are substantially greater than at the other regions. Note that error bars have been omitted for clarity but are provided in Table 1.

all locations and exceeded 1 mm only in the xiphoid region at 360 N. As expected, moving a plate towards the xiphoid (3X vs. 3XO configuration) decreased the distraction in this region; this decrease was coupled with a substantial increase at the MS2 region due to moving the plate away from this region. Similarly, replacing the lower X-plate with a Box-plate (3X vs. 2X-1Box) produced smaller displacements in this lower region but also resulted in significantly larger distractions at the MS2 region. As anticipated, the distractions at the MS2 location were significantly reduced by the addition of another X-plate (3X vs. 3X-1Box), resulting in low distractions (< 2 mm) at all locations including the xiphoid. Interestingly, the largest distraction in the xiphoid region occurred with the 4X configuration, possibly due to the difficulty in positioning these plates on the narrow surface of the xiphoid process (see Discussion).

The distraction varied between configurations at the M, MS3, MS2, and X locations (Table 1). Specifically, 2X-1Box is significantly different than 3X ($p = 0.014$) in the M location, 2X-1Box is significantly different than 3X ($p = 0.026$) and 4X ($p = 0.029$) in the MS3 location, 2X-1Box is significantly different than 3X ($p < 0.001$), 4X ($p < 0.001$), 3X-1Box ($p < 0.001$), and 3XO ($p < 0.018$) in the MS2 location, and 4X is significantly different than 2X-1Box ($p < 0.001$), 3X-1Box ($p < 0.001$), 3XO ($p < 0.001$), and 3X ($p < 0.017$) in the X location. Interestingly, there were no statistical differences between the configurations using 3X plates (3X, 3XO, and 3X-1Box), thus in this case there appeared to be little effect of plate positioning or even adding a Box-plate. As might be expected from its previously discussed instability, differences in distraction between configurations were

TABLE 1. Average distraction and standard deviation at each of the seven marker locations (defined in Fig. 1b) for all five configurations at an applied force of 360 N ($n = 3$ for each configuration).

Configuration	Distraction (mm) \pm SD (mm) at 360 N						
	M	MS5	MS4	MS3	MS2	MS1	X
3X	0.37 ± 0.26^d	0.64 ± 0.45	0.40 ± 0.23	0.39 ± 0.33^d	0.41 ± 0.12^d	0.56 ± 0.60	1.96 ± 0.85^c
3XO	0.71 ± 1.05	1.32 ± 0.75	1.49 ± 0.77	1.76 ± 0.92	1.78 ± 1.24^d	0.67 ± 1.12	1.18 ± 1.69^c
4X	1.99 ± 1.05	0.52 ± 0.81	0.56 ± 0.29	0.42 ± 0.41^d	0.51 ± 0.53^d	1.98 ± 0.61	$4.24 \pm 1.26^{a b d e}$
2X-1Box	2.70 ± 0.97^a	2.32 ± 1.29	1.76 ± 1.24	$2.57 \pm 1.56^{a b}$	$4.05 \pm 1.16^{a b c e}$	1.32 ± 0.72	0.03 ± 0.53^c
3X-1Box	1.04 ± 0.91	0.83 ± 0.47	1.14 ± 0.75	0.91 ± 0.96	0.79 ± 0.78^d	0.36 ± 0.35	0.35 ± 0.28^c

Note: a, b, c, d, and e indicates significantly different than the 3X, 3XO, 4X, 2X-1Box, and 3X-1Box configurations, respectively ($p < 0.05$).

found most frequently at the xiphoid (X location). The second most variable location was MS2, likely due to moving plates away from this region in various configurations. The most variable configuration was 2X-1Box, which differed from most other configurations at the most locations. No differences were found between configurations at the MS5 and MS4 locations hence it appears that the configurations are all equally stable in the upper midsternum. Despite the low number of samples ($n = 3$) for each group, the power of the comparison between the plate configurations was high (power = 0.99 with $\alpha = 0.05$) due to the very large differences between the configurations.

In general, the distraction increased approximately linearly with the force applied and was highest in the xiphoid region (e.g., 3X configuration in Fig. 4). However, negative distractions were occasionally observed at lower forces (60–180 N) at the M and MS1 locations (Fig. 4), possibly due to bending (see Discussion); these distractions were relatively small (≤ 0.25 mm) compared to the distractions observed at the higher forces. Although we only measured anterior distractions (plated side of the sterna), substantial separation of the posterior (non-plated) side of the sternal models was also observed. In some cases the posterior displacements appeared to be larger than the distractions on the anterior (plated) side of the sterna although they were not routinely quantified.

The FE analysis of the stresses on the polyurethane model (Fig. 3c, e) indicates that the *in vitro* stress distribution is highly variable on the center plane and the stresses are especially high at the xiphoid due to the two tethers situated relatively close together, the relatively small thickness in this region, and the high stress concentration at the “rib-body” junction (Fig. 3b). In contrast, our estimation of the theoretical force distribution along the midline of a sternum *in vivo* indicates that the manubrium would be expected to experience larger loads than the xiphoid *in vivo* since it is made of denser and thicker bone (Fig. 3d, e). It is also important to note that the principle strains in the FE model were all $< 1\%$, indicating that the model

stayed within the elastic limit during the *in vitro* tests and the distractions were due to elastic deformation at the screws and bending between the rigid plates.

DISCUSSION

Our findings provide several strategies for effective surgical use of commercially available sternal fixation plates. Surgeons generally assume that additional plates are beneficial and as a precaution use between five and seven plates. Interestingly, we observed an increase in distractions at both the xiphoid and the manubrium when we increased the number of plates (3X vs. 4X configuration). These distractions appear to be the result of awkward plate positioning on the narrow xiphoid process. The increased number of screws present within close proximity of each other may also alter the stress distribution in the bone and act as stress concentrators. In fact, we have observed clinically that excessively plated sterna have a tendency to perforate along the lines of screws; thus, simply increasing the number of plates alone is not necessarily advantageous.

The replacement of a fourth X-plate with a Box-plate (3X-1Box) shows significant improvement in sternal stability at the xiphoid and substantial improvement at the other locations with all distractions below 2 mm at 360 N. This increased stability could be due to the Box-plate’s small size, which enables it to be placed lower on the narrow xiphoid than an X-plate, allowing its lower crossbar to reinforce this unstable area. This finding agrees with previous studies on wire fixation of model sterna where lower reinforcement substantially improved stability.⁸ However, placement of a device on the xiphoid is limited *in vivo* due to cartilaginous regions; wires may pull through and screws may not achieve adequate purchase in this softer area. These effects are not reproduced accurately in the plastic models.

Removing the lower X-plate from the 3X-1Box configuration (2X-1Box) allows large distractions at

the MS2 location. The increased distraction was expected because there was no plate supporting the load at this location. Furthermore, although surgeons are concerned with distraction at the xiphoid, simply moving one plate towards the xiphoid does not adequately secure the rest of the sternum. In fact, both configurations that leave the central region unsupported by moving a plate towards the xiphoid (2X-1Box and 3XO) experience significantly larger distractions than all other configurations at the MS2 region. Centrally located X-plates, therefore, are an integral part of all stable configurations because of the large area they support. Our findings suggest that a minimum of three X-plates are needed to provide adequate fixation along the sternum.

Although we improved on the uniformity of the force applied along the length of the sternum over previous methods,^{17,24} it is unclear if any of these loading schemes produces a distribution of loads at the midline representing the *in vivo* state since the native distribution is unknown. Based on our analysis of the stresses in the model sterna *in vitro*, the load in the xiphoid region seems disproportionately large, indicating that our system may overestimate distraction at the xiphoid. However, it has been argued that the confluence of multiple ribs at the xiphoid and the large movement of this region with inspiration yield stresses in the xiphoid that are higher than in the manubrium. In contrast, our estimation of the load distribution based on cortical bone density (Fig. 3e) indicates that higher stresses occur in the manubrium than the xiphoid region. Future *in vivo* studies are needed to measure the loading patterns in cadavers and/or animal models to determine the correct *in vitro* loading. The effect of lateral, transverse and shear loading,⁶ and coughing and breathing cyclic loading patterns¹³ should also be considered to realistically represent the *in vivo* loading conditions.

In our studies, we observed small negative local distractions and relatively large distraction of the posterior edges of the sternal models that have not been reported in studies of wire fixation. Basic mechanical analyses indicate that these interesting behaviors may be attributed to bending moments produced by point loadings acting at distances from the plates and screws. Although we attempted to apply uniform loading along the sternal midline by using a large number of tethers, beam bending analysis demonstrates that negative displacements observed at the MS1 location are likely to occur due to the fixation screws acting as fulcrums (see Fig. 5). Furthermore, static analysis of a transverse cross-section of the sternum indicates that loading the rib struts laterally produces a substantial bending moment in the plates due to the sternal curvature and the location of the

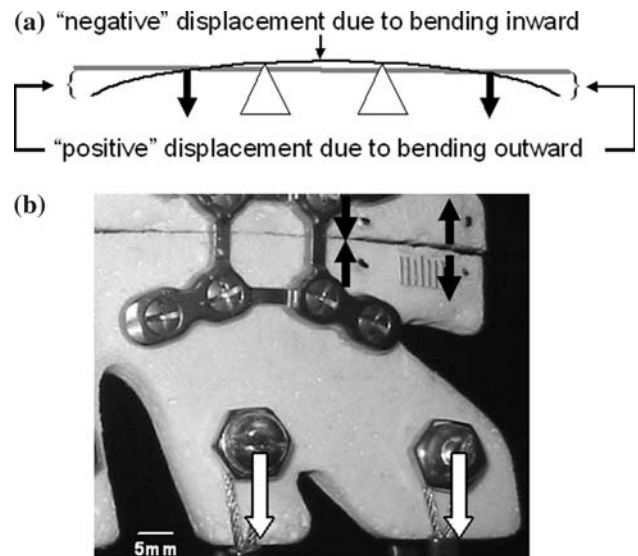


FIGURE 5. Basic beam in bending analysis, shown in schematic (a) and photograph (b), demonstrates a possible explanation for the negative distraction values recorded in a few locations. The bending analysis suggests that the inner screws in the plates that secure the bisected sternum can act as fulcrums and produce localized inward bending of the models.

plates above the line of force (Fig. 6b) which produces distractions on the posterior sternal surface (Fig. 6c). This bending moment is minimal in wire fixation due to the symmetry of the wires (Fig. 6b) possibly explaining why posterior distractions have not been reported previously in similar testing devices. We hypothesize that these posterior distractions would not occur *in vivo* since the loads are most likely directed along the direction of the rib struts, and the expanding movement of the ribs during breathing would force the posterior edges together (see Fig. 6d). Further *in situ* measurements are needed to test this hypothesis.

In vitro methods such as those used in this study provide an economical means for uniformly comparing many different closure techniques. Other methods involving animal models¹⁹ and cadavers¹⁵ may be more physiologically and anatomically relevant but are not optimal for systematic studies of plate fixation as they are costly and non-uniform. Moreover polyurethane sternal models have lateral distraction-force relationships and pullout properties within the same range as cadaver sterna but with much lower variability^{11,23,24} and have thus been used extensively and successfully in sternotomy closure studies.^{6,8} However, while the model sterna were also used in part to eliminate variability due to patient size, in the future sterna of various sizes should be used to determine if the number of plates should be increased or decreased. Additionally, while polyurethane models were suitable for this study, it is clear that further validation of the model

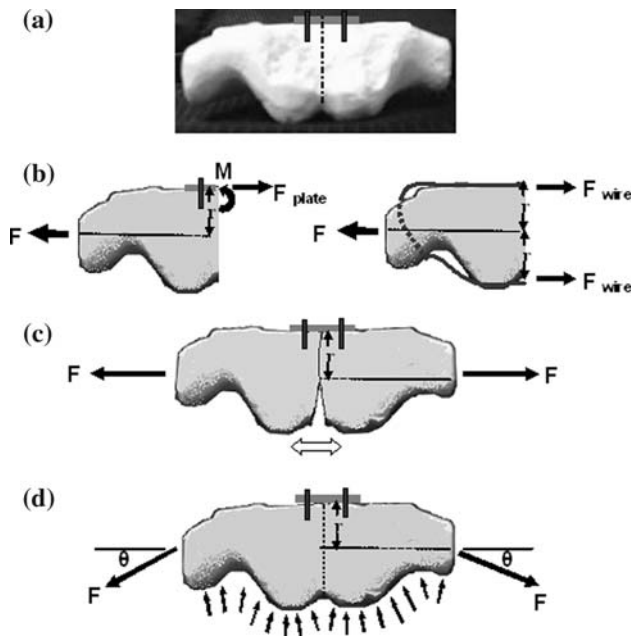


FIGURE 6. (a) On-end photograph of a sternal model showing the plate placement on the upper (anterior) surface. (b) Free body diagrams of wire and plate fixation demonstrate that a moment is produced in plated sterna subjected to lateral loading to achieve equilibrium whereas a similar moment is not produced in wire-fixed sterna. (c) Schematic showing that with the lateral loading used in this study, a moment is produced by the applied force at a distance ($M = r \times F$) creating the observed posterior distraction as indicated by the open arrow. (d) This posterior distraction is not expected to occur *in vivo* due to loading along the rib axis; the vertical component of force is counterbalanced by intrathoracic pressure (indicated by the small arrows in the schematic).

materials and the loading protocols used in *in vitro* tests is needed, and that results from these tests must be applied with prudence in the clinic. Furthermore, *in vivo* studies to determine the specific magnitude and directions of forces that act at the sternal midline are ongoing to enable the design of more physiologically accurate testing methodologies whether utilizing synthetic or cadaveric sterna.

CONCLUSION

In summary, we have shown that the stability of sternal fixation is greatly dependent on the closure device type and placement. Under quasistatic uniform lateral loading, the most stable configuration we tested is the 3X-1Box-plate configuration, and it appears that the susceptible xiphoid region may be adequately secured with a Box-plate. This study represents an important step in the continuing effort to determine optimal plating configurations that yield better sternal healing to aid the recovery of high risk patients undergoing cardiac surgery.

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