Abstract
Rigid fixation of bony structures has been introduced and implemented as a means to improve stability and reduce motion. Tight fixation has been reported as an essential factor for successful healing. A variety of devices including plates, intramedullary nails, pedicle screws and interbody fusion devices are used in orthopaedic, spinal and cranial facial procedures to provide rigid fixation. The sternum, however, remains one of the few bones that is not rigidly fixated.

The purpose of this study was to compare the mechanical properties of wire cerclage with rigid fixation using plates and screws in human cadaveric sterna. Thirty-one sterna were tested in lateral distraction, rostro-caudal shear, and anterior/posterior shear using a pneumatic test system to determine strength and stiffness.

Rigid fixation with plates was shown to exhibit superior mechanical properties compared to wire cerclage. When tested in lateral distraction, the stiffness of the plates was more than 400% greater than peristernal wires (p<0.05). Similarly, the yield load (560N vs. 397N) was also significantly better in sterna that were rigidly fixated.

Rigid fixation of the sternum following a median sternotomy with SternaLock plates results in superior stability, stiffness and strength when compared to peristernal wires.

Introduction
Immobilization supports bony union. This was recognized thousands of years ago by the Egyptians, who splinted fractures. A clinical study demonstrated higher fusion rates when rigid fixation or metal to metal devices were used as compared to laminar fixation with hooks or wires. A variety of rigid fixation systems have been developed and utilized in orthopedic applications, including intramedullary nails, spinal fusion devices, external fixators, and cranial and maxillofacial plates.

These systems give the surgeon the necessary tools to stabilize the bone, allowing for bone remodeling and healing to progress.

Sternal stability and union following a sternotomy is an important step in returning the patient to normal activity. One factor in the development of sternal wound infections is bony instability after sternotomy. Wire cerclage has historically been used to reduce the sternum. Sternal separation and dehiscence following closure with wire cerclage has been reported to occur at a rate of 0.3–8%. These complications are often costly, and have been linked to mortality rates of 10-40%.

To date, few studies have been published comparing the mechanical properties of rigid fixation with sternal plates to the traditional method of wire cerclage. An in vitro study demonstrated that rigid plates provide significantly more stable fixation than wires. A separate study in baboons demonstrated rigid fixation resulted in earlier union with primary osseous healing, suggesting greater inherent stability.

Objective
To compare the mechanical properties (stiffness, yield load, and ultimate load) between wire cerclage and rigid sternal fixation using SternaLock plates in cadaveric sterna.

Methods
Thirty-one cadaveric sterna were used in this analysis. Each sternum sample was accompanied by CT scans, and the age and gender of the donor. Each sternum was divided along the midline and closed with peristernal wires or SternaLock plates, consistent with a sternotomy procedure. A cardiothoracic surgeon assisted in the wiring and plating.

Group A (n=15; Fig.1a) consisted of divided sterna closed with three trans-sternal wires at the manubrium and five peristernal wires along the body of the sterna. Group B (n=16; Fig. 1b) used two “X” plates on the sternum body.
and an “L” plate at the manubrium, as well as, 3 wires at the
manubrium and two additional wires at the xiphoid process.

Samples were stored at -20°C prior to testing, and placed
into a standard freezer 24 hours before testing. The night
prior to testing, the specimens were allowed to completely
thaw in a refrigerator. Samples were placed in a room-tem-
perature lab several hours before testing.

The cadaveric sternae were mounted using custom
fixturing designed to apply load to the sternae in one of
three methods: lateral distraction (Fig. 2a), longitudinal
(rostro-caudal) shear (Fig. 2b), or transverse (anterior-
posterior) shear (Fig. 2c). This was selected in an effort
to simulate the natural forces that would be applied to the
sternum in vivo.

The midline of the divided sternum was aligned parallel
to the clamps so that the load was through the midline
to minimize rotational artifacts and the construct was
mounted in a pneumatic materials testing system (Bose
SmartTest SP, Eden Prairie, MN). Displacement of the
sternal halves was measured at the midline using a three-
dimensional texture correlation technique
(Correlated Solutions, Columbia SC).

Each test was conducted using a displacement control
mode at a rate of 25 mm/min until failure, which was

Figure 1. Image of the 2 groups, wire cerclage (left) and rigid fixation
with SternaLock plates (right).

Figure 2. Sterna were tested in 3 separate directions; lateral distraction
(Fig. 2a), longitudinal (R/C) shear (Fig. 2b), and transverse (A/P)
shear (Fig. 2c).
defined as the point where fracture of the sternum, ribs, or construct occurred, or greater than 2 mm of displacement.

The following mechanical properties were evaluated:

- Stiffness: resistance to elastic deformation or movement when force is applied
- Yield load: the ability of the construct to resist stress before permanent damage is inflicted to the sternum or device
- Ultimate load: stress capacity of the construct before permanent damage is inflicted to the sternum or device

The mechanical parameters were evaluated using an ANOVA model (Minitab, v 15.2) with each of the mechanical parameters as dependent variables, and fixation method, gender, and first order interaction as factors and age as a covariate. Tukey post-hoc testing on the mean values was performed and significance was reported when p<0.05.

**Results**

Mean age for the tested sterna was 71.8 ± 9.3 years, and 61.3% of the sterna were obtained from female donors.

In general, the SternaLock plates exhibited superior mechanical properties compared to peristernal wires in both stiffness and strength.

When loaded in lateral distraction, the stiffness of the SternaLock plates was 400% greater than peristernal wires (p<0.05; Fig 3). Increased stiffness for the SternaLock plates was also demonstrated in longitudinal shear, where the stiffness of plates was more than 1600% greater than peristernal wires (p<0.05).

SernaLock plates were also found to have superior yield load compared to peristernal wires (Fig. 4). When tested in lateral distraction, the SternaLock plates resisted sternal separation until a mean force of 559.6N was applied, compared with 396.6N for peristernal wires (p<0.05). Similarly, in longitudinal shear, the SternaLock plates were nearly 2x stronger than peristernal wires (p>0.05).

The failure mode when testing the two constructs was also found to be dramatically different. When catastrophic failure was observed in sterna closed by peristernal wires, the wire cut into the sternal body in 77.8% (7/9) of cases (Figure 5). Fixation with SternaLock plates was strong enough that failure of the system through screw backout was not observed. In fact, fixation was such that catastrophic failure of the construct or at the midline never occurred. Failure was commonly observed as rib fracture or intercostal muscle tearing, resulting in loss of grip on the cadaveric thorax section. Therefore, peristernal wires were found to resist only half as much force as SternaLock plates prior to failure, and the amount of force the SternaLock plates were able to withstand prior to failure was often more than required to fracture the surrounding bones.
Discussion

Rigid plate fixation is designed to resist lateral distraction much more effectively than wire cerclage, but another major advantage is the ability to resist forces from other directions. Wire cerclage methods primarily resist motion in the lateral direction. When loaded in longitudinal and transverse directions, the sternum is very compliant and is allowed to move with little resistance. Rigid plate fixation is designed to effectively resist force from transverse shear, longitudinal shear, as well as, lateral distraction.

The total force applied to the sternum as a function of various activities has been evaluated. In one study, it was estimated that the total force applied to a sternotomy as a result of coughing ranged from 220N – 350N in the subjects evaluated. In the current study, 60% (3/5) of the sterna that were closed with wires were found to have a yield load that was less than 350N.

Immobilization supports bony union. Tight fixation and blood supply are the essential factors for successful healing. In a study conducted by Sargent using baboons, the presence of woven bone was found eight weeks after operation using popular wire closure techniques. In animals stabilized with rigid fixation, the presence of woven bone could be found only four weeks after operation. Histomorphometric analysis indicated the midline sternotomy gap was less in animals treated with plates and screws compared with wires. Rigidly fixing the sternum with plates and screws resulted in earlier union with primary osseous healing.

Conclusions

Rigid fixation of the sternum following a median sternotomy with Sternalock plates results in superior stability, stiffness and strength when compared to peristernal wires in laboratory testing.

References


This white paper is authored by Brian Hatcher, Ph.D. who is the Director of Research for Biomet Microfixation. This study was funded by Biomet Microfixation.

Non clinical studies are not necessarily indicative of human clinical results.