Development of a Standardized Method for Comparing Biomechanical Properties of Various Sternal Closure Techniques

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ABSTRACT

Development of a Standardized Method for Comparing Biomechanical Properties of Various Sternal Closure Techniques

By: Ramzi Hawit

Background:

33.6% of all deaths in America are caused by cardiovascular disease. An estimated 82.6 million adults (>1 in 3) in America have some form of cardiovascular disease. There were over 400,000 bypass surgeries requiring open-heart surgery. Sternal dehiscence is associated with a morbidity rate of over 47% if mediastinitis supervenes. A rigid closure is required to avoid healing complications, and wire, plates, and bands are all used in an attempt to make a better closure. The purpose of this study is to compare multiple closures and validate a new testing method.

Methods:

Polyurethane foam blocks will be used, as an alternative to cadavers, to provide homogeneous samples to test and compare multiple closure techniques. Each closure was performed by an engineer after instruction from a cardiothoracic surgeon and the SternaLock plate manufacturers. Seven different closure techniques (single suture, double suture, figure-eight suture, Robicsek weave, Sternalock Silver, Sternalock Blu, and Sternalock Wide Ladder) were compared in both lateral distraction and longitudinal shear. Statistical analysis was used to show the differences in stiffness, yield force, failure force, and yield displacement of each closure method.

Results:

Under lateral distraction, double wire closure showed the greatest stiffness followed by the Sternalock plates. The Sternalock plates had the greatest failure and yield forces, whereas the double wire performed significantly poorer. The longitudinal testing revealed that the wires provide no resistance to the shearing forces on the sternum, but the screws for plates can allow for multidirectional loading.

Conclusions:

Overall Sternalock plates are less likely to fail in all directions compared to wired closures. Even though double wire closures displayed a higher average lateral stiffness, the high stress concentrations created by wires allowed for easy foam cutting and much lower yield force and failure force. Testing using foam blocks as sternal analogues produces highly reproducible results, with less variance than cadaveric tests.

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1 Background

1.1 Sternum Anatomy

The sternal plate, also called the breastbone, is in the center of the chest extending from the base of the neck to below the diaphragm. The sternum consists of three parts: the manubrium, the gladiolus or body, and the xiphoid process. The manubrium is a large triangular plate that makes up the upper part of the sternum. The manubrium supports the clavicles and the first set of ribs. The body of the sternum is attached to the bottom of the manubrium and supports the second through seventh ribs. The xiphoid process is the lowest and weakest part of the sternum, created from a thin piece of ossified cartilage.

The sternum creates a foundation for the entire thoracic cavity. It has attachments from the clavicles, ribs, and muscles. The strength of the sterna plate easily withstands the stresses created by skeletal movement and provides stability and protection for vital organs.

1.2 Median Sternotomy

The sternum has been used as the access point to the vital organs in the thoracic cavity for surgical procedures. This involves using an incision to completely divide the sternum vertically and is called a median sternotomy. The median sternotomy is used because it grants outstanding exposure of vital organs and has been associated with low amount of postoperative pain and good healing rates in most patients.

Median sternotomy is primarily associated with open-heart surgery. It has been widely used by cardiothoracic surgeons since 1957 to give unobstructed access to the heart. Open-heart surgery is commonly used to treat coronary artery disease, correct congenital heart defects, replace damaged valves, and heart transplantation. This procedure continues to be fundamentally important in the treatment of cardiovascular disease which continues to be the leading cause of death in the United States with 803,504 cases annually, which is over 1 out of every 3 deaths [1]. Even though the mortality rate due to cardiovascular disease has decreased slightly, the burden on the healthcare system is becoming increasingly heavy with the total number of inpatient cardiovascular operations and procedures jumping 27%, from 5,382,000 in 1997 to 6,846,000 in 2007. In 2007 there were an estimated 408,000 coronary artery bypass procedures, and 106,000 valve replacements. In 2009, there were 2,211 heart transplantations, and an average of 22,900 corrections for congenital heart defects. In-hospital mortality rate (deaths per 100 CABG discharges) declined from 4.3 to 3.5 from 2002 to 2004[2]. This shows that at least 14,280 deaths a year are attributed to complications that arise from open-heart surgeries.

The median sternotomy procedure involves making a midline incision from the top of the sternum to past the xiphoid. An oscillating saw is then used to divide the sternum vertically down the midline. Sternal spreader is then used to keep the sternal halves separated and give access to the pericardium.

The advantages of a median sternotomy are the easy access and well tolerated healing by most patients. It has been associated with low amount of postoperative pain and heals well, but healing complications after a median sternotomy can include sternal malunion, non-union and infection. Postoperative dehiscence is a serious complication, and if mediastinitis supervenes then it is

associated with 14 to 47% mortality rate [9]. Increased risk factors for postoperative dehiscence including obesity, diabetes, chronic obstructive pulmonary disease (COPD), advanced age, osteoporosis, smoking, chronic cough, bilateral internal mammary artery harvesting, chest re-exploration, and prolonged ventilator use are seen to put more stress on the closure or inhibit the healing. With so many risk factors it is important to have very stable techniques to allow healing for patients that would otherwise have a very long or incomplete recovery.

After the surgery is completed the two sternal halves need to be fixed firmly to each other to allow for bone healing. This sternal closure needs to be rigid and reliable to allow the sternum to heal correctly. Many different sternal closure methods have been used in an attempt to create the most stable closure. Some of the methods used include stainless-steel sutures, steel coils, sternal bands, reinforced wire, braided cables, nylon bands, and rigid fixation plates. Healing after a median sternotomy can be very slow with no sternal healing after three months and complete healing in only half of the patients after six months. This indicates the great the importance of the sternal closure to long-term stability [6].

1.3 Closure Techniques

Many different sternal closure methods have been used in an attempt to create the most stable closure. Some of the methods used include stainless-steel sutures, sternal bands, reinforced wire, braided cables, nylon bands, and rigid fixation plates. Each hospital uses its own preferred method of closure and each surgeon performs each method with what they think is the best technique and they have the most confidence in executing. Everyone is concerned with which

closure technique will prove to be the most stable, reliable, easiest to use, cost effective, and has the simple removal method to regain access if a need arises.

1.3.1 Stainless-steel wire sutures

Sternal wire fixation was first used to close a median sternotomy by Milton in 1897 and was later popularized by Julian and colleagues in 1957. Stainless-steel sutures are used to close the sternal opening. These can be peristernal (around the entire sternum body) sutures or transsternal (through the sternal body) sutures. They are used to pull the sternum together and a compressive closure force is applied as the surgeon twists the two ends of the wire together. This method is performed relatively quickly and is the most commonly used due to its simplicity and familiarity.

Figure 1-1: Upper row: single transsternal, single peristernal, alternating trans and peristernal Lower row: figure-eight peristernal, figure-eight pericostal, and Robicsek weave [3].

Stainless-steel wire is the most commonly used method by thoracic surgeons. As seen in Figure 1-1 there have been many different techniques tried to improve the closure with wire sutures. Even though it has been proven very effective and is used as a benchmark to compare new closure methods, it still fails with potentially fatal consequences. Wire failures commonly occur when the wire cuts into the bone [4]. There have been cases where wires have broken, usually at the base of the twist where stress concentrations are greatest, or become unraveled. Failure of a single loop has a cascading effect where since the failed wire is no longer able to apply closure force the other wires have more force applied to them causing them to fail in turn. The normal closure techniques have been modified to include figure-eight and Robicsek weave patterns to diminish the amount of bone cutting that occurs. Both of these techniques strive to increase the surface area of the wires in contact with the sternum. The Robicsek weave uses a pericostal wire on each side of the sternum as a cradle for the closure sutures. This greatly disperses any stress concentrations and minimizes bone cutting. It has been used with success on patients with two or more risk factors for sternal dehiscence, with only a 2.5% incidence of dehiscence versus 12.5% normal closure [14].

1.3.2 Reinforced wire closures

Stainless-steel wire closures have been shown to cut through bone causing sternal separation. A simple wire is dependent on bone strength no matter the pattern used to suture the wound closed. To neutralize this problem methods have been developed to distribute the load of the wires over a larger area. Most methods developed involve placing a stainless-steel or titanium plate between the wire and sternum to prevent cutting. These methods reduce the dependency on bone strength and have been shown to increase the stability of closures on weak or damaged sterna [5].

Figure 1-2: Pectofix Dynamic Sternal Fixation [DSF] stainless-steel plates [6].

Figure 1-3: The sternal reinforcement device (DSS: Sternal Synthesis Device [Mikai SpA, Vicenza, Italy]) consists of separate clips made of 0.7 mm titanium sheet [5].

1.3.3 Rigid plate fixation

Rigid fixation techniques were first developed for orthopedic surgeons. Similar to cardiothoracic surgeons, who currently use wires to create sternal closures, craniomaxillofacial and orthopedic surgeons once used wires for bone fixation. Morbidity and complications associated with wire fixation in the craniofacial and axial skeleton were similar to those found by cardiothoracic surgeons in sternotomy closures. These complications included infection, separation, instability, motion, nonunion, and delayed healing. Researchers developed rigid plates to reduce these complications by decreasing motion at the fracture site, lowering postoperative pain and

improving primary bone healing. The overwhelming benefits of rigid plates have nearly replaced all wires in orthopedic and craniomaxillofacial surgery [7]. It is believed that the historical success of rigid fixation in other fields will also be seen with sternal closures when applied to thoracic surgery.

Rigid plate fixation started out with straight plates, but testing showed that screws too close to the sternal separation tended to break through. The fractured bone caused the screws to lose purchase weakening the entire closure eventually leading to failure. This problem led to the straight plates being redesigned into an H configuration, which allowed for all the screws to be placed in strong positions with plenty of surrounding bone and less prone to fail [7]. This H configuration has been accepted and modified in products like SternaLock to create more custom plates for sternal closures.

Figure 1-4: A) custom four-holed titanium H plate [7]. B) : A complete closure using SternaLock, titanium locking plates (W. Lorenz Surgical, Jacksonville, FL) [8]. C) Sternalock Blu x-plate

1.4 Sternal models

Not all testing can be performed on patients without previous simulations to verify the stability of a closure. In-vitro testing is necessary to examine the strengths and weaknesses of each closure technique and to provide a comparison to current closure methods. Sternal models are needed to perform in-vitro testing and the best tests would replicate both the physiology of the sternum and the loading characteristics it experiences.

1.4.1 Biological models

Biological models involve using the sterna from other animals, such as a dog, sheep, pig or cow, to test how closure techniques will react with bone. Human cadavers are best suited for testing, but are expensive and difficult to obtain in sufficient numbers. Porcine sterna are very easily obtained and inexpensive, allowing for lots of testing. Porcine sterna are similar in size to human sterna but still have significant physiological differences including the shape and density of the sternum. Porcine sterna have a very small sternal angle and the bone itself is massive with a thick cortical layer. There is a wide variability in the dimensions of a porcine model due to the weight, age and breed of the pigs used [9]. This can cause a wide range of results with low reproducibility.

1.4.2 Bone analogues

Nonbiological sternal analogues are usually made from casting solid polyurethane foam into a sternal model. Even though they are not the same as a biological model they can approximate the biomechanical properties of cadaveric sterna and give reliable information on sternal closure

stability and performance in bone. Testing has shown that sternal analogues have less variability than human tissue giving a high reproducibility of results and the ability to detect small differences in sternal stability between closure types. The attractions of testing with these sternal models are that they are much less expensive than cadaveric testing, can be performed more quickly, have less data variability, and eliminate the need to perform multiple tests on a single sternum [10]. These all combine to make testing of large groups a real possibility at the same time improving data quality. The uniform properties of the sternal models are also a limitation in that they do not reproduce the variability and biological complexities seen in living patients.

1.4.3 Cadaveric models

Although using other sternal models can yield significant data in determining how closure techniques will perform nothing can reproduce the biomechanical complexity of a live human sternum better than a cadaveric model. The drawbacks to using cadaveric models in testing include a tremendous variability in sternal size, thickness and bone density [6]. These variations compounded with the high cost and low availability of cadaveric sterna inhibits comparative testing of sternal closures without performing multiple tests on the same sternum.

1.5 Previous testing

Griffin and Cohen performed a biomechanical study of three closure techniques; figure-eight stainless-steel wires, figure-eight stainless-steel cables, and Pectofix Dynamic Sternal Fixation [DSF] stainless-steel plates. The tests were executed on polyurethane foam sternal models that simulate the properties of cancellous bone. Griffin cites the tremendous variability in bone

Figure 1-5: Custom fixture allowing mounting of specimens into test stand to apply lateral distraction (a) longitudinal shear (b), or transverse shear (c) [6].

density, sternal size, and sternal thickness between cadaver specimens and the shape and size differences between humans and animals as the reasons to use a sternal analogue. The sternal analogues allow for reproducibility in testing and give reasonable expectations of performance in bone. The samples were potted in custom fixtures and external force was applied as seen in Figure 1-5. The sample was pulled apart at 10mm/min until fracture occurred in the sternum, a rib, or the closure device. The testing found the DSF plate system more rigid in distraction and transverse shear modes. The DSF provides 25% more resistance to yield compared to wires under transverse shear, and the cables had a higher resistance to failure than the wires in all modes of loading [6].

Zeitani and Penta de Peppo performed similar testing on reinforced wiring device using polyurethane foam models. These models were drilled through the ribs and lateral distraction force was applied through a pair of steel cables. Three strain gauges were placed across the sternal midline and a load-displacement curve was collected. The results showed that the DSS reinforced group failed at 1200N and the single loop control group failed at an average of 580N. The DSS also showed much less displacement at higher loads [5].

Casha and Yang measured the force-displacement curves of six different fixation techniques using a metal sternal model. They tested straight wires, figure-eight wires, repair technique, Ethibond, Sterna-band and multitwist closure. The testing used a steel jig as the sternal model, with all holes radiused and polished to decrease stresses on the wires. Wiring was pretensioned to 10N and the jig was separated at 2mm per minute and force and displacement data was collected. All results were highly reproducible indicating that the physical properties of each group of wires tested were for all intents identical. At 20kg force the twisted wires used for sternotomy closures start to untwist. The most rigid closure was the multitwist displacing only 0.37mm. Straight wires displaced 0.78mm, figure-eight 1.20mm, Sterna-band 1.37mm, repair wires 5.08mm, Ethibond 9.37mm. This test only measured the rigidity of each closure construct without any consideration of the interaction it would have on bone [11].

Losanoff and Foerst developed a biological sternal closure model using an entire porcine sterna. A special stainless-steel clamp with multiple spikes was used to attach to the testing device. Two techniques were tested; single peristernal and pericostal figure-eight. The specimens were subjected to a gradually increasing pulling force in distraction at a rate of 5mm/min until failure occurred. The data collected was a continuous force (N) over time (min) plot. Load elongation data and failure mode were recorded. The specimens withstood a pulling force of 730-916 N compared to 260-490N reported to cause dehiscence of sternotomy closures on human cadavers. Wire failures occurred infrequently at the base of where the wires were twisted and were characterized by wires cutting through cortical bone. When ribs fractured it was considered a

failure in the testing method and the results were omitted. Overall peristernal wires showed significantly more rigidity over the pericostal figure-eight [9].

Ozaki and Buchaman used the sterna from human cadavers to compare wire closures against two different types of titanium plating, straight plates and H plates. Testing the sterna involved placing the rib ends into rectangular aluminum molds, then filling the molds with chemically cured polymethyl methacrylate. Each of 10 sterna was mechanically tested using the uniaxial servohydraulic testing machine as seen in Figure 1-6. The sterna underwent repetitive loading for 10 second cycles using a 22.5kg load. Stiffness measurements were calculated from the average slope of the load versus displacement curves. Stiffness data for each cycle were recorded and analyzed. In addition, a strain gauge was used to measure lateral sternal displacement across the median sternotomy. Rib fracture which occurred in 3 out of 10 were removed from results. Results showed that the custom titanium H plates showed a significant increase in stiffness and less lateral displacement than the wired sterna [7].

Figure 1-6: Ozaki test setup with potted sternum undergoing compression by the uniaxial servohydraulic testing machine.

Baril and Brailovski tested braided tubular superelastic (BTS) sutures, like a commonly used monofilament stainless-steel (MSS) suture but made of memory alloy. They used sternal models made of polyurethane and applied forces up to a maximum of 1200N. They measured the load applied, the displacement at four points along the sternum, and the compression force applied at the sternum midline. The static testing used to measure the rigidity of the closure used incremental increase of tensile separation force on the sternal halves 200N by step. The testing allowed a 30 second dwell time to allow for stabilization, calculation of compressive force and measurement of sternal separation at all four control points. After each increment tensile force was brought back to zero to measure residual compressive force and permanent displacement at midline. This testing was able to calculate the rigidity of the closure and the amount of force necessary to initiate sternal separation. It was also able to see the amount of compressive force reapplied after each loading step to see how much better BTS sutures reapplied compression. In most cases the rib struts failed before the closure system failed, therefore the maximum tensile separation force of the closure could not be reached. Zero compression force measured at the midline were very different tensile separation forces of 1034+57N for BTS and 1221+73N for MSS, which is the minimum force required to cause separation. MSS separation force is 15% higher than BTS, and the MSS sutures allow a smaller opening than BTS sutures. But in dynamic testing the BTS reapplies 11% more compression force than MSS after a hundred cycles [12].

Figure 1-7: (a) Schematic overview of the test bench; (b) closed sternum model with BTS suture [12]

Özel Avrupa compiled a retrospective study comparing the effects of two sternal closure techniques, simple wiring and figure-eight wiring, to the development and outcome of non-microbial sternal dehiscence. Medical records of all adult patients (n=6211) that underwent a median sternotomy between January 2002 and August 2008 were reviewed for the development of non-microbial sternal dehiscence. The outcomes of 90 (1.44%) cases that developed dehiscence were analyzed. The two wiring techniques had similar rates of dehiscence (1.46% for figure-eight and 1.43% for simple wiring) [13].

2 Objectives

The objectives of this study are to compare performance characteristics of multiple sternal closures techniques and evaluate a new testing method. Three Sternalock plate closures will be tested along with widely used peristernal wiring techniques, such as: single suture, double suture, figure-eight, and the Robicsek weave. The results will be used to indicate which methods are

best and if the differences are significant enough to choose one closure method over another. The tests will be performed on polyurethane foam blocks and the data collected will be compared to previous testing done on cadavers.

Complications that occur with sterna dehiscence are coupled with startlingly high mortality rates. To avoid these complications stiffer and stronger closures are required to avoid wound disturbance from coughing and physical loading. At the same time cadavers are expensive and have a diverse range of sizes and densities. To have more consistent and reliable results to compare closure techniques a less expensive and highly reproducible test is needed.

Hypothesis: The Sternalock plates, especially Sternalock Wide Ladder, will create stronger closures than the wired closures. Also the foam block test will be more consistent and reproducible than cadaver test while showing the same trends for each closure.

3 Methods

Biomet Microfixation (Jacksonville, Florida) provided 168 machined polyurethane foam blocks of two densities to be used as sterna analogues of 12mm thickness. Both 20lb/ft³ and 10lb/ft³ polyurethane foam blocks were used to simulate the properties of cancellous bone and osteoporotic bone. Previous tests have used polyurethane foam models successfully to replicate human cancellous bone in osteoporotic and sternal studies. Polyurethane foam blocks will be used, as an alternative to cadavers, to provide homogeneous samples to test and compare multiple closure techniques. Each closure was performed by an engineer after instruction from a

cardiothoracic surgeon and the SternaLock plate manufacturers. Seven different closure techniques (single suture, double suture, figure-eight suture, Robicsek weave, Sternalock Silver, Sternalock Blu, and Sternalock Wide Ladder) were compared in both lateral distraction and longitudinal shear. All wire techniques used M650 monofilament wire from Ethicon (Georgia) and left one intercostals space open near where the manubrium and sternum would meet. The single wire groups used five single peristernal sutures; the double wire groups threaded two wires around the sternum at once and twisted all together to create a double suture. The figure-eight groups used three peristernal figure-eight sutures with the twist on the wire perpendicular to the midline and the bottom two sutures overlapping one intercostal space. The Robicsek weave was wired the same as the single wire sutures with first weaving separate wires through the intercostals and around each rib. The Sternalock systems from Biomet Microfixation (Jacksonville, Florida) used one L-plate and either two X-plates or two wide ladder plates.

3.1 Setup

Each foam block is attached to a u-bolt with 4 thru bolts to evenly apply force across the midline. For lateral distraction tests thin film pressure sensors for I-scan system (Tekscan, Boston, MA) are placed between the two foam blocks before the closure is created. This pressure film allows for tracking of compressive force as the closure is created and as the test runs. A clamp is then used to hold the two sterna halves together as the wire closures are created. Biomet Microfixation (Jacksonville, FL) provided alignment fixtures for the correct placement of plates, and the clamp was used to ensure close to equal initial compressive force. Initial compressive force was targeted to be over 70 N. The sample is then speckled with black ink--1mm dots sprayed randomly and evenly over the foam are best. The sample can then be attached by u-bolt

and the thru bolts to the testing fixture. The same test fixture was used for all lateral and longitudinal tests, and two ¼ inch bolts are used to attach the fixture, in either load direction, to the load frame (Bose SmartTest SP, Eden Prairie, MN). During the test the load frame is controlled and data collected by WinTest Digital Control Electronics and WinTest Software (Bose Corporation, Minnetonka, MN) and Vic-3D (Correlated Solutions Inc, Columbia, SC) to get accurate displacement and force data.

3.2 Sample Loading

A new sample is used for each test to get accurate profile of how each closure performs. Each closure type was tested in both lateral distraction and longitudinal shear to track and compare performance. The displacement and force are gathered during each test to calculate the closure stiffness, yield load, displacement at yield, and failure force. Failure is defined as a catastrophic failure, like wire breakage or foam fractures, or when the closure allows 2mm of displacement at the midline. The static monotonic tests are done at a rate of 3mm/min, to allow for data collection.

3.3 Data Extraction

The test frame stressed each sample monotonically either laterally or longitudinally, while collecting data. The force and displacement data is collected by computer and exported to a text file. The data can then be displayed in a force vs. displacement graph, and the desired bio mechanical properties can be evaluated.

Stiffness, or rigidity, is the resistance to deformation against an applied force. The linear beginning portion of the graph is created by elastic deformation, and displacement will return to zero along this line. This is also an easy place to calculate stiffness using the equation $\text{Force} = \text{Stiffness} * \text{Displacement} + b$. An algorithm was developed to calculate the stiffness by finding the least squares regression line of all the data points with 10-35% the ultimate force. This gave a consistently straight part of the line.

Figure 3-1: Typical force-displacement curve and definition of biomechanical properties. Stiffness is the slope of the linear portion of the line, and yield is defined when the curve deviates from being linear. Failure force is either the max force or when the closure allows 2mm of displacement.

The yield load is the amount of force a closure can withstand before permanent (plastic) deformation occurs. The yield load was found by using a secant slope method where the calculated stiffness is reduced to 95% and the intersection of this new line with the force vs. displacement curve indicates the yield force. This is because it points out where the graph is no longer linear or where plastic deformation begins. The sample algorithm uses this intersection point to find the yield force and displacement at yield. This yield displacement is where failure first

begins with usually wires or screws being pulled through the foam (bone). A larger displacement before yielding would allow a construct to avoid permanent damage and loss of compressive force.

The ultimate or failure force was simply calculated as the maximum force before a displacement of 2mm occurs. It is a good indicator of the amount of force the construct could withstand before it no longer aids in healing and may impede recovery.

3.4 Analysis of Data

For each of the 7 closure types 3 tests were performed in each direction for each foam density, for a total of 84 tests. The stiffness, yield force, yield displacement and failure force for each test were evaluated by Minitab 16.1 (Minitab Inc., State College PA). An ANOVA general linear model was used to analyze the data. The four biomechanical properties were used as dependent variables and direction, foam density and closure method were used as independent variables. Tukey post-hoc testing was used to indicate when statistically significant differences were reported $p < 0.05$.

4 Results

The closure stiffness, yield force, displacement at yield and the failure force have been recorded for each test. The results of the testing will be displayed in comparison for each closure method. The plots will identify trends by labelling test groups with differences that are statistically

significant. Interaction plots are included to help identify trends and significant interactions between variables. A comparison will be made between previous cadaveric testing and this testing done with foam blocks.

4.1 Lateral Distraction

Each closure method had 6 samples tested in lateral distraction, 3 low-density 10lb foam tests and 3 high-density 20lb foam tests. The only exception was in the low-density Sternalock Silver tests where an extra test was performed. In the table below failure modes are indicated by numbers: 1 for wires cutting through foam, 2 for screws cutting through foam, 3 for foam fractures, and 4 for plate bending.

Table 4-1: List of all the lateral testing with resultant values of key biomechanical properties.

Test Name	Density lb/ft ³	Stiffness N/mm	Yield Force N	Yield Disp mm	Ult Force @ 2mm	Failure Mode	Compressive Force
lateral 10lb double #1	10	909.61	243.50	0.34	374.80	1.00	46.70
lateral 10lb double #2	10	751.11	256.50	0.44	376.70	1.00	61.50
lateral 10lb double #3	10	561.91	237.60	0.45	381.30	1.00	61.30
lateral 10lb Fig8 #1	10	250.82	159.50	0.69	228.50	1.00	20.50
lateral 10lb Fig8 #2	10	209.19	168.30	0.94	228.20	1.00	39.10
lateral 10lb Fig8 #3	10	443.35	204.20	0.59	285.10	1.00	67.00
lateral 10lb Robicesk #1	10	280.37	325.40	0.92	422.10	1.00	38.60
lateral 10lb Robicesk #2	10	231.95	310.90	1.08	380.90	1.00	83.80
lateral 10lb Robicesk #3	10	251.43	302.30	1.00	391.90	1.00	55.60
lateral 10lb single #1	10	959.52	173.00	0.27	279.90	1.00	55.00
lateral 10lb single #2	10	642.59	195.30	0.39	284.20	1.00	50.20
lateral 10lb single #3	10	1101.86	196.40	0.28	291.90	1.00	66.90
lateral 10lb Sternalock blu #1	10	553.12	403.50	0.79	599.50	2.00	56.30
lateral 10lb Sternalock blu #2	10	664.40	379.90	0.68	561.80	2.00	49.70
lateral 10lb Sternalock blu #3	10	638.62	411.40	0.76	596.30	2.00	37.80
lateral 10lb Sternalock silv #1	10	489.11	514.10	1.22	664.50	2.00	5.30
lateral 10lb Sternalock silv #2	10	749.02	548.80	0.77	768.20	2.00	90.50
lateral 10lb Sternalock silv #3	10	685.43	550.00	0.83	774.40	2.00	74.90
lateral 10lb Sternalock silv #4	10	366.60	531.30	1.44	629.40	2.00	16.20
lateral 10lb Sternalock wide #1	10	520.72	466.10	1.00	657.00	2.00	57.90
lateral 10lb Sternalock wide #2	10	704.06	475.10	0.73	736.60	2.00	74.10
lateral 10lb Sternalock wide #3	10	521.31	444.70	0.83	655.10	2.00	24.70
lateral 20lb double #1	20	1190.67	763.40	0.61	1213.80	1.00	108.60
lateral 20lb double #2	20	1479.72	788.90	0.52	1293.20	1.00	142.60
lateral 20lb double #3	20	1383.45	771.10	0.53	1247.30	1.00	77.90
lateral 20lb Fig8 #1	20	340.51	730.40	1.72	799.00	1.00	110.30
lateral 20lb Fig8 #2	20	380.99	657.30	1.37	812.50	1.00	90.50
lateral 20lb Fig8 #3	20	385.73	666.00	1.38	829.20	1.00	55.60
lateral 20lb Robicesk #1	20	527.84	628.60	0.93	881.90	1.00	92.00
lateral 20lb Robicesk #2	20	338.30	630.80	1.33	763.30	1.00	71.60
lateral 20lb Robicesk #3	20	424.20	604.00	1.08	783.60	1.00	108.60
lateral 20lb single #1	20	270.81	548.40	1.52	643.50	1.00	77.10
lateral 20lb single #2	20	672.16	539.90	0.75	861.90	1.00	60.00
lateral 20lb single #3	20	456.24	551.00	0.99	795.40	1.00	51.80
lateral 20lb Sternalock blu #1	20	998.56	1223.80	1.32	1516.80	3.00	56.00
lateral 20lb Sternalock blu #2	20	976.69	1220.10	1.42	1480.00	3.00	2.10
lateral 20lb Sternalock blu #3	20	1068.16	1235.50	1.25	1581.70	3.00	56.00
lateral 20lb Sternalock silv #1	20	1123.05	1189.30	1.22	1580.50	3.00	10.60
lateral 20lb Sternalock silv #2	20	1106.24	1069.70	1.04	1463.80	4.00	79.40
lateral 20lb Sternalock silv #3	20	901.74	958.10	1.14	1331.30	3.00	15.90
lateral 20lb Sternalock wide #1	20	935.52	1314.10	1.60	1542.20	3.00	7.20
lateral 20lb Sternalock wide #2	20	1045.24	1530.30	1.58	1762.20	3.00	73.00
lateral 20lb Sternalock wide #3	20	881.92	1331.30	1.64	1515.20	3.00	16.30

4.1.1 Lateral Stiffness

Table 4-2: The mean stiffness (ranked highest to lowest) of each testing group defined by closure type and foam density.

Tests that do not share a grouping letter are significantly different.

Lateral Closure Stiffness									
Density	Closure Type	Mean	St Dev	Grouping					
20	Double	1351.3	147.2	A					
20	SL Silver	1043.7	123.2	A	B				
20	SL Blu	1014.5	47.8		B				
20	SL Wide	954.2	83.3		B				
10	Single	901.3	235		B	C			
10	Double	740.9	174		B	C	D		
10	SL Blu	618.7	58.2			C	D	E	
10	SL Wide	582	105.7				D	E	F
10	SL Silver	572.5	176.3				D	E	F
20	Single	466.4	201				D	E	F
20	Robicsek	430.1	94.9					E	F
20	Figure 8	369.1	24.9					E	F
10	Figure 8	301.1	124.9						F
10	Robicsek	254.6	24.4						G

Figure 4-1: Bar graph displays the mean stiffness of each high-density closure in lateral distraction. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Stiffness is measured in newtons per millimeter displacement. Error bars show +/- one standard deviation.

As seen above the high-density testing showed double wire closures to have the greatest rigidity with the average stiffness 308 N/mm higher than the next closest closure. The Sternalock plates grouped together very closely with a stiffness of about 1000 N/mm, and were significantly more rigid than the rest of the wired closures. The figure-eight, Robicsek weave, and single wire closures all grouped together with the lowest stiffness values generally around 420 N/mm. The high density foam tests show that the double wire can be three times stiffer than other wire closures while the Sternalock closures have over twice the stiffness of single wire closures in high density foam.

Figure 4-2: Bar graph displays the mean stiffness of each low-density closure in lateral distraction. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Stiffness is measured in newtons per millimeter displacement. Error bars show $\pm$ one standard deviation.

When looking at the low-density tests single wire closures have the highest average stiffness of about 900 N/mm but a large standard deviation, and are statistically similar with double wire closures and Sternalock Blu plates. The averages for the other Sternalock closures are so close they are not significantly different from the double or Sternalock Blu closures. Similarity with high-density testing comes from the close grouping of the plated closures and with the figure-eight and Robicsek weave once again the least rigid closures with approximately half the stiffness values of the other closures.

Figure 4-3: Interaction plot showing the effects of density on closure type in regards to stiffness in the lateral direction.

The effects of foam density are seen to greatly influence stiffness for each closure type. There is also a significant interaction between density and closure type where one type of closure reacts more or less to density changes or completely differently than the other closure types. This interaction is displayed clearly by single wire closures actually averaging higher rigidity in lower density foam. A less noticeable example is how double wire closure stiffness increases much more than other closures during high-density testing.

4.1.2 Lateral Yield Force

Table 4-3: The mean yield force (ranked highest to lowest) of each testing group defined by closure type and foam density.

Tests that do not share a grouping letter are significantly different.

Lateral Yield Force													
Density	Closure Type	Mean	St Dev	Grouping									
20	SL Wide	1391.9	120.2	A	B								
20	SL Blu	1226.5	8.04		B	C							
20	SL Silver	1072.4	115.6			C	D						
20	Double	774.5	13.08					E					
20	Figure 8	684.6	39.9					E	F				
20	Robicsek	621.1	14.88					E	F	G			
20	Single	546.4	5.81						F	G	H		
10	SL Silver	536.1	16.95						F	G	H		
10	SL Wide	462	15.62							G	H	I	
10	SL Blu	398.3	16.39								H	I	J
10	Robicsek	312.9	11.67									I	J
10	Double	245.9	9.67										J
10	Single	188.2	13.2										J
10	Figure 8	177.3	23.7										K

Figure 4-4: Bar graph displays the mean yield force for each high-density closure test in lateral distraction. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Yield force is measured in newtons. Error bars show +/- one standard deviation.

The Sternalock Wide Ladder closures had the highest yield force of 1392 N in lateral distraction, which is shown to be significantly greater than Sternalock Silver. The Sternalock Blu test average is statistically similar to both the other two Sternalock plate closures, which all have significantly higher yield strength than any of the wired closures. The greatest disparity between wired closures comes between double wire and single wire closures, showing that double wire closure yield strength is significantly stronger than single wire sutures.

Figure 4-5: Bar graph displays the mean yield force for each low-density closure test in lateral distraction. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Yield force is measured in newtons. Error bars show +/- one standard deviation.

In low-density testing Sternalock Silver displayed the greatest yield strength of 536 N. The yield force of the other two Sternalock closures were close enough to the Sternalock Silver to be statistically similar. The difference between yield forces was closer in low-density testing showing that Sternalock Blu, the weakest plate closure, was only significantly stronger than the figure-eight sutures. The Robicsek weave had the highest yield force for wired closures, but the difference was not statistically significant.

Figure 4-6: Interaction plot showing the effects of density on closure type in regards to yield force in the lateral direction.

The effects of foam density are seen to greatly influence yield force for each closure type. There is also a significant interaction between density and closure type. The plot above shows the Sternalock closures have a larger increase in yield force during high-density testing than wired closures. It also shows within close groups that higher density foam increases yield force different amounts for each closure type.

4.1.3 Lateral Yield Displacement

Table 4-4: The mean displacement at yield (ranked highest to lowest) of each testing group defined by closure type and foam density. Tests that do not share a grouping letter are significantly different.

Lateral Displacement at Yield									
Density	Closure Type	Mean	St Dev	Grouping					
20	SL Wide	1.61	0.03	D	E	F	G	H	I
20	Figure 8	1.49	0.20	D	E	F	G	H	I
20	SL Blu	1.33	0.09	D	E	F	G	H	I
20	SL Silver	1.13	0.09		E	F	G	H	I
20	Robicsek	1.11	0.20		E	F	G	H	I
20	Single	1.09	0.39		E	F	G	H	I
10	SL Silver	1.07	0.32			F	G	H	I
10	Robicsek	1.00	0.08			F	G	H	I
10	SL Wide	0.85	0.14			F	G	H	I
10	SL Blu	0.74	0.06				G	H	I
10	Figure 8	0.74	0.18				G	H	I
20	Double	0.55	0.05					H	I
10	Double	0.41	0.06					H	I
10	Single	0.31	0.07						I

Figure 4-7: Bar graph displays the mean post yield displacement for each high-density closure test in lateral distraction. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Yield displacement is measured in millimeters. Error bars show $\pm$ one standard deviation.

Figure 4-8: Bar graph displays the mean displacement at yield for each high-density closure test in lateral distraction. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Yield displacement is measured in millimeters. Error bars show +/- one standard deviation.

Post yield displacement measures the amount of plastic deformation that remains if the sample is stretched to the failure point of 2mm. The yield displacement measured the amount of midline separation before yield occurred; a large yield displacement indicates an ability to bear a load without becoming permanently damaged. Sternalock Wide Ladder and figure-eight sutures allowed for the largest amount of displacement before yielding, but none of the differences were statistically significant. The double wire sutures permitted the least amount of displacement, which would translate into the largest post-yield displacement.

Figure 4-9: Bar graph displays the mean post yield displacement for each low-density closure test in lateral distraction. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Yield displacement is measured in millimeters. Error bars show +/- one standard deviation.

Figure 4-10: Bar graph displays the mean displacement at yield for each low-density closure test in lateral distraction. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Yield displacement is measured in millimeters. Error bars show +/- one standard deviation.

The low-density lateral testing showed double and single wire sutures having the lowest yield displacement, but none of these differences were statistically significant.

Figure 4-11: Interaction plot showing the effects of density on closure type in regards to yield displacement in the lateral direction.

The effects of foam density are seen to greatly influence yield displacement for each closure type. There is also a significant interaction between density and closure type. There is a general trend of increased yield displacement for higher density but it is clear that foam density affects Sternalock Silver, double wire, and Robicsek weave closures less than it does the others.

4.1.4 Lateral Failure Force

Table 4-5: The mean failure force (ranked highest to lowest) of each testing group defined by closure type and foam density. Tests that do not share a grouping letter are significantly different.

Lateral Failure Force									
Density	Closure Type	Mean	St Dev	Grouping					
20	SL Wide	1606.5	135.5	A					
20	SL Blu	1526.2	51.5	A					
20	SL Silver	1458.5	124.7	A					
20	Double	1251.4	39.9	B					
20	Figure 8	813.6	15.13	C	D				
20	Robicsek	809.6	63.4	C	D				
20	Single	766.9	111.9	C	D	E			
10	SL Silver	709.1	73.3		D	E			
10	SL Wide	682.9	46.5		D	E			
10	SL Blu	585.9	20.9			E	F		
10	Robicsek	398.3	21.3				F	G	
10	Double	377.6	3.34					G	
10	Single	285.3	6.08					G	
10	Figure 8	247.3	32.8					G

Figure 4-12: Bar graph displays the mean failure force for each high-density closure test in lateral distraction. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Failure force is measured in newtons when the closure fails or exceeds 2mm of displacement. Error bars show +/- one standard deviation.

The failure force for the closures was taken at 2mm displacement. The three Sternalock closures took the most amount of force to cause failure, about 200-350 N more than double wire closures. As seen above the plates performed significantly better than the wired closures, and double wire sutures performed better than the other wired closures.

Figure 4-13: Bar graph displays the mean failure force for each low-density closure test in lateral distraction. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Failure force is measured in newtons when the closure fails or exceeds 2mm of displacement. Error bars show +/- one standard deviation.

The low-density tests followed the results of the high-density tests in that the Sternalock plates performed significantly better than the wired closures. The Robicsek weave did have the highest wired failure force, although not significantly different from other wired tests, it was high enough to be seen as statistically similar to Sternalock Blu closures.

Figure 4-14: Interaction plot showing the effects of density on closure type in regards to failure force in the lateral direction.

The effects of foam density are seen to greatly influence failure force for each closure type.

There is also a significant interaction between density and closure type. The plot above shows double wire closures have a much larger increase of failure force in high-density foam than the other wire closures.

4.1.5 Lateral Separation Energy

4-6: The mean separation energy (ranked highest to lowest) of each testing group defined by closure type and foam density. Tests that do not share a grouping letter are significantly different.

Closure Type	Density	Mean	Grouping			
SL Blu	20	1846.3	A			
SL Wide	20	1823.3	A			
SL Silver	20	1808.1	A			
Double	20	1798.1	A			
Robicsek	20	1128.3	B			
Figure 8	20	1064.9	B			
Single	20	1031.4	B			
SL Silver	10	942	B			
SL Wide	10	918.2	B	C		
SL Blu	10	827.2	B	C	D	
Double	10	614.3		C	D	E
Robicsek	10	569.3			D	E
Single	10	490.1				E
Figure 8	10	350.2				E

4-15: Bar graph displays the mean separation energy for each high-density closure test in lateral distraction. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Separation energy is measured energy to create 2mm of displacement. Error bars show +/- one standard deviation.

The separation energy is the amount of work needed to create a displacement of 2mm. A higher separation energy would be better indicator of a closures stability. The high density foam tests showed the Sternalock plates and double wire sutures as significantly better than the other wired closures. Same trend shown in low density foam tests, but although double wire closure is still in a grouping with the plates it dropped enough to be considered similar to the other wired closures.

4.2 Rostro-caudal Shear

Each closure method had 6 samples tested in longitudinal shear, 3 low-density 10lb foam tests and 3 high-density 20lb foam tests. In the table below failure modes are indicated by numbers: 1 for wires cutting through foam, 2 for screws cutting through foam, 3 for foam fractures, and 4 for plate bending.

Table 4-7: List of all the longitudinal testing with resultant values of key biomechanical properties.

Test Name	Density lb/ft ³	Stiffness N/mm	Yield Force N	Yield Disp mm	Ult Force @ 2mm	Failure Mode
RC 10lb double #1	10	20.36	63.70	2.23	60.00	1.00
RC 10lb double #2	10	14.69	68.70	3.95	43.90	1.00
RC 10lb double #3	10	21.98	55.90	2.09	55.20	1.00
RC 10lb Fig8 #1	10	30.78	61.40	1.43	71.30	1.00
RC 10lb Fig8 #2	10	52.13	51.30	0.71	71.30	1.00
RC 10lb Fig8 #3	10	45.40	62.90	1.21	79.10	1.00
RC 10lb Robicsek #1	10	10.71	64.30	3.99	40.00	1.00
RC 10lb Robicsek #2	10	18.85	55.90	2.08	54.20	1.00
RC 10lb Robicsek #3	10	21.27	52.50	1.50	58.40	1.00
RC 10lb Sernalock Blu #1	10	168.67	408.30	2.36	373.60	2.00
RC 10lb Sernalock Blu #2	10	151.21	411.90	3.06	312.10	2.00
RC 10lb Sernalock Blu #3	10	212.96	339.10	1.61	386.60	2.00
RC 10lb Sernalock Silver #1	10	162.72	486.60	3.27	369.30	2.00
RC 10lb Sernalock Silver #2	10	266.73	322.80	1.25	427.90	2.00
RC 10lb Sernalock Silver #3	10	288.40	291.60	1.03	411.40	2.00
RC 10lb single #1	10	8.26	46.80	3.98	29.10	1.00
RC 10lb single #2	10	14.79	64.30	3.91	39.60	1.00
RC 10lb single #3	10	10.69	53.80	3.98	33.00	1.00
RC 10lb Sternalock wide #1	10	204.71	503.50	2.75	385.90	2.00
RC 10lb Sternalock wide #2	10	194.26	657.50	3.59	416.30	2.00
RC 10lb Sternalock wide #3	10	193.59	674.40	3.51	464.70	2.00
RC 20lb Double #1	20	30.97	23.60	0.00	98.40	1.00
RC 20lb Double #2	20	32.26	12.50	0.00	152.10	1.00
RC 20lb Double #3	20	23.01	20.30	0.00	117.10	1.00
RC 20lb Fig8 #1	20	40.46	115.40	1.80	120.70	1.00
RC 20lb Fig8 #2	20	47.00	134.70	1.62	146.80	1.00
RC 20lb Fig8 #3	20	46.44	138.10	1.99	138.10	1.00
RC 20lb Robicsek #1	20	28.82	7.20	0.00	108.40	1.00
RC 20lb Robicsek #2	20	21.16	13.30	0.00	70.10	1.00
RC 20lb Robicsek #3	20	31.38	19.70	0.00	135.50	1.00
RC 20lb Single #1	20	11.11	17.40	0.00	47.70	1.00
RC 20lb Single #2	20	25.21	27.30	0.00	82.90	1.00
RC 20lb Single #3	20	28.03	8.90	0.00	136.20	1.00
RC 20lb Sternalock Blu #1	20	506.15	953.00	2.03	941.70	4.00
RC 20lb Sternalock Blu #2	20	503.52	888.20	2.07	868.90	3.00
RC 20lb Sternalock Blu #3	20	458.98	1135.00	2.56	948.20	3.00
RC 20lb Sternalock Silver #1	20	518.40	1176.00	2.57	959.10	3.00
RC 20lb Sternalock Silver #2	20	465.40	885.60	2.20	822.40	3.00
RC 20lb Sternalock Silver #3	20	445.76	1324.50	3.14	942.00	3.00
RC 20lb Sternalock wide #1	20	454.32	1487.00	3.85	772.00	4.00
RC 20lb Sternalock wide #2	20	429.64	1594.50	4.24	759.20	4.00
RC 20lb Sternalock wide #3	20	486.86	1460.00	3.21	985.10	4.00

4.2.1 Longitudinal Closure Stiffness

Table 4-8: The mean stiffness (ranked highest to lowest) of each testing group defined by closure type and foam density.

Tests that do not share a grouping letter are significantly different.

Longitudinal Closure Stiffness						
Density	Closure Type	Mean	St Dev	Grouping		
20	SL Blu	489.5	26.5	G		
20	SL Silver	476.5	37.6	G	H	
20	SL Wide	456.9	28.7	G	H	
10	SL Silver	239.3	67.2	G	H	I
10	SL Wide	197.5	6.24	G	H	I
10	SL Blu	177.6	31.8		H	I
20	Figure 8	44.6	3.63			I
10	Figure 8	42.8	10.92			I
20	Double	28.7	5.01			I
20	Robicsek	27.1	5.32			I
20	Single	21.4	9.06			I
10	Double	19	3.83			I
10	Robicsek	16.9	5.53			I
10	Single	11.2	3.3			I

Figure 4-16: Bar graph displays the mean stiffness of each high-density closure in longitudinal shear. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Stiffness is measured in newtons per millimeter displacement. Error bars show +/- one standard deviation.

The Sternalock plates all performed significantly better than the wired closures. In comparison wired closures had almost no resistance to longitudinal shear.

Figure 4-17: Bar graph displays the mean stiffness of each low-density closure in longitudinal shear. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Stiffness is measured in newtons per millimeter displacement. Error bars show +/- one standard deviation.

The Sternalock plates all performed much better than the wired closures in low-density tests as well. The low-density tests showed no statistically significant differences because the stiffness values are only small fraction of the other testing.

Figure 4-18: Interaction plot showing the effects of density on closure type in regards to stiffness in the longitudinal direction.

The effects of foam density are seen to greatly influence stiffness for each closure type. There is also a significant interaction between density and closure type. It could not be any clearer that while the plate closures are aided by increased foam density, the wire closures are almost not affected at all.

4.2.2 Longitudinal Yield Force

Table 4-9: The mean yield force (ranked highest to lowest) of each testing group defined by closure type and foam density.

Tests that do not share a grouping letter are significantly different.

Longitudinal Yield Force							
Density	Closure Type	Mean	St Dev	Grouping			
20	SL Wide	1513.8	71.2	A			
20	SL Silver	1128.7	223	D			
20	SL Blu	992.1	128	D			
10	SL Wide	611.8	94.2		E		
10	SL Blu	386.4	41			H	
10	SL Silver	367	104.7			H	
20	Figure 8	129.4	12.24				N
10	Double	62.8	6.45				N
10	Figure 8	58.5	6.31				N
10	Robicsek	57.6	6.07				N
10	Single	55	8.81				N
20	Double	18.8	5.7				N
20	Single	17.9	9.21				N
20	Robicsek	13.4	6.25				N

Figure 4-19: Bar graph displays the mean stiffness of each high-density closure in longitudinal shear. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Stiffness is measured in newtons per millimeter displacement. Error bars show +/- one standard deviation.

Sternalock Wide Ladder performed significantly better than any other tests with a yield force averaging 1513 N. The Sternalock Blu and Sternalock Silver grouped together with the next highest yield force. The only wired closure to put up any resistance to yield was the figure-eight sutures, but they were not significantly different from the other wire closures.

Figure 4-20: Bar graph displays the mean stiffness of each low-density closure in longitudinal shear. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Stiffness is measured in newtons per millimeter displacement. Error bars show +/- one standard deviation.

Again with the low-density tests Sternalock Wide Ladder performed significantly better than any other tests with a yield force averaging 612 N. The Sternalock Blu and Sternalock Silver grouped together with the next highest yield force. The wired closures showed almost no resistance to longitudinal shear forces.

Figure 4-21: Interaction plot showing the effects of density on closure type in regards to yield force in the longitudinal direction.

The effects of foam density are seen to greatly influence yield force for each closure type. There is also a significant interaction between density and closure type. It could not be any clearer that while the plate closures are aided by increased foam density, the wire closures are almost not affected at all.

4.2.3 Longitudinal Yield Displacement

Table 4-10: The mean displacement at yield (ranked highest to lowest) of each testing group defined by closure type and foam density. Tests that do not share a grouping letter are significantly different.

Longitudinal Displacement at Yield							
Density	Closure Type	Mean	St Dev	Grouping			
10	Single	3.96	0.04	A			
20	SL Wide	3.77	0.52	A	B		
10	SL Wide	3.28	0.46	A	B	C	
10	Double	2.76	1.04	A	B	C	
20	SL Silver	2.64	0.47	A	B	C	
10	Robicsek	2.52	1.30	A	B	C	E
10	SL Blu	2.34	0.73		B	C	E
20	SL Blu	2.22	0.30			C	E
10	SL Silver	1.85	1.24			C	E
20	Figure 8	1.80	0.19			C	E
10	Figure 8	1.12	0.37				E J
20	Single	0.00	0.00				J
20	Robicsek	0.00	0.00				J
20	Double	0.00	0.00				J

Figure 4-22: Bar graph displays the mean post yield displacement for each high-density closure test in longitudinal shear.

Means not sharing the same grouping letter are significantly different ($p < 0.05$). Yield displacement is measured in millimeters. Error bars show $\pm$ one standard deviation.

Figure 4-23: Bar graph displays the mean displacement at yield for each high-density closure test in longitudinal shear. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Yield displacement is measured in millimeters. Error bars show +/- one standard deviation.

Here the Sternalock Wide Ladder once again performed best with the highest yield displacement with the other two Sternalock plates close behind with figure-eight sutures. The other wired closures began to yield almost immediately as the tests began. Post yield displacement measures the amount of plastic deformation that remains if the sample is stretched to the failure point of 2mm. All the plated closure showed no post yield displacement.

Figure 4-24: Bar graph displays the mean post yield displacement for each high-density closure test in longitudinal shear. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Yield displacement is measured in millimeters. Error bars show $\pm$ one standard deviation.

Figure 4-25: Bar graph displays the mean displacement at yield for each low-density closure test in longitudinal shear. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Yield displacement is measured in millimeters. Error bars show $\pm$ one standard deviation.

This testing shows single sutures as having the highest yield displacement. But it should be noted that these wired tests had irregular loading curves which made calculation of the yield displacement very inaccurate. The Sternalock Silver is the only plate closure to show any post yield displacement.

Figure 4-26: Interaction plot showing the effects of density on closure type in regards to yield displacement for testing in the longitudinal direction.

The effects of foam density are seen to greatly influence yield displacement for each closure type. There is also a significant interaction between density and closure type. This can be seen by different reactions by each closure type by a change in foam density.

4.2.4 Longitudinal Failure Force

Table 4-11: The mean longitudinal failure force (ranked highest to lowest) of each testing group defined by closure type and foam density. Tests that do not share a grouping letter are significantly different.

Longitudinal Failure Force					
Density	Closure Type	Mean	St Dev	Grouping	
20	SL Blu	919.6	44	C	
20	SL Silver	907.8	74.5	C	
20	SL Wide	838.8	126.9	C	
10	SL Wide	422.3	39.7		G
10	SL Silver	402.9	30.2		G
10	SL Blu	357.4	39.8		G
20	Figure 8	135.2	13.29		J
20	Double	122.5	27.3		J
20	Robicsek	104.7	32.9		J
20	Single	88.9	44.6		J
10	Figure 8	73.9	4.5		J
10	Double	53	8.27		J
10	Robicsek	50.9	9.64		J
10	Single	33.9	5.31		J

Figure 4-27: Bar graph displays the mean failure force for each high-density closure test in longitudinal shear. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Failure force is measured in newtons when the closure fails or exceeds 2mm of displacement. Error bars show +/- one standard deviation.

Sternalock closures performed significantly better than any other tests with an average failure force of about 900 N. The wired closures showed almost no resistance to longitudinal shear forces.

Figure 4-28: Bar graph displays the mean failure force for each low-density closure test in longitudinal shear. Means not sharing the same grouping letter are significantly different ($p < 0.05$). Failure force is measured in newtons when the closure fails or exceeds 2mm of displacement. Error bars show +/- one standard deviation.

Low-density testing paralleled results of the high-density tests. Sternalock closures performed significantly better than any other tests with an average failure force of about 400 N. The wired closures showed almost no resistance to longitudinal shear forces.

Figure 4-29: Interaction plot showing the effects of density on closure type in regards to failure force for testing in the longitudinal direction.

The effects of foam density are seen to greatly influence failure force for each closure type.

There is also a significant interaction between density and closure type. It can be seen that while the plate closures are greatly aided by increased foam density, the wire closures only have a slight increase in failure force.

4.3 Cadaveric versus Foam Model Testing

The cadaveric results were taken from previous testing on the same equipment; the most notable difference in the set up is that the cadavers were secured in vices by their ribs. There were 4-5 cadaveric tests performed for each closure in both lateral distraction and longitudinal shear.

4.3.1 Stiffness Comparison of Foam versus Cadaver testing

Table 4-12: The average stiffness values of closures for cadaver and foam testing, grouped by closure type and load direction.

Cadaver vs Foam: Stiffness							
Direction	Closure Type	Stiffness, N/mm			StDev		
		Cadaver	20lb	10lb Foam	Cadave	20lb	10lb Foam
Lateral	Single	631.0	466.4	901.3	201.0	364.0	147.2
	SL Silver	3165.0	1043.7	572.5	1034.0	123.2	176.3
Longitudinal	Single	66.5	21.4	11.3	27.2	9.1	3.3
	SL Silver	722.0	476.5	239.3	323.0	37.6	67.2

Figure 4-30: Side by side comparison of stiffness for foam and cadaveric testing. The columns represent the mean values of high and low density foam, or both male and female cadavers.

The graph above shows that foam testing and cadaveric testing follow the same general trend of lower stiffness for longitudinal closure stiffness. The testing also showed a significantly higher stiffness for Sternalock Silver closures on cadavers, 2421 N/mm more than foam testing. The results indicate significant interactions between the testing model and closure type.

Figure 4-31: Interaction plot showing the effects of using foam blocks instead of cadavers on closure types and direction in regards to stiffness.

4.3.2 Yield Force Comparison of Foam versus Cadaver testing

Table 4-13: The average yield force of closures for cadaver and foam testing, grouped by closure type and load direction.

Cadaver vs Foam: Yield Force							
Direction	Closure Type	Yield Force, N			StDev		
		Cadaver	20lb Foam	10lb Foam	Cadaver	20lb Foam	10lb Foam
Lateral	Single	352.9	546.4	188.2	118.2	5.8	13.2
	SL Silver	595.0	1072.4	536.1	291.0	115.6	16.95
Longitudinal	Single	129.2	17.9	55	44.1	19.2	8.8
	SL Silver	124.9	1128.7	367	65.2	223.0	104.7

Figure 4-32: Side by side comparison of yield force for foam and cadaveric testing. The columns represent the mean values of high and low density foam, or both male and female cadavers.

The lateral testing resulted in comparable yield force results, with insignificant differences in the means. But during longitudinal shear it can be seen foam tests perform significantly better than cadaveric tests. This interaction between closure type and test model is displayed clearly below.

Figure 4-33: plot showing the effects of using foam blocks instead of cadavers on closure types and direction in regards to yield force.

4.3.3 Yield Displacement Comparison of Foam versus Cadaver testing

Table 4-14: The average yield displacement for cadaver and foam testing, grouped by closure type and load direction.

Cadaver vs Foam: Yield displacement							
Direction	Closure Type	Yield Disp, mm			StDev		
		Cadaver	20lb Foam	10lb Foam	Cadaver	20lb Foam	10lb Foam
Lateral	Single	0.47	1.09	0.31	0.18	0.39	0.07
	SL Silver	0.14	1.13	1.07	0.12	0.09	0.32
Longitudinal	Single	1.82	0.00	3.96	1.30	0.00	0.04
	SL Silver	0.60	2.64	1.85	0.63	0.47	1.24

Figure 4-34: Side by side comparison of yield displacement for foam and cadaveric testing. The columns represent the mean values of high and low density foam, or both male and female cadavers.

The differences in yield displacement show the double wire closure reacting similarly with both test models during lateral distraction. The longitudinal tests have such a large deviation it would be hard to make relevant comparisons. There is a significant interaction between closure type and test model for yield displacement as well.

Figure 4-35: plot showing the effects of using foam blocks instead of cadavers on closure types and direction in regards to displacement at yield.

4.4 Summary Charts

To give an overview of how each closure compares with every other test group in this study; these charts give visual comparison of performance characteristics in each direction.

Figure 4-36: Comparison of closure stiffness for every closure separated by density and direction. The columns represent mean values of each test group. Error bars show +/- one standard deviation.

Figure 4-37: Comparison of yield force for every closure separated by density and direction. The columns represent mean values of each test group. Error bars show +/- one standard deviation.

Figure 4-38: Comparison of yield displacement for every closure separated by density and direction. The columns represent mean values of each test group. Error bars show +/- one standard deviation.

Figure 4-39: Comparison of failure force for every closure separated by density and direction. The columns represent mean values of each test group. Error bars show +/- one standard deviation.

5 Discussion

The goals of this project are to compare the quality of sternal closures created by different closure methods, and to establish a new bench mark to replace cadaveric testing. It is expected that Sternalock plates will outperform the wired closure methods. The results of the foam testing should also show the same trends as cadaveric testing.

5.1 Lateral Distraction Testing

5-1: The two images above are high-density Sternalock Wide Ladder (top) and double wire closures at maximum displacement during lateral distraction. Midline separation can clearly be seen since tests were allowed to run past 2mm failure mark, and the mode of failure can clearly be seen. The Sternalock plates failed by foam fracture and the double wires cut through the foam model.

When comparing results of the lateral distraction testing it can be seen that the Sternalock plates performed better overall than wired closures. This broad generalization needs to be examined more closely to see the differences in high and low density testing to give a clear view of the data. The high-density testing showed double wire sutures as significantly ($p<0.05$) more rigid than most other sutures, and the Sternalock plates closely grouped together and significantly more rigid than the remaining wire closures. The low density testing was very much similar, except single wire sutures displayed the highest stiffness. This could be explained by looking at the standard deviation of the stiffness and small yield displacement for single sutures. Although the yield displacement results did not indicate any significant differences it can be seen that in low density tests single and double wire sutures began to yield with the least amount of displacement. This could account for the unexpected low density jump in stiffness for single sutures by just giving fewer data points along the elastic slope to calculate the true stiffness. The yield displacement for high and low density tests indicated double wire sutures to have lower values; this trend shows that the rigid configuration of the wires less adept at transferring force to the foam when the construct is strained.

The Sternalock plates had significantly higher values than the wired closures. Sternalock Wide Ladder had the largest yield force, high enough to be significantly different than Sternalock Silver, and Sternalock Blu was in a close second. The low density tests had the plates performing better than the wires, but the differences were much less. Low density for Sternalock Silver had the highest yield force and was significantly different than the wired closures. Even though the

results of the plates were still close some of the wired closures, like the Robicsek weave, has yield forces that were close enough to be considered similar. This is explained by looking at the failure modes, all low density tests failed due to foam cutting. This indicates that screws can distribute more force than wires before beginning to destroy weak bone. The high density failures confirm this showing that wires still cut through foam and have lower yield forces, while most of the plates were able to distribute the force well enough that the foam model fractured instead of getting cut by the screws. This foam interaction can also be seen when comparing failure forces. The failure forces for high density foam show Sternalock plates having significantly stronger closures, and double wire being significantly stronger than the other wired closures. The pattern continues with the low density tests, Sternalock tests stronger than wired closures. The low density tests have double wire closures dropping down to group with the rest of the wired tests, and the Robicsek weave increasing enough to be similar to one of the plates. The increase for Robicsek weave in low density testing shows that the weave is able to distribute more force over a larger area, but the difference is not significant enough to be relevant.

5.2 Rostro-caudal Shear Testing

5-2: The two images above are high-density Sternalock Blu (right) and single wire closures at maximum displacement during longitudinal shear. Midline displacement as the blocks slide past each other can clearly be seen since tests were allowed to run past 2mm failure mark. The Sternalock plates failed single wires cut through the foam model.

Resistance to longitudinal shear is important to wound healing because movements of the patient are transferred through the skeleton and sternum. The test setup used a u-bolt and was able to apply the shear directly to the midline. The results showed that wires are not set up to resist load in this direction, the wires allowed the plates to slide past each other even before wire cutting

began. The friction created by the compressive force of the wires seems to be the only resistance to longitudinal movement and is easily overcome. The figure-eight suture was the only setup to offer any resistance but it was not significantly different from the other wire closures. The yield displacement data for low-density wire tests is misleading because even though they all yield almost at once the force-displacement graphs did not follow normal paths making calculation of displacement at yield uncertain.

The Sternalock plates performed significantly better than wires and were able to resist the longitudinal shear force because they are fixed to the sternum by screws. The stiffness results showed all the plates to be statistically similar with the low density tests predictably lower. The yield force data showed Sternalock Wide Ladder to be significantly more resistant to yielding than the other two Sternalock plates. This extra resistance to yield is most likely created by the extra screws used to mount each plate, allowing same force over more area. The high density yield displacement ranked Sternalock Wide Ladder as highest and the difference statistically significant from Sternalock Blu, while Sternalock Silver was similar to both other plates. The low density tests showed Sternalock Wide Ladder with largest displacement at yield compared to the other plates, though this difference was not statistically significant. The failure force of the Sternalock plates showed all three performing the same. The only significant differences in the yield force and displacement at yield point to the ladder structure and extra screws being more capable of distributing loads than x-plates. A noted difference in high-density failure modes is that the Sternalock Wide Ladder failed from plate bending while the other two Sternalock plates failed from foam fractures. This shows that the extra screws can help disperse the load into the sternum, but are not as strong as the x-plates.

5.3 Cadavers versus Foam Blocks

It was hoped that foam blocks could be used as an accurate representation of the human sternum, therefore replacing the need for using cadavers. The cadaver testing data was taken from a previous study done by Wong and Griffin who tested at 25mm/min in contrast to our 3mm/min. When comparing the single wire closures to Sternalock Silver tests analysis showed significant interactions between the test model and closure type. This indicates that the closures each respond differently to the change in testing material, or at the rate the tests were performed. Only two closure types were compared, and other types of closures may respond similarly to cadavers or foam blocks. Significant interactions could also be caused by the loading method. The cadaveric tests used clamps to transfer the force through the ribs to the sternum, this study used u-bolts to transfer the force directly to the midline. This would cause the pulling to come from the inside and minimize the strain put on the test model were not in direct contact with the sternal closing structure. Use of the foam blocks was able to remove the variability caused by using human sterna and gave reproducible results.

5.4 3D Correlation

This study used Vic-3D (Correlated Solutions Inc, Columbia, SC) to capture and analyze visual data during each test. This was thought to be a good way to see the stress concentrations and accurately measure the midline displacement not just the overall displacement of the sample. It was seen that the u-bolt used to mount each sample to the testing fixture did not allow for strain across the sample so the resultant displacement across the midline was 1:1 with the total displacement measured by the load frame. The load frame displacement and load data were used just like most previous studies of sterna closures. The 3D correlation was not very useful, but

was able to record each test live by collecting pictures and allowed for closure examination of failure modes.

6 Conclusions

- Overall Sternalock plates are less likely to fail in all directions compared to wired closures. Even though double wire closures displayed a higher average lateral stiffness, the high stress concentrations created by wires allowed for easy foam cutting and much lower yield force and failure force. The plates being screwed into place resist force from any direction, whereas the wires can only resist lateral distraction.
- Testing using foam blocks as sternal analogues produces highly reproducible results, with less variance than cadaveric tests. It shows how closures interact with foam as separation force applied to the closure.
- Evidence shows that using foam blocks in this testing form does not accurately represent cadaveric testing. There should be more comparisons of different closure methods to confirm this finding.

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A. Appendix

General Linear Model: K, N/mm versus Direction, Closure Type, Density

Factor	Type	Levels	Values
Direction	fixed	2	Lateral, Longitudinal
Closure Type	fixed	7	Double, Figure 8, Robicsek, Single, SL Blu, SL Silver, SL Wide
Density	fixed	2	10, 20

Analysis of Variance for K, N/mm, using Adjusted SS for Tests

Source	DF	Seq SS	Adj SS	Adj MS	F	P
Direction	1	5799368	5842007	5842007	621.66	0.000
Closure Type	6	2280712	2356479	392747	41.79	0.000
Density	1	706461	674940	674940	71.82	0.000
Direction*Closure Type	6	1147565	1136343	189390	20.15	0.000
Direction*Density	1	78248	72250	72250	7.69	0.007
Closure Type*Density	6	846345	841616	140269	14.93	0.000
Direction*Closure Type*Density	6	427899	427899	71317	7.59	0.000
Error	57	535651	535651	9397		
Total	84	11822250				

S = 96.9401 R-Sq = 95.47% R-Sq(adj) = 93.32%

Unusual Observations for K, N/mm

Obs	K, N/mm	Fit	SE Fit	Residual	St Resid
1	909.61	740.87	55.97	168.73	2.13 R
3	561.91	740.87	55.97	-178.97	-2.26 R
11	642.59	901.32	55.97	-258.73	-3.27 R
12	1101.86	901.32	55.97	200.53	2.53 R
17	749.02	572.54	48.47	176.48	2.10 R
19	366.60	572.54	48.47	-205.95	-2.45 R
23	1190.67	1351.28	55.97	-160.61	-2.03 R
32	270.81	466.40	55.97	-195.59	-2.47 R
33	672.16	466.40	55.97	205.75	2.60 R

R denotes an observation with a large standardized residual.

Grouping Information Using Tukey Method and 95.0% Confidence

Direction	N	Mean	Grouping
Lateral	43	685.7	A
Longitudinal	42	160.7	B

Means that do not share a letter are significantly different.

Grouping Information Using Tukey Method and 95.0% Confidence

Closure Type	N	Mean	Grouping
SL Silver	13	583.0	A
SL Blu	12	575.1	A
SL Wide	12	547.7	A
Double	12	535.0	A
Single	12	350.1	B
Figure 8	12	189.4	C
Robicsek	12	182.2	C

Means that do not share a letter are significantly different.