

**Biomechanical Comparison of Wire Circlage and Rigid
Plate Fixation for Median Sternotomy Closure
in Human Cadaver Specimens**

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By
Mark Steven Wong
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COMMITTEE MEMBERSHIP

TITLE: Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation for Median Sternotomy Closure in Human Cadaver Specimens

AUTHOR: Mark Wong

DATE SUBMITTED: April 19th 2010

COMMITTEE CHAIR: Dr. Lanny Griffin, Department Chair – Biomedical Engineering

COMMITTEE MEMBER: Dr. Dan Walsh, Senior Associate Dean

COMMITTEE MEMBER: Dr. Scott Hazelwood, Associate Professor

ABSTRACT

Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation for Median Sternotomy Closure in Human Cadaver Specimens

By: Mark Steven Wong

Background:

Over 700,000 patients per year undergo open-heart surgery. Healing complication rates can be up to 5% of patients who undergo this procedure, with a morbidity rate of 50% if mediastinitis supervenes. A secure and rigid fixation of surgically divided sternum is critical to avoid healing complications. The purpose of this study was to compare the yield load, construct stiffness, ultimate load, displacement at ultimate load, and post-yield behavior of three sternotomy closure methods (Peristernal wires or Sternalock titanium plates) when stressed in each of three directions: lateral distraction, rostro-caudal (longitudinal) shear distraction, and anterior-posterior (transverse) shear in a cadaveric model.

Methods:

Forty-two fresh cadaver models were divided into three test groups: group A, B, and C. A cardiothoracic surgeon divided each cadaveric sternum longitudinally and repaired peristernal wires or one of two Sternalock configurations. Tests were performed using a materials testing system that applied force at a constant displacement rate in a uniaxial direction until the construct catastrophically failed. Mechanical behavior was monitored using a 3D texture correlation system to create a real-time three-dimensional representation of strain directions. The resulting displacement pattern is analogous to a finite element contour plot of displacements, Lagrange Strain, or velocity. Statistical analysis was used to show the different mechanical properties of each closure method.

Results:

When loaded in lateral distraction, both Sternalock configurations surpassed the rigidity of peristernal wires by 600%. Some evidence was also found linking Sternalock with stiffer behavior in the rostro-caudal direction. Though not statistically significant, a trend was observed showing that constructs using the Sternalock also had higher yield loads, as well as, less post-yield displacement when compared to peristernal wires.

Conclusions:

Data gathered showed the superior performance of the Sternalock system in stiffness in both longitudinal distraction and rostro-caudal shear. Implications for use of the Sternalock system are faster healing times, lower complication rates, and success of the procedure.

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Table of Contents

1.	LIST OF FIGURES	viii
2.	LIST OF TABLES	xiii
3.	BACKGROUND	1
3.1.	THE STERNUM	1
3.2.	OPEN-HEART SURGERY	1
3.3.	MEDIAN STERNOTOMY.....	3
3.3.1.	<i>Surgical Procedure</i>	4
3.3.2.	<i>Sternal closure after a median sternotomy</i>	5
3.3.3.	<i>Osseous Healing Rates</i>	7
3.3.4.	<i>Advantages of the median sternotomy</i>	9
3.4.	CLOSURE TECHNIQUES	10
3.4.1.	<i>Stainless steel wire fixation</i>	10
3.4.2.	<i>Polymer sutures</i>	15
3.4.3.	<i>Steel sternal bands</i>	15
3.4.4.	<i>Reinforced wire techniques</i>	16
3.4.5.	<i>Rigid-plate fixation</i>	16
3.4.6.	<i>Complications</i>	19
3.4.7.	<i>Constriction of blood supply</i>	23
3.5.	MODELS.....	26
3.5.1.	<i>Bone analogues</i>	26
3.5.2.	<i>Cadaveric models</i>	27
3.5.3.	<i>Mathematical models</i>	27
3.5.4.	<i>Digital image correlation</i>	28
4.	OBJECTIVES	30
5.	TEST METHODS	31
5.1.	SAMPLE PREPARATION	33
5.2.	TEST SET-UP.....	34
5.3.	MECHANICAL LOADING	37
5.4.	DIGITAL TEXTURE CORRELATION.....	38
5.5.	DATA EXTRACTION	42
5.6.	CONSTRUCT ANALYSIS.....	45
5.7.	STATISTICAL ANALYSIS.....	46
6.	RESULTS	49
6.1.	LATERAL DISTRACTION	49
6.1.1.	<i>Stiffness</i>	50
6.1.2.	<i>Yield Load</i>	53
6.1.3.	<i>Maximum Load</i>	57
6.1.4.	<i>Post-Yield Displacement</i>	61
6.2.	ROSTRO-CAUDAL SHEAR.....	65
6.2.1.	<i>Stiffness</i>	66
6.2.2.	<i>Yield Load</i>	69
6.2.3.	<i>Maximum Load</i>	72
6.2.4.	<i>Post-Yield Displacement</i>	75
6.3.	ANTERIOR-POSTERIOR SHEAR	78
6.3.1.	<i>Stiffness</i>	79
6.3.2.	<i>Yield Load</i>	82
6.3.3.	<i>Maximum Load</i>	84

6.3.4.	<i>Post-Yield Displacement</i>	85
6.4.	MALES VERSUS FEMALES	85
6.5.	ADDITIONAL GRAPHS	88
7.	DISCUSSION	90
7.1.	LATERAL DISTRACTION	90
7.2.	ROSTRO-CAUDAL SHEAR	92
7.3.	ANTERIOR-POSTERIOR SHEAR	94
7.4.	TEXTURE CORRELATION	96
7.5.	INCREASED HEALING RATE	96
7.6.	BLOOD SUPPLY.....	97
7.7.	GENDER DIFFERENCES	98
7.8.	NATURE OF FAILURE.....	98
7.8.1.	<i>Type of failure</i>	99
7.8.2.	<i>Location of failure</i>	100
7.9.	STATISTICAL POWER.....	101
7.10.	POST-YIELD DISPLACEMENT	102
8.	CONCLUSIONS	102
	REFERENCES	104
	APPENDIX A: STATISTICAL ANALYSIS – LATERAL DISTRACTION	109
	APPENDIX B: STATISTICAL ANALYSIS – ROSTRO-CAUDAL SHEAR	123
	APPENDIX C: STATISTICAL ANALYSIS – ANTERIOR-POSTERIOR SHEAR	137

1. List of Figures

FIGURE 3.1: A COMPLETE VERTICAL INCISION ALONG THE STERNUM USING AN OSCILLATING POWER SAW [3].3

FIGURE 3.2: SEPARATING THE STERNUM.4

FIGURE 3.3: A CLAMP IS USED TO HOLD OPEN THE STERNUM AND EXPOSE THE PERICARDIUM.5

FIGURE 3.4: UPPER ROW: SINGLE TRANSSTERNAL, SINGLE PERISTERNAL, ALTERNATING TRANS AND PERISTERNAL LOWER ROW: FIGURE-EIGHT PERISTERNAL, FIGURE-EIGHT PERICOSTAL, AND ROBICSEK [10].11

FIGURE 3.5: ILLUSTRATION OF A TRANSTERNAL WIRE CLOSURE [18].13

FIGURE 3.6: ILLUSTRATION OF A PERISTERNAL WIRE CLOSURE [18].13

FIGURE 3.7: ILLUSTRATION OF A PERICOSTAL FIGURE-OF-EIGHT WIRE CLOSURE[18].14

FIGURE 3.8: COIL-REINFORCED STERNAL WIRE [22].16

FIGURE 3.9: STERNAL REINFORCEMENT DEVICE DSS: STERNAL SYNTHESIS DEVICE (MIKAI SPA, VINCENZA, ITALY) [23].16

FIGURE 3.10: PHOTOGRAPH OF A CUSTOMIZED 2.3MM, FOUR-HOLE TITANIUM ALLOY H-PLATE (KLS-MARTIN L.P., JACKSONVILLE, FL) [28].....17

FIGURE 3.11: AN ARTIST'S DRAWING OF A STERNUM FIXED WITH WIRES AND RIGID PLATES[29].19

FIGURE 3.12: TISSUE IMMEDIATELY SURROUNDING THE INFECTED AREA IS REMOVED [42].22

FIGURE 3.13: RADIOGRAPH OF WHOLE INJECTED STERNOCHONDRAL SPECIMEN. IMA – INTERNAL MAMMARY ARTERY, SEA – SUPERIOR EPIGASTRIC ARTERY, MPA – MUSCULOPHRENIC ARTERY [43].24

FIGURE 3.14: SIMPLIFIED DIAGRAM OF STERNUM, ILLUSTRATING BLOOD SUPPLY VIA INTERNAL MAMMARY ARTERIES. IMA – INTERNAL MAMMARY ARTERY, S – STERNAL BRANCH, GS – GIGLI SAW, PD – PERIOSTEAL DIATHERMY [43].24

FIGURE 3.15: IDEALIZED DRAWING OF CROSS-SECTIONAL VIEW OF A STERNUM AND ITS BLOOD SUPPLY. IMA – INTERNAL MAMMARY ARTERY, P – PERFORATING BRANCH, M – MEDIAL, S – STERNUM, PM – PECTORALIS MAJOR [43].25

FIGURE 3.16: EXAMPLE ANALYSIS OF THE HUMAN STERNUM BY A NUMERICAL METHOD [45].28

FIGURE 3.17: THE DIGITAL IMAGE CORRELATION SYSTEM TRACKS THE GREY VALUE PATTERN, OR 'SPECKLE,' IN SMALL SUBSETS DURING DEFORMATION28

FIGURE 5.1: THE TEST FRAME USED IN THIS STUDY (BOSE SMARTTEST SP, EDEN PRAIRIE, MN).....31

FIGURE 5.2: PICTURES OF THE THREE CLOSURE TECHNIQUES USED IN THE STUDY. A) PERISTERNAL WIRES, B) STERNALOCK WITH L-PLATE, C) STERNALOCK WITH BOX-PLATE.....33

FIGURE 5.3: THE CADAVERIC STERNUM MUST BE COATED WITH A SPECIAL HIGH-CONTRAST "SPECKLE" TO RECORD AN ACCEPTABLE AMOUNT OF DATA.....34

FIGURE 5.4: PICTURE OF THE ALIGNMENT TOOL DESIGNED FOR THIS PROJECT WITH ONE SIDE OF THE SPIKED CLAMPS IN POSITION.36

FIGURE 5.5: A PICTURE OF THE TEST SET-UP USED. A LOAD FRAME TRANSFERS TENSION TO THE STERNAL CONSTRUCT VIA A SET OF SPIKED CLAMPS. AN ARRAY OF CAMERAS RECORD DATA THROUGHOUT THE TEST.37

FIGURE 5.6: PHOTOGRAPHS OF EACH DIRECTION TESTED IN THE STUDY. STARTING FROM TOP LEFT FIGURE – A) LATERAL DISTRACTION, B) ROSTRO-CAUDAL SHEAR, C) ANTERIOR-POSTERIOR SHEAR.38

FIGURE 5.7: AN EXAMPLE 3-DIMENSIONAL SHAPE CONSTRUCTED BY VIC-3D USING AN ARRAY OF OPTICAL CAMERAS.....	38
FIGURE 5.8: EXAMPLE COLORATIONS OF STRESS CONCENTRATIONS IN A) LATERAL DISTRACTION AND B) LONGITUDINAL SHEAR.	40
FIGURE 5.9: A RECTANGLE IS DRAWN ON THE TOP HALF OF THE STERNUM INDICATING THE AREA THAT DATA WAS EXTRACTED FROM.....	41
FIGURE 5.10: A RECTANGLE IS DRAWN ON THE BOTTOM HALF OF THE STERNUM INDICATING THE AREA THAT DATA WAS EXTRACTED FROM.	41
FIGURE 5.11: LOAD–DISPLACEMENT CURVE AND DEFINITIONS OF TERMS. STIFFNESS IS	42
FIGURE 6.1: RIGIDITY (STIFFNESS) OF THE VARIOUS FIXATION METHODS TESTED IN LATERAL DISTRACTION. DATA DENOTED BY AN ASTERISK ARE SIGNIFICANT ($P < 0.05$). COLUMNS DENOTE MEAN VALUES. STIFFNESS IS MEASURED IN NEWTONS OF FORCE PER MILLIMETER DISPLACEMENT. ERROR BARS INDICATE ONE STANDARD DEVIATION.	50
FIGURE 6.2: RIGIDITY (STIFFNESS) OF THE VARIOUS FIXATION METHODS TESTED IN LATERAL DISTRACTION SEPARATED BY GENDER. COLUMNS DENOTE MEAN VALUES. STIFFNESS IS MEASURED IN NEWTONS OF FORCE PER MILLIMETER DISPLACEMENT. ERROR BARS INDICATE ONE STANDARD DEVIATION. COLUMNS DENOTED WITH LETTER ‘C’ ARE STATISTICALLY DIFFERENT ($P < 0.05$) THAN COLUMNS DENOTED WITH THE LETTER ‘A,’ LIKEWISE ‘B’ IS DIFFERENT THAN ‘D.’	51
FIGURE 6.3: SIDE BY SIDE COMPARISON PLOT OF MAIN EFFECTS WITH REGARDS TO CONSTRUCT STIFFNESS TESTED IN LATERAL DISTRACTION.	52
FIGURE 6.4: INTERACTION PLOT DESCRIBING THE EFFECT OF GENDER ON EACH CONSTRUCT IN REGARDS TO STIFFNESS TESTED IN LATERAL DISTRACTION.....	53
FIGURE 6.5: YIELD STRENGTH OF THE VARIOUS FIXATION METHODS TESTED IN LATERAL DISTRACTION. COLUMNS DENOTE MEAN VALUES. YIELD STRENGTH IS MEASURED IN NEWTONS OF FORCE. ERROR BARS INDICATE ONE STANDARD DEVIATION.....	54
FIGURE 6.6: YIELD STRENGTH OF THE VARIOUS FIXATION METHODS TESTED IN LATERAL DISTRACTION SEPARATED BY GENDER. COLUMNS DENOTE MEAN VALUES. YIELD STRENGTH IS MEASURED IN NEWTONS OF FORCE. ERROR BARS INDICATE ONE STANDARD DEVIATION.....	55
FIGURE 6.7: SIDE BY SIDE COMPARISON PLOT OF MAIN EFFECTS WITH REGARDS TO YIELD STRENGTH TESTED IN LATERAL DISTRACTION.....	56
FIGURE 6.8: INTERACTION PLOT DESCRIBING THE EFFECT OF GENDER ON EACH CONSTRUCT IN REGARDS TO YIELD STRENGTH TESTED IN LATERAL DISTRACTION.	57
FIGURE 6.9: MAXIMUM STRENGTH OF THE VARIOUS FIXATION METHODS TESTED IN LATERAL DISTRACTION. COLUMNS DENOTE MEAN VALUES. MAXIMUM STRENGTH IS MEASURED IN NEWTONS OF FORCE. ERROR BARS INDICATE ONE STANDARD DEVIATION.....	58
FIGURE 6.10: MAXIMUM STRENGTH OF THE VARIOUS FIXATION METHODS TESTED IN LATERAL DISTRACTION SEPARATED BY GENDER. COLUMNS DENOTE MEAN VALUES. MAXIMUM STRENGTH IS MEASURED IN NEWTONS OF FORCE. ERROR BARS INDICATE ONE STANDARD DEVIATION.....	59
FIGURE 6.11: SIDE BY SIDE COMPARISON PLOT OF MAIN EFFECTS WITH REGARDS TO MAXIMUM STRENGTH TESTED IN LATERAL DISTRACTION.	60
FIGURE 6.12: INTERACTION PLOT DESCRIBING THE EFFECT OF GENDER ON EACH CONSTRUCT IN REGARDS TO YIELD STRENGTH TESTED IN LATERAL DISTRACTION.	61

FIGURE 6.13: POST-YIELD BEHAVIOR OF THE VARIOUS FIXATION METHODS TESTED IN LATERAL DISTRACTION. COLUMNS DENOTE MEAN VALUES. POST-YIELD DISPLACEMENT IS MEASURED IN MILLIMETERS. ERROR BARS INDICATE ONE STANDARD DEVIATION.....	62
FIGURE 6.14: POST-YIELD BEHAVIOR OF THE VARIOUS FIXATION METHODS TESTED IN LATERAL DISTRACTION SEPARATED BY GENDER. COLUMNS DENOTE MEAN VALUES POST-YIELD DISPLACEMENT IS MEASURED IN MILLIMETERS. ERROR BARS INDICATE ONE STANDARD DEVIATION.....	63
FIGURE 6.15: SIDE BY SIDE COMPARISON PLOT OF MAIN EFFECTS WITH REGARDS TO POST-YIELD DISPLACEMENT TESTED IN LATERAL DISTRACTION.....	63
FIGURE 6.16: INTERACTION PLOT DESCRIBING THE EFFECT OF GENDER ON EACH CONSTRUCT IN REGARDS TO POST-YIELD DISPLACEMENT TESTED IN LATERAL DISTRACTION.....	64
FIGURE 6.17: RIGIDITY (STIFFNESS) OF THE VARIOUS FIXATION METHODS TESTED IN LONGITUDINAL SHEAR. COLUMNS DENOTE MEAN VALUES. STIFFNESS IS MEASURED IN NEWTONS OF FORCE PER MILLIMETER DISPLACEMENT. ERROR BARS INDICATE ONE STANDARD DEVIATION.	66
FIGURE 6.18: RIGIDITY (STIFFNESS) OF THE VARIOUS FIXATION METHODS TESTED IN LONGITUDINAL SHEAR SEPARATED BY GENDER. COLUMNS DENOTE MEAN VALUES. STIFFNESS IS MEASURED IN NEWTONS OF FORCE PER MILLIMETER DISPLACEMENT. ERROR BARS INDICATE ONE STANDARD DEVIATION.....	67
FIGURE 6.19: SIDE BY SIDE COMPARISON PLOT OF MAIN EFFECTS WITH REGARDS TO STIFFNESS TESTED IN LONGITUDINAL SHEAR.	68
FIGURE 6.20: INTERACTION PLOT DESCRIBING THE EFFECT OF GENDER ON EACH CONSTRUCT IN REGARDS STIFFNESS TESTED IN LONGITUDINAL SHEAR.	69
FIGURE 6.21: YIELD STRENGTH OF THE VARIOUS FIXATION METHODS TESTED IN LONGITUDINAL SHEAR. COLUMNS DENOTE MEAN VALUES. YIELD STRENGTH IS MEASURED IN NEWTONS OF FORCE. ERROR BARS INDICATE ONE STANDARD DEVIATION.....	70
FIGURE 6.22: YIELD STRENGTH OF THE VARIOUS FIXATION METHODS TESTED IN LONGITUDINAL SHEAR SEPARATED BY GENDER. COLUMNS DENOTE MEAN VALUES. YIELD STRENGTH IS MEASURED IN NEWTONS OF FORCE. ERROR BARS INDICATE ONE STANDARD DEVIATION.....	70
FIGURE 6.23: SIDE BY SIDE COMPARISON PLOT OF MAIN EFFECTS WITH REGARDS TO YIELD STRENGTH TESTED IN LONGITUDINAL SHEAR.....	71
FIGURE 6.24: INTERACTION PLOT DESCRIBING THE EFFECT OF GENDER ON EACH CONSTRUCT IN REGARDS YIELD STRENGTH TESTED IN LONGITUDINAL SHEAR.....	72
FIGURE 6.25: MAXIMUM STRENGTH OF THE VARIOUS FIXATION METHODS TESTED IN LONGITUDINAL SHEAR. COLUMNS DENOTE MEAN VALUES. MAXIMUM STRENGTH IS MEASURED IN NEWTONS OF FORCE. ERROR BARS INDICATE ONE STANDARD DEVIATION.....	73
FIGURE 6.26: MAXIMUM STRENGTH OF THE VARIOUS FIXATION METHODS TESTED IN LONGITUDINAL SHEAR SEPARATED BY GENDER. COLUMNS DENOTE MEAN VALUES. MAXIMUM STRENGTH IS MEASURED IN NEWTONS OF FORCE. ERROR BARS INDICATE ONE STANDARD DEVIATION.	74
FIGURE 6.27: SIDE BY SIDE COMPARISON PLOT OF MAIN EFFECTS WITH REGARDS TO MAXIMUM STRENGTH TESTED IN LONGITUDINAL SHEAR.....	74
FIGURE 6.28: INTERACTION PLOT DESCRIBING THE EFFECT OF GENDER ON EACH CONSTRUCT IN REGARDS MAXIMUM STRENGTH TESTED IN LONGITUDINAL SHEAR.....	75
FIGURE 6.29: POST-YIELD BEHAVIOR OF THE VARIOUS FIXATION METHODS TESTED IN LONGITUDINAL SHEAR. COLUMNS DENOTE MEAN VALUES. POST-YIELD DISPLACEMENT IS MEASURED IN MILLIMETERS. ERROR BARS INDICATE ONE STANDARD DEVIATION.	76

FIGURE 6.30: POST-YIELD OF THE VARIOUS FIXATION METHODS TESTED IN LONGITUDINAL SHEAR SEPARATED BY GENDER. COLUMNS DENOTE MEAN VALUES. POST-YIELD DISPLACEMENT IS MEASURED IN MILLIMETERS. ERROR BARS INDICATE ONE STANDARD DEVIATION.	77
FIGURE 6.31: SIDE BY SIDE COMPARISON PLOT OF MAIN EFFECTS WITH REGARDS TO POST-YIELD DISPLACEMENT TESTED IN LONGITUDINAL SHEAR.	77
FIGURE 6.32: INTERACTION PLOT DESCRIBING THE EFFECT OF GENDER ON EACH CONSTRUCT IN REGARDS POST-YIELD DISPLACEMENT TESTED IN LONGITUDINAL SHEAR.	78
FIGURE 6.33: RIGIDITY (STIFFNESS) OF THE VARIOUS FIXATION METHODS TESTED IN TRANSVERSE SHEAR. COLUMNS DENOTE MEAN VALUES. STIFFNESS IS MEASURED IN NEWTONS OF FORCE PER MILLIMETER DISPLACEMENT. ERROR BARS INDICATE ONE STANDARD DEVIATION.	80
FIGURE 6.34: RIGIDITY (STIFFNESS) OF THE VARIOUS FIXATION METHODS TESTED IN LONGITUDINAL SHEAR SEPARATED BY GENDER. COLUMNS DENOTE MEAN VALUES. STIFFNESS IS MEASURED IN NEWTONS OF FORCE PER MILLIMETER DISPLACEMENT. ERROR BARS INDICATE ONE STANDARD DEVIATION.	81
FIGURE 6.35: SIDE BY SIDE COMPARISON PLOT OF MAIN EFFECTS WITH REGARDS TO STIFFNESS TESTED IN TRANSVERSE SHEAR.	81
FIGURE 6.36: INTERACTION PLOT DESCRIBING THE EFFECT OF GENDER ON EACH CONSTRUCT IN REGARDS STIFFNESS TESTED IN TRANSVERSE SHEAR.	82
FIGURE 6.37: YIELD STRENGTH OF THE VARIOUS FIXATION METHODS TESTED IN LONGITUDINAL SHEAR. COLUMNS DENOTE MEAN VALUES. YIELD STRENGTH IS MEASURED IN NEWTONS OF FORCE. ERROR BARS INDICATE ONE STANDARD DEVIATION.	83
FIGURE 6.38: YIELD STRENGTH OF THE VARIOUS FIXATION METHODS TESTED IN LONGITUDINAL SHEAR SEPARATED BY GENDER. COLUMNS DENOTE MEAN VALUES. YIELD STRENGTH IS MEASURED IN NEWTONS OF FORCE. ERROR BARS INDICATE ONE STANDARD DEVIATION.	84
FIGURE 6.39: COMPARING STIFFNESS BETWEEN MALE AND FEMALE SPECIMEN. COLUMNS DENOTE CUMULATIVE VALUES FOR ALL FIXATION METHODS.	85
FIGURE 6.40: COMPARING YIELD STRENGTH BETWEEN MALE AND FEMALE SPECIMEN. COLUMNS DENOTE CUMULATIVE VALUES FOR ALL FIXATION METHODS. AN ASTERISK INDICATES STATISTICALLY SIGNIFICANCE BETWEEN MALE AND FEMALE SPECIMEN.	86
FIGURE 6.41: COMPARING MAXIMUM STRENGTH BETWEEN MALE AND FEMALE SPECIMEN. COLUMNS DENOTE CUMULATIVE VALUES FOR ALL FIXATION METHODS.	87
FIGURE 6.42: COMPARING POST-YIELD DISPLACEMENT BETWEEN MALE AND FEMALE SPECIMEN. COLUMNS DENOTE CUMULATIVE VALUES FOR ALL FIXATION METHODS.	87
FIGURE 6.43: RIGIDITY (STIFFNESS) OF THE VARIOUS FIXATION METHODS TESTED IN VARIOUS DIRECTIONS AND SEPARATED BY GENDER. COLUMNS DENOTE MEAN VALUES. STIFFNESS IS MEASURED IN NEWTONS OF FORCE PER MILLIMETER DISPLACEMENT. ERROR BARS INDICATE ONE STANDARD DEVIATION.	88
FIGURE 6.44: YIELD STRENGTH OF THE VARIOUS FIXATION METHODS TESTED IN VARIOUS DIRECTIONS AND SEPARATED BY GENDER. COLUMNS DENOTE MEAN VALUES. YIELD STRENGTH IS MEASURED IN NEWTONS OF FORCE. ERROR BARS INDICATE ONE STANDARD DEVIATION.	89
FIGURE 6.45: MAXIMUM STRENGTH OF THE VARIOUS FIXATION METHODS TESTED IN VARIOUS DIRECTIONS AND SEPARATED BY GENDER. COLUMNS DENOTE MEAN VALUES. MAXIMUM STRENGTH IS MEASURED IN NEWTONS OF FORCE. ERROR BARS INDICATE ONE STANDARD DEVIATION.	89
FIGURE 6.46: POST-YIELD DISPLACEMENT OF THE VARIOUS FIXATION METHODS TESTED IN VARIOUS DIRECTIONS AND SEPARATED BY GENDER. COLUMNS DENOTE MEAN VALUES. POST-YIELD DISPLACEMENT IS MEASURED MILLIMETERS. ERROR BARS INDICATE ONE STANDARD DEVIATION.	90

FIGURE 7.1: PICTURE TAKEN AT MAXIMUM DISPLACEMENT IN THE LATERAL DISTRACTION DIRECTION. SEPARATION CAN BE OBSERVED AT THE MIDLINE AND RIB FRACTURES CAN BE SEEN ALONG THE BOTTOM CLAMP.90

FIGURE 7.2: PICTURE TAKEN AT MAXIMUM DISPLACEMENT IN THE LONGITUDINAL DIRECTION. SLANTED WIRES INDICATE PLASTIC DEFORMATION AT THE MIDLINE.93

FIGURE 7.3: PICTURE TAKEN AT MAXIMUM DISPLACEMENT IN THE TRANSVERSE DIRECTION. FAILURE DID NOT OCCUR DURING THIS TEST.94

FIGURE 7.4: PICTURE TAKEN FROM A CAMERA USED IN THE DIGITAL IMAGE CORRELATION CAPTURE SYSTEM.95

FIGURE 7.5: PICTURE TAKEN AFTER FAILURE OF THE DEVICE OCCURRED. A SCREW THAT FASTENED THE PLATE TO THE STERNUM BECAME DISLODGED.99

FIGURE 7.6: PICTURE TAKEN AFTER CLAMPS WERE REMOVED FROM THE STERNUM. OBVIOUS TEARING OF THE INTERCOSTAL MUSCLES HAD TAKEN PLACE, AS WELL AS FRACTURE OF ASSOCIATED RIBS IN THE AREA.100

2. List of Tables

TABLE 5.1: TEST DESIGN FOR THE OVERALL STUDY.	48
TABLE 6.1: DESCRIPTION OF THE SAMPLE GROUP TESTED IN LATERAL DISTRACTION WITH VALUES FOR EACH BIOMECHANICAL PROPERTY.....	49
TABLE 6.2: MEAN STIFFNESS VALUES FOR EACH STERNAL-CLOSURE TECHNIQUE TESTED IN LATERAL DISTRACTION, SEPARATED BY GENDER.....	50
TABLE 6.3: MEAN YIELD VALUES FOR EACH STERNAL-CLOSURE TECHNIQUE TESTED IN LATERAL DISTRACTION, SEPARATED BY GENDER.....	53
TABLE 6.4: MEAN MAXIMUM-LOAD VALUES FOR EACH STERNAL-CLOSURE TECHNIQUE TESTED IN LATERAL DISTRACTION, SEPARATED BY GENDER.	57
TABLE 6.5: MEAN POST-YIELD VALUES FOR EACH STERNAL-CLOSURE TECHNIQUE TESTED IN LATERAL DISTRACTION, SEPARATED BY GENDER.....	61
TABLE 6.6: DESCRIPTION OF THE SAMPLE GROUP TESTED IN THE LONGITUDINAL DISTRACTION WITH VALUES FOR EACH BIOMECHANICAL PROPERTY.....	65
TABLE 6.7: MEAN STIFFNESS VALUES FOR EACH STERNAL-CLOSURE TECHNIQUE TESTED IN LONGITUDINAL SHEAR, SEPARATED BY GENDER.	66
TABLE 6.8: MEAN YIELD VALUES FOR EACH STERNAL-CLOSURE TECHNIQUE TESTED IN LONGITUDINAL SHEAR, SEPARATED BY GENDER.	69
TABLE 6.9: MEAN MAXIMUM-LOAD VALUES FOR EACH STERNAL-CLOSURE TECHNIQUE TESTED IN LONGITUDINAL SHEAR, SEPARATED BY GENDER.	72
TABLE 6.10: MEAN POST-YIELD VALUES FOR EACH STERNAL-CLOSURE TECHNIQUE TESTED IN LONGITUDINAL SHEAR, SEPARATED BY GENDER.	75
TABLE 6.11: DESCRIPTION OF THE SAMPLE GROUP TESTED IN THE TRANSVERSE DISTRACTION WITH VALUES FOR EACH BIOMECHANICAL PROPERTY.....	78
TABLE 6.12: MEAN STIFFNESS VALUES FOR EACH STERNAL-CLOSURE TECHNIQUE TESTED IN TRANSVERSE SHEAR, SEPARATED BY GENDER.	79
TABLE 6.13: MEAN YIELD VALUES FOR EACH STERNAL-CLOSURE TECHNIQUE TESTED IN TRANSVERSE SHEAR, SEPARATED BY GENDER.....	82
TABLE 6.14: MEAN YIELD VALUES FOR EACH STERNAL-CLOSURE TECHNIQUE TESTED IN TRANSVERSE SHEAR.....	83

3. Background

3.1. The Sternum

Also known as the breastplate, the sternum is located in the mid-thoracic (chest) region of the human body. The sternum is an elongated flat bone that makes up the core of the anterior thoracic wall. The clavicles, ribs, and muscle all make critical attachments to the sternum. The sternum provides a strong structural foundation for the entire thoracic region for different components that provide protection for vital organs and a means for skeletal movement. Thus, the sternum is the most critical component of structural support to the entire thorax.

The sternum is made up of three regions: the manubrium, gladiolus, and xiphoid process. The manubrium is thick, broad, and makes up the upper part of the sternum. The manubrium supports the first two ribs, as well as, the clavicles and transitions into the main body of the sternum. The gladiolus or body of the sternum is a long flat bone thinner than the manubrium that connects the second through sixth ribs via cartilage. The xiphoid process makes up the bottom region of the sternum, articulating the seventh costal cartilage. The xiphoid is the thinnest and inherently weakest component of the sternum.

3.2. Open-Heart Surgery

Open-heart surgery is often directly associated with a median sternotomy, though not a median sternotomy can technically be utilized in other operations. Still, open-heart surgery makes up the vast majority of operations requiring a median sternotomy.

699,000 open-heart procedures were performed in United States in 2005[1]; this number has grown from 666,000 in 2003. This number is projected to grow in the future due to an aging population with increasing rates of obesity and cardiovascular disease. Of the 699,000 surgeries in 2005, this included 106,000 valve replacements, 469,000 bypass surgeries, and 2,192 heart transplants. Healing complication rates are between 0.3% and 5% of cases and mortality rates can be up to 47% if mediastinitis supervenes[2]. From these statistics, we find that up to 34,950 complications, and up to 16,427 mortalities are associated with open-heart surgeries each year.

Open-heart surgery is defined as a procedure that involves sternal division and a subsequent incision along the pericardium. However, a significant number of procedures require division of the sternum without the need to access the pericardium (open-chest surgery), for example, revision surgeries required by 5% of open-heart surgery patients who develop postoperative healing complications. Therefore, the actual quantities of operations that require anterior access of the chest via sternal division exceed the 699,000 open heart surgeries.

The most common procedure requiring a midline sternotomy is coronary artery bypass grafting (CABG). During this procedure a midline incision is used to gain access to the heart and aorta. In a traditional CABG, a heart-lung machine is used to bypass blocked blood vessels, as well as oxygenate and circulate blood during surgery while heart muscle is stopped.

The median sternotomy incision remains an extremely popular incision used by cardiac surgeons. The vast number of these surgeries performed each year outnumbers that of any other cardiac procedure. Although they have a low probability of occurrence, a large amount of healing complications have been associated with surgeries requiring sternal division; these complications have been directly linked to an uncomfortable rate of mortality. A closer analysis should be done to understand the shortcomings of sternal closure techniques and how we can improve the postoperative healing process.

3.3. Median Sternotomy

A large proportion of surgical operations require access into vital organs in the thoracic cage. The sternum is a commonly used access point to vital organs in surgical procedures. The median sternotomy is a preferred option because of its excellent exposure of vital organs and it is perceived to be well tolerated by most patients.

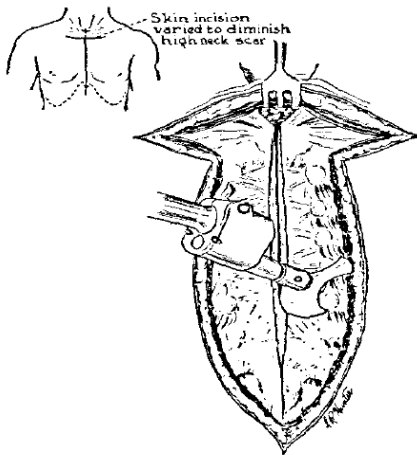


Figure 3.1: A complete vertical incision along the sternum using an oscillating power saw [3].

A complete vertical division was first used by Milton in 1897 to gain access to the posterior mediastinum. This approach was used sporadically for various purposes until

the complete vertical incision was popularized by Julian in 1957, which he favored over a similar transverse bilateral thoracotomy. Since then the median sternotomy has grown to be the most popular incision performed by cardiac surgeons.

3.3.1. Surgical Procedure



Figure 3.2: Separating the sternum.

During a median sternotomy, the patient is placed on his back and a vertical, midline incision is made from above the sternal notch to well past the xiphoid region. To minimize visible scars, a transverse skin incision can be made at the third intercostal space. An incision is made along the linea alba through the lower part of the incision, and an oscillating saw is used to divide the sternum down its midline. The incision made by the saw is carried upward into the deep cervical fascia and must intersect the interclavicular ligament. The pericardium can then be opened between the pleural reflections[3].

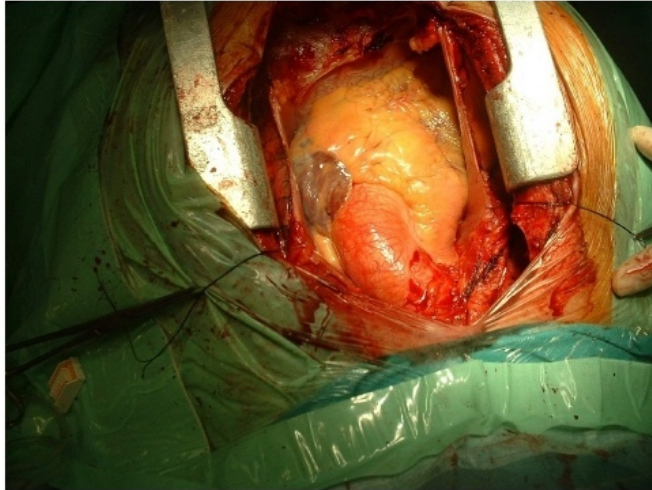


Figure 3.3: A clamp is used to hold open the sternum and expose the pericardium.

3.3.2. Sternal closure after a median sternotomy

After the particular cardiac surgery involving the median sternotomy is completed, the two halves of sternum need to be secured. This is called the closure technique and its purpose is to unify the divided sternum to allow for osseous healing. Various methods are utilized to accomplish this, including different configurations of stainless steel sutures, steel coils, steel bands, reinforced wire configurations, nylon bands, and rigid-fixation plates.

In his initial evaluation of the procedure in 1957, Julian immediately recognized:

“The solidity of the closure is important because it completely immobilizes the chest from abnormal movements and renders the postoperative period more comfortable. The security of wire sutures is essential[3].”

In the four cases used in Julian’s evaluation, the second case resulted in the death of the patient due to wound disruption. The sensitivity of the sternum in the postoperative

healing phase has been a major problem since the early evaluation phase in the history of this procedure; the period of time immediately following a median sternotomy remains to be a prime concern when considering candidates for surgery.

A secure and rigid fixation of the sternum is critical to avoiding healing complications. Without sufficient stability at the osteotomy site, patients can suffer from pain, respiratory problems, wound leakage, sternal non-union or malunion, osteomyelitis, pseudoarthrosis, dehiscence, and mediastinitis. Patients often require corrective surgery when sufficient a secure sternal union cannot be achieved several days after operation. In severe cases, patients require sternal debridement and reconstructive surgery. Additional procedures required in ensuring a stable fixation and correct healing of the sternum introduces unnecessary risk to complications like infection, as well as added cost and lengthened time required in the hospital.

Alternative closure techniques continue to be explored due to the inadequate performance of current devices. It has been shown that a fixation technique which is more effective at providing a rigid construct of sternum postoperatively will result in earlier union of the sternal halves with typical cellular elements and stromal tissue at the osteotomy site [4]. Insufficient postoperative sternal rigidity or sternal instability in the early postoperative period has been associated with a two to four times greater incidence of wound complications, mediastinitis, and chronic sternal infections [5]. Separate reports have also claimed that this insufficient stability is one of the most important factors

influencing the development of mediastinitis [6]. It is statistically shown that in cases where mediastinitis supervenes, 47% of patients die [2].

3.3.3. Osseous Healing Rates

Immediately after a fracture, blood vessels in the immediate area constrict to prevent any further bleeding. Soon after, a blood clot forms around the injury site and between bone fragments as a result of hematoma. All cells inside and around the blood clot deteriorate, leaving only inflammatory cells to populate the area. These inflammatory cells include macrophages, monocytes, lymphocytes, and fibroblasts; they form a matrix called granulation tissue. Still not vascularized, oxygen is taken from exposed muscle and bone directly around the injury site. As leukocytes remove the blood clot, vascular ingrowth advances and replaces collagen.

On average of six weeks after an injury, a fibrocartilage callus can be observed, formed temporarily from fibroblasts and chondroblasts to cover the length of the bone fracture. Introduced osteoids form woven bone, which consist of a large amount of osteocytes and grows very quickly. However, woven bone is significantly weaker to the slow growing lamellar bone because it only contains a smaller number of randomly oriented collagen fibers where lamellar bone consists of highly organized sheets of fibers with high collagen content. Woven bone is eventually mineralized and is completely replaced by lamellar bone. Three months after injury, mineralized bone can usually be observed. Bone fracture healing is completed when bone remodeling restores the original shape and mechanical strength.

The early postoperative phase is critical because any movement around the fracture could result in severed blood vessels, or damaging the fragile granulation tissue. Also, extended amounts of time that bone is left unhealed increased the risk for infection. Treatment of any bone damage is therefore aimed at stabilization of the injury, particularly in the early postoperative phase. This is achieved by completely immobilizing the injury site and the surrounding area throughout the entire healing process.

Bitkover conducted a study evaluating computed tomography images of mainstream steel suture closure techniques. These images revealed that the bone callus involved in healing was not found in images three months after operation. Cortical bone growth bridging the length of the sternotomy was not visible until six months post-operation. Therefore, from this study, no specific timeline was found determining when the callus, or woven bone begins to form between three and six months after the sternotomy was performed [7]. This longer-than-average time observed in the formation of the fibrocartilage callus and mineralized bone suggests that the osteotomy site is not sufficiently stabilized and allowing disruption during the healing phase. The implication of this study is that there is a large amount of room to improve the efficiency of the closure technique used (stainless steel wire sutures).

In a study conducted by Sargent using baboons, the presence of woven bone was found eight weeks after operation using popular wire closure techniques [4]. The interesting

finding from this study is that using an alternative, more stable rigid fixation method, the presence of woven bone could be found only four weeks after operation. This reveals how much the closure technique can effect osseous healing, and how crucial it is to completely immobilize the osteotomy site. Some consideration should be made on the implications of any physiological differences between baboons and human patients, but the study does reveal the potential of a more efficient closure technique.

3.3.4. Advantages of the median sternotomy

Minimally invasive surgeries such as minimally invasive direct coronary bypass (MIDCAB), off-pump coronary artery bypass (OPCAB), and robotic assisted coronary artery bypass (RACAB) have gained popularity because it can be performed without while the heart is still beating and using a much smaller incision, which often translates to shorter hospital stays. However, a complete midline sternotomy remains the more popular method because it can be performed quickly, is a familiar procedure to surgeons, provides access and exposure to chest structures, and is well tolerated by most patients [8, 9]. Surgeons have clear access to observe vital organs and to perform any intervention necessary. Also, many procedures may be more difficult to perform on a beating heart than on a still heart. In most cases, the procedure is relatively painless and heals well.

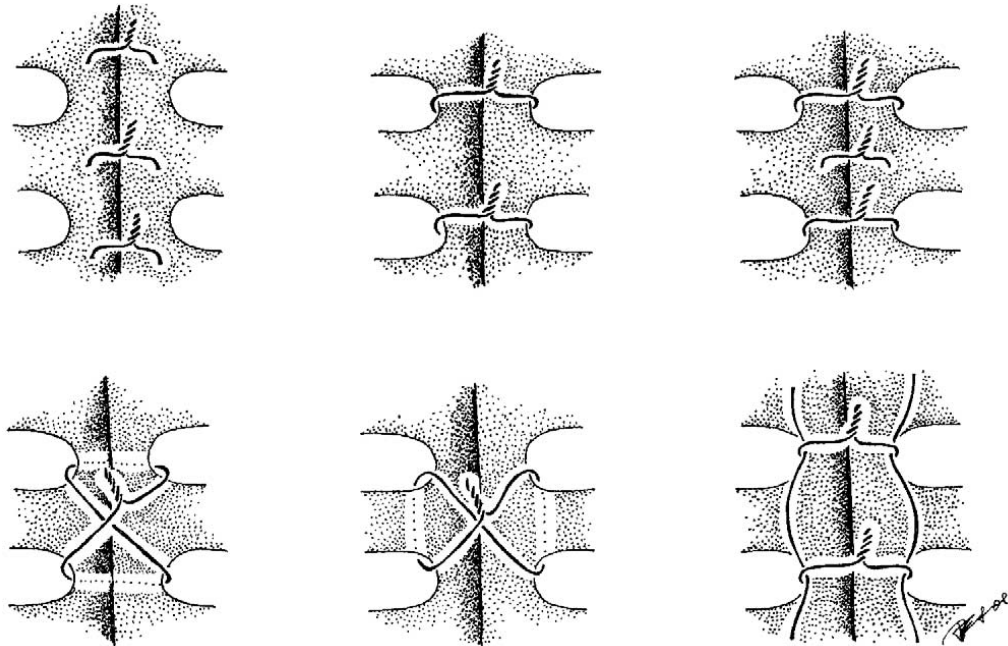
Minimally invasive cardiac surgeries decrease visualization of the operative site, and are technically more difficult. Postoperative pain is not always decreased when compared to a median sternotomy. Multiple incisions may also be required with a less invasive approach, decreasing the cosmetic appeal of minimally invasive techniques.

3.4. Closure Techniques

Many different methods and approaches in ensuring a stable and reliable sternal closure have been explored. These include nylon bands, stainless steel wires, reinforced steel wires, steel bands, and rigid plate fixation. Different hospitals in different regions have their own procedural guidelines, while some wait to choose their method after observation of the sternum. Inside this, each surgeon has their own preferences to each particular method. Concerns surrounding each method include stability, reliability, cost, ease of use, speed, complexity in removing the device in the event of a complication, and familiarity.

3.4.1. Stainless steel wire fixation

Stainless steel wires wrap around or thread through sternal halves to combat physiologic forces from transversely separating the surgically divided sternum. Tension is applied by twisting the two ends into a knot and the resulting compressive force prevents any unwanted movement of the sternum during the healing phase. The tension of the knot is estimated by the surgeon, determined by hand. This part of the procedure is relatively simple and can be completed quickly.



**Figure 3.4: Upper row: single transsternal, single peristernal, alternating trans and peristernal
Lower row: figure-eight peristernal, figure-eight pericostal, and Robicsek [10].**

Previous studies have shown the efficacy of this closure technique, as well as its superiority over other non-rigid closure methods [11, 12]. Stainless steel wire closure techniques are the most popular closure technique used by cardiac surgeons. Steel wires have been the primary closure method since Julian's initial evaluation of the procedure in 1957. Because of this familiarity, cardiac surgeons have been extremely reluctant to institute alternative techniques. In addition, steel wires are very cost effective and simple to manage in the event of revision surgery.

Wire failures are usually characterized with wire cutting through bone rather than the wire breaking or unraveling [13]. If the wire cuts into the bone, the wire is no longer tight and in contact at all pointed with bone. There are less compressive forces acting against the bone and repetitive respiratory motion of the chest wall will further loosen wires and cut the sternum into segments [14]. However, this is not the only complication

that exists, during mechanical testing unwinding of the knot is a common issue, and in canine studies, wire breakage is a fairly common occurrence [15]. Wire breakage, however, is not a primary concern unless tightened to the point where the material is compromised. Also, an underlying issue is that cadaver models are unable to identify pain associated with the wire knot under the skin [13].

Comparing stainless steel wire fixation with alternative techniques in an accurate and encompassing characterization is extremely difficult because countless configurations and combinations exist. Among steel wire techniques, every hospital and surgeon has their own preferred method. Also, different configurations are more suited for different applications, for example the Robicsek technique has been found to be particularly effective in stabilizing cases where other methods have previously failed [16].

3.4.1.1. Transternal wires

The standard closure of the sternum after sternotomy utilizes surgical steel sutures passed through the sternum approximately 1 cm on each side [17]. After passing through the sternum, the loose suture wires are then crossed, pulled, and twisted several times to apply a compressive force on the sternal halves. The wire sutures may easily cut through the bone under simultaneous load from several directions [18]. Several modifications have been explored to prevent penetration of the bone, including, combinations of mattress and wires, figure-eight configurations, double-cross wires, and interlocking multitwisted wires [18].

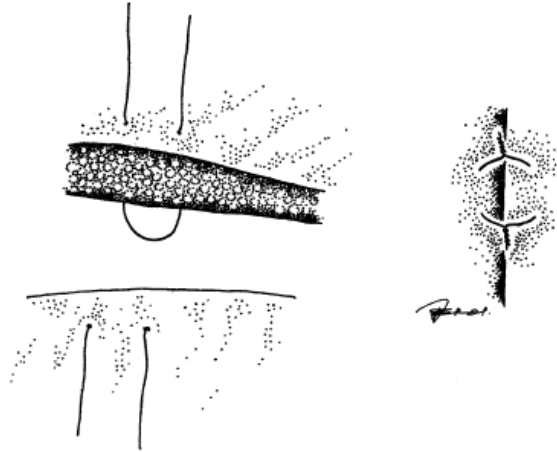


Figure 3.5: Illustration of a transternal wire closure [18].

3.4.1.2. Peristernal wires

Peristernal sutures reinforce the lateral table of the sternum by wrapping around the whole sternal body. This allows tighter closures with less likelihood of the wires cutting through cortical bone [18]. Advantages for single sutures have been published [19] but most surgeons have adopted figure-eight interlocking closures [20, 21]. Figure-eight peristernal wires are faster, simpler, and more reliable than similarly configured transternal wires [18, 20, 21].

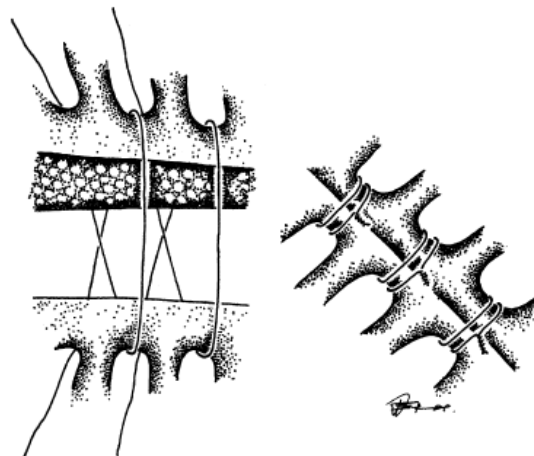


Figure 3.6: Illustration of a peristernal wire closure [18].

3.4.1.3. Pericostal wires

Pericostal wire closure techniques rely upon the costal cartilages outside the operative area by wrapping around a single rib [18].

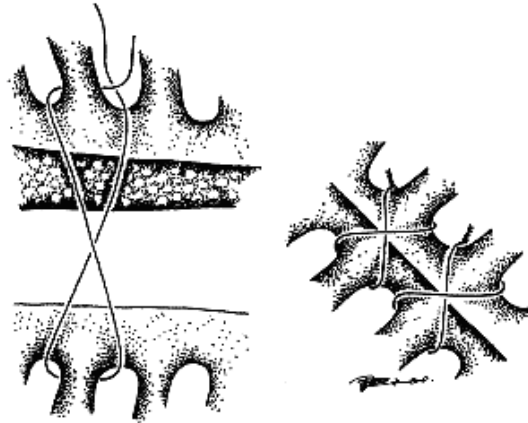


Figure 3.7: Illustration of a pericostal figure-of-eight wire closure[18].

3.4.1.4. Figure-of-eight

A figure-of-eight closure is characterized by steel wire wrapped around the manubrium in the shape of an 8. A series of figure-eight is the closure choice for the most human cardiothoracic surgeons [15].

The configuration that is optimal for clinical use has been a disputed topic. One claim asserts that figure-eight pericostal closure (Figure 3.7) has the highest failure rate compared to other popular steel wire methods [10], while others claim that figure-eight suturing is safer than simple wires [6] and have the least permanent displacement under load [15]. Clinical observation suggests that figure-of-eight, results in uneven tension. The advantage of this method is that the force that it applies on bone is distributed over a larger surface area and reinforces sternal segments [15].

3.4.2. Polymer sutures

Performed in the same manner as steel sutures, nylon bands have been ruled out as an effective technique. The nominal gauge of steel wires and polyester bands are identical and therefore are characterized by the same surface area. The high elastic modulus allows it to stretch under load, and the actual diameter of the polyester suture shrinks. This means that the force applied on the manubrium is distributed under a decreased surface area and is more likely to cut through bone [8]. This also correlates to clinical data in which the good results of steel closures were not replicated with the use of nylon bands and cuts through bone at over four times the rate of standard steel wire closures [2, 8].

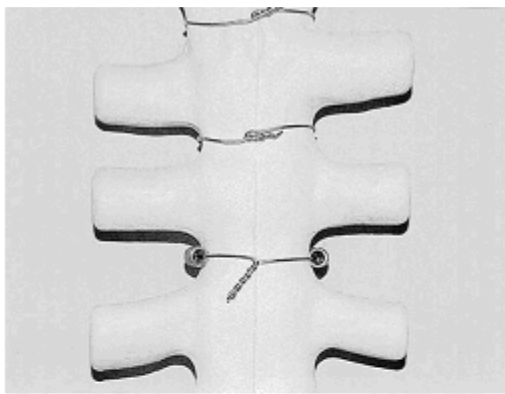
3.4.3. Steel sternal bands

Steel sternal bands are used to achieve a larger force distribution by wrapping a wide steel band peristernally around the manubrium. In practice, more wires are usually involved in a sternal closure than bands, but this can also be attributed to its larger size. Because of the larger size of sternal bands, they risk traumatizing surrounding tissue and cannot be placed through the manubrium or around the rest of the sternum [22].

In applications that allow for this device to be used, sternal bands are particularly effective. They cut through bone at a quarter of the rate of standard steel wire closures and are twice as rigid. The use of a more reliable, rigid closure can result in the reduction in postoperative pain and postoperative hospital stay [8].

3.4.4. Reinforced wire techniques

The exposed weakness of the stainless steel wire technique is the wire's ability to cut through bone and its dependence on bone strength. To correct this, techniques have been developed to allow for forces to be distributed over larger surface areas while retaining the simplicity of standard steel wire closures and therefore allowing less dependence on bone strength. Examples of this include coil jacketed wires and titanium sheets strategically placed under the wire on either side of the sternum.



A

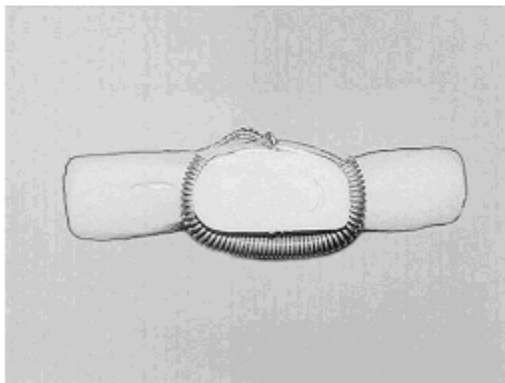
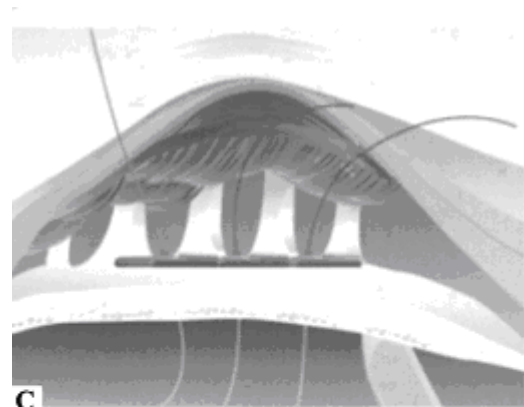
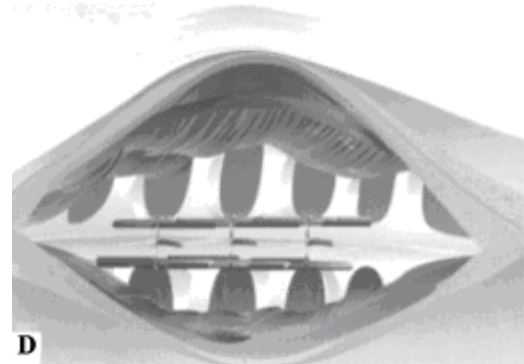


Figure 3.8: Coil-reinforced sternal wire [22].



C



D

Figure 3.9: Sternal reinforcement device DSS: Sternal Synthesis Device (Mikai SpA, Vicenza, Italy) [23].

3.4.5. Rigid-plate fixation

Cranio-maxillofacial and orthopedic surgeons have historically used wires for bone fixation, similar to cardiothoracic surgeons. Morbidity and complications associated with wire fixation of these other two applications were also similar, including infection,

separation, instability, motion, non-union, and delayed healing. Rigid fixation techniques have been developed to provide superior stiffness at an injury site to aid in osseous healing rates and reduced complication rates. The implementation of rigid fixation techniques has significantly reduced bone healing complications in the areas of craniomaxillofacial and orthopedic surgery [24-27]. This translates to fewer hospitalization days and an earlier return to normal function. The advantages of rigid fixation have led to the near-complete replacement of wire fixation in orthopedic, craniomaxillofacial, otolaryngologic, oral, and neurologic surgery [28].

3.4.5.1. H-shaped titanium plates

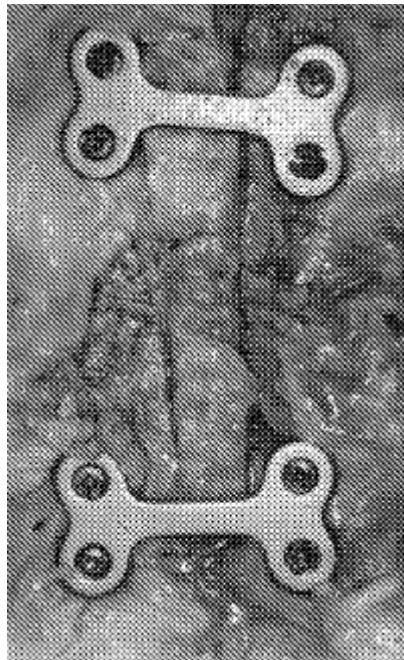


Figure 3.10: Photograph of a customized 2.3mm, four-hole titanium alloy H-plate (KLS-Martin L.P., Jacksonville, FL) [28].

Ozaki *et al.* cited compelling advantages of rigid fixation over wire fixation in promoting good bone healing. H-plates made from a titanium alloy were developed to experiment on a rigid fixation technique to close a median sternotomy. The study obtained results

showing that the H-plates developed had a statistically significant sternal stiffness, less sternal motion, and fewer failures when compared to sternum closed with wires [28].

The mechanical behavior of the device-cadaver construct is not entirely dependent on the rigid plate on screws, but also largely dependent on the bone that they are screwed into. Screws must be placed into the thickest and densest possible bone, properly drilled with appropriately sized screws. Concerns with this new technology included the high cost of the plates and damage of underlying structures by the drill.

3.4.5.2. The Biomet Sternalock

Originally developed by Walter Lorenz Inc, the Sternalock system is a titanium plating system, screwing directly into divided the manubrium to fasten itself. The system utilizes two X-plates at the mid-body and one L-plate as inferiorly on the sternum as possible, in conjunction with wires at the manubrium and xiphoid for extra stability in physiologically weaker areas. Implant time for this device has been claimed to be shorter than wire closure techniques [29].

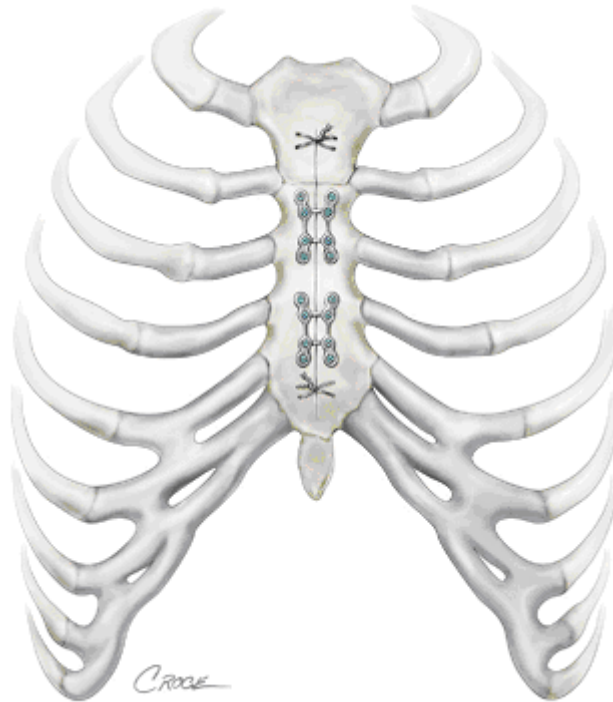


Figure 3.11: An artist's drawing of a sternum fixed with wires and rigid plates[29].

3.4.6. Complications

Potential healing complications that can develop after a median sternotomy include sternal mal-union and non-union, dehiscence, mediastinitis, and lingering incision pain. The presence of an individual complication is associated with the presence of additional complications, as well as directly related to sternal instability, or insufficient sternal approximation [30]. The presence of healing complications may lead to hardware failure and occasionally, death [5, 7, 12, 31-33].

A surgical debridement would be performed as soon as possible in the event of dehiscence or mediastinitis [34]. In a procedure first described by Schumacker and Mandelbaum in 1963, the infected area undergoes debridement, sternal reclosure and mediastinal antibiotic irrigation [35]. The average additional hospital cost to treat post

sternotomy mediastinitis is \$500,000 [36]. The alternate cost of a better closure technique is extremely cheap in comparison. Prevention of postoperative complications is fiscally sound, and more importantly, it has the potential to save lives.

Increased motion at the sternotomy site can worsen a patient's postoperative sternal pain, which may lead to atelectasis and pneumonia secondary to a decreased inspiratory effort [28].

3.4.6.1. Increased risk factors

A thorough understanding of risk factors can aid in predicting the incidence of serious complications. Postoperative healing complications can occur in up to 5% of patients [2, 11, 18, 37], and historical data has revealed that the use of sternal wires on a select group of patients exhibiting "high risk factors" is insufficient as a closure technique [38].

Univariate risk factors include: insulin-dependent diabetes, obesity, postoperative bleeding, prolonged ventilation, surgical reexploration, use of one or two internal mammary artery (IMA) grafts, number of diseased vessels, postoperative intra-aortic balloon pump (IABP) use, blood transfusions, and female gender [39]. Multivariate analysis revealed five independent risk factors including obesity, insulin-dependent diabetes, IMA grafting, blood transfusions, and surgical reexploration [39].

3.4.6.2. Sternal mal-union and non-union

When the rigidity of the closure technique is insufficient and a degree of motion is allowed between the sternal halves, bone healing is interrupted. This interruption results

in delayed healing, and in some cases the bone continues to heal as two individual pieces rather than in union. This can occur in partial areas of the sternum, yielding a partial joining of the separated sternum, or sternal mal-union. In more severe cases, this takes place along the entire incision line, resulting in a complete sternal non-union.

The sternum is relied upon for structural support by many major organs and undergoes repeated stress cycles from menial physical tasks. From respiration alone the sternum goes under approximately 20 loading and unloading cycles, coughing caused by other conditions can dramatically increase loading characteristics. In a healthy individual, external forces act upon the thorax and the structural support created by the ribcage prevents the majority of the force to be transmitted to vital organs. Likewise, forces produced from respiration are contained by the firm encapsulation of bone.

When the structural integrity of the thorax is incomplete or severely compromised, the patient experiences an incapacitating pain. Patients are overcome with pain during everyday tasks and their lifestyles become increasingly limited.

3.4.6.3. Dehiscence

Dehiscence is defined as a reopening of a wound that was previously closed, as is the case in postoperative sternotomy patients. The wound ruptures along the sutured incision line often with discharge. Dehiscence is a result of poor wound healing and often occurs within the first 2 weeks postoperatively before significant bone healing [30].

“Dehiscence occurs when failure stress of the sternum is exceeded as forces such as those produced by coughing are applied to the sternotomy [40].”

Dehiscence is the most commonly reference healing complication in median-sternotomy related literature and the largest postoperative concern when a median sternotomy is performed. Dehiscence is directly related to a life-threatening complication known as mediastinitis; in all cases of mediastinitis developing in patients, dehiscence was present.

3.4.6.4. Mediastinitis

Mediastinitis is an infection involving the mediastinum, or thorax. This condition is characterized by a bacterial infection causing inflammation and a rupture of the wound. As infections can progress rapidly in this region, mediastinitis must be treated immediately. Mediastinitis is the most serious postoperative healing complication that can occur. As previously stated, it has been shown that in a statistical sample, 47% of patients who develop this serious complication die [2, 16, 31, 38, 41].

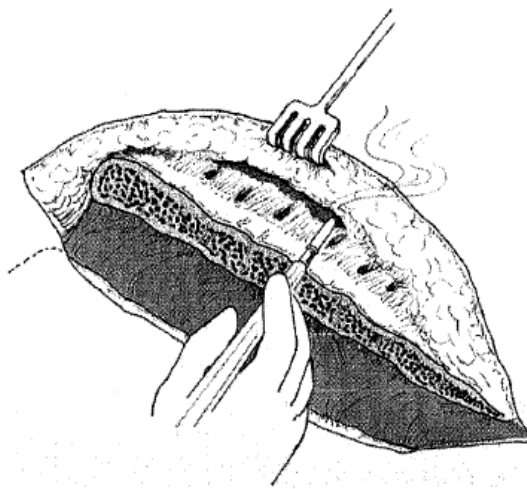


Figure 3.12: Tissue immediately surrounding the infected area is removed [42].

If not treated immediately, infection will rapidly spread and further complications, such as, sepsis, respiratory insufficiency, or multi-organ failure can occur [42]. Treatment of mediastinitis and dehiscence alike involves removal of compromised tissue and prevention of any infection from progressing. Specifically, this entails an array of antibiotics and an immediate sternal debridement without the removal of bone, and in advanced cases of mediastinitis a complete sternal debridement was carried out. Even with proper treatment, the likelihood of patient survival is limited.

Typically mediastinitis occurs in conjunction with dehiscence and rarely develops independently. This has been observed in multiple studies. Such is the basis for theorizing that eliminating sternal dehiscence, or preserving wound closure integrity, advances in mediastinitis prevention can be made.

3.4.7. Constriction of blood supply

The arterial blood supply of the adult human sternum is only significantly derived from its periosteal plexus fed by segmental sternal branches of the internal mammary artery. When the periosteal arterial plexus is obliterated or isolated, no collateral blood supply is available to the cortical sternal bone [43].



Figure 3.13: Radiograph of whole injected sternochondral specimen. IMA – internal mammary artery, SEA – superior epigastric artery, MPA – Musculophrenic artery [43].

Internal mammary arteries (IMA) run along the length of the sternum supplying blood to the entire area and supply slender arteries which run between fascicles of the intercostal muscles. A perforating branch is given off at almost all of the first five intercostal spaces and present as much smaller vessels below the fifth space. This branch passes forward through internal intercostal muscle and supply overlying subcutaneous fat and skin.

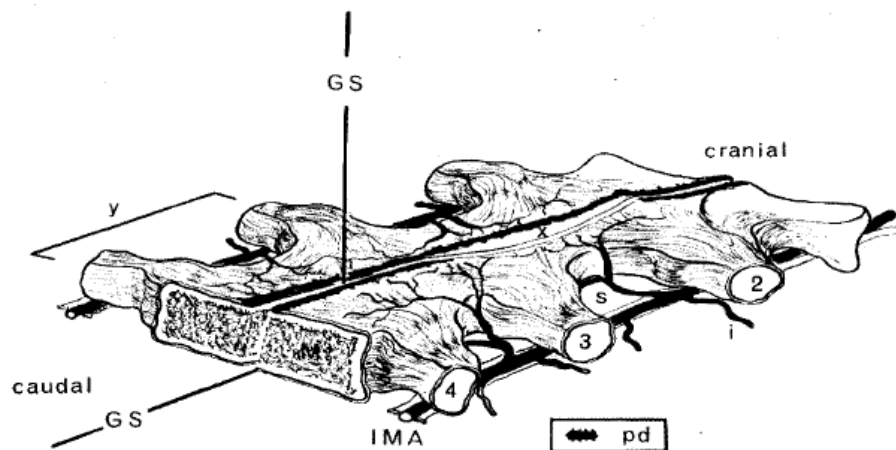


Figure 3.14: Simplified diagram of sternum, illustrating blood supply via Internal mammary arteries. IMA – internal mammary artery, s – sternal branch, GS – Gigli saw, pd – Periosteal diathermy [43].

Sternal branches exist in each interchondral space and pass medially toward the sternum from both sides. Each branch bifurcates into an upper and lower branch, running across the sternum. The upper and lower branches anastomose, or rejoin with each other, then again with their counterparts on the opposite side. Sternal branches run across the sternum parallel to bone and taper off very rapidly, disappearing within the peripheral marrow cavity.

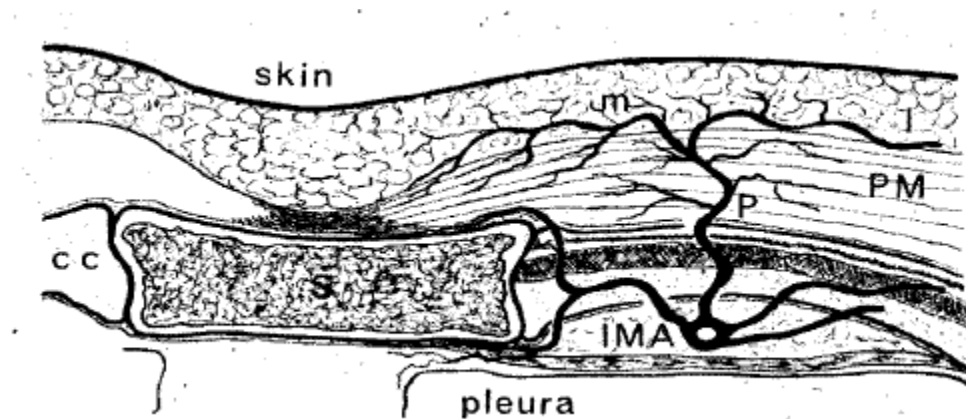


Figure 3.15: Idealized drawing of cross-sectional view of a sternum and its blood supply.
IMA – internal mammary artery, P – Perforating branch, m – Medial, S – Sternum, PM – Pectoralis major [43].

In a study conducted by Arnold, three peristernal tapes were secured circumferentially at the second, fourth, and sixth spaces. These peristernal tapes were found to interrupt the IMA on either side of the sternum and reduce vessel density in the adjoining periosteum [43]. Interruption of vasculature supplying the manubrium will undoubtedly decrease bone healing rates and may give way to numerous other complications. Contact area around the manubrium should be minimized to allow for optimal blood supply during healing. Compounded with the main shortcoming of the median sternotomy, insufficient rigidity of the construct, the result is an extremely difficult problem to fix. With current

technology, more wires must be added to achieve a stiffer construct, however this increased surface contact area around the manubrium will further interrupt its blood supply.

3.5. Models

All bench-top and in-vitro testing do not have been proven to provide any direct clinical correlation to how sternotomy closure devices will behave. These due diligence tests that provide data before clinical trials can provide insights to strengths and weaknesses of particular closure methods. While different modeling techniques have strengths and weaknesses, bench-top models are a necessary step in developing a viable sternotomy closure device.

3.5.1. Bone analogues

Cohen and Griffin conducted a study comparing three sternotomy closure techniques with the use of a synthesized polyurethane foam model [31]. In an effort to thoroughly evaluate the mechanical properties of the devices included in the study and minimize any inconsistency in the model, they used a bone analogue. They cited the large variability in bone density, sternal size, and sternal thickness when using cadaveric specimen. Also, animal models possess size and shape differences that cannot be ignored. Compressed foam has been developed to simulate cancellous and cortical bone [44].

3.5.2. Cadaveric models

Although supportive data from animal and bone analogues are beneficial in obtaining a good understanding of how a closure technique will behave, nothing can replace data from a human cadaveric study. Because of the unique shape of the human sternum, the use of a cadaver is the best way to assess the sternal closure stability. The configuration that a wire assumes around the sternum influences the way in which tension is applied to the sternum and thus affects stability [11].

3.5.3. Mathematical models

The finite element method is widely used for structural analysis problems in engineering research and practice. A numerical technique analyzing different sternal closure techniques was attempted by Bruhin *et al.* to investigate displacement and stress distribution of the sternum embedded in the human chest. Acquiring an in depth knowledge of the strain and stress distributions and force transfer was seen as an opportunity to determine the optimal sternal closure technique. The advantage of a numerical technique was that realistic conditions regarding traction forces at any point of the sternum could be mimicked quantitatively [45].

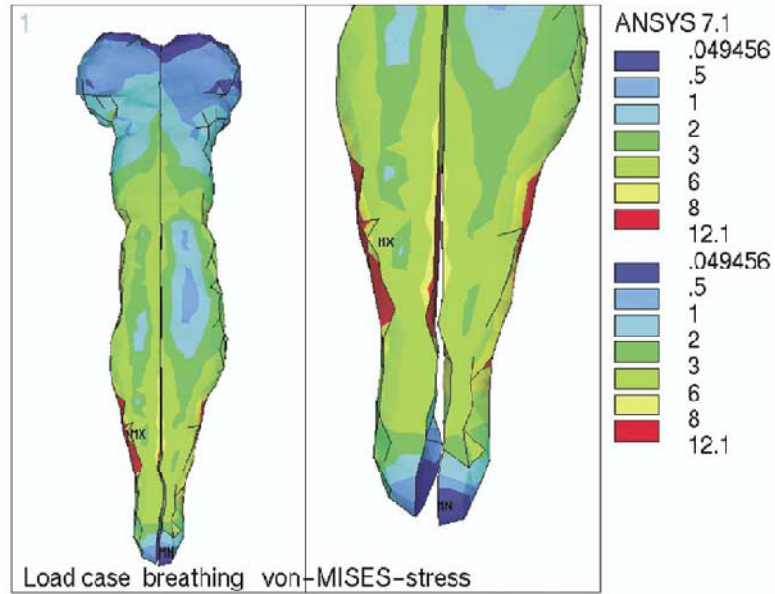


Figure 3.16: Example analysis of the human sternum by a numerical method [45].

3.5.4. Digital image correlation

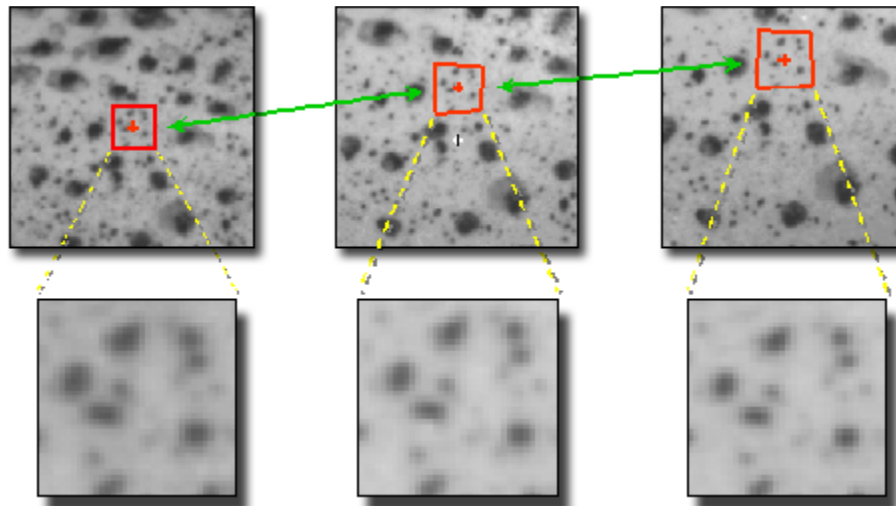


Figure 3.17: The digital image correlation system tracks the grey value pattern, or ‘speckle,’ in small subsets during deformation

Measuring deformation can be easily done by tracking the displacement of markers on the surface of the sample. Each marker is treated as a node with an associate finite element. The difference in position for each marker defines a displacement vector.

Digital image correlation is a well developed technique widely used for other areas of engineering research[46-48]. To enhance the resolution of the technique, a “speckle” can

be applied to increase the amount of points identified by the computer. Limited applications of biomechanics have been attempted, such as, the analysis bone surfaces and soft tissue.

4. Objectives

The objective of this study is to compare the performance of the Biomet Microfixation (Jacksonville, Florida) Sternalock plating system and an established peristernal wire closure technique in a mechanical system. Results of this study will evaluate whether this rigid fixation technique is significantly superior to mainstream methods and worth further evaluation and implementation.

The prevalence of healing complications and the high rate of mortality associated with these problems continue to harm up to 47% of patients undergoing median sternotomies each year [2]. These healing complications are directly linked to closure techniques that do not meet necessary stiffness requirements. Therefore, the most appropriate way to fix this problem is to do our best to prevent all complications as best as we can – a more stiff closure technique.

Specific Aim: evaluate the relative mechanical performance of the Sternalock plating system when compared with an established peristernal wire closure techniques when applied to a median sternotomy.

Hypothesis: Biomet Microfixation's Sternalock plating system will provide a more stiff structure with more strength to separated sternal halves when compared to peristernal wire closure techniques.

5. Test Methods

Forty-two fresh human cadaveric sterna were obtained from Biomet Microfixation in Jacksonville, Florida. Each sternum sample was accompanied by CT scans, a seven-digit specimen number, and the age and sex of the donor. Each sternum was divided along the midline and closed with peristernal wires or Sternalock plates, consistent with a sternotomy procedure. Sterna were received surgically divided and closure technique applied and stored at -20° Celsius. Samples were separated into the three groups of closure techniques and numbered from 1-42.

Figure 5.1 shows the servopneumatic materials testing system (Bose SmartTest SP, Eden Prairie, MN) used for this study. A constant displacement of 25 mm/min was applied by using WinTest Digital Control Electronics and WinTest Software (Bose Corporation, Minnetonka, MN).

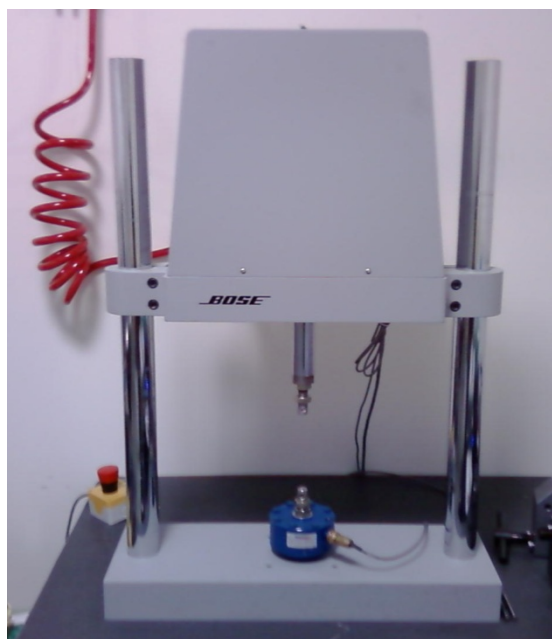


Figure 5.1: The test frame used in this study (Bose SmartTest SP, Eden Prairie, MN).

The study utilized a human cadaveric sternum to model the biomechanical behavior under stress. Griffin studied the efficacy of the use of a polyurethane foam bone analogue in modeling cancellous bone to provide reproducibility in testing [31]. However, a human cadaveric model is uniquely suited to provide a clinical representation of biomechanical behavior, due to the overwhelming complexity of the biological composite structure of the thorax. Variability in bone density, sternal size, cortical bone thickness, and sternal thickness experienced in clinical settings can be accounted for with the use of a human cadaveric model.

42 fresh cadaver models were divided into three test groups. Group A employed a mainstream wire closure technique. Group B and group C utilized the Sternalock plating technique (Biomet Microfixation, Jacksonville Florida). Figure 5.2a shows an example of a group A sternum, closed with three peristernal wires at the manubrium and five trans-sternal wires along the body of the sterna. Group B was characterized by 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 (Figure 5.2b). Group C sterna were closed with a “Box” plate and 2 wires at the manubrium and two “X” plates at the sternum body with two wires at the xiphoid process, shown in Figure 5.2c.

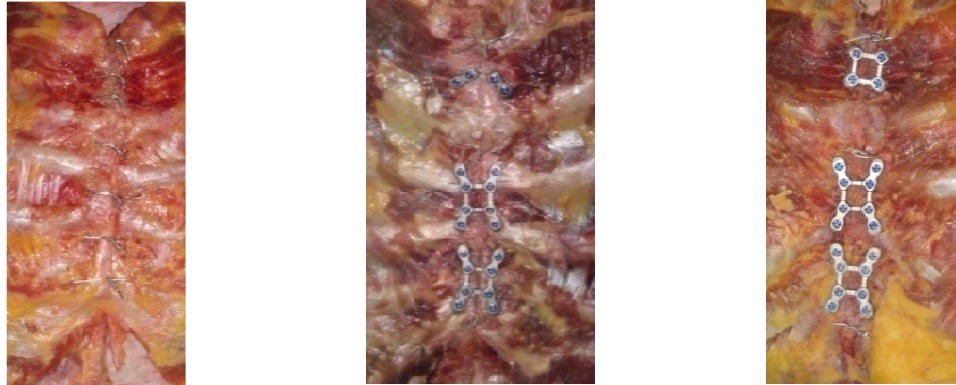


Figure 5.2: Pictures of the three closure techniques used in the study. a) peristernal wires, b) Sternalock with L-plate, c) Sternalock with box-plate.

5.1. Sample Preparation

Samples were removed from the -20°C deep freeze a day before testing and placed into a standard freezer. The night prior to testing, the specimen were allowed to completely thaw in a refrigerator. Then, several hours prior to testing, samples were placed in a room-temperature lab.

When the specimen reached room-temperature it was dried with a paper towel and a coat of white shoe polish (Meltonian Boot & Shoe Cream polish) was applied in a 3 inch area on either side of the incision line. This coat was allowed to dry for 20minutes. A “speckle” pattern was then applied over the white area-of-interest by sprinkling black ink (Sanford: Higgins Black Magic) and allowed to dry for 30 minutes (Figure 5.3). The desired size of black-ink “speckles” were 1 millimeter in diameter. The combination of the white polish and black waterproof ink was designed to provide added contrast to aid in data collection to increase the resolution of the digital image correlation system.



Figure 5.3: The cadaveric sternum must be coated with a special high-contrast "speckle" to record an acceptable amount of data.

A polish was chosen for this application because it demonstrated good adhesion qualities with the fresh cadaver model and did not crack during high mechanical loads, characterized by large displacement values. The black waterproof drawing ink was used in combination with the shoe wax because it produced the most opacity after drying, and subsequently a higher contrast.

5.2. Test Set-up

To grip the sterna, a set of aluminum clamps were constructed. These clamps were machined from aluminum blocks with tapped holes that held an array of 65mm length cranial screws, designed to firmly hold tissue and bone to withstand applied directional forces. Larger bolts were passed through a set of analogous clearance holes on either

sides of the clamp to hold the clamp in place over the sample. ¼ inch bolts were used to secure the clamps to the mechanical test frame. The sternotomy line being parallel to the clamp plates was verified prior to each test, as well as top plate parallel to the bottom plate.

Three sets of test fixtures were used, each designed to apply load in a different load on the construct. Figure 5.6a shows the intended configuration to apply lateral distraction, Figure 5.6b – longitudinal shear, and Figure 5.5c – transverse shear.

Alignment of the cadaver model with the test fixture and subsequent application of force is a highly emphasized parameter. The midline of the sternum must be parallel to the spiked clamps to achieve uniform application of force along the entire length of the osteotomy site. The midline and clamps must also be perpendicular to the displacement of the test frame. The bulk head of the test frame should also intersect the sternum with an approximately equal length on either side to minimize any rotational effects during testing. Therefore, an alignment tool was made to aid in loading the sternum onto spiked clamps that were designed to firmly hold ribs and flesh during mechanical testing. This alignment tool regulated the distance at which clamps gripped the sternum from the midline. The tool also ensured that the clamps gripped the sample parallel to the midline in every case. This was further adjusted as needed to ensure that alignment was achieved for every test.

The alignment tool was placed on a table-top and one side of each of the spiked clamps was positioned on top of the tool (Figure 5.4). A sternum was then placed –on top of the open clamps with the posterior side of the sternum facing up. From this view, it could be verified that the sternotomy line was parallel to the clamps. The matching second side of each spiked clamps where then positioned using the tool, and tightened around the sternum. Each screw located on the clamps was then tightened by hand to ensure that a firm grip on the ribs was achieved.

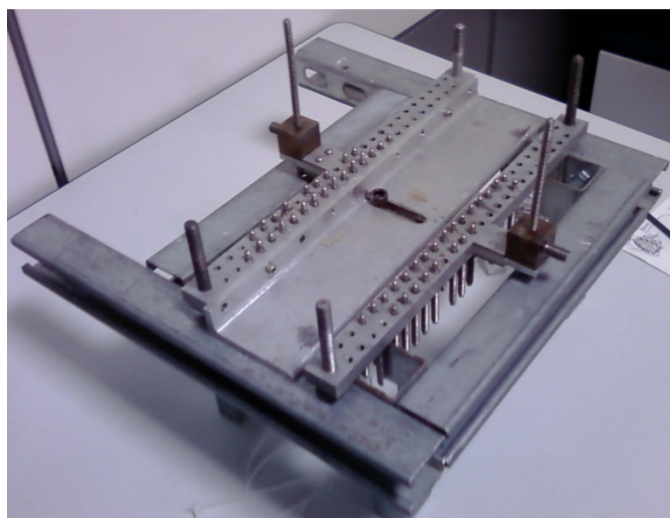


Figure 5.4: Picture of the alignment tool designed for this project with one side of the spiked clamps in position.

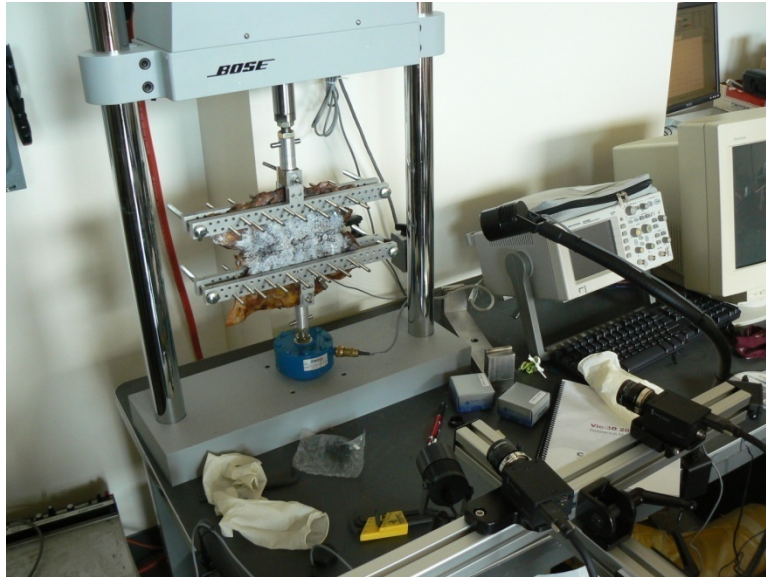


Figure 5.5: A picture of the test set-up used. A load frame transfers tension to the sternal construct via a set of spiked clamps. An array of cameras record data throughout the test.

The specimen was properly loaded inside the clamps with appropriate accessories for each differing test and attaching the clamps to the load frame, shown in Figure 5.5. Data was captured by Vic-3D (Correlated Solutions Inc, Columbia, SC), a digital image correlation system. This system utilized two optical cameras along with 3-D correlation algorithms to provide full-field 3-D shape, displacement and strain data for mechanical testing.

5.3. Mechanical Loading

The cadaver model was stressed in three different modes to rigorously test the biomechanical properties of the sternotomy closure technique: lateral distraction, longitudinal shear, and transverse shear. In each of these directions, a monotonic materials test was used in this application, pulling the construct at a constant 25 mm/min until failure. Failure is defined as 2mm of displacement at the midline, fracture of the sternum, fracture of ribs, or tearing of intercostals muscles resulting in loss of grip.

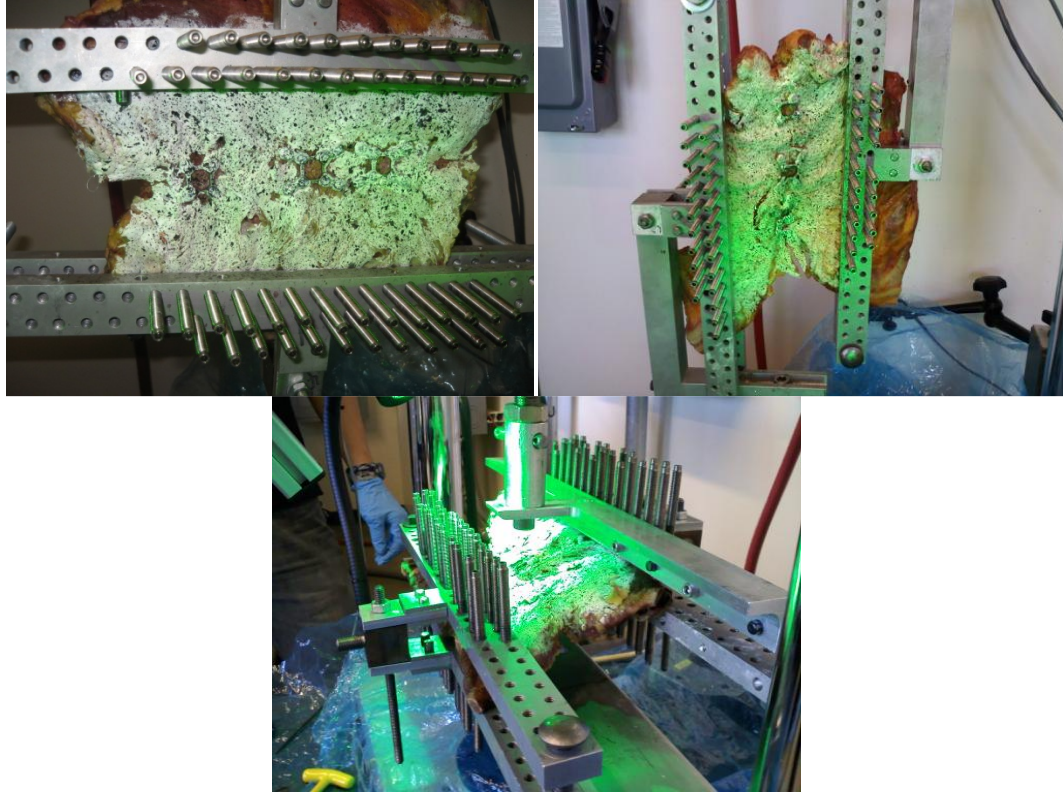


Figure 5.6: Photographs of each direction tested in the study. Starting from top left figure – a) lateral distraction, b) rostro-caudal shear, c) anterior-posterior shear.

5.4. Digital Texture Correlation

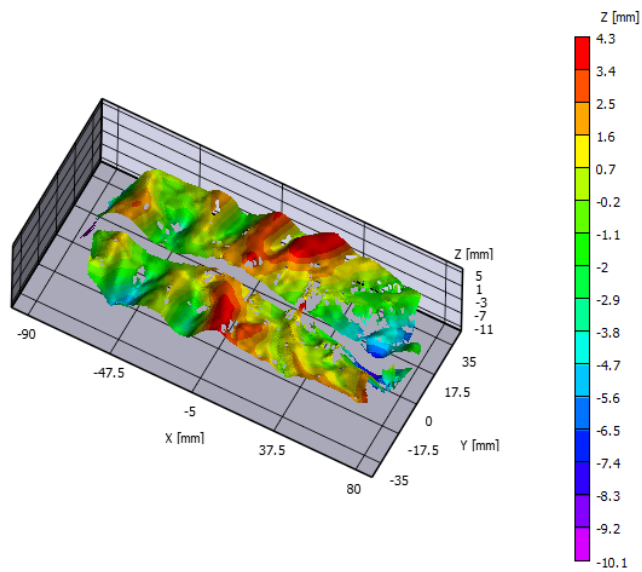


Figure 5.7: An example 3-dimensional shape constructed by Vic-3D using an array of optical cameras.

Vic-3D (Correlated Solutions Inc, Columbia, SC), a Digital Image Correlation system was used to capture images at 3 frames per second of the sternum during mechanical loading. The system utilized two cameras placed at approximately 10 degrees to the left and right of the sample. The 3-D correlation algorithms processed the images to provide full-field 3-D shape, displacement and strain data of the cadaver construct during mechanical testing, shown by Figure 5.7. The resulting displacement pattern is analogous to a finite element contour plot of displacements, Lagrange Strain, or velocity.

The “speckle” pattern that was previously applied consisted of a non-shine shoe-wax and small drops of waterproof black ink. This “speckle” pattern provides assistance to the digital image correlation software by providing the extra contrast needed to track pixel displacement during testing.

For group A, two “areas-of-interest” were established in Vic-3D, one for each sternal half around the speckled area and separated along the incision line. Figure 5.8 shows examples of a sternum closed with peristernal wires stressed in both lateral distraction and longitudinal shear with coloration for strain rates, red indicates high displacement. For group B and group C, an “area-of-interest” was also drawn for each of the sternum halves, but also around the titanium plates. This was done to instruct the texture correlation software that there are two separate solid materials under stress.

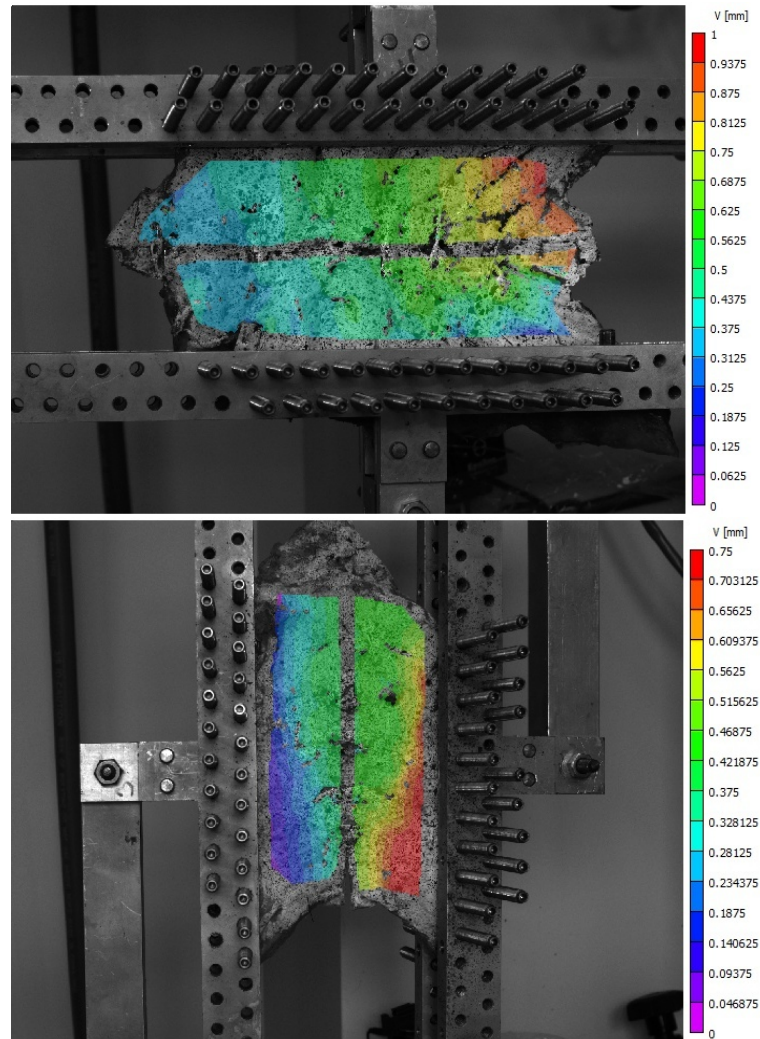


Figure 5.8: Example colorations of stress concentrations in a) lateral distraction and b) longitudinal shear.

The texture correlation system captured images at an interval of 0.3 seconds, or 3.33 frames per second. Average rate of vertical displacement between the sternal halves was found on either side of the midline incision. With this data, a force by displacement graph was constructed for each area between titanium plates.

A rectangle was drawn that included the length of the sternal body, approximately 5 millimeters away from the midline on either side, shown in Figure 5.9 and Figure 5.10.

Inside this rectangle, the vertical movement of each pixel inside this defined rectangle is averaged at each point in time. The manubrium and xiphoid regions were ignored due to issues of reproducibility. The behavior of the manubrium always showed zero displacement at the midline, and therefore, an infinite stiffness, before failure was observed in the construct. The xiphoid region universally showed displacement at the midline first. However, the steel wire placed in this area to further stabilize the xiphoid in sterna closed with Sternalock plates caused cutting of bone and subsequent erratic behavior.

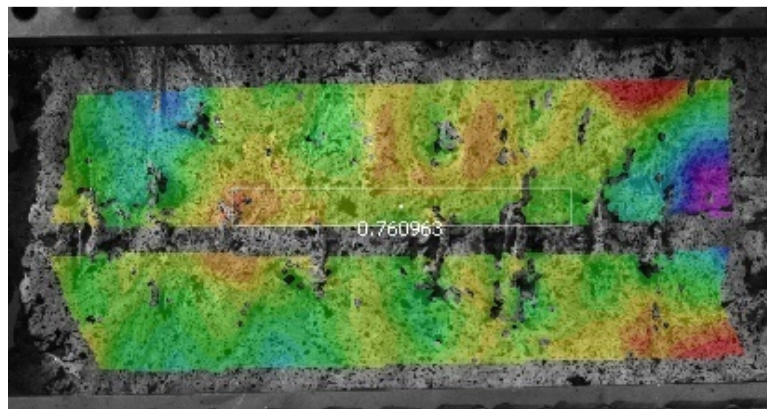


Figure 5.9: A rectangle is drawn on the top half of the sternum indicating the area that data was extracted from.

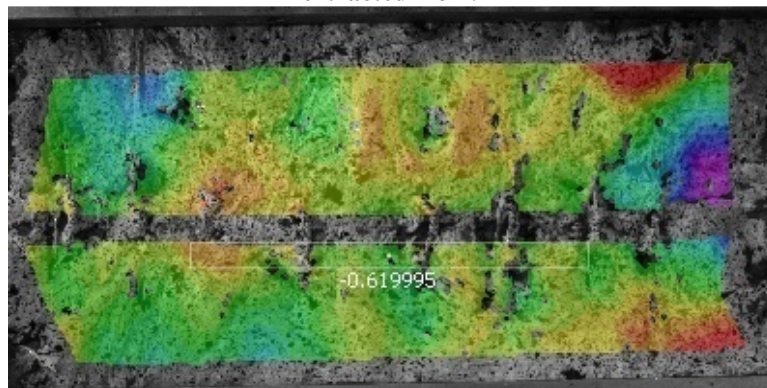


Figure 5.10: A rectangle is drawn on the bottom half of the sternum indicating the area that data was extracted from.

5.5. Data Extraction

Samples were stressed monotonically in one of three directions until they broke using a servopneumatic testing system. Data collected during this test constructs a Force vs. Displacement graph similar to Figure 5.11.

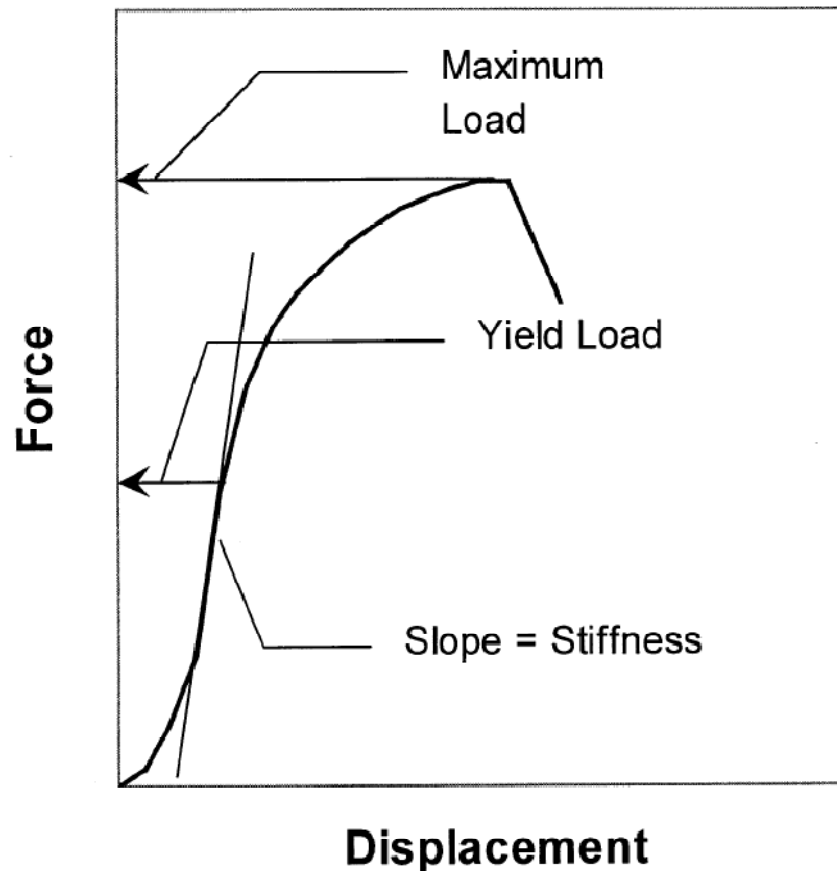


Figure 5.11: Load–displacement curve and definitions of terms. Stiffness is the slope of the linear portion of the curve. The yield load is the force applied that causes the curve to become nonlinear. Above this point of the curve, displacement is at least partially irreversible after removing the force. Maximum load is the force required to cause catastrophic failure of the system.

These unidirectional tests evaluated the biomechanical properties in lateral distraction, longitudinal shear, or transverse shear. From the force vs. displacement graph constructed by the data output, values for construct stiffness, yield load, and ultimate load

could be calculated. With these values, the displacement at yield load and post-yield displacement could be found from the given data points.

Stiffness is the resistance to elastic deformation when force is applied. The upward linear portion of the graph is characterized by elastic deformation, in other words, the construct will return to its original state when the applied force is removed. The slope of this linear portion is referred to as Young's Modulus or modulus of elasticity and is the measure of stiffness of a material or construct, more specifically the ratio of stress to strain during elastic deformation. This equation is in the form of $y = mx + b$, with "m" representing the slope and stiffness of the construct. An algorithm was developed to calculate the modulus of elasticity. 60 consecutive data points were isolated within the upward linear section of the graph starting at point 1. If the linear trend fit to these points did not have an R^2 value over 0.96, the next set of 60 consecutive data points were taken with an increment of 1 data point, in other words, points 2-62. A negative slope could not be accepted, and a negative stiffness cannot exist. If a negative slope was found in a region of the sternum, the stiffness was taken to be infinite and quantified as zero displacement at that region. This method ensured that the largest and most linear slope was chosen for each region.

The yield load is the stress capacity of the construct before permanent damage is inflicted to the sternum or device. This is also known as the stress limit associated with elastic deformation, or the ability to return to the original state. Elastic deformation is characterized by the upward linear section of the force vs. displacement graph. To find

the yield load, a secant slope method was used. An interval of 60 data points were used to best represent linear portion to calculate the modulus of elasticity. Multiplying this previously found slope or stiffness by 0.95, a line was then extrapolated over the force vs. displacement graph. The point of intersection between the two lines defined as departure from linearity and taken to be the yield load for the construct of divided sternum and closure technique.

The ultimate load is absolute maximum load that can be sustained without failure of the construct. In our model, the ultimate load refers to the load experienced by the construct immediately before catastrophic failure. Failure can be characterized by breakage of the ribs, tearing of intercostal muscles, wire fracture, plate fracture, or loss of screw fixation. Also, failure can occur at the area the clamp gripped the sternum, in the ribs, where the ribs meet the sternum body, and on the sternum body.

Post-yield displacement is evidence of wires cutting into the cadaveric sternum model, or other damage to bone. This leads to sterna malunion and nonunion of the sternotomy and is not a desirable outcome. Post-yield displacement was found by recording the displacement at the midline when the yield and ultimate loads were met; these values were subtracted to quantify how much more the construct in-elastically displaced before catastrophic failure.

5.6. Construct Analysis

As the sternum is pulled upward, the sternal halves displace at different rates, depending on the construct stiffness. If the closure is not stiff enough, the upper half of the sternum will displace at a rate higher than the corresponding half and a gap at the sternotomy line can be observed. With an exceptionally stiff construct, there will be no relative displacement immediately surrounding the incision line and no gap can be observed. The closure technique keeps the sternal halves together and moves in union. Overall, the specimen is still displacing at the same rate, but that strain is transferred to ribs and fascia. However, our concern is the device and its interaction with the specimen.

Relative displacement between the sternal halves is the desired output, and what we use in our force vs. displacement graph. This is calculated by first analyzing the vertical displacement or V (mm) of the top sternal half and subtracting that by the vertical displacement of the lower sternal half. These vertical displacement values were analyzed for every frame throughout the entirety of the test in real-time.

Instead of picking one point on the top half and one point on the bottom half and tracking the vertical displacement of those points throughout the duration of the test, we took the average vertical displacement inside a defined area on both sides of the sternum. After capturing the images taken during the test, the digital texture correlation software has the capability of defining these areas in the form of rectangles, and extracting data pertaining to the vertical displacement within the defined area. The resulting .csv file with the

extracted values contains the image-frame number and an associated vertical displacement value.

For Group A, consisting of sternum closed by pericostal wires, two rectangles were drawn to include the immediate area around the entire length of the incision line. One rectangle included the top half, and another incorporated the bottom half. The difference in the two values resulted in the total vertical displacement around the sternotomy line.

Group B was characterized by sternum closed by Biomet SternaLock plates. Because of the size and complex geometry of the titanium plates, the texture correlation software was unable to gather data on the plates or the immediate area surrounding them. Small rectangular areas were defined between each plate and on the ends for the top and bottom half of the sternum, totally four sections for each sternal half. Analysis of vertical displacement data extracted from these four rectangular areas resulted in relative vertical displacement values for each of the four sections. Each of these vertical displacements was graphed on a force vs. displacement graph.

5.7. Statistical Analysis

A total of 42 cadaveric models were tested, approximately 5 models per group for each direction of force applied on the construct, shown in table 1. Each biomechanical parameter (stiffness, yield load, and maximum load) were evaluated using an ANOVA model (Minitab, v15.2, State College, PA). Each of the biomechanical parameters was modeled as dependent variables, with fixation method, gender, and first order interaction

as factors. Age was used as a covariate. Tukey post-hoc testing was performed and strong statistical evidence was reported when $p < 0.05$.

Table 5.1: Test Design for the overall study.

#	Donor Code	Group	Age	Sex	Test Method
1	C080467	B	84	F	Lateral Distraction
2	C080516	A	70	M	Lateral Distraction
3	S080889	C	61	M	Lateral Distraction
4	S080883	C	64	F	Lateral Distraction
5	S080811	B	65	F	Lateral Distraction
6	C080621	B	63	F	Lateral Distraction
7	S080849	A	73	M	Lateral Distraction
8	C080571	B	59	M	Lateral Distraction
9	S080874	A	73	F	Lateral Distraction
10	S080963	B	65	M	Lateral Distraction
11	C080547	C	64	F	Lateral Distraction
12	S080826	A	82	M	Lateral Distraction
13	C080684	B	59	F	Lateral Distraction
14	S082064	C	68	M	Lateral Distraction
15	C080542	C	88	F	Lateral Distraction
16	S080719	A	69	F	Longitudinal Shear
17	S080900	B	65	M	Longitudinal Shear
18	C080189	B	65	M	Longitudinal Shear
19	S080782	A	81	F	Longitudinal Shear
20	S080902	A	79	F	Longitudinal Shear
21	S080882	B	82	F	Longitudinal Shear
22	S080938	C	67	M	Longitudinal Shear
23	S080879	C	70	F	Longitudinal Shear
24	S081057	C	72	F	Longitudinal Shear
25	C080709	A	70	F	Longitudinal Shear
26	S080129	B	62	F	Longitudinal Shear
27	S080988	A		F	Longitudinal Shear
28	C080570	B	70	F	Longitudinal Shear
29	S080535	C	81	M	Longitudinal Shear
30	S080923	C	84	M	Longitudinal Shear
31	S080850	A	76	M	Transverse Shear
32	S080450	A	65	F	Transverse Shear
33	C080582	B	80	F	Transverse Shear
34	C080526	A	82	M	Transverse Shear
35	S081013	B	68	M	Transverse Shear
36	S081047	C	69	M	Transverse Shear
37	S080029	B	50	F	Transverse Shear
38	C060260	B	77	F	Transverse Shear
39	S081007	A	89	M	Transverse Shear
40	S080950	A	79	F	Transverse Shear
41	C080345	B	85	F	Transverse Shear
42	S060167	C	80	M	Transverse Shear

6. Results

Each of the desired biomechanical parameters will be evaluated separately for each of the methods. Each of the main factor plots will include an asterisk if the differences are significant. Interaction plots will be shown to elucidate trends, even if the interaction is not significant. In all of the models, age is not a significant factor. The average age of cadaveric samples was calculated to be 72 years with a standard deviation of 9. 43% of all the specimen tested are male.

6.1. Lateral Distraction

Table 6.1: Description of the sample group tested in lateral distraction with values for each biomechanical property.

#	Donor Code	Group	Age	Sex	Stiffness	Yield Load	Ultimate Load	Post-Yield Disp
1	C080516	A	70	M	927.801	378.401	838.020	0.412
4	S080897	A	67	M	255.660	262.000	309.000	1.957
7	S080849	A	73	M	612.116	493.012	691.694	0.868
12	S080826	A	82	M	453.284	333.094	435.287	0.741
9	S080874	A	73	F	532.608	207.072	606.784	1.341
8	C080571	B	59	M	1515.230	1020.005	1082.848	0.099
10	S080963	B	65	M	3671.435	638.667	736.665	0.099
5	S080811	B	65	F	3181.039	228.047	617.691	0.983
6	C080621	B	63	F	4609.300	526.070	612.825	0.005
13	C080684	B	59	F	2160.049	546.039	696.224	0.130
2	S080889	C	61	M	3062.800	730.000	816.000	0.000
14	S082064	C	68	M	4840.485	550.737	633.297	0.008
3	S080883	C	64	F	680.077	168.393	436.462	1.200
11	C080547	C	64	F	650.084	492.760	656.454	0.247
15	C080542	C	88	F	7200.000	510.000	553.000	0.000

Testing in lateral distraction, 5 samples were used from each sternal-closure technique.

The average age of this set of cadaveric sternum is 68 years, a total of 8 males and 7 females were tested. 4 males and 1 female closed with peristernal wires, 2 males and 3

females closed with Sternalock using an “L” plate at the manubrium, and 2 males and 3 females closed with Sternalock using a box-plate to stabilize the manubrium. The use of only 1 female specimen closed with peristernal wires was identified as a potential statistical weakness of the model.

6.1.1. Stiffness

Table 6.2: Mean stiffness values for each sternal-closure technique tested in lateral distraction, separated by gender.

Stiffness				
Group	Averages		Standard Dev	
	M	F	M	F
A	562.215	366.627	284.010	0.000
B	2593.332	3316.796	1524.668	1230.256
C	3951.642	2843.387	1257.013	3772.967

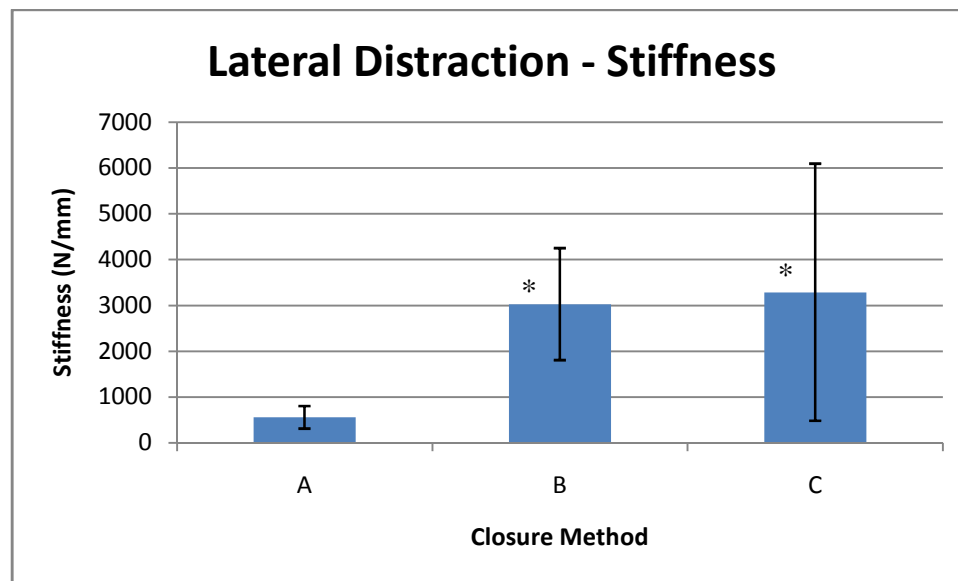


Figure 6.1: Rigidity (stiffness) of the various fixation methods tested in lateral distraction. Data denoted by an asterisk are significant ($p < 0.05$). Columns denote mean values. Stiffness is measured in newtons of force per millimeter displacement. Error bars indicate one standard deviation.

Closure methods B and C were both found to be statistically significant when compared to group A ($p=0.002$ and $p=0.004$, respectively). Meaning that both plate configurations

were significantly stiffer when compared to sterna closed by peristernal wires. Sternalock systems using L-plates were found to have a 2471 N/mm higher mean stiffness of over peristernal wires while plate systems using box-plates had 2730 N/mm more than wires. Sternalock constructs were approximately six times stiffer than wire closures.

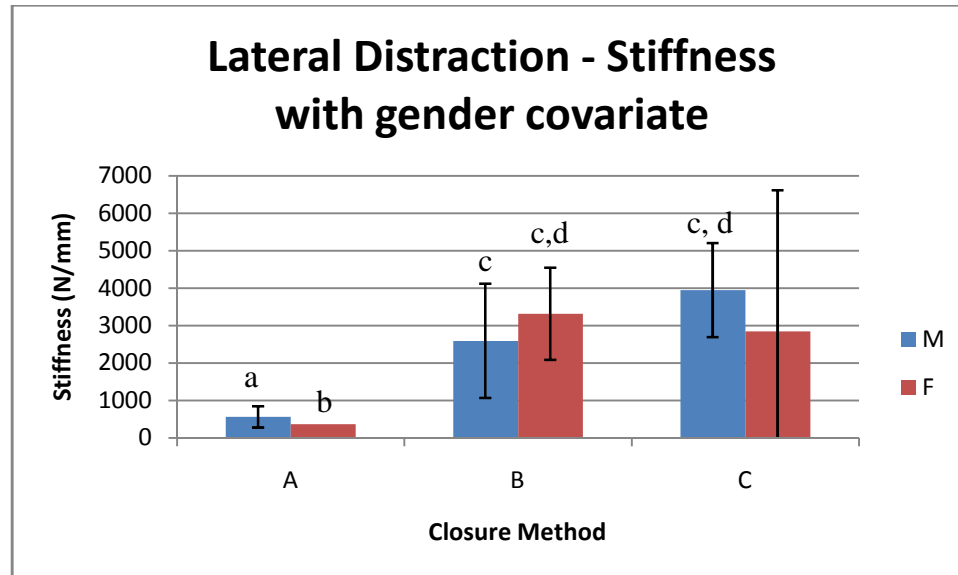


Figure 6.2: Rigidity (stiffness) of the various fixation methods tested in lateral distraction separated by gender. Columns denote mean values. Stiffness is measured in newtons of force per millimeter displacement. Error bars indicate one standard deviation. Columns denoted with letter 'c' are statistically different ($p < 0.05$) than columns denoted with the letter 'a,' likewise 'b' is different than 'd.'

When analyzed further with gender considered as a covariate, it was found that males from group B ($p=0.03$), females from group B ($p=0.008$) and males from group C ($p=0.009$) were statistically different when compared to female group A sterna; females from group C were found to be almost significant ($p=0.12$). When compared to male group A sterna, females from group B, and males from group C were found to be significantly different ($p=0.04$ in both examples); males from group B were almost significant ($p=0.11$). No difference was found between any of the sternum closed with Sternalock devices when compared to each other. Females in group C had a very high

amount of variability due to a combination of unusually high and low outliers. This explains the higher variability seen in all group C sternum in Figure 6.2.

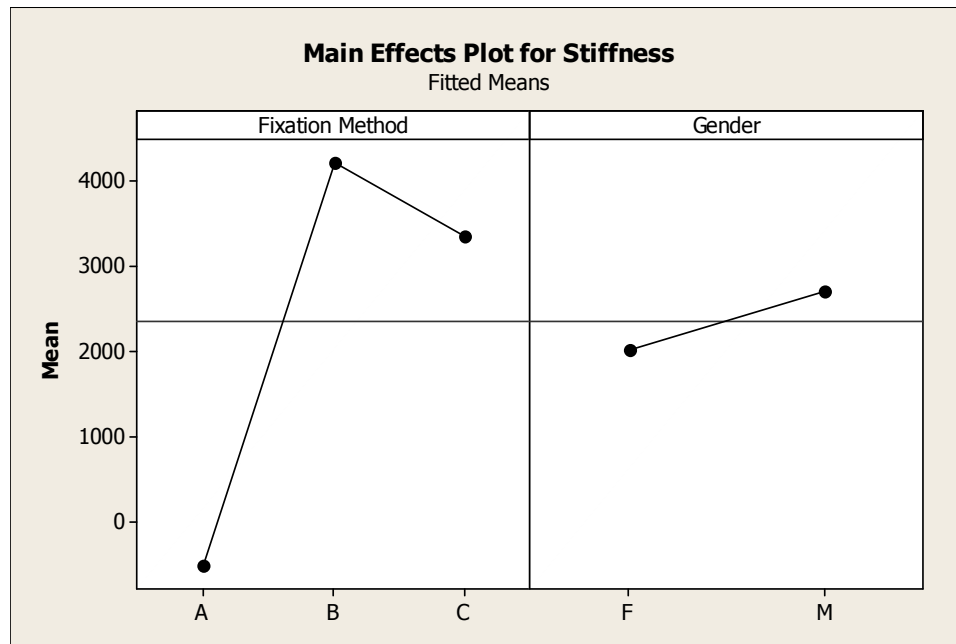


Figure 6.3: Side by side comparison plot of main effects with regards to construct stiffness tested in lateral distraction.

Figure 6.3 illustrates that though gender had an effect on the data, fixation method had bar far the most dramatic effect on stiffness. Both groups B and C sterna show dramatically higher values of stiffness. Gender exhibited a limited influence on the constructs stiffness.



Figure 6.4: Interaction plot describing the effect of gender on each construct in regards to stiffness tested in lateral distraction.

Due to much smaller values, very little change in stiffness was observed (Figure 6.4) when comparing group A sternum. A substantially higher stiffness in group C males versus females is found during this test and proves to be a trend among all biomechanical characteristics. In an unusual case, group B sternum showed a slight but statistically insignificant decrease in males versus females.

6.1.2. Yield Load

Table 6.3: Mean yield values for each sternal-closure technique tested in lateral distraction, separated by gender.

Group	Yield Load			
	Averages		Standard Dev	
	M	F	M	F
A	366.627	207.072	96.925	0.000
B	829.336	433.385	269.646	178.108
C	640.369	390.384	126.758	192.444

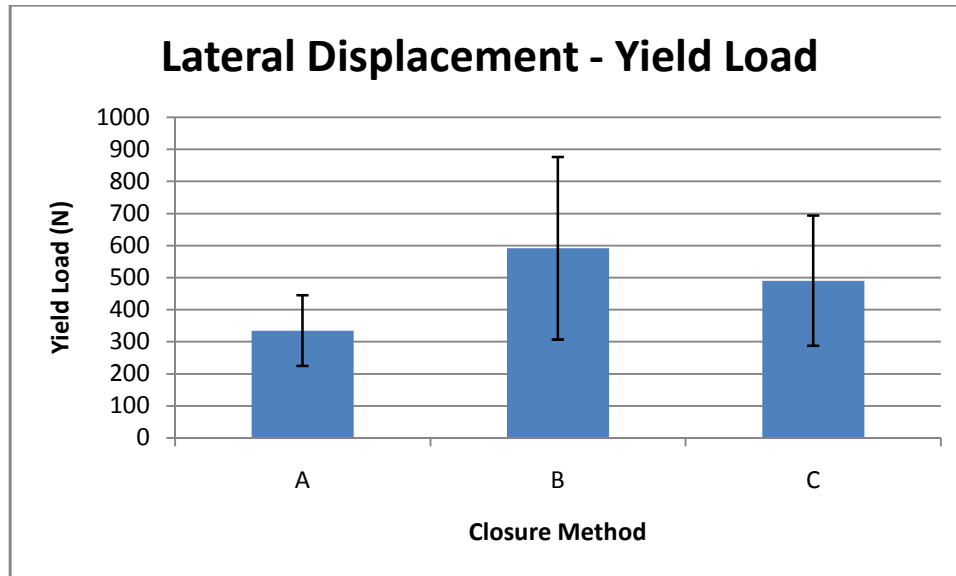


Figure 6.5: Yield strength of the various fixation methods tested in lateral distraction. Columns denote mean values. Yield strength is measured in newtons of force. Error bars indicate one standard deviation.

Closure methods B and C both consistently displayed higher yield loads than group A. This trend did not prove to be statistically significant ($p=0.10$ and $p=0.24$, respectively) when compared with group A, but it showed a trend towards higher yield strengths for sternum closed with Sternalock devices. Group B showed 257 N higher mean yield strength when compared to group A specimen, group C was observed to have a higher mean of 156 N. More indicative results may be revealed from testing larger sample sizes.

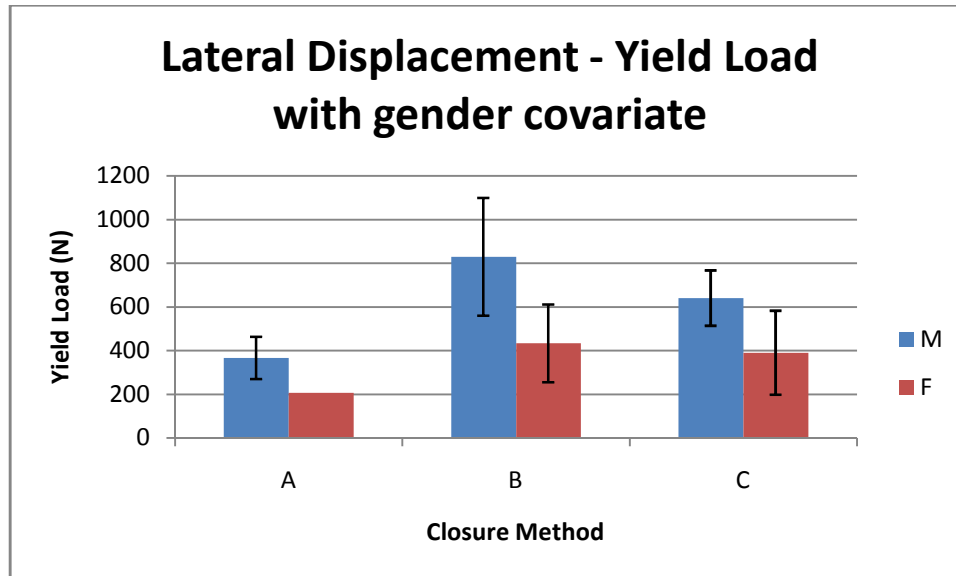


Figure 6.6: Yield strength of the various fixation methods tested in lateral distraction separated by gender. Columns denote mean values. Yield strength is measured in newtons of force. Error bars indicate one standard deviation.

No statistically significant differences were found between any closure methods. Group B males were found to be almost statistically different ($p=0.17$ in both cases) when compared to both males and females from group A. From this graph, we can begin to see a trend in the model that male specimen exhibited larger yield strengths than females. This may provide an underlying cause for lower yield strengths and a possible link between gender and yield strength.

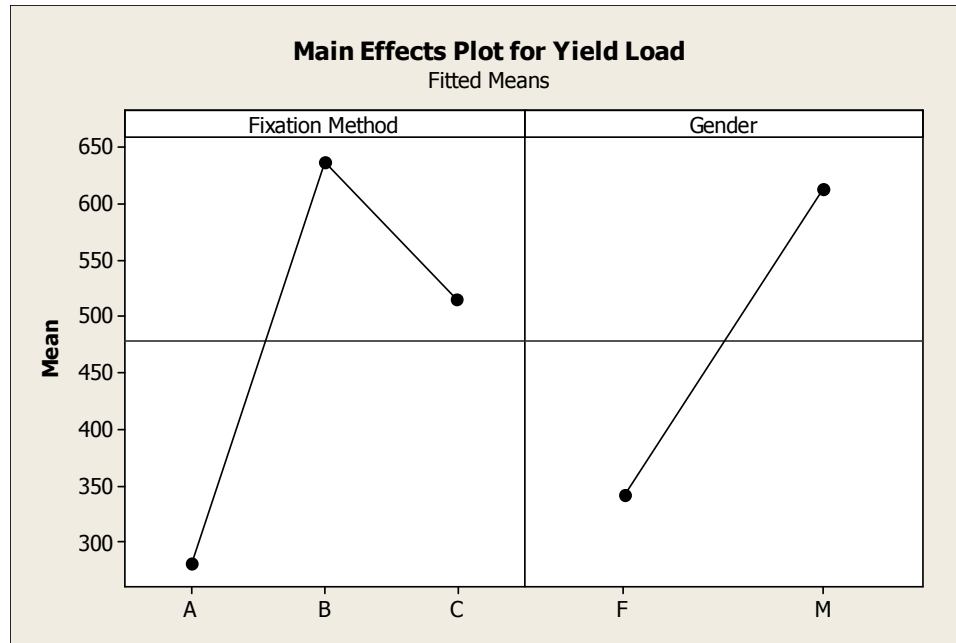


Figure 6.7: Side by side comparison plot of main effects with regards to yield strength tested in lateral distraction.

Figure 6.7 illustrates the effect of fixation method and gender on the mean stiffness of the sternal construct. Much like its effect on stiffness, fixation method contributes a primary influence on construct yield strength. Gender has a more pronounced effect on yield strength than it did on the stiffness of the model, showing higher strength values for males than females. Although not found to be statistically significant, the figure illustrates a possible trend in the data.

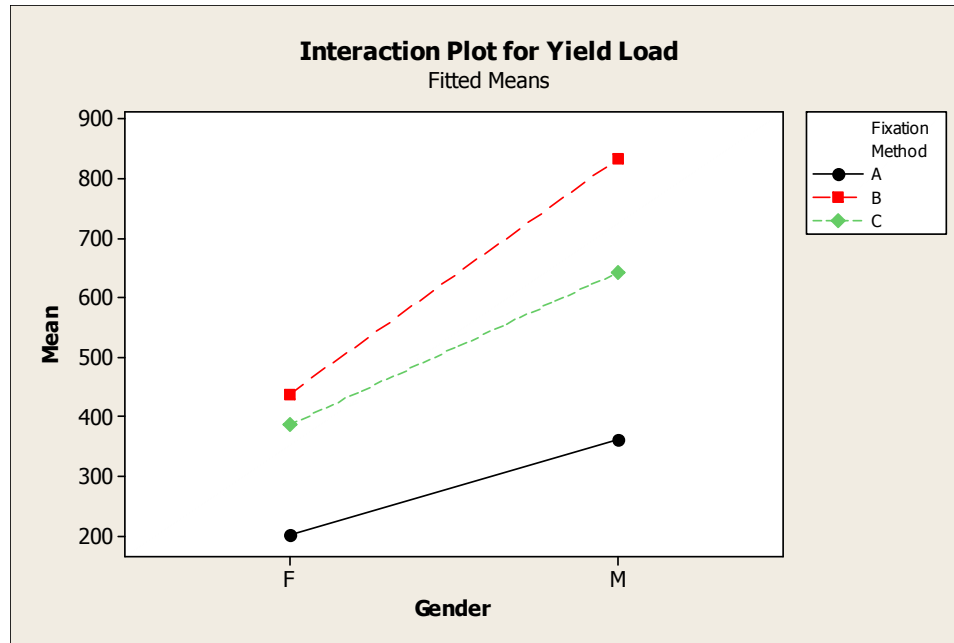


Figure 6.8: Interaction plot describing the effect of gender on each construct in regards to yield strength tested in lateral distraction.

Considerable effects of gender are found to influence yield strength of sternal constructs. Figure 6.8 breaks down how gender affects each sternal closure technique. These affects are larger in sternum closed with Sternalock device than models closed with peristernal wires, similar to effects on stiffness (Figure 6.4). In all closure methods, closures of male cadavers exhibited a higher tolerance of load before plastically deforming.

6.1.3. Maximum Load

Table 6.4: Mean maximum-load values for each sternal-closure technique tested in lateral distraction, separated by gender.

Group	Ultimate Load			
	Averages		Standard Dev	
	M	F	M	F
A	568.500	606.784	240.072	0.000
B	909.756	642.247	244.788	46.809
C	724.649	548.639	129.190	110.061

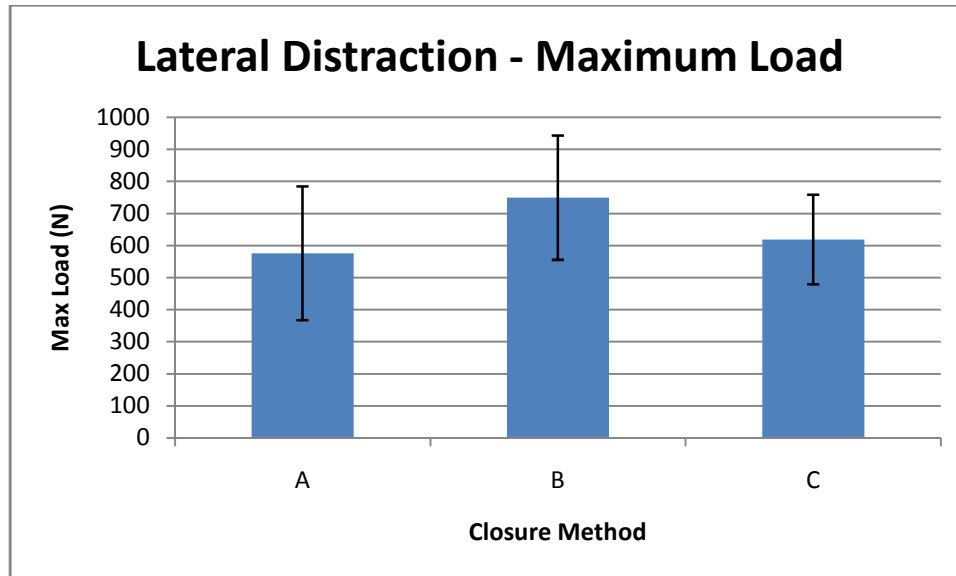


Figure 6.9: Maximum strength of the various fixation methods tested in lateral distraction. Columns denote mean values. Maximum strength is measured in newtons of force. Error bars indicate one standard deviation.

No differences were statistically found between the maximum strengths of the different closure methods tested. Very slight changes between the different test groups can be observed in Figure 6.9. Group C sterna had a mean maximum load only 43 N higher than group A while group B showed a mean 173 N higher. Although differences were found to be small and insignificant, this fits an overall model illustrating the advantages of Sternalock plates over conventional peristernal wire closures.

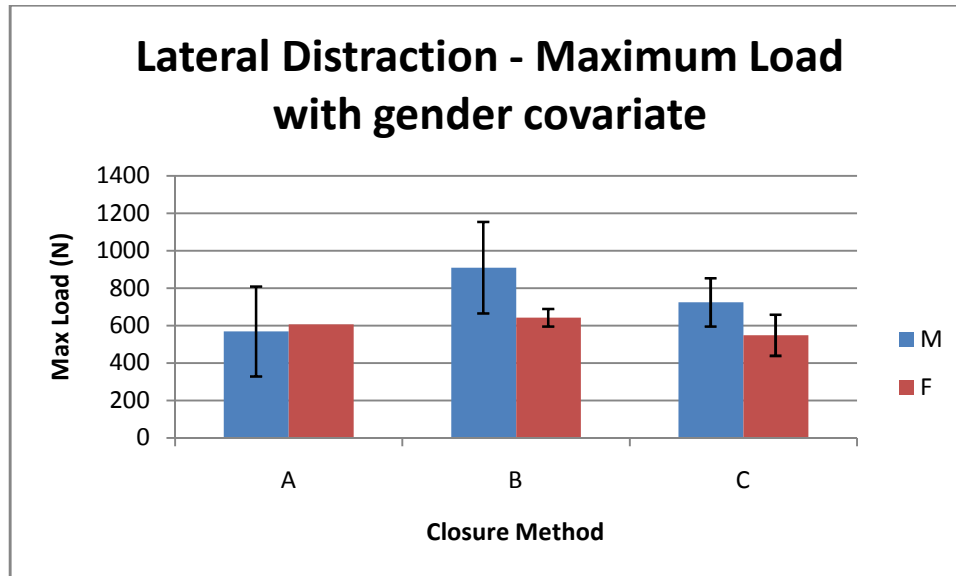


Figure 6.10: Maximum strength of the various fixation methods tested in lateral distraction separated by gender. Columns denote mean values. Maximum strength is measured in newtons of force. Error bars indicate one standard deviation.

Implementing gender as a covariate, the same insignificant result was found for maximum strength. There was virtually no difference found between male and female genders in group A samples, while it can be observed that female specimen in groups B and C catastrophically fail at lower loads. Given the slight differences in values, variability, and overall statistical power when comparing this biomechanical property, very little can be concluded from Figure 6.9 and Figure 6.10.

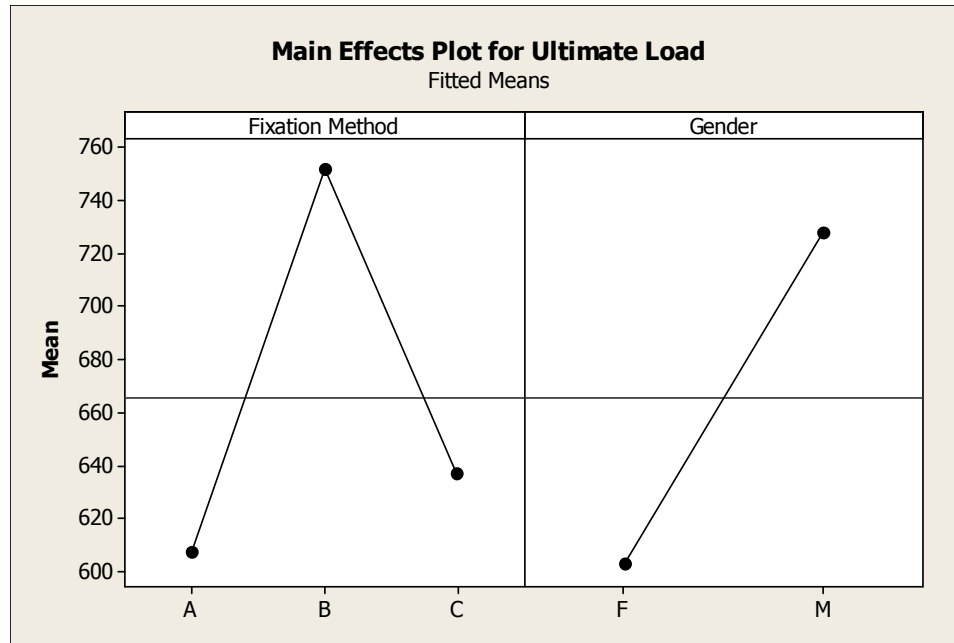


Figure 6.11: Side by side comparison plot of main effects with regards to maximum strength tested in lateral distraction.

Figure 6.11 shows that the overall effect of different fixation methods and genders on the mean ultimate load is similar. Although as large changes on the plot, the scaling is such that the actual range is only 160 newtons. This small difference when comparing larger numbers amplifies the changes seen in this model. Figure 6.11 shows the relative influence found in the two primary factors in biomechanical behavior – fixation method and gender.

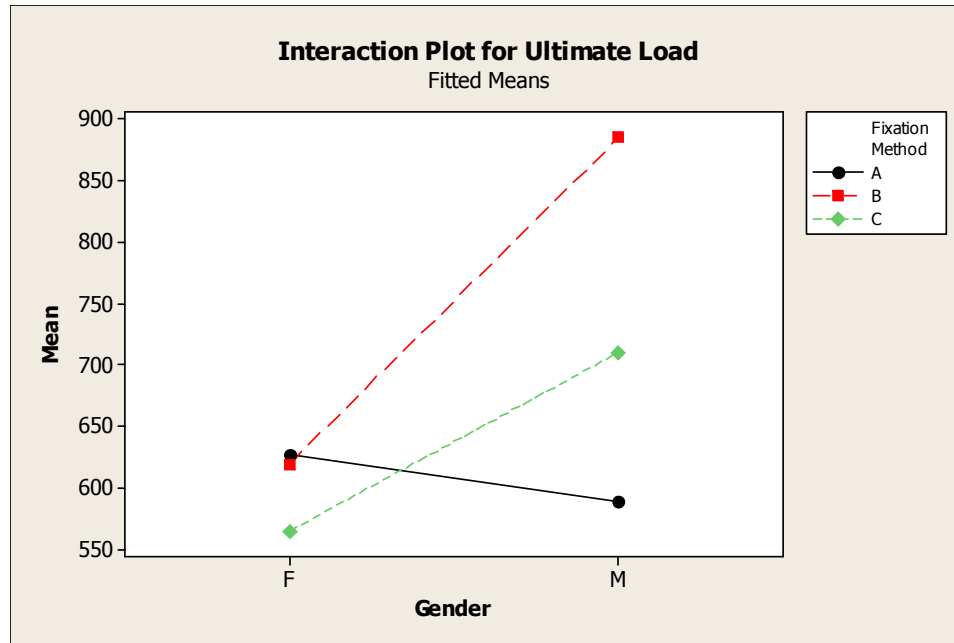


Figure 6.12: Interaction plot describing the effect of gender on each construct in regards to yield strength tested in lateral distraction.

Gender has little, if any, effect on group A specimen (Figure 6.12), a result shared with stiffness and yield strength in Figure 6.4 and Figure 6.8, respectively. The influence of gender on ultimate strength has a much larger consequence in sternum closed with Sternalock plates. Male specimens were found to withstand larger loads before catastrophically failing.

6.1.4. Post-Yield Displacement

Table 6.5: Mean post-yield values for each sternal-closure technique tested in lateral distraction, separated by gender.

Group	Post-Yield Displacement			
	Averages		Standard Dev	
	M	F	M	F
A	0.994	1.341	0.670	0.000
B	0.099	0.373	0.000	0.532
C	0.004	0.482	0.006	0.633

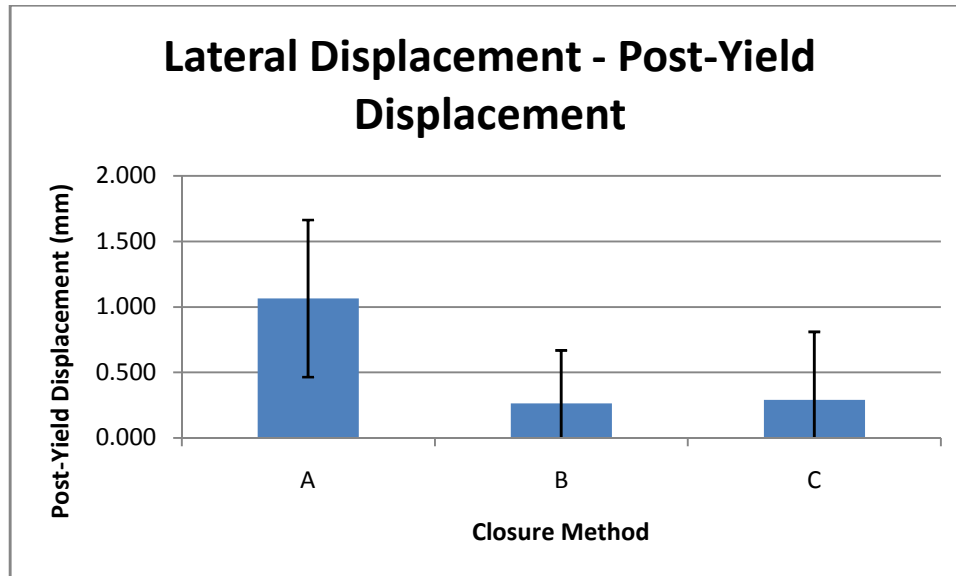


Figure 6.13: Post-yield behavior of the various fixation methods tested in lateral distraction. Columns denote mean values. Post-yield displacement is measured in millimeters. Error bars indicate one standard deviation.

Peristernal wire-sternum constructs exhibited higher displacement after yielding (Figure 6.13). This translates to movement at the midline between point at which yield was met and catastrophic failure occurred. High post-yield displacement values are undesirable in a sternal construct because it is often symptomatic of physiologic damage occurring before complete failure takes place. Both Sternalock systems were found to be almost significantly different when compared to wire closures ($p=0.06$ for group B and $p=0.07$ for group C).

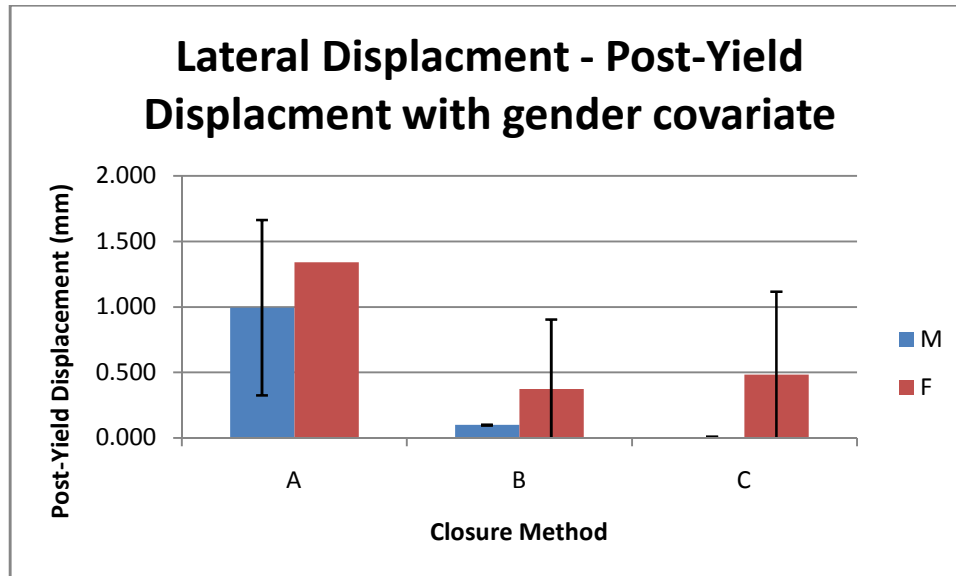


Figure 6.14: Post-yield behavior of the various fixation methods tested in lateral distraction separated by gender. Columns denote mean values Post-yield displacement is measured in millimeters. Error bars indicate one standard deviation.

No statistical evidence was found to support the differences seen due to small sample sizes associated with this study. Though hard to see in Figure 6.14, the 2 male group C specimen had a mean post-yield displacement of 0.002 mm.

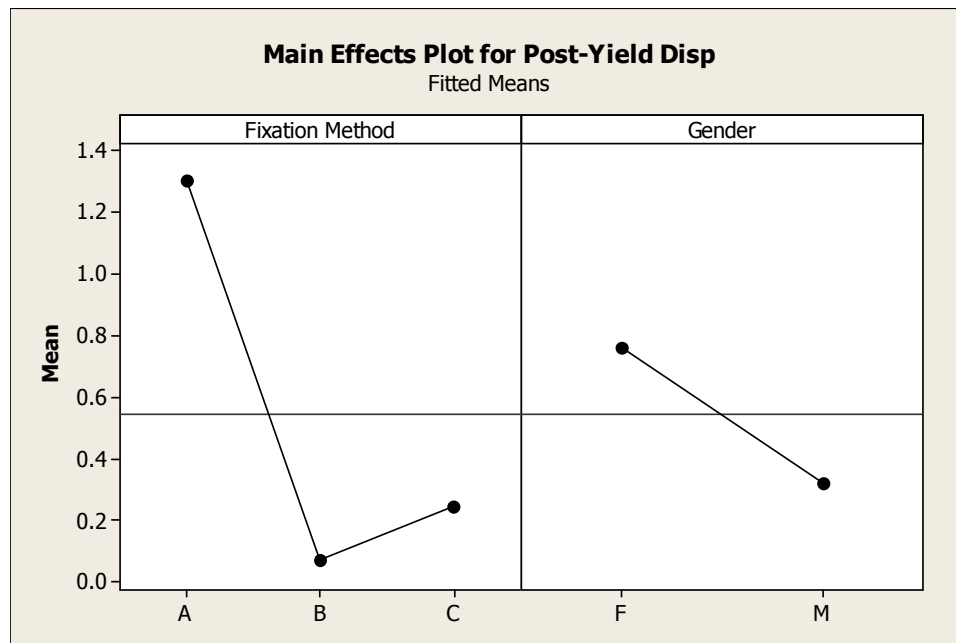


Figure 6.15: Side by side comparison plot of main effects with regards to post-yield displacement tested in lateral distraction.

Illustrated by the comparison plot in Figure 6.15, fixation method has a dramatic effect on post-yield displacement. Figure 6.13 and Figure 6.14 show evidence for large but statistically insignificant support of Sternalock systems providing advantageous performance. Figure 6.15 also shows that gender has a smaller influence on post-yield displacement when compared to the device used for closure. Overall, male specimens were found to displace less after yielding and leading up to complete failure.

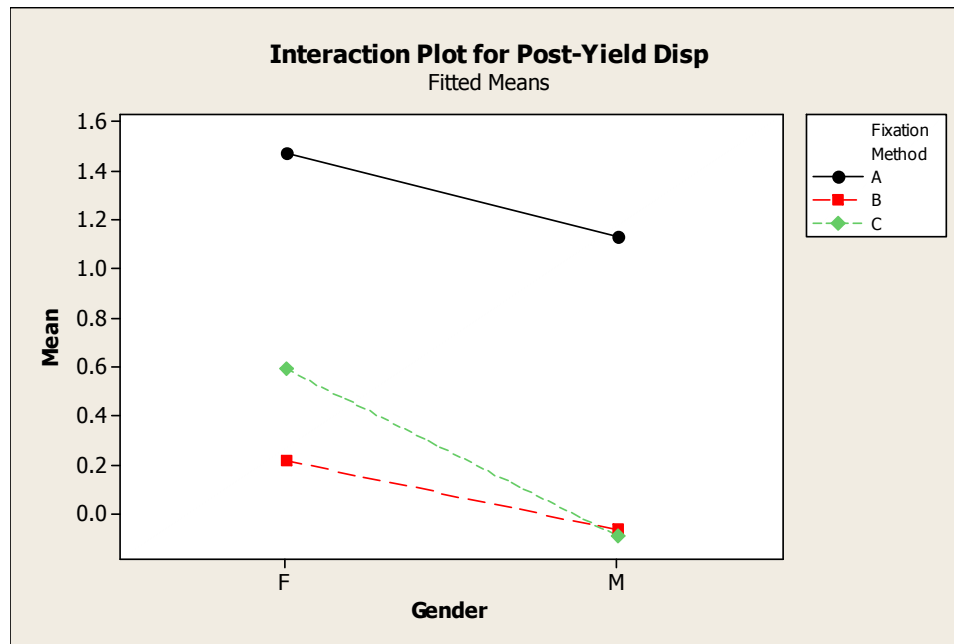


Figure 6.16: Interaction plot describing the effect of gender on each construct in regards to post-yield displacement tested in lateral distraction.

Evidence shown in Figure 6.16 displays the effect of gender on post-yield displacement for each fixation method. Males consistently had less post-yield displacement in every sternal closure technique.

6.2. Rostro-Caudal Shear

Table 6.6: Description of the sample group tested in the longitudinal distraction with values for each biomechanical property.

#	Donor Code	Group	Age	Sex	Stiffness	Yield Load	Ultimate Load	Post-Yield Disp
16	S080719	A	69	F	129.790	85.581	328.731	328.155
19	S080782	A	81	F	50.726	126.022	356.586	355.338
20	S080902	A	79	F	161.004	83.399	216.301	215.923
25	C080709	A	70	F	48.732	194.486	497.878	495.103
27	S080988	A		F	32.963	147.669	312.454	308.572
17	S080900	B	65	M	1184.349	178.041	373.031	372.879
18	C080189	B	65	M	1746.441	90.111	335.946	335.899
21	S080882	B	82	F	1740.698	60.578	216.637	216.600
26	S080129	B	62	F	2157.580	119.645	344.001	343.955
28	C080570	B	70	F	580.690	40.609	157.401	157.363
22	S080938	C	67	M	539.953	178.125	381.254	380.988
29	S080535	C	81	M	1946.021	348.448	745.895	745.588
30	S080923	C	84	M	776.952	133.237	285.269	284.901
23	S080879	C	70	F	687.114	171.581	379.576	379.372
24	S081057	C	72	F	248.068	127.700	171.833	171.372

The average age of specimen tested in the rostro-caudal direction is 73 years, 5 males and 10 females were included in this group. A total of 15 specimen were used and separated into groups of 5 to represent each sternal-closure technique. 5 females closed with peristernal wires, 2 males and 3 females closed with Sternalock using an L-plate at the manubrium, and 3 males and 2 females closed with Sternalock using a box-plate to stabilize the manubrium. No male specimen were available to use in group A, this weakens the comprehensive outlook on the study.

6.2.1. Stiffness

Table 6.7: Mean stiffness values for each sternal-closure technique tested in longitudinal shear, separated by gender.

Stiffness				
Group	Averages		Standard Dev	
	M	F	M	F
A	-	84.643	-	56.965
B	1465.395	1492.989	397.459	817.108
C	1087.642	467.591	752.763	310.452

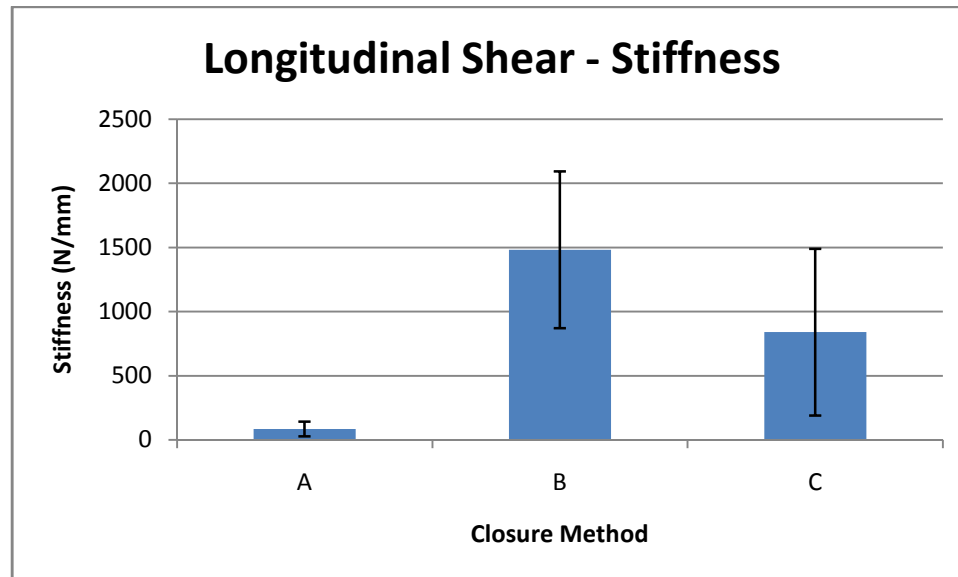


Figure 6.17: Rigidity (stiffness) of the various fixation methods tested in longitudinal shear. Columns denote mean values. Stiffness is measured in newtons of force per millimeter displacement. Error bars indicate one standard deviation.

As shown by Figure 6.17, both Sternalock configurations exhibited higher stiffness values. Though not statistically significant, these advantages in stiffness can be observed from this graph. Sternum closed with peristernal wires was tested to have a mean stiffness of 84 N/mm with a standard deviation of 45 N/mm in the longitudinal direction – virtually no resistance to displacement. Group B’s test results show almost a 1400 N/mm increase in stiffness when compared to peristernal wires, group C sterna showed a 755 N/mm gain in rigidity when compared to wires.

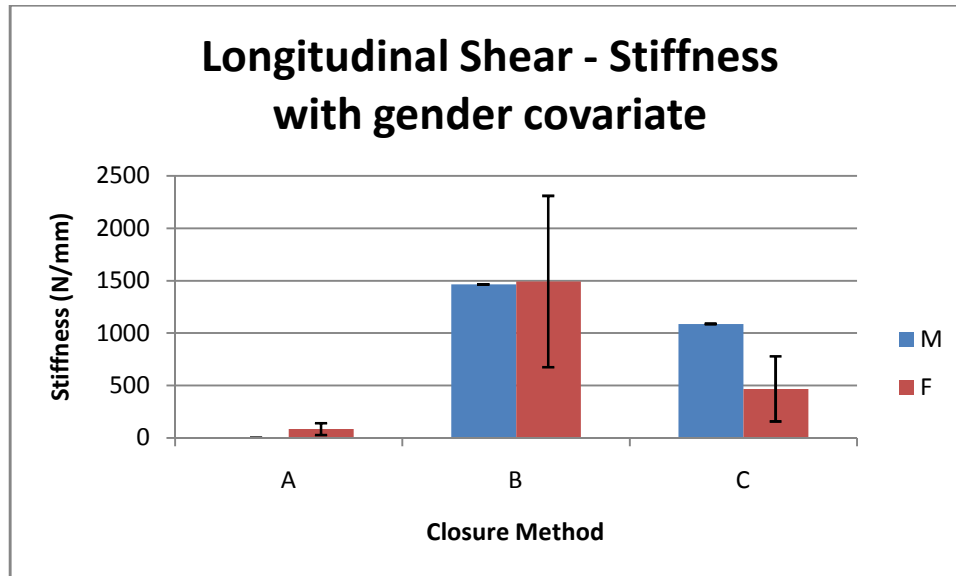


Figure 6.18: Rigidity (stiffness) of the various fixation methods tested in longitudinal shear separated by gender. Columns denote mean values. Stiffness is measured in newtons of force per millimeter displacement. Error bars indicate one standard deviation.

No males in group A were tested in this direction. In the test group that was tested in rostro-caudal shear, they were found to have a stiffness of 84 N/mm (Figure 6.18).

Group B females we found to be statistically different when compared to group A females. Group B specimen had very similar mean stiffness values when compared to each other, while female group C specimen had a mean stiffness much lower than males in that group.

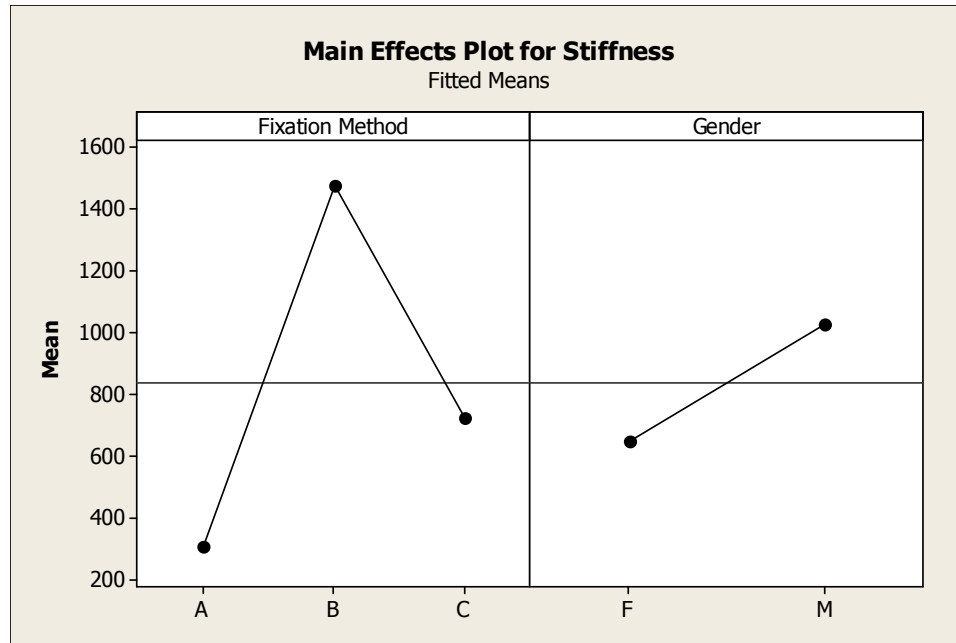


Figure 6.19: Side by side comparison plot of main effects with regards to stiffness tested in longitudinal shear.

Fixation method was found to be the primary effect on stiffness when looking at mean values (Figure 6.19). Group B had the largest mean stiffness out of the three closure techniques, 1481 N/mm. Group C was found to have a lower than expected stiffness value, 839 N/mm. Figure 6.18 cites the source of this low value from the 2 female specimens tested in this group. Group C sterna tested still had over a 750 N/mm gain in stiffness over sterna closed with wires. Gender also had an influence, with males testing 655 N/mm stiffer than female counterparts.



Figure 6.20: Interaction plot describing the effect of gender on each construct in regards stiffness tested in longitudinal shear.

In all examples, male specimen were found to exhibit higher stiffness values than female (Figure 6.20). Similar to findings illustrated by Figure 6.18, gender had a minimal effect on mean stiffness in group B. The interaction plot for gender in group A should be disregarded as no male specimen was tested in this direction. A difference of over 600 N/mm was recorded in the mean stiffness of subjects closed with Sternalock using box-plates.

6.2.2. Yield Load

Table 6.8: Mean yield values for each sternal-closure technique tested in longitudinal shear, separated by gender.

Yield Load				
Group	Averages		Standard Dev	
	M	F	M	F
A	-	127.431	-	46.363
B	134.076	73.611	62.176	41.098
C	219.937	149.640	113.534	31.029

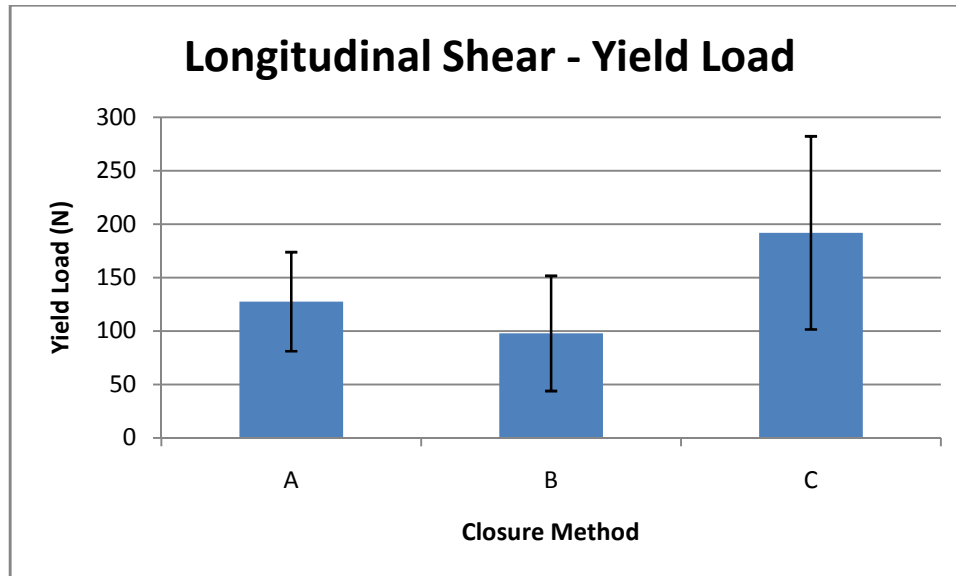


Figure 6.21: Yield strength of the various fixation methods tested in longitudinal shear. Columns denote mean values. Yield strength is measured in newtons of force. Error bars indicate one standard deviation.

Figure 6.21 reveals very little differences of mean yield strength values between the three fixation methods. The range of mean yield strength is only 94 N, the range of all the individual specimen is approximately 300 N. No statistically significance was found.

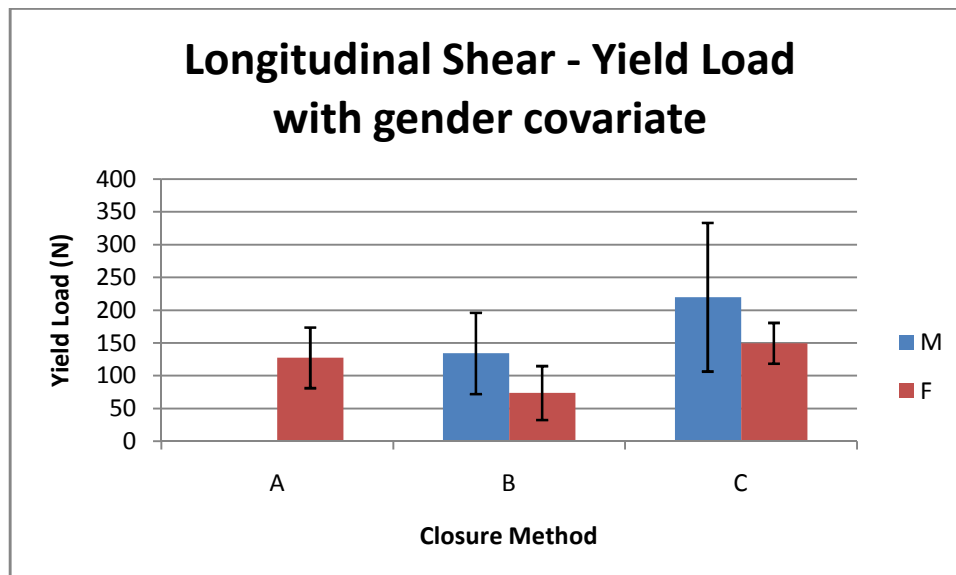


Figure 6.22: Yield strength of the various fixation methods tested in longitudinal shear separated by gender. Columns denote mean values. Yield strength is measured in newtons of force. Error bars indicate one standard deviation.

No male specimen was tested in group A (Figure 6.22). Testing of female specimen resulted in lower mean yield strength when compared to similar male specimen for groups B and C. Analogous to results found without consideration of gender, no statistical significance was found when comparing this biomechanical property.

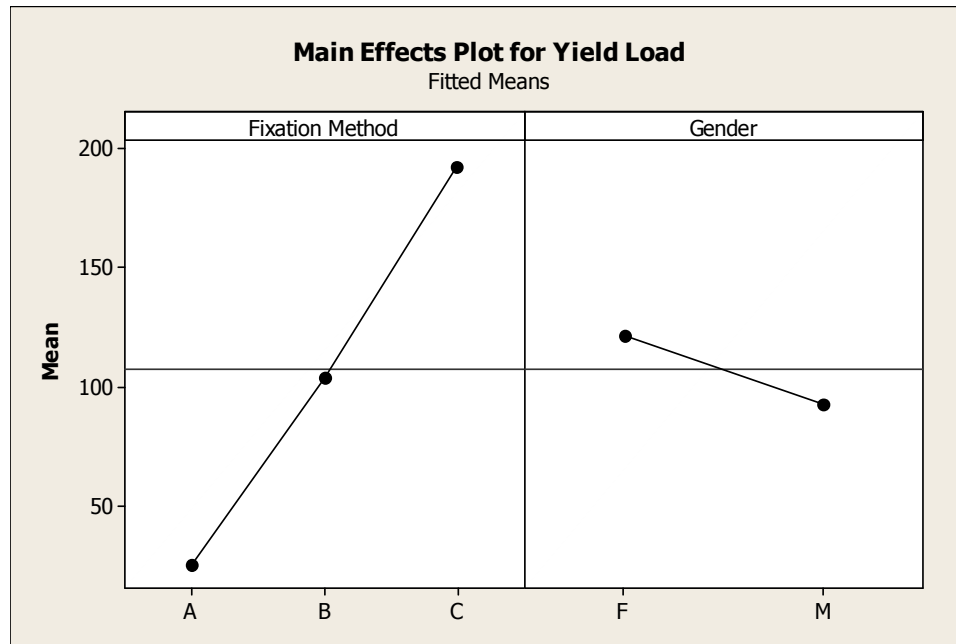


Figure 6.23: Side by side comparison plot of main effects with regards to yield strength tested in longitudinal shear.

Primary effect on mean yield strength was found to be a dependence on the fixation method applied to the sternal construct. Gender was not found to have an influential effect on the amount of load the construct can withstand before yielding (Figure 6.23).

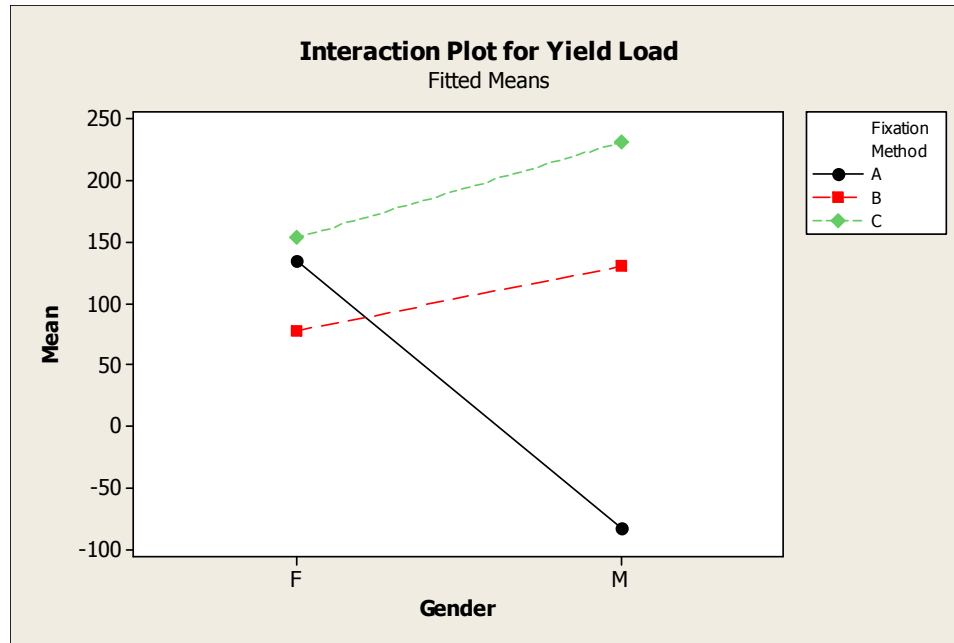


Figure 6.24: Interaction plot describing the effect of gender on each construct in regards yield strength tested in longitudinal shear.

The plot for group A should be disregarded since there were no male specimen tested. Sternal constructs in groups B and C showed larger capacities for load before plastically deforming for males (Figure 6.24). This difference was not large and was ultimately found to be statistically insignificant.

6.2.3. Maximum Load

Table 6.9: Mean maximum-load values for each sternal-closure technique tested in longitudinal shear, separated by gender.

Group	Ultimate Load			
	Averages		Standard Dev	
	M	F	M	F
A	-	342.390	-	101.685
B	354.489	239.346	26.223	95.350
C	470.806	275.704	243.020	146.896

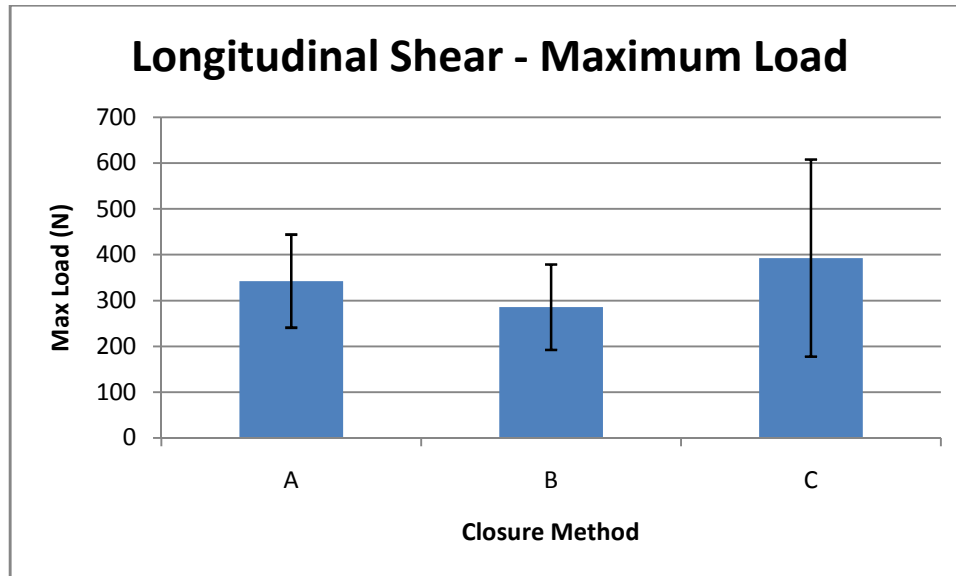


Figure 6.25: Maximum strength of the various fixation methods tested in longitudinal shear. Columns denote mean values. Maximum strength is measured in newtons of force. Error bars indicate one standard deviation.

Much like results found for yield strength in longitudinal shear, differences in maximum strength for the three fixation methods were found to be minimal (Figure 6.25). The range for mean ultimate strengths is 107 N. No statistical significance was found, and there did not seem to be any type of correlation between the fixation method and the amount of force the construct was able to endure before completely failing.

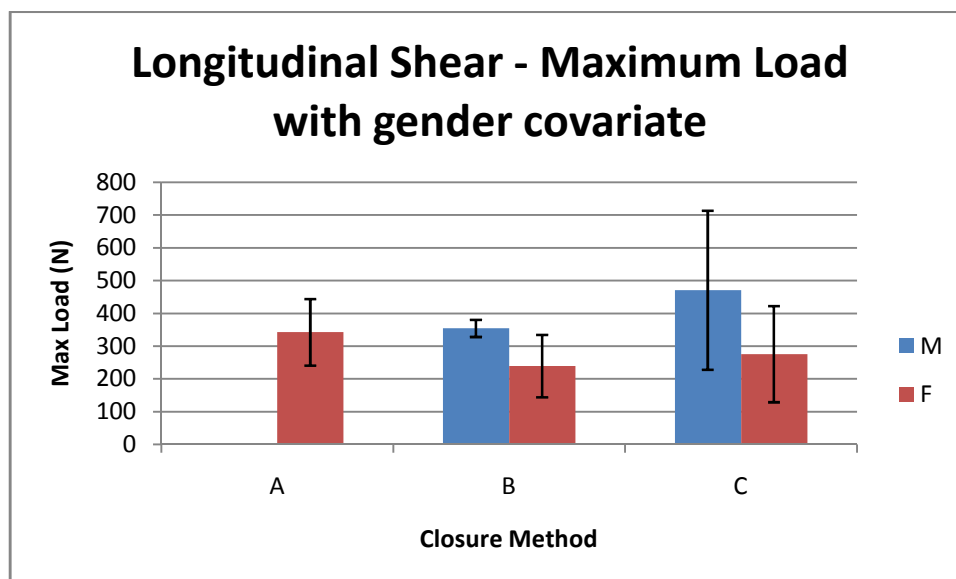


Figure 6.26: Maximum strength of the various fixation methods tested in longitudinal shear separated by gender. Columns denote mean values. Maximum strength is measured in newtons of force. Error bars indicate one standard deviation.

No sterna closed with peristernal wires taken from male cadavers were tested. Figure 6.26 shows that very little differences were observed in mean ultimate strength. A slight trend showing weakness in female specimen is observed again. Overall, the capacity a sternal construct is able to withstand before catastrophic failure occurs is approximately 300 N in the longitudinal direction. No correlation has been found that would show evidence of a fixation method having an advantage over others.

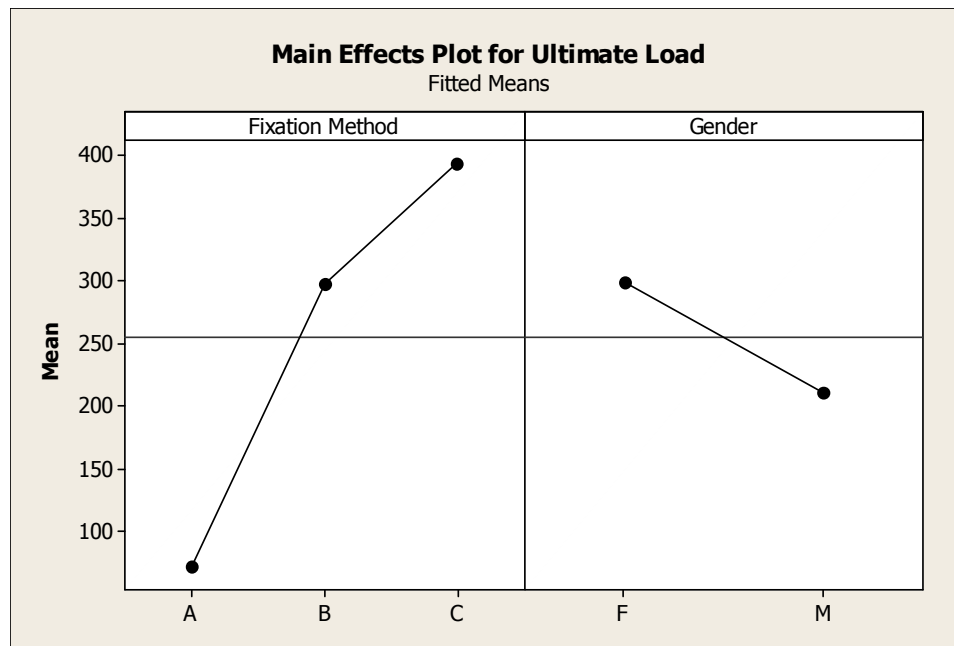


Figure 6.27: Side by side comparison plot of main effects with regards to maximum strength tested in longitudinal shear.

Gender was shown to not have as much of an impact on mean ultimate load capacity when compared to fixation method (Figure 6.27).

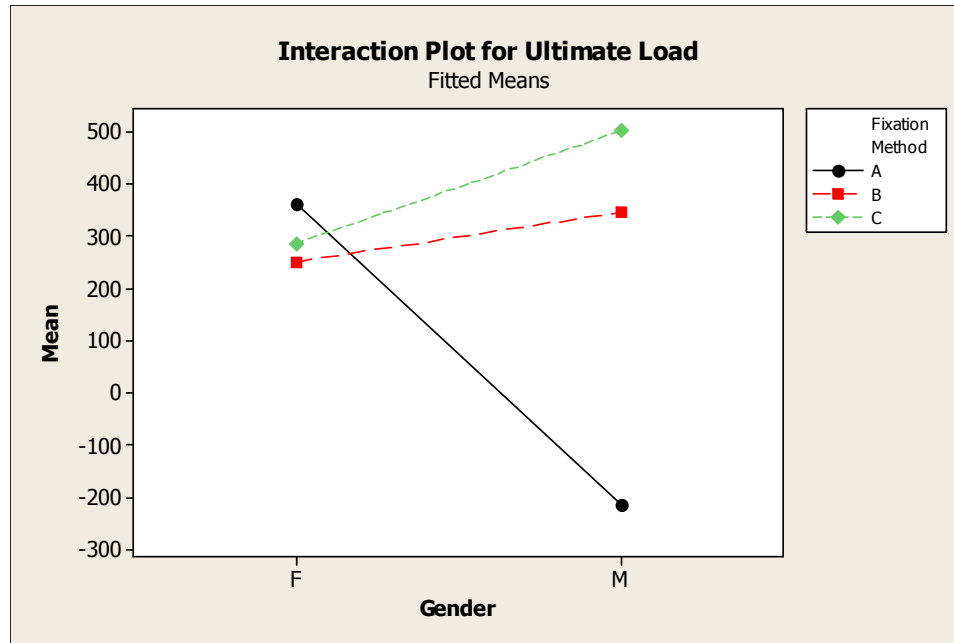


Figure 6.28: Interaction plot describing the effect of gender on each construct in regards maximum strength tested in longitudinal shear.

The interaction plot for group A should be disregarded because no male specimen was tested with that fixation method (Figure 6.28). Male specimens were found to have a larger capacity for stress in Sternalock constructs. However, this was a small amount and found to be statistically insignificant.

6.2.4. Post-Yield Displacement

Table 6.10: Mean post-yield values for each sternal-closure technique tested in longitudinal shear, separated by gender.

Group	Post-Yield Displacement			
	Averages		Standard Dev	
	M	F	M	F
A	-	8.295	-	3.986
B	0.785	0.643	0.398	0.564
C	2.733	1.885	2.390	2.345

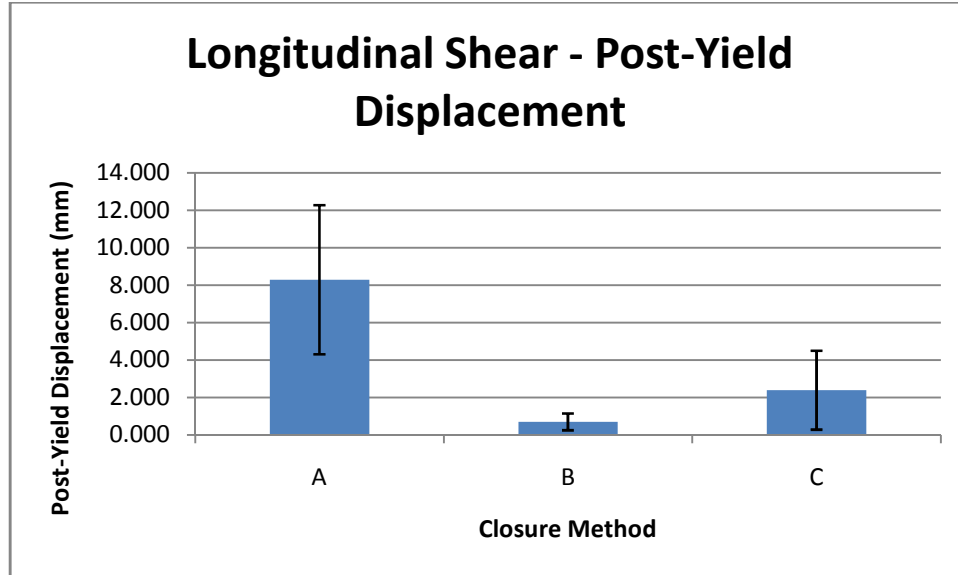


Figure 6.29: Post-yield behavior of the various fixation methods tested in longitudinal shear. Columns denote mean values. Post-yield displacement is measured in millimeters. Error bars indicate one standard deviation.

A very clear trend links sternum closed with peristernal wires with high post-yield displacement. This trend is not statistically significant, but a difference can easily be seen from Figure 6.29. Sternalock systems using L-plates were found to displace just 1 millimeter before failing. A similar system using box-plates were found to displace as much as 5 millimeters. Sternum closed with peristernal wires were observed to displace as much as 15 millimeters before catastrophic failure was reached.

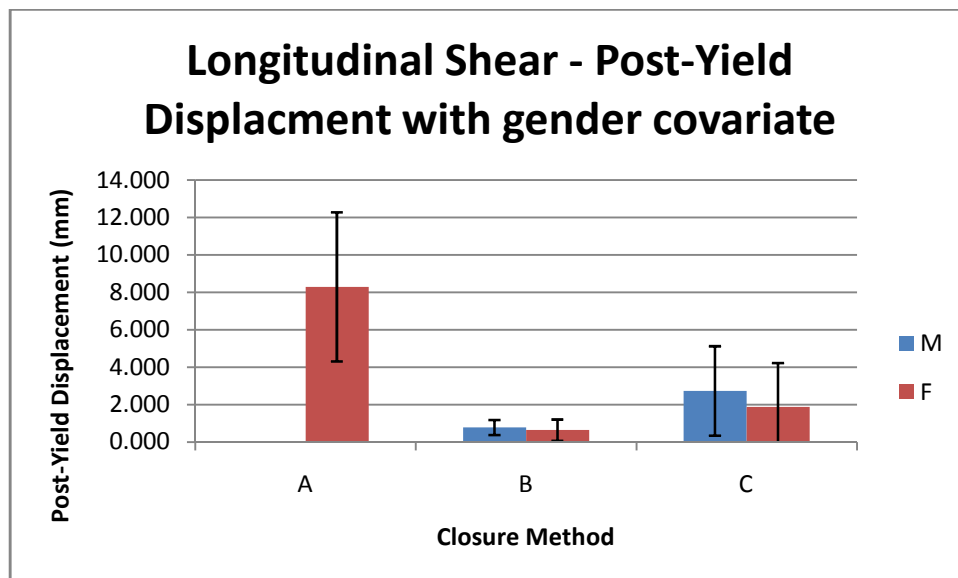


Figure 6.30: Post-yield of the various fixation methods tested in longitudinal shear separated by gender. Columns denote mean values. Post-yield displacement is measured in millimeters. Error bars indicate one standard deviation.

A gender comparison for group A sterna was unavailable. Negligible differences between male and female specimen were found in fixation methods that we were able to make this comparison (Figure 6.30).

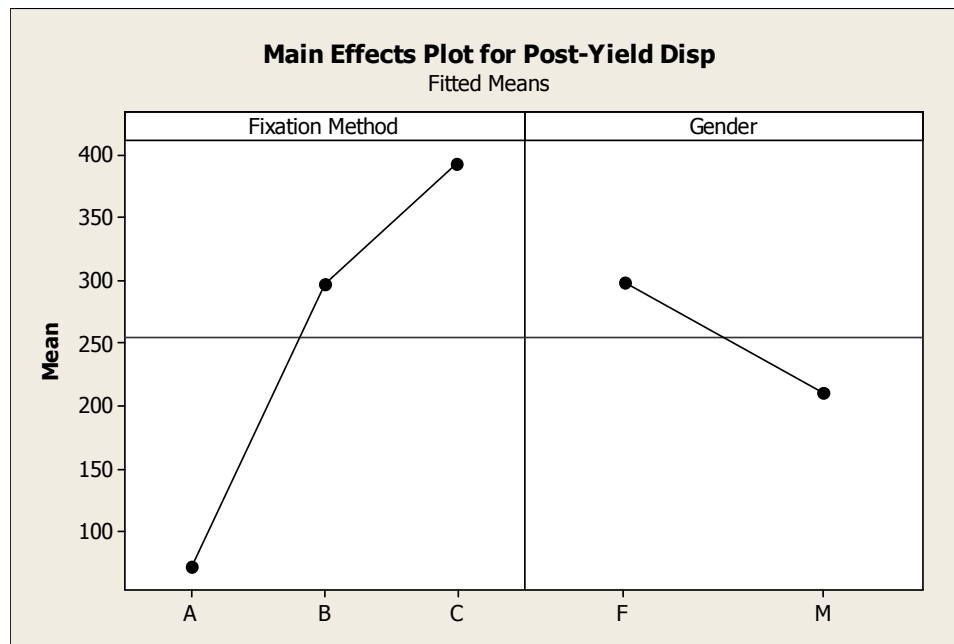


Figure 6.31: Side by side comparison plot of main effects with regards to post-yield displacement tested in longitudinal shear.

Fixation method had the larger effect on mean post-yield displacement; gender provided a secondary influence on this biomechanical behavior (Figure 6.31).

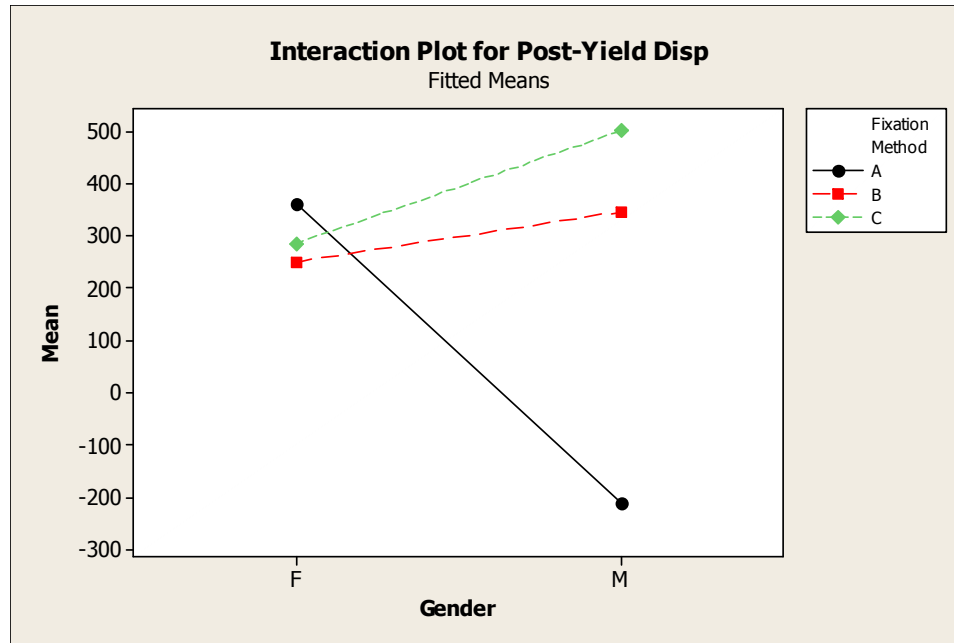


Figure 6.32: Interaction plot describing the effect of gender on each construct in regards post-yield displacement tested in longitudinal shear.

The line depicting the interaction of gender in group A sternum should be disregarding since no males were tested in this group (Figure 6.32). Gender had a minimal effect on this biomechanical behavior.

6.3. Anterior-Posterior Shear

Table 6.11: Description of the sample group tested in the transverse distraction with values for each biomechanical property.

#	Donor Code	Group	Age	Sex	Stiffness	Yield Load
31	S080850	A	76	M	110.823	48.999
34	C080526	A	82	M	66.350	-
39	S081007	A	89	M	-	-
32	S080450	A	65	F	34.507	23.493
40	S080950	A	79	F	46.401	22.989
35	S081013	B	68	M	32.570	-
33	C080582	B	80	F	113.650	-
37	S080029	B	50	F	8.857	129.042
38	C060260	B	77	F	117.158	51.684
41	C080345	B	85	F	-	-
36	S081047	C	69	M	107.317	104.039
42	S060167	C	80	M	132.657	55.879

Of specimen tested in the anterior-posterior shear direction, the average age was 75 years with 6 males and 6 females. 12 sternums were tested. 5 samples using peristernal wires, 5 samples using Sternalock with L-plates, and 2 using Sternalock with box-plates. No female specimen was tested with box-plates.

Table 12 shows several weaknesses in data collection. Calculating biomechanical behaviors of the cadaveric constructs was very difficult when stressing in the transverse direction. The cadaver-device constructs had a very large amount of compliance due to the length of the ribs and presence of intercostal muscles, this made it difficult to apply force to the midline of the sternum.

6.3.1. Stiffness

Table 6.12: Mean stiffness values for each sternal-closure technique tested in transverse shear, separated by gender.

Stiffness				
Group	Averages		Standard Dev	
	M	F	M	F
A	88.586	40.454	31.447	8.410
B	32.570	79.888	0.000	61.540
C	119.987	-	17.918	-



Figure 6.33: Rigidity (stiffness) of the various fixation methods tested in transverse shear. Columns denote mean values. Stiffness is measured in newtons of force per millimeter displacement. Error bars indicate one standard deviation.

No fixation method was found to be statistically different than another (Figure 6.33).

Peristernal wires appeared to be almost identical in stiffness to Sternalock with L-plates, only a 4 N/mm difference in mean stiffness. A moderate gain in stiffness can be observed for Sternalock with box-plates in Figure 6.33, a 55 N/mm difference when compared to peristernal wires.

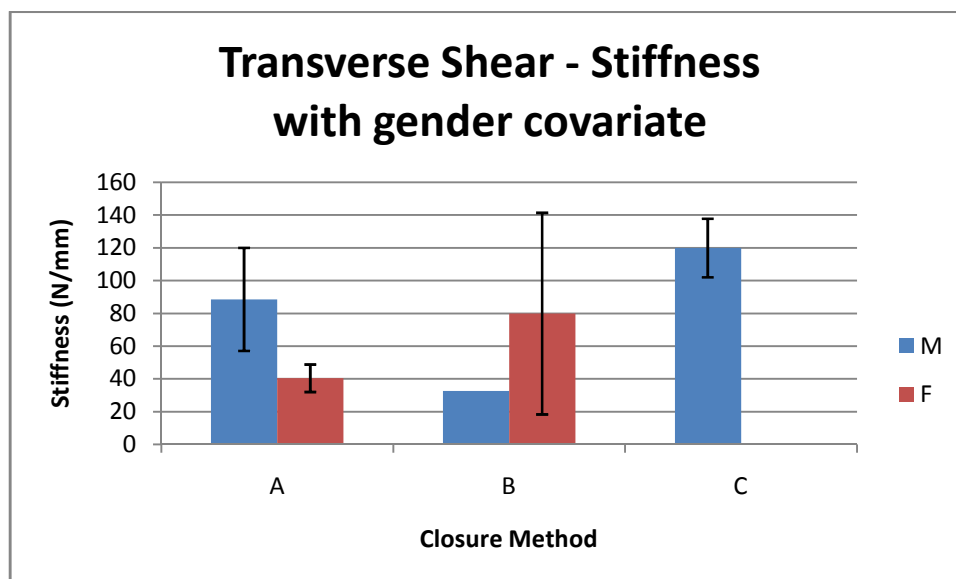


Figure 6.34: Rigidity (stiffness) of the various fixation methods tested in longitudinal shear separated by gender. Columns denote mean values. Stiffness is measured in newtons of force per millimeter displacement. Error bars indicate one standard deviation.

No female samples were tested in group C. No trends or correlations are able to be made from the data recorded and shown in Figure 6.34.

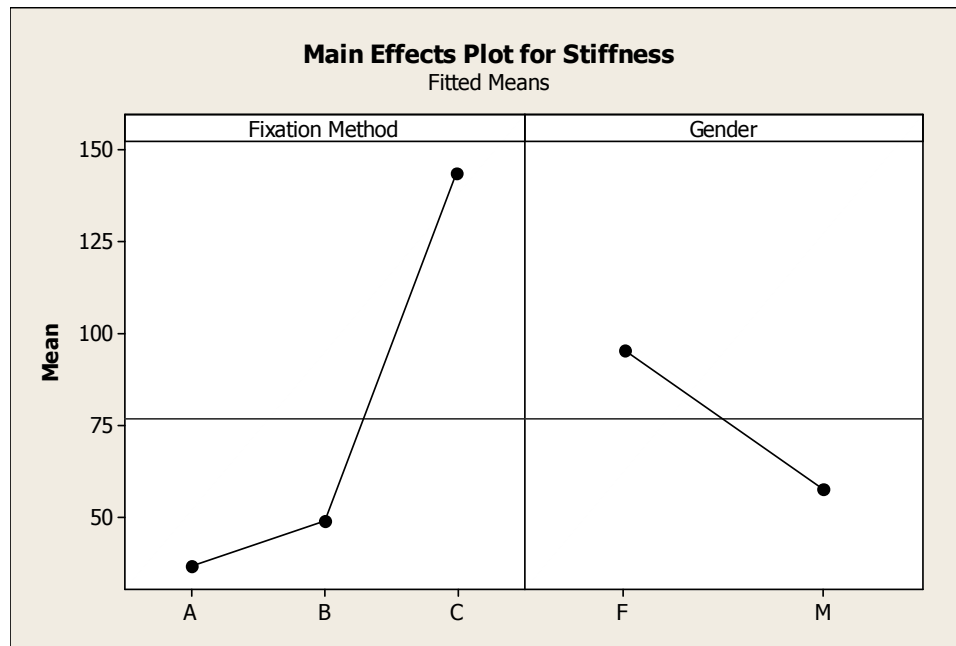


Figure 6.35: Side by side comparison plot of main effects with regards to stiffness tested in transverse shear.

Fixation method is shown to be the primary influence on mean stiffness of the construct. Gender has a secondary effect on this biomechanical property. The overall scale of Figure 6.35 allows us to analyze the source of different stiffness values, but the small difference of overall values does not provide enough statistical power to draw any direct relationships between fixation method, gender, and mean stiffness.



Figure 6.36: Interaction plot describing the effect of gender on each construct in regards stiffness tested in transverse shear.

The interaction plot describing fixation method C should be disregarding because no female samples were tested in this group. Figure 6.36 shows very little effect of different genders to both sternums closed with peristernal wires and Sternalock systems using L-plates.

6.3.2. Yield Load

Table 6.13: Mean yield values for each sternal-closure technique tested in transverse shear, separated by gender.

Yield Load				
Group	Averages		Standard Dev	
	M	F	M	F
A	48.999	23.241	0.000	0.356
B	-	90.363	-	54.701
C	79.959	-	34.054	-

Table 6.14: Mean yield values for each sternal-closure technique tested in transverse shear.

Yield Load		
Group	Average	Std Dev
A	31.827	14.874
B	90.363	54.701
C	79.959	34.054

Table 15 was included because there are so many vacancies in table 14. Weaknesses in table 14 make it difficult to read no conclusions can be drawn from analyzing gender.

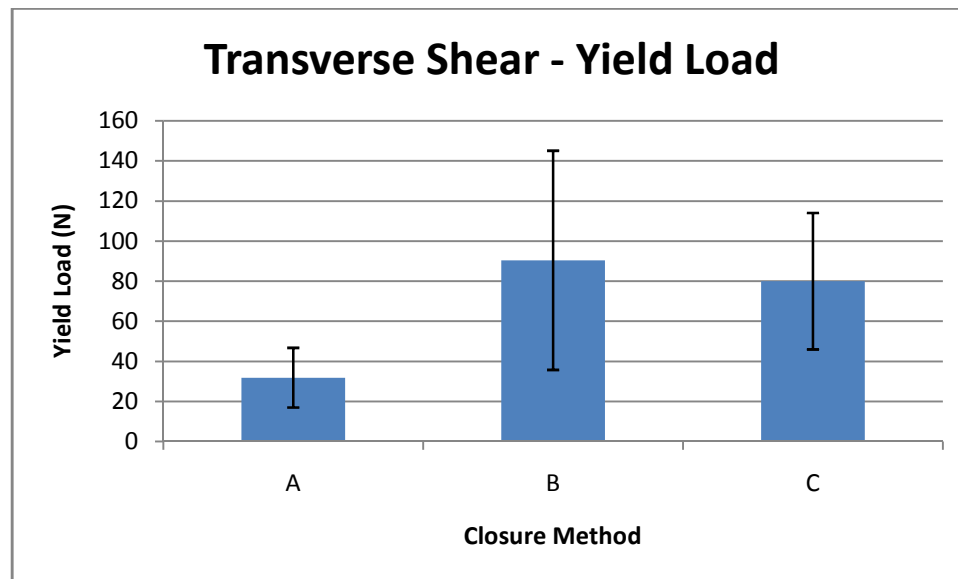


Figure 6.37: Yield strength of the various fixation methods tested in longitudinal shear. Columns denote mean values. Yield strength is measured in newtons of force. Error bars indicate one standard deviation.

No fixation method was found to have statistically different yield strength when compared to each other. The constructs capacity for stress before plastically deforming did appear to be influence by different closure techniques in the anterior-posterior direction. A trend of Sternalock systems having a higher yield strength can be observed from Figure 6.37, however, this trend was not found to be statistically significant. The largest change, the difference between group B and group A was only found to be 59 N.

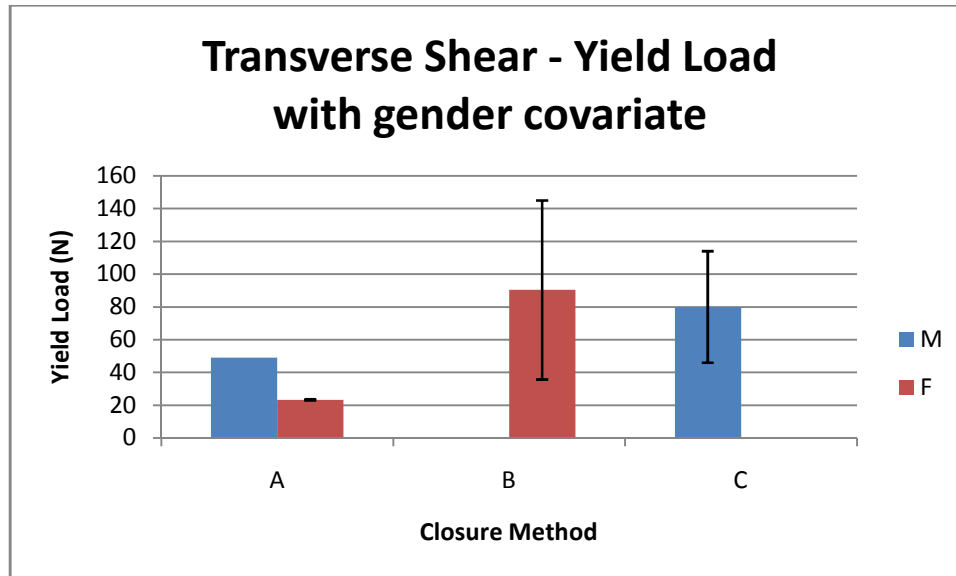


Figure 6.38: Yield strength of the various fixation methods tested in longitudinal shear separated by gender. Columns denote mean values. Yield strength is measured in newtons of force. Error bars indicate one standard deviation.

No data was recorded for males in group B and no females were tested from group C.

This shows weaknesses in the study for transverse shear. The one thing Figure 6.38 reveals is that females had a slightly lower stiffness when compared to males in group A.

6.3.3. Maximum Load

Data was unavailable for the maximum strength when tested in the anterior-posterior direction. The maximum displacement of the load frame was approximately 3 inches. At maximum displacement, failure was not achieved for the sternal construct. Cited in section 7.3, force was very inefficiently transferred to the sternum using the test fixtures for the anterior-posterior direction. The high compliance of the sternum makes it extremely difficult to collect viable data in this direction.

6.3.4. Post-Yield Displacement

Because catastrophic failure was never reached for this test group, a post-yield displacement was unavailable for each construct.

6.4. Males versus Females

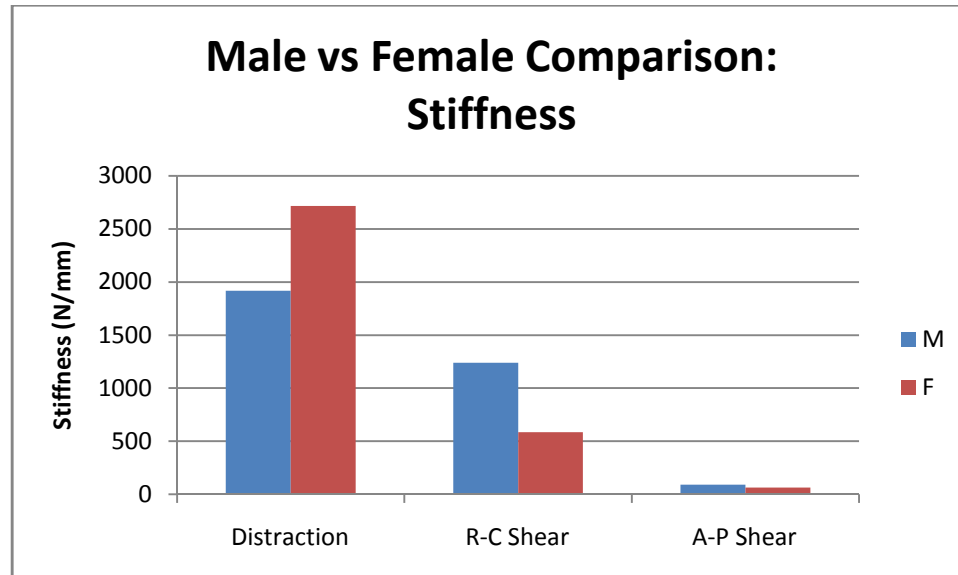


Figure 6.39: Comparing stiffness between male and female specimen. Columns denote cumulative values for all fixation methods.

Trends have been noted that link gender and mean stiffness for groups organized by fixation method. Overall no statistical differences can be observed from Figure 6.39. In Figure 6.39, all fixation methods were averaged to produce the graph. This may not be the best way to analyze the gender relationship since plated fixation methods tended to exhibit higher stiffness values, skewing the averaged values in Figure 6.39 towards the behavior of groups B and C.

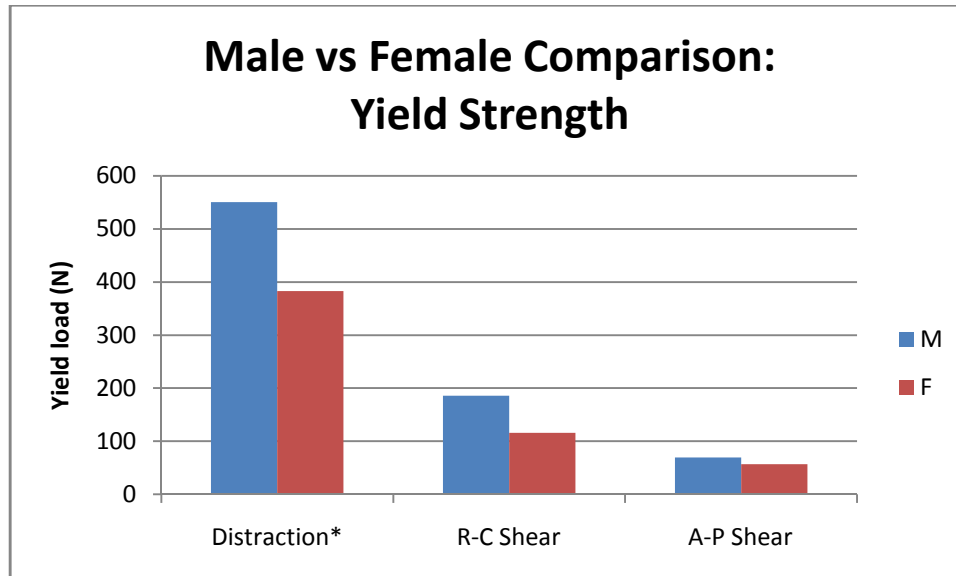


Figure 6.40: Comparing yield strength between male and female specimen. Columns denote cumulative values for all fixation methods. An asterisk indicates statistically significance between male and female specimen.

A trend can be seen associating male specimen with a higher capacity for stress before plastically deforming (Figure 6.40). When tested in lateral distraction, males were found to be statistically different ($p=0.03$) when compared to similarly tested females; males had a mean stiffness of 550 N while females were tested to have 382 N. Statistical differences were not found in rostro-caudal shear and anterior-posterior shear, however, a trend can be observed showing higher yield strengths for male specimen. This data suggests that males can be associated with larger yield-strengths.

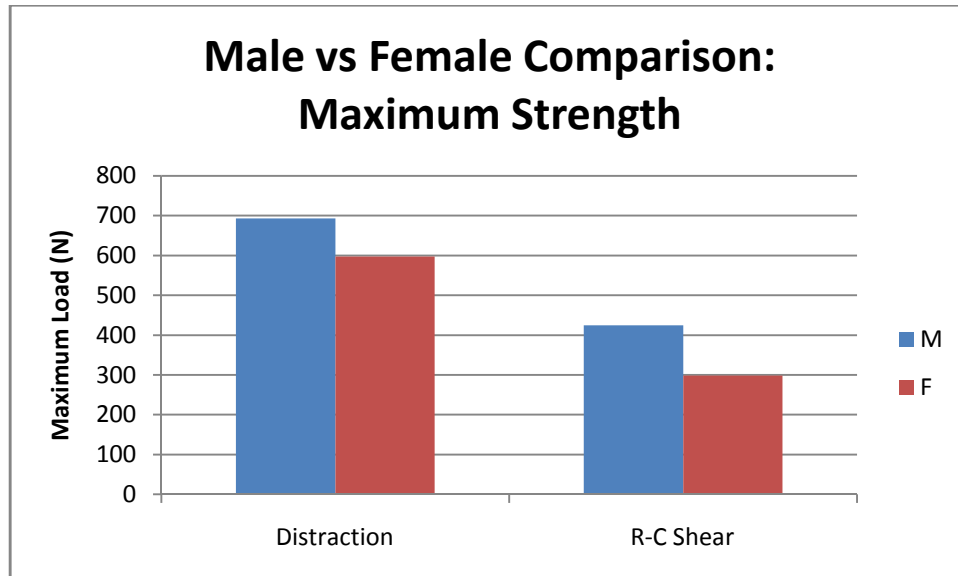


Figure 6.41: Comparing maximum strength between male and female specimen. Columns denote cumulative values for all fixation methods.

No statistical differences were found when comparing similarly tested males and females (Figure 6.41). Male specimens were consistently stronger, able to withstand larger amounts of stress before reaching catastrophic failure. However, these differences were small, 95N and 126N for distraction and longitudinal shear, respectively. This data suggests that males are associated with larger maximum-strengths.

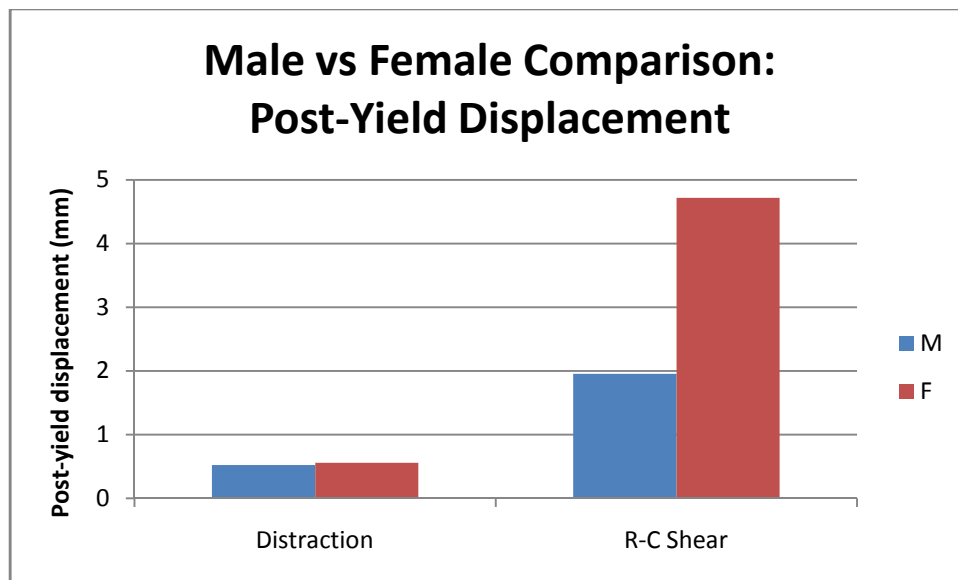


Figure 6.42: Comparing post-yield displacement between male and female specimen. Columns denote cumulative values for all fixation methods.

Difference in male versus female specimen when tested in lateral distraction was found to be almost statistically significant ($p=0.19$). When tested in rostro-caudal shear, females displaced much more after yielding when compared to males. This difference did not prove to be statistically different.

6.5. Additional Graphs

Figures 6.43-6.46 bring perspective to the findings of this study. The magnitude of the differences found can be compared to other fixation methods, other directions of applied stress, and the opposite gender.

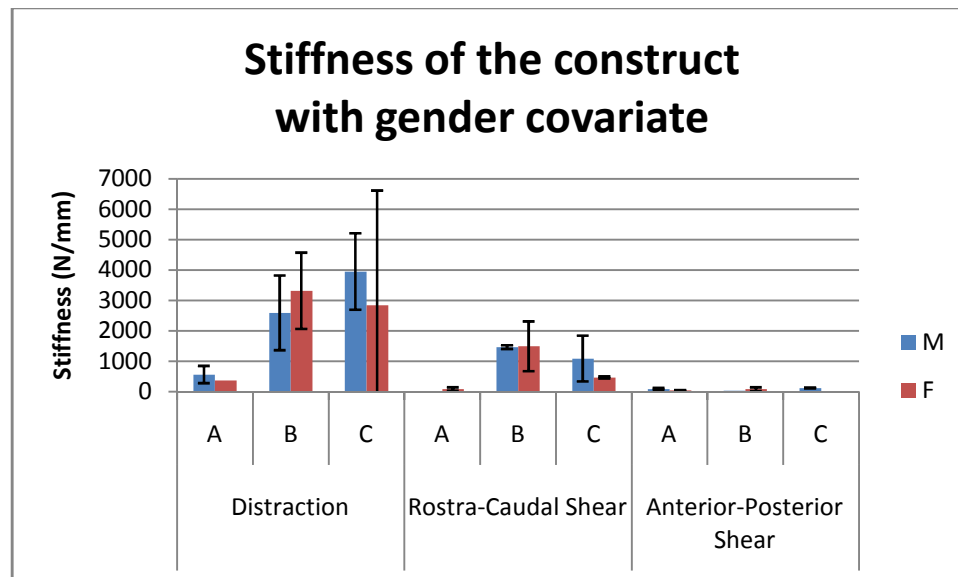


Figure 6.43: Rigidity (stiffness) of the various fixation methods tested in various directions and separated by gender. Columns denote mean values. Stiffness is measured in newtons of force per millimeter displacement. Error bars indicate one standard deviation.

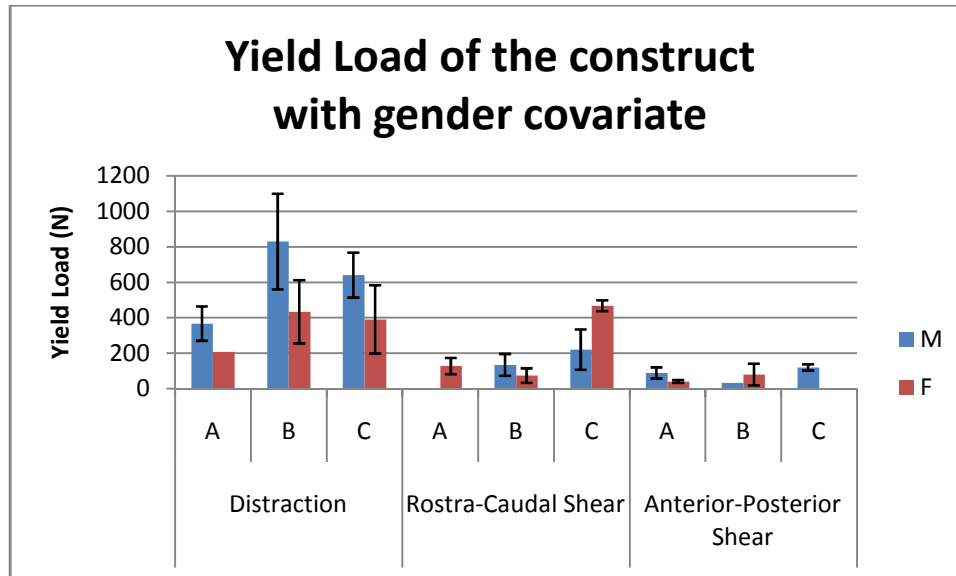


Figure 6.44: Yield strength of the various fixation methods tested in various directions and separated by gender. Columns denote mean values. Yield strength is measured in newtons of force. Error bars indicate one standard deviation.

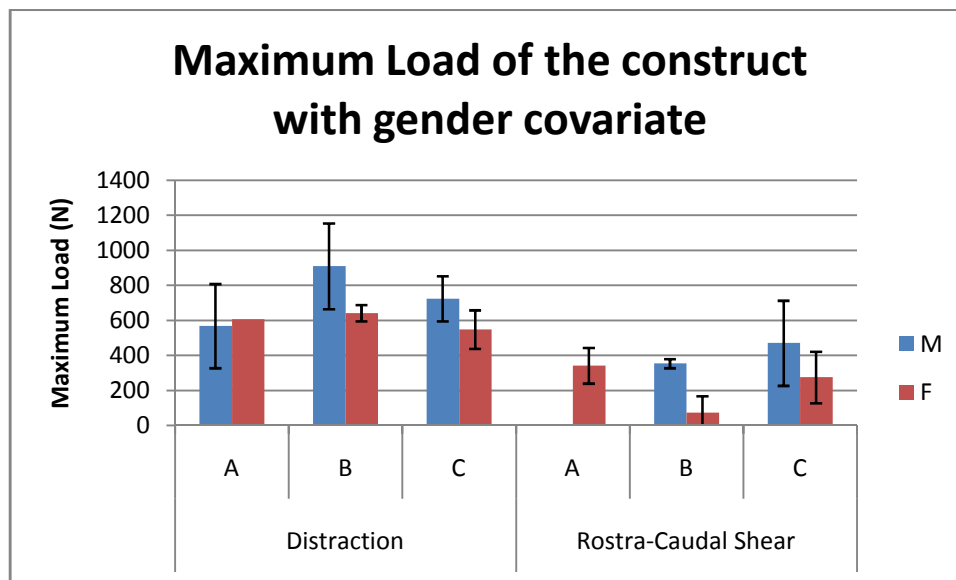


Figure 6.45: Maximum strength of the various fixation methods tested in various directions and separated by gender. Columns denote mean values. Maximum strength is measured in newtons of force. Error bars indicate one standard deviation.

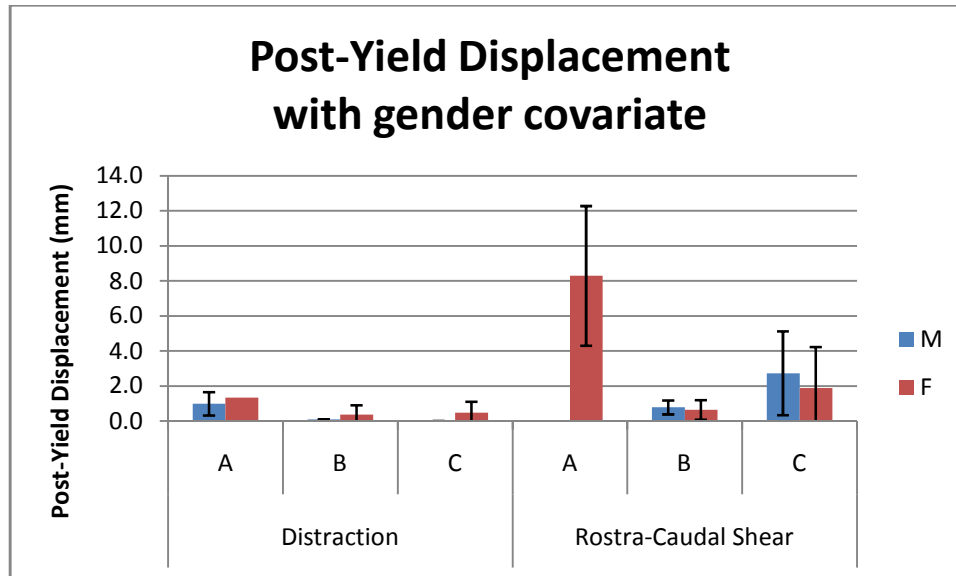


Figure 6.46: Post-yield displacement of the various fixation methods tested in various directions and separated by gender. Columns denote mean values. Post-yield displacement is measured millimeters. Error bars indicate one standard deviation.

7. Discussion

7.1. Lateral distraction



Figure 7.1: Picture taken at maximum displacement in the lateral distraction direction. Separation can be observed at the midline and rib fractures can be seen along the bottom clamp.

It was found that both Sternalock configurations were statistically different ($p < 0.05$) when comparing stiffness to sternum closed with peristernal wires. A loose trend was found for the same when analyzing yield strength ($p < 0.23$). No conclusions could be

drawn from each tested fixation method with regards to maximum strength. A loose trend was also found when analyzing data for post-yield displacement, Sternalock systems were found to be more superior to peristernal wires ($p < 0.07$).

Substantial advantages in performance were observed from all the biomechanical properties analyzed for Sternalock devices when compared to peristernal wires, excluding maximum strength. Overall, displacement at the midline for sternum involving Sternalock devices was almost not detectable. When stressed in lateral distraction, Sternalock plates were very efficient at transferring load to the sternum without allowing elastic or inelastic deformation at the osteotomy site. Figure 18a shows a coloration map of stress concentrations for a sternum closed with peristernal wires. Red color indicates high stress areas, these areas were seen to be more likely to displace at higher rates. A peristernal wire closure was not sufficient to stabilize the xiphoid region when increased loads were applied to the construct.

Lateral distraction is the biomechanical property most commonly discussed in literature. A very large amount of data has been compiled on stiffness – cadaver models [11], bone analogues [49], porcine models [50], canine models [15]. No new information is being reported in this study on the lateral distraction of cadaveric models except the validation of the Sternalock device.

7.2. Rostro-caudal shear

Longitudinal shear is not widely used in evaluating new median sternotomy closure devices. However, this can be an important metric to further understand the limits and failure modes in devices very commonly implanted in a very wide patient-group. An older and more mature procedure, median sternotomy closures have become sufficiently capable of resisting motion during lateral distraction but little progress has been made to resist load in directions that are physiologically known to occur. The test fixtures used to apply stress in the rostro-caudal direction were very effective to transferring load through the midline of the construct. Minimal rotation was seen to occur and viable data recorded during testing.

Peristernal wires are not well suited to resist motion in the longitudinal direction. Due to the inherent nature of this fixation method, this wire configuration can only resist load in one direction. Wires are tightened to provide a compressive force around the cortical bone of the sternal body; this provides the action in resisting forces in lateral distraction. Resistance in the longitudinal or transverse direction is completely dependent on friction between the sternal halves, as the halves are merely being compressed together. Even in the one mode of resistance capable by peristernal wire closures, load is not efficiently transferred to the construct. Multiple point loads are created around cortical bone that tend to concentrate stress in small areas. This often leads to stainless steel wires cutting through the sternal body and is very commonly observed in clinical settings.

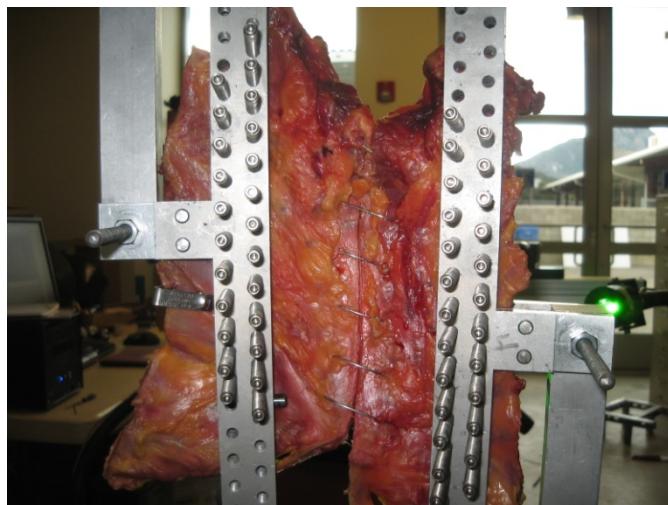


Figure 7.2: Picture taken at maximum displacement in the longitudinal direction. Slanted wires indicate plastic deformation at the midline.

Figure 7.2 shows a sternal construct closed with peristernal wires after testing. Wires wrapped around the sternal body are applied perpendicular to the midline of the sternotomy. Figure 7.2 shows the peristernal wires slanted after maximum displacement was achieved by the load frame and catastrophic failure had occurred. This suggests that after the construct had gone through a phase of elastic deformation and began to yield, the two sternal halves began sliding across each other. The sternum has permanently displaced relative to each other. This is the mode for post-yield behavior in peristernal wires when subjected to load in the longitudinal direction.

Only one statistical difference was found when testing in the rostro-caudal direction. When comparing females in groups A and B, the difference their stiffness was found to be statistically significant. Noticeable trends that Sternalock devices possessed advantageous properties were observed in the evaluation of stiffness and post-yield displacement (Figure 6.17 and Figure 6.29). Otherwise, no statistically significant data

was calculated. No separation in yield strength and maximum strength performance could be drawn from the data.

7.3. Anterior-posterior shear

Anterior-posterior, or transverse shear is also an important metric in evaluation median sternotomy closure techniques. Forces identical to this are seen in a clinical setting when a patient might roll on his or her back or bend in a particular direction.

Very little data was gathered from testing in this direction. Several obstacles existed that prevented us from recording meaningful data. No female specimen were available that were closed with Sternalock devices using box-plates (group C). Several data points were omitted due to Vic-3d being unable to process information.

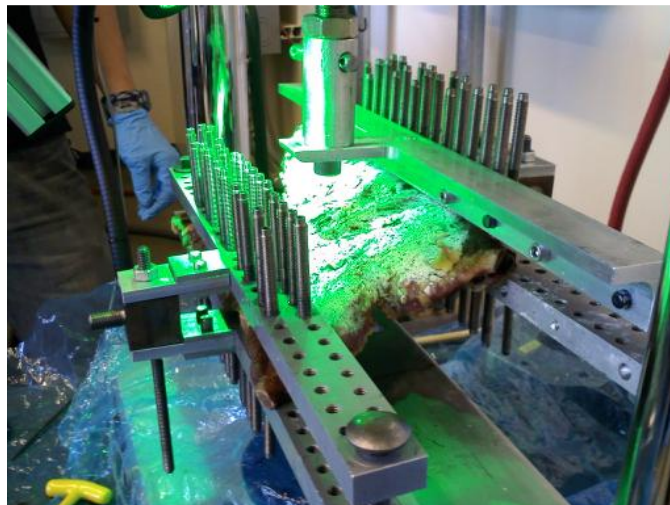


Figure 7.3: Picture taken at maximum displacement in the transverse direction. Failure did not occur during this test.

A very large amount of physiological compliance was present. This was due to the length of the ribs, presence of intercostal muscles, and cumbersome nature of the test-fixtures used. Additional test fixtures were created and added to the system shown in

Figure 7.3. This additional fixturing is difficult to see in the photograph, it involved bars that would apply force on the sternum closer to the midline of the construct. This attempt to avoid compliance was not sufficient to cause catastrophic failure in the device.

Due to the nature of the optical cameras, very little data was able to be captured during the tests. The positioning required that would allow an unobstructed view of the midline involved very close placement of the cameras to the sample, shown in Figure 7.4. This provided difficulties for the correlation software, and was not always able to extract meaningful data.



Figure 7.4: Picture taken from a camera used in the digital image correlation capture system.

You can also see issues in the camera's perspective from Figure 7.4. Deformation occurring due to the displacement of the test frame is neither vertical of the frame (y-axis), nor towards the camera (z-axis). Analysis of motion in one of these conventional directions is what Vic-3D is set up to do, one at a time.

It may not be critical to evaluate this test mode in depth, as it is expected that the high compliance seen in our test fixture will also be experienced to a larger extent in any clinical setting. The combination of low expected forces with high compliance of the system may prevent yield or maximum strength to be reached for the construct.

7.4. Texture correlation

The force versus displacement graph obtained by a load read-out given by the load frame is often the data gathered in similar studies. This references the overall stress experienced by the load cell against the displacement measured by the load frame. Three dimensional texture correlation (Correlated Solutions Inc, Columbia, SC) was seen as an opportunity to comprehensively analyze biomechanical properties. Overall load experienced by the system could be referenced to the displacement at the midline of the construct, more accurately characterizing the properties of the model.

A three-dimensional map was created using Vic-3D (Correlated Solutions Inc, Columbia, SC) that revealed high stress areas, rates of strain, and videos to analyze the mode of failure. This system is capable of more analysis than what was utilized for this study and the use of it is recommended for future studies.

7.5. Increased healing rate

During the early post-operative phase after a median sternotomy, a very fragile fibrocartilage callus will form over the osteotomy site. This is the beginning of bone healing and ultimately leads to woven bone and mineralized bone. Beginning several

weeks after surgery until 3 months post-operation, the fibrocartilage callus and woven bone provide the primary action for the healing process. This phase requires protection, as revascularization occurs. Complete immobilization of the area is critical to prevent severed blood vessels or damaging the woven bone. Sufficient immobilization may lead to faster healing times when compared to the insufficient immobilization achieved by wire closure methods [6].

A high stiffness or rigidity of the device-thorax construct will prevent any motion at the osteotomy site. Since the devices tested possessed maximum strength values in excess of what is typically experienced in-vivo, stiffness is seen as the most important and most practical factor in improving a sternal closure device.

7.6. Blood supply

As shown in Figure 3.14, internal mammary arteries run parallel to the sternal body and lead to branches that run across the sternum. The existence of blood vessels yields the possibility of interrupting blood flow to the area with any device that will wrap around the sternal body [28]. Any disruption of this blood flow may have the serious consequences of sternal ischemia, delayed wound healing and an increased sternal complication rate [28, 43, 51]. Ozaki *et al.* speculated that rigid plate fixation does not circumferentially compress the sternum and will not likely damage local sternal blood supply and subsequently lower the risk of sternal complications [28]. This is something that this study was not able to measure or evaluate, but is surely an advantage of the Sternalock device.

7.7. Gender differences

The only statistically significance found showing the difference between the biomechanical properties of males and females was data for yield strength when tested under longitudinal distraction. Consistent trends were found for each property that was analyzed with the exception of stiffness data tested in distraction (a difference opposite of the trend was found). Differences were repeatedly noted in all tests. Maximum strength and post-yield displacement both showed statistically insignificant trends towards higher performance for male specimen. However, this study lacked the statistical power to prove this difference.

7.8. Nature of failure

An important note from this study is the location and nature of failures during testing. Failure modes for particular devices can give important insight to its weaknesses. Classification of these failures can be put into two categories: device or physiologic failure.

7.8.1. Type of failure

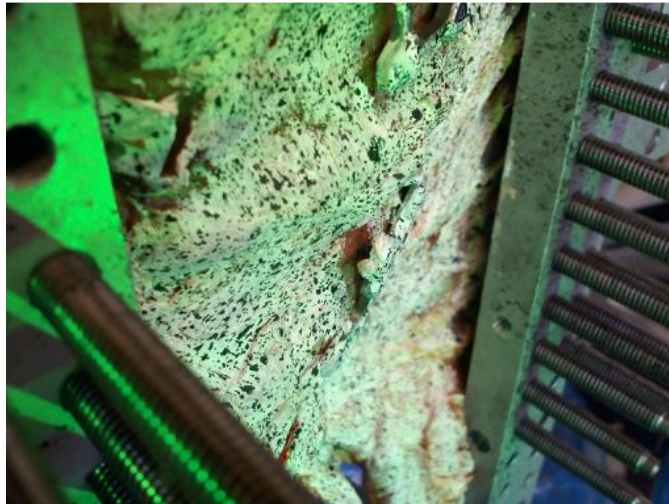


Figure 7.5: Picture taken after failure of the device occurred. A screw that fastened the plate to the sternum became dislodged.

Device failure was not often observed during this study. One case recorded was a Sternalock device in which the first X-plate had a screw that became dislodged from the sternum. The screw popped out, losing traction from its threads during catastrophic failure. This screw can be seen in Figure 7.5 in the middle of the photograph.

Examples of device failures that were seen in this study could be wire fracture, plate fracture, or untwisting of wires. However, device failures were extremely rare in this study and are not expected to be common in a clinical setting.

Physiologic failure was commonly noted in sternum closed by Sternalock devices. Sternal union was so much stiffer than it would be normally in a healthy sternum that rib fracture and intercostals muscle tearing was often seen. Examples of this are in Figure 7.1 and Figure 7.6. In Figure 7.1, light can be seen protruding through the cadaver in the area of the lower clamp, this indicates rib fracture and separation. Physiologic failure

may suggest that the true biomechanical properties of yield and maximum strength may be beyond what we were capable of measuring in this model.

7.8.2. Location of failure



Figure 7.6: Picture taken after clamps were removed from the sternum. Obvious tearing of the intercostal muscles had taken place, as well as fracture of associated ribs in the area.

Using wire circlage as a closure method, failures were observed with wires began to cut through cortical bone. This is consistent with results published by previous studies, and have been seen to cause healing complications. The failure mode observed in Sternalock systems occurred away from the midline of the sternum. Rib fractures and intercostals muscle tear along the grip line of the clamps were often noted with minimal separation at the midline (Figure 7.6). Although we found significantly higher stiffness values and trends towards higher yield strengths for these Sternalock constructs, it can be inferred that the yield strengths and maximum strengths found are not completely representative of the device-sternum interface; the data found is a representation of the mechanical

properties of the interaction between the clamps and cadaveric ribs. Because the closure at the midline was so rigid, stress fields were shifted further away from midline and resulted in catastrophic failure. This is more evidence supporting better performance of Sternalock devices.

7.9. Statistical power

42 cadaver models were used for this study. 3 fixation methods were tested to catastrophic failure in 3 different directions. Gender was also found to moderately influence biomechanical properties. The 42 specimen were divided into 9 groups, leaving 4.6 specimens per group – approximately 5. Considering gender in each of these groups, statistical analysis was often only left with 2 or 3 specimen in each group evaluated. In most cases, statistical power could not be achieved and sample sizes could not provide statistically significant differences between the three fixation methods. Trends were observed and interpreted in the data, but a future study with a larger sample size or more narrow focus could be done to verify these findings. Larger quantities could not be obtained for this study due to the large cost of cadavers.

A weakness in this study was the inability to test both male and female specimen in each group for every direction. Only 5 male specimens were available in group B and 5 female specimens for group C. An attempt was made to include at least 2 samples of each gender in each fixation method but this was not possible due to uneven proportions of samples. To further analyze the role of gender on biomechanical properties, a sufficient number of samples from each gender should be tested in each direction.

7.10. Post-Yield Displacement

Post-yield displacement is an indicator of damage to the bone in a cadaver model. This may translate into very undesirable outcomes in clinical settings. In the case of sternum closed with peristernal wires, this is usually characterized by wire cutting through bone. This has been cited for the reason for sternal mal-union or non-union, dehiscence, and mediastinitis. Therefore, wire cutting through bone, or any damage to bone should be avoided at all costs. Due to the minimal displacement associated with sternum closed with Sternalock devices, very little post-yield displacement occurred. This is evidence for limited damage to the bone before catastrophic failure.

8. Conclusions

- 1) Overall, Sternalock is less likely to fail under both lateral distraction and longitudinal shear. This rigid plate fixation device demonstrates superior rigidity, and shows promise for larger yield load and maximum load values. Rigid plate fixation is more equipped to provide support in all directions that might occur in a clinical setting, where peristernal wires only support a sternal construct in one direction.
- 2) Post-sternotomy constructs require a high resistance to movement. A completely immobilized union can allow for uninterrupted osseous healing and correlated with decreased healing times.

- 3) Directly linked to bone damage, post-yield displacement occurred in limited amounts with Sternalock devices. This may prevent healing complications such as sternal mal-union, non-union, dehiscence, or mediastinitis.
- 4) Evidence has been shown that revealed differences in mechanical behavior between cadaveric models of male and female subjects.
- 5) Sternalock plates were found to be stiffer and stronger than the native physiology of the thorax. Under high loads, sternum closed with Sternalock devices failed due to weaknesses in native tissue rather than related to the device.

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Appendix A: Statistical Analysis – Lateral distraction

General Linear Model: Stiffness, Yield Load, ... versus Fixation Met, Gender

Factor	Type	Levels	Values
Fixation Method	fixed	3	A, B, C
Gender	fixed	2	F, M

Analysis of Variance for Stiffness, using Adjusted SS for Tests

Source	DF	Seq SS	Adj SS	Adj MS	F	P
Age	1	2879103	25789181	25789181	20.93	0.002
Fixation Method	2	39360861	35164464	17582232	14.27	0.002
Gender	1	1480229	1429128	1429128	1.16	0.313
Fixation Method*Gender	2	6886150	6886150	3443075	2.79	0.120
Error	8	9855121	9855121	1231890		
Total	14	60461464				

S = 1109.91 R-Sq = 83.70% R-Sq(adj) = 71.48%

Term	Coef	SE Coef	T	P
Constant	-12108	3165	-3.83	0.005
Age	212.49	46.44	4.58	0.002

Unusual Observations for Stiffness

Obs	Stiffness	Fit	SE Fit	Residual	St Resid
4	453.28	2474.62	694.75	-2021.34	-2.34 R
5	532.61	532.61	1109.91	0.00	* X

R denotes an observation with a large standardized residual.

X denotes an observation whose X value gives it large leverage.

Analysis of Variance for Yield Load, using Adjusted SS for Tests

Source	DF	Seq SS	Adj SS	Adj MS	F	P
Age	1	80659	489	489	0.02	0.904
Fixation Method	2	92512	176994	88497	2.79	0.121
Gender	1	250129	218428	218428	6.88	0.031
Fixation Method*Gender	2	28319	28319	14160	0.45	0.655
Error	8	253984	253984	31748		
Total	14	705604				

S = 178.180 R-Sq = 64.00% R-Sq(adj) = 37.01%

Term	Coef	SE Coef	T	P
Constant	415.1	508.1	0.82	0.438
Age	0.926	7.456	0.12	0.904

Unusual Observations for Yield Load

Obs	Yield Load	Fit	SE Fit	Residual	St Resid
-----	------------	-----	--------	----------	----------

Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

5 207.07 207.07 178.18 0.00 * X

X denotes an observation whose X value gives it large leverage.

Analysis of Variance for Ultimate Load, using Adjusted SS for Tests

Source	DF	Seq SS	Adj SS	Adj MS	F	P
Age	1	83731	9172	9172	0.27	0.616
Fixation Method	2	22323	36453	18227	0.54	0.601
Gender	1	64108	46216	46216	1.37	0.275
Fixation Method*Gender	2	44490	44490	22245	0.66	0.542
Error	8	268952	268952	33619		
Total	14	483603				

S = 183.355 R-Sq = 44.39% R-Sq(adj) = 2.68%

Term	Coef	SE Coef	T	P
Constant	938.5	522.8	1.80	0.110
Age	-4.007	7.672	-0.52	0.616

Unusual Observations for Ultimate Load

Obs	Ultimate Load	Fit	SE Fit	Residual	St Resid
5	606.78	606.78	183.35	-0.00	* X

X denotes an observation whose X value gives it large leverage.

Analysis of Variance for Post-Yield Disp, using Adjusted SS for Tests

Source	DF	Seq SS	Adj SS	Adj MS	F	P
Age	1	0.0794	0.4297	0.4297	1.51	0.255
Fixation Method	2	2.1831	2.4930	1.2465	4.37	0.052
Gender	1	0.5907	0.5700	0.5700	2.00	0.195
Fixation Method*Gender	2	0.1009	0.1009	0.0505	0.18	0.841
Error	8	2.2839	2.2839	0.2855		
Total	14	5.2380				

S = 0.534307 R-Sq = 56.40% R-Sq(adj) = 23.70%

Term	Coef	SE Coef	T	P
Constant	2.409	1.524	1.58	0.153
Age	-0.02743	0.02236	-1.23	0.255

Unusual Observations for Post-Yield Disp

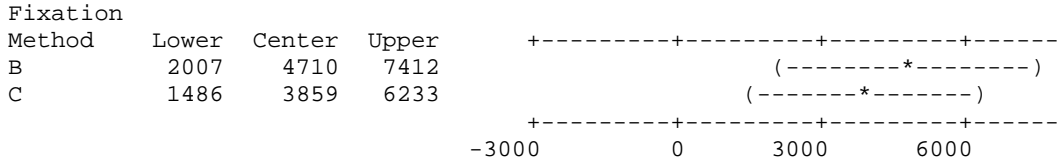
Obs	Post-Yield Disp	Fit	SE Fit	Residual	St Resid
5	1.34083	1.34083	0.53431	0.00000	* X

X denotes an observation whose X value gives it large leverage.

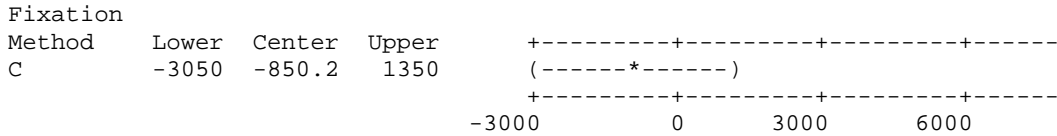
Tukey 95.0% Simultaneous Confidence Intervals
Response Variable Stiffness

Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

All Pairwise Comparisons among Levels of Fixation Method
Fixation Method = A subtracted from:



Fixation Method = B subtracted from:



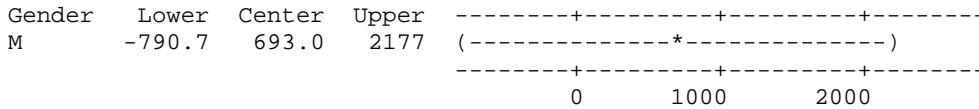
Tukey Simultaneous Tests
Response Variable Stiffness
All Pairwise Comparisons among Levels of Fixation Method
Fixation Method = A subtracted from:

Fixation Method	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	4710	945.9	4.979	0.0027
C	3859	830.8	4.645	0.0042

Fixation Method = B subtracted from:

Fixation Method	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	-850.2	770.1	-1.104	0.5382

Tukey 95.0% Simultaneous Confidence Intervals
Response Variable Stiffness
All Pairwise Comparisons among Levels of Gender
Gender = F subtracted from:



Tukey Simultaneous Tests
Response Variable Stiffness
All Pairwise Comparisons among Levels of Gender
Gender = F subtracted from:

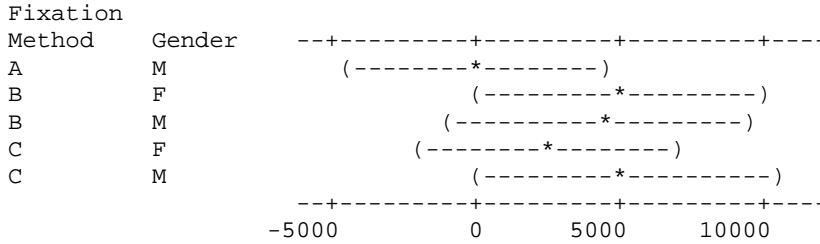
Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
M	693.0	643.4	1.077	0.3129

Tukey 95.0% Simultaneous Confidence Intervals
Response Variable Stiffness
All Pairwise Comparisons among Levels of Fixation Method*Gender
Fixation Method = A

Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

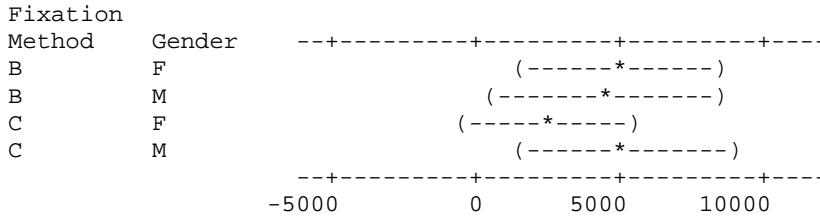
Gender = F subtracted from:

Fixation				
Method	Gender	Lower	Center	Upper
A	M	-4507	29.61	4566
B	F	28	5050.74	10074
B	M	-911	4398.11	9707
C	F	-2165	2523.27	7212
C	M	50	5225.19	10400



Fixation Method = A
Gender = M subtracted from:

Fixation				
Method	Gender	Lower	Center	Upper
B	F	1431.8	5021	8610
B	M	389.1	4369	8348
C	F	-610.0	2494	5597
C	M	1396.9	5196	8994



Fixation Method = B
Gender = F subtracted from:

Fixation				
Method	Gender	Lower	Center	Upper
B	M	-4357	-653	3052
C	F	-6225	-2527	1170
C	M	-3548	174	3897

-5000 0 5000 10000

Fixation Method = B
Gender = M subtracted from:

Fixation				
Method	Gender	Lower	Center	Upper
C	F	-5949	-1875	2200
C	M	-3253	827	4907

-5000 0 5000 10000

Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

Fixation Method = C
Gender = F subtracted from:

Fixation Method	Gender	Lower	Center	Upper
C	M	-1215	2702	6619

Tukey Simultaneous Tests
Response Variable Stiffness
All Pairwise Comparisons among Levels of Fixation Method*Gender
Fixation Method = A
Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
A	M	29.61	1241	0.02386	1.0000
B	F	5050.74	1374	3.67590	0.0486
B	M	4398.11	1452	3.02864	0.1149
C	F	2523.27	1282	1.96754	0.4313
C	M	5225.19	1416	3.69139	0.0476

Fixation Method = A
Gender = M subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	F	5021	981.8	5.114	0.0080
B	M	4369	1088.5	4.013	0.0312
C	F	2494	849.0	2.937	0.1297
C	M	5196	1039.1	5.000	0.0091

Fixation Method = B
Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	M	-653	1013	-0.644	0.9837
C	F	-2527	1011	-2.499	0.2293
C	M	174	1018	0.171	1.0000

Fixation Method = B
Gender = M subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	F	-1875	1115	-1.682	0.5758
C	M	827	1116	0.741	0.9704

Fixation Method = C
Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	M	2702	1071	2.522	0.2228

Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

Tukey 95.0% Simultaneous Confidence Intervals
Response Variable Yield Load
All Pairwise Comparisons among Levels of Fixation Method
Fixation Method = A subtracted from:

Fixation Method	Lower	Center	Upper
B	-79.3	354.5	788.3
C	-148.1	232.9	613.9

-----+-----+-----+-----+-----
 (-----*-----)
 (-----*-----)
 -----+-----+-----+-----+-----
 -350 0 350 700

Fixation Method = B subtracted from:

Fixation Method	Lower	Center	Upper
C	-474.8	-121.6	231.6

-----+-----+-----+-----+-----
 (-----*-----)
 -----+-----+-----+-----+-----
 -350 0 350 700

Tukey Simultaneous Tests
Response Variable Yield Load
All Pairwise Comparisons among Levels of Fixation Method
Fixation Method = A subtracted from:

Fixation Method	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	354.5	151.9	2.335	0.1077
C	232.9	133.4	1.746	0.2473

Fixation Method = B subtracted from:

Fixation Method	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	-121.6	123.6	-0.9837	0.6067

Tukey 95.0% Simultaneous Confidence Intervals
Response Variable Yield Load
All Pairwise Comparisons among Levels of Gender
Gender = F subtracted from:

Gender	Lower	Center	Upper
M	32.74	270.9	509.1

-----+-----+-----+-----+-----
 (-----*-----)
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 150 300 450

Tukey Simultaneous Tests
Response Variable Yield Load
All Pairwise Comparisons among Levels of Gender
Gender = F subtracted from:

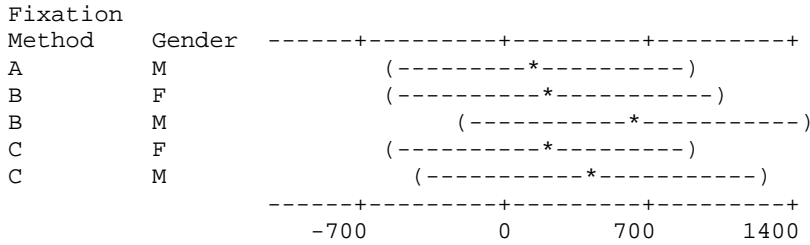
Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
M	270.9	103.3	2.623	0.0305

Tukey 95.0% Simultaneous Confidence Intervals
Response Variable Yield Load

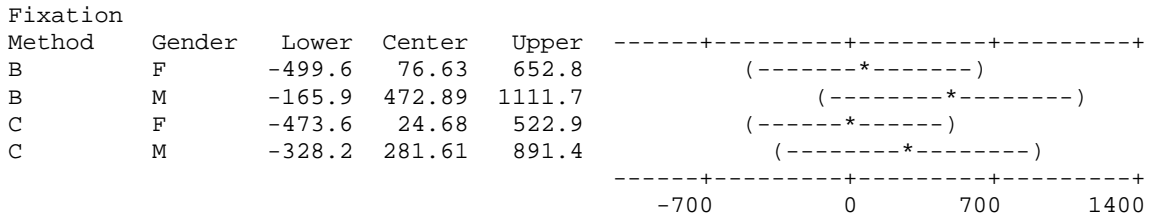
Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

All Pairwise Comparisons among Levels of Fixation Method*Gender
Fixation Method = A
Gender = F subtracted from:

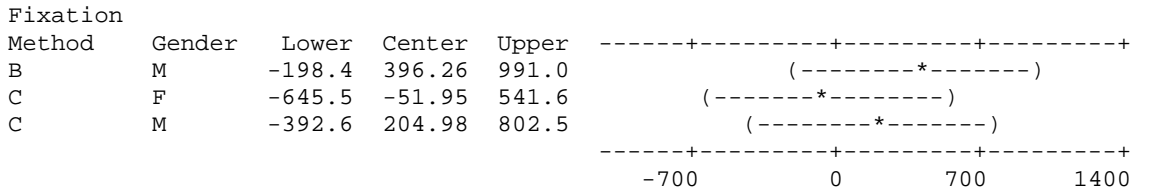
Fixation Method	Gender	Lower	Center	Upper
A	M	-568.7	159.6	887.8
B	F	-570.2	236.2	1042.6
B	M	-219.8	632.4	1484.7
C	F	-568.4	184.2	936.9
C	M	-389.6	441.2	1271.9



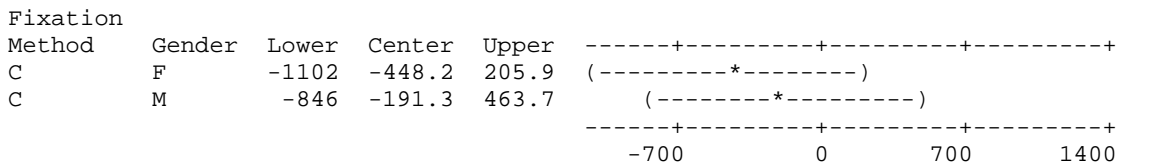
Fixation Method = A
Gender = M subtracted from:



Fixation Method = B
Gender = F subtracted from:



Fixation Method = B
Gender = M subtracted from:



Fixation Method = C
Gender = F subtracted from:

Fixation

Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

Method	Gender	of Means	Difference	T-Value	P-Value
A	M	-38.28	205.0	-0.1868	1.0000
B	F	-7.28	227.0	-0.0321	1.0000
B	M	258.89	239.9	1.0792	0.8769
C	F	-62.15	211.9	-0.2934	0.9996
C	M	83.80	233.8	0.3584	0.9989

Fixation Method = A
Gender = M subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	F	31.00	162.2	0.1911	0.9999
B	M	297.18	179.8	1.6526	0.5916
C	F	-23.87	140.2	-0.1702	1.0000
C	M	122.09	171.7	0.7112	0.9751

Fixation Method = B
Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	M	266.17	167.4	1.5901	0.6253
C	F	-54.87	167.1	-0.3284	0.9993
C	M	91.08	168.2	0.5415	0.9924

Fixation Method = B
Gender = M subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	F	-321.0	184.1	-1.744	0.5432
C	M	-175.1	184.4	-0.950	0.9218

Fixation Method = C
Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	M	146.0	177.0	0.8246	0.9544

Tukey 95.0% Simultaneous Confidence Intervals
Response Variable Post-Yield Disp
All Pairwise Comparisons among Levels of Fixation Method
Fixation Method = A subtracted from:

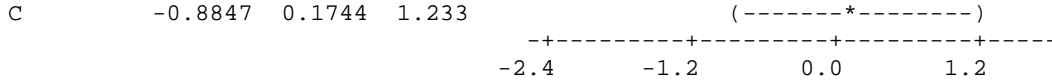
Fixation Method	Lower	Center	Upper	
B	-2.530	-1.229	0.07185	(-----*-----)
C	-2.197	-1.055	0.08797	(-----*-----)

-+-----+-----+-----+-----
-2.4 -1.2 0.0 1.2

Fixation Method = B subtracted from:

Fixation Method	Lower	Center	Upper	
				-+-----+-----+-----+-----

Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens



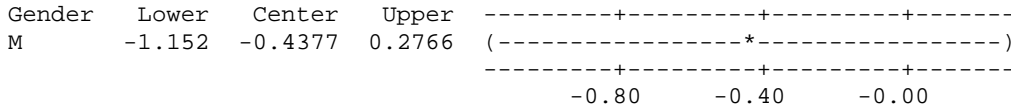
Tukey Simultaneous Tests
Response Variable Post-Yield Disp
All Pairwise Comparisons among Levels of Fixation Method
Fixation Method = A subtracted from:

Fixation Method	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	-1.229	0.4554	-2.699	0.0631
C	-1.055	0.4000	-2.637	0.0692

Fixation Method = B subtracted from:

Fixation Method	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	0.1744	0.3707	0.4703	0.8869

Tukey 95.0% Simultaneous Confidence Intervals
Response Variable Post-Yield Disp
All Pairwise Comparisons among Levels of Gender
Gender = F subtracted from:

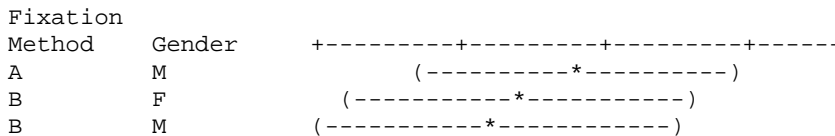


Tukey Simultaneous Tests
Response Variable Post-Yield Disp
All Pairwise Comparisons among Levels of Gender
Gender = F subtracted from:

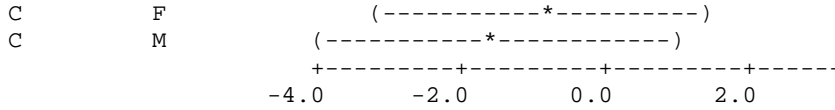
Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
M	-0.4377	0.3097	-1.413	0.1954

Tukey 95.0% Simultaneous Confidence Intervals
Response Variable Post-Yield Disp
All Pairwise Comparisons among Levels of Fixation Method*Gender
Fixation Method = A
Gender = F subtracted from:

Fixation Method	Gender	Lower	Center	Upper
A	M	-2.530	-0.346	1.8375
B	F	-3.679	-1.261	1.1573
B	M	-4.099	-1.544	1.0121
C	F	-3.143	-0.886	1.3711
C	M	-4.061	-1.570	0.9214

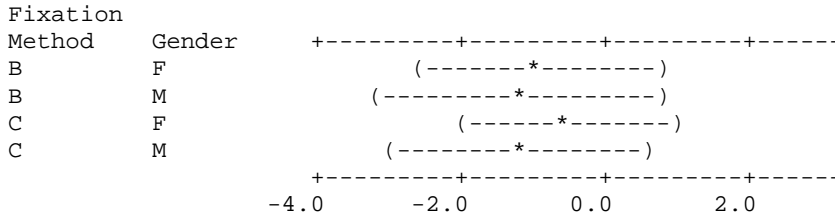


Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens



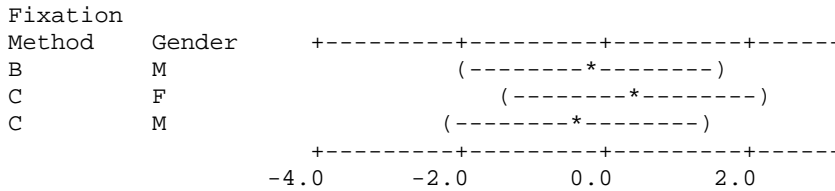
Fixation Method = A
Gender = M subtracted from:

Fixation Method	Gender	Lower	Center	Upper
B	F	-2.642	-0.914	0.8135
B	M	-3.113	-1.197	0.7185
C	F	-2.034	-0.539	0.9546
C	M	-3.052	-1.223	0.6054



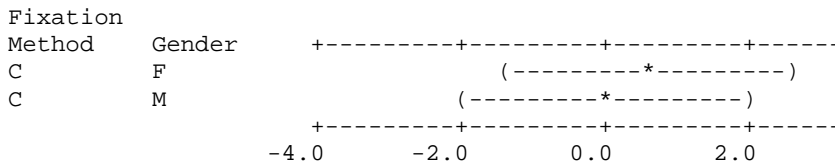
Fixation Method = B
Gender = F subtracted from:

Fixation Method	Gender	Lower	Center	Upper
B	M	-2.066	-0.2827	1.501
C	F	-1.405	0.3750	2.155
C	M	-2.101	-0.3089	1.483



Fixation Method = B
Gender = M subtracted from:

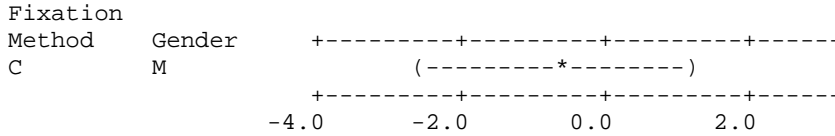
Fixation Method	Gender	Lower	Center	Upper
C	F	-1.304	0.65766	2.619
C	M	-1.990	-0.02620	1.938



Fixation Method = C
Gender = F subtracted from:

Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

Fixation Method	Gender	Lower	Center	Upper
C	M	-2.569	-0.6839	1.202



Tukey Simultaneous Tests

Response Variable Post-Yield Disp

All Pairwise Comparisons among Levels of Fixation Method*Gender

Fixation Method = A

Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
A	M	-0.346	0.5974	-0.580	0.9897
B	F	-1.261	0.6614	-1.906	0.4607
B	M	-1.544	0.6991	-2.208	0.3279
C	F	-0.886	0.6174	-1.435	0.7089
C	M	-1.570	0.6814	-2.304	0.2923

Fixation Method = A

Gender = M subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	F	-0.914	0.4727	-1.935	0.4469
B	M	-1.197	0.5240	-2.285	0.2992
C	F	-0.539	0.4087	-1.320	0.7684
C	M	-1.223	0.5002	-2.446	0.2453

Fixation Method = B

Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	M	-0.2827	0.4878	-0.5795	0.9897
C	F	0.3750	0.4869	0.7702	0.9654
C	M	-0.3089	0.4902	-0.6302	0.9852

Fixation Method = B

Gender = M subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	F	0.65766	0.5366	1.22572	0.8141
C	M	-0.02620	0.5372	-0.04878	1.0000

Fixation Method = C

Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	M	-0.6839	0.5158	-1.326	0.7654

Appendix B: Statistical Analysis – Rostro-caudal shear

General Linear Model: Stiffness, Yield Load, ... versus Fixation Met, Gender

Factor	Type	Levels	Values
Fixation Method	fixed	3	A, B, C
Gender	fixed	2	F, M

Analysis of Variance for Stiffness, using Adjusted SS for Tests

Source	DF	Seq SS	Adj SS	Adj MS	F	P
Age	1	389934	35630	35630	0.12	0.738
Fixation Method	2	5139054	2007460	1003730	3.35	0.082
Gender	1	264247	92938	92938	0.31	0.591
Fixation Method*Gender	2	199527	199527	99763	0.33	0.726
Error	9	2700341	2700341	300038		
Total	15	8693104				

S = 547.757 R-Sq = 68.94% R-Sq(adj) = 48.23%

Term	Coef	SE Coef	T	P
Constant	262	1471	0.18	0.863
Age	8.44	24.49	0.34	0.738

Unusual Observations for Stiffness

Obs	Stiffness	Fit	SE Fit	Residual	St Resid
6	0.00	-0.00	547.76	0.00	* X
11	580.69	1481.74	317.93	-901.05	-2.02 R

R denotes an observation with a large standardized residual.
X denotes an observation whose X value gives it large leverage.

Analysis of Variance for Yield Load, using Adjusted SS for Tests

Source	DF	Seq SS	Adj SS	Adj MS	F	P
Age	1	18504	752	752	0.16	0.697
Fixation Method	2	19561	16928	8464	1.82	0.217
Gender	1	7642	552	552	0.12	0.738
Fixation Method*Gender	2	6586	6586	3293	0.71	0.518
Error	9	41833	41833	4648		
Total	15	94126				

S = 68.1771 R-Sq = 55.56% R-Sq(adj) = 25.93%

Term	Coef	SE Coef	T	P
Constant	190.7	183.1	1.04	0.325
Age	-1.226	3.049	-0.40	0.697

Unusual Observations for Yield Load

Obs	Yield Load	Fit	SE Fit	Residual	St Resid
6	0.000	0.000	68.177	-0.000	* X

Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

13 348.448 215.441 40.919 133.007 2.44 R

R denotes an observation with a large standardized residual.
X denotes an observation whose X value gives it large leverage.

Analysis of Variance for Ultimate Load, using Adjusted SS for Tests

Source	DF	Seq SS	Adj SS	Adj MS	F	P
Age	1	100451	5025	5025	0.23	0.641
Fixation Method	2	17717	33976	16988	0.78	0.485
Gender	1	42944	5147	5147	0.24	0.638
Fixation Method*Gender	2	42847	42847	21423	0.99	0.409
Error	9	194901	194901	21656		
Total	15	398860				

S = 147.159 R-Sq = 51.14% R-Sq(adj) = 18.56%

Term	Coef	SE Coef	T	P
Constant	469.8	395.3	1.19	0.265
Age	-3.170	6.580	-0.48	0.641

Unusual Observations for Ultimate Load

Obs	Ultimate Load	Fit	SE Fit	Residual	St Resid
6	0.000	0.000	147.159	-0.000	* X
13	745.895	459.183	88.322	286.712	2.44 R

R denotes an observation with a large standardized residual.
X denotes an observation whose X value gives it large leverage.

Analysis of Variance for Post-Yield Disp, using Adjusted SS for Tests

Source	DF	Seq SS	Adj SS	Adj MS	F	P
Age	1	100059	4924	4924	0.23	0.645
Fixation Method	2	17776	33796	16898	0.78	0.486
Gender	1	43028	4989	4989	0.23	0.642
Fixation Method*Gender	2	42364	42364	21182	0.98	0.412
Error	9	194520	194520	21613		
Total	15	397747				

S = 147.015 R-Sq = 51.09% R-Sq(adj) = 18.49%

Term	Coef	SE Coef	T	P
Constant	467.5	394.9	1.18	0.267
Age	-3.138	6.574	-0.48	0.645

Unusual Observations for Post-Yield Disp

Obs	Post-Yield Disp	Fit	SE Fit	Residual	St Resid
6	0.000	0.000	147.015	-0.000	* X
13	745.588	458.988	88.235	286.601	2.44 R

R denotes an observation with a large standardized residual.

Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

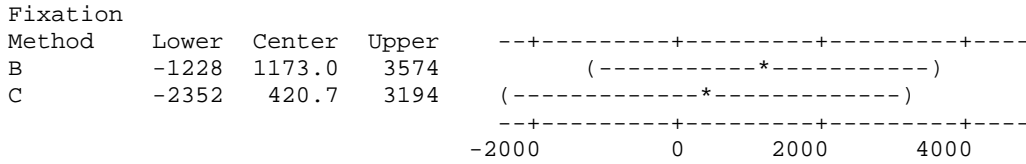
X denotes an observation whose X value gives it large leverage.

Tukey 95.0% Simultaneous Confidence Intervals

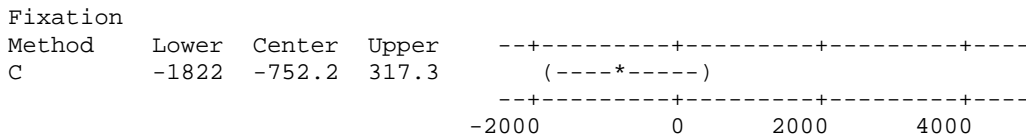
Response Variable Stiffness

All Pairwise Comparisons among Levels of Fixation Method

Fixation Method = A subtracted from:



Fixation Method = B subtracted from:



Tukey Simultaneous Tests

Response Variable Stiffness

All Pairwise Comparisons among Levels of Fixation Method

Fixation Method = A subtracted from:

Fixation Method	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	1173.0	859.7	1.3645	0.3980
C	420.7	992.8	0.4238	0.9067

Fixation Method = B subtracted from:

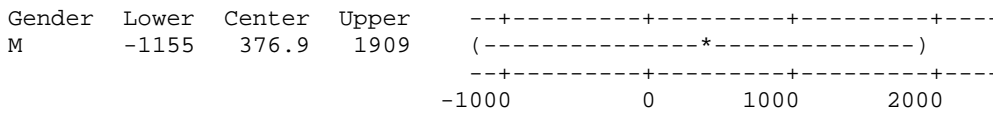
Fixation Method	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	-752.2	382.9	-1.965	0.1768

Tukey 95.0% Simultaneous Confidence Intervals

Response Variable Stiffness

All Pairwise Comparisons among Levels of Gender

Gender = F subtracted from:



Tukey Simultaneous Tests

Response Variable Stiffness

All Pairwise Comparisons among Levels of Gender

Gender = F subtracted from:

Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
M	376.9	677.2	0.5566	0.5914

Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

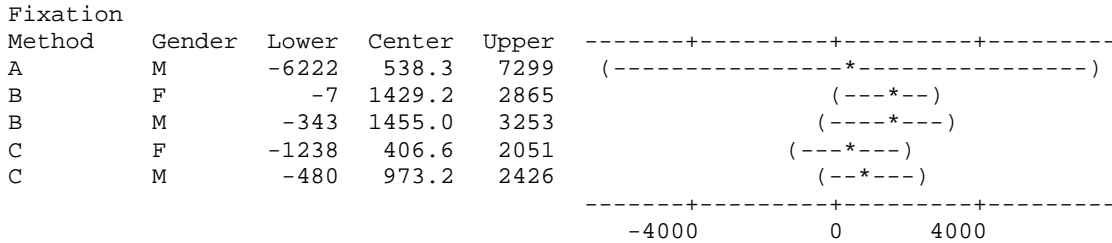
Tukey 95.0% Simultaneous Confidence Intervals

Response Variable Stiffness

All Pairwise Comparisons among Levels of Fixation Method*Gender

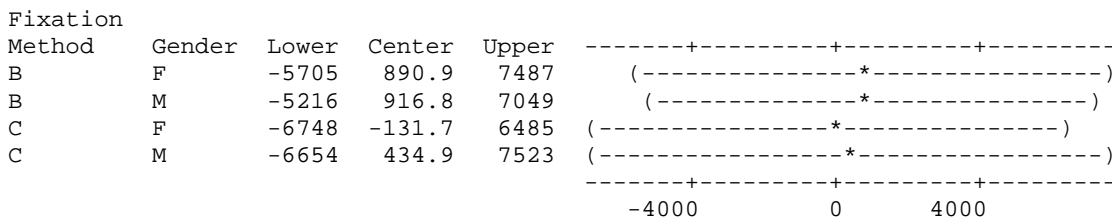
Fixation Method = A

Gender = F subtracted from:



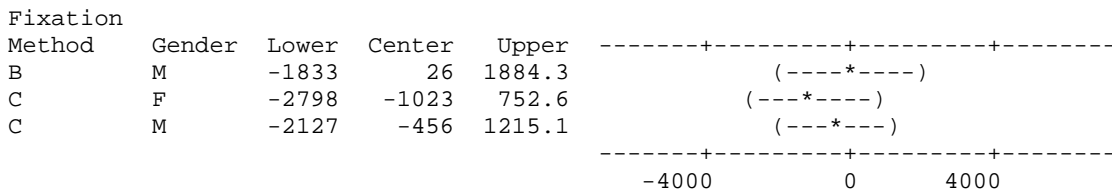
Fixation Method = A

Gender = M subtracted from:



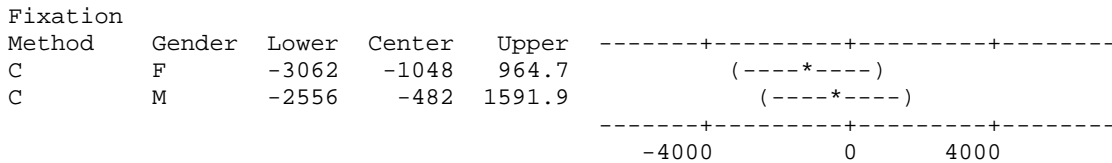
Fixation Method = B

Gender = F subtracted from:



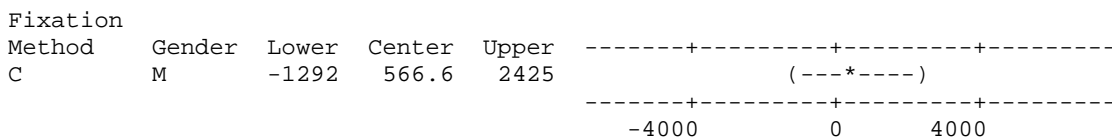
Fixation Method = B

Gender = M subtracted from:



Fixation Method = C

Gender = F subtracted from:



Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

Tukey Simultaneous Tests

Response Variable Stiffness

All Pairwise Comparisons among Levels of Fixation Method*Gender

Fixation Method = A

Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
A	M	538.3	1904.6	0.2826	0.9997
B	F	1429.2	404.6	3.5326	0.0514
B	M	1455.0	506.4	2.8730	0.1315
C	F	406.6	463.4	0.8774	0.9429
C	M	973.2	409.3	2.3778	0.2575

Fixation Method = A

Gender = M subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	F	890.9	1858	0.47946	0.9958
B	M	916.8	1728	0.53065	0.9933
C	F	-131.7	1864	-0.07064	1.0000
C	M	434.9	1997	0.21779	0.9999

Fixation Method = B

Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	M	26	523.5	0.049	1.0000
C	F	-1023	500.1	-2.045	0.3890
C	M	-456	470.8	-0.969	0.9170

Fixation Method = B

Gender = M subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	F	-1048	567.1	-1.849	0.4842
C	M	-482	584.2	-0.825	0.9553

Fixation Method = C

Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	M	566.6	523.5	1.082	0.8769

Tukey 95.0% Simultaneous Confidence Intervals

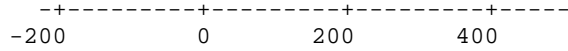
Response Variable Yield Load

All Pairwise Comparisons among Levels of Fixation Method

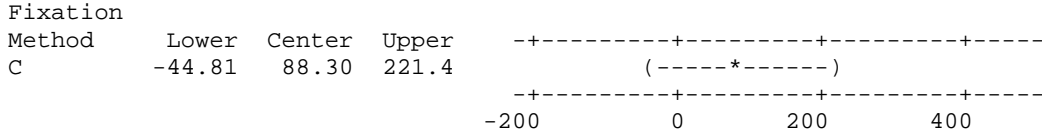
Fixation Method = A subtracted from:

Fixation Method	Lower	Center	Upper	
B	-220.4	78.47	377.3	(-----*-----)
C	-178.4	166.77	511.9	(-----*-----)

Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens



Fixation Method = B subtracted from:



Tukey Simultaneous Tests

Response Variable Yield Load

All Pairwise Comparisons among Levels of Fixation Method

Fixation Method = A subtracted from:

Fixation Method	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	78.47	107.0	0.7333	0.7507
C	166.77	123.6	1.3496	0.4052

Fixation Method = B subtracted from:

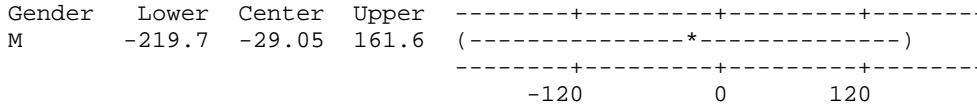
Fixation Method	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	88.30	47.66	1.853	0.2077

Tukey 95.0% Simultaneous Confidence Intervals

Response Variable Yield Load

All Pairwise Comparisons among Levels of Gender

Gender = F subtracted from:



Tukey Simultaneous Tests

Response Variable Yield Load

All Pairwise Comparisons among Levels of Gender

Gender = F subtracted from:

Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
M	-29.05	84.29	-0.3447	0.7383

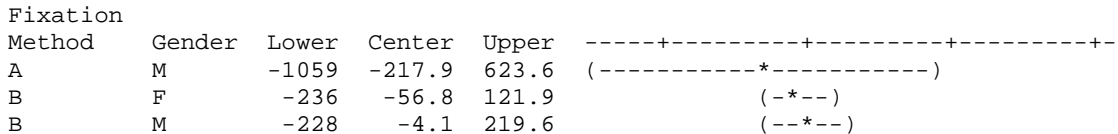
Tukey 95.0% Simultaneous Confidence Intervals

Response Variable Yield Load

All Pairwise Comparisons among Levels of Fixation Method*Gender

Fixation Method = A

Gender = F subtracted from:



Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

C	F	18.8	57.68	0.326	0.9993
C	M	96.8	50.94	1.901	0.4577

Fixation Method = A
Gender = M subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	F	161.1	231.3	0.6965	0.9777
B	M	213.8	215.0	0.9942	0.9087
C	F	236.7	232.0	1.0203	0.8998
C	M	314.8	248.6	1.2664	0.7954

Fixation Method = B
Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	M	52.70	65.16	0.8087	0.9587
C	F	75.62	62.25	1.2149	0.8199
C	M	153.68	58.59	2.6228	0.1858

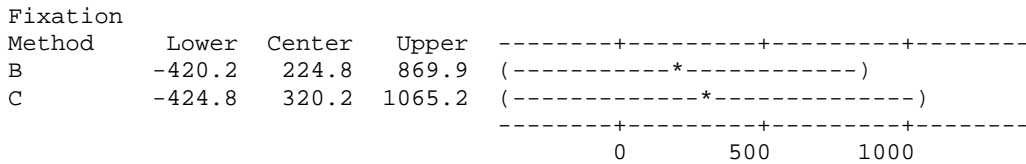
Fixation Method = B
Gender = M subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	F	22.92	70.59	0.3247	0.9993
C	M	100.98	72.71	1.3888	0.7330

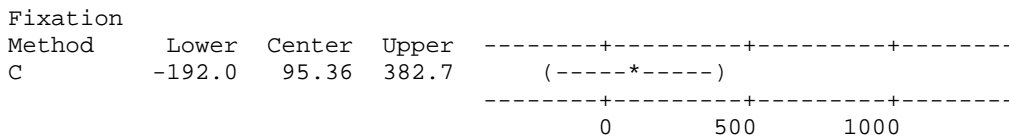
Fixation Method = C
Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	M	78.06	65.16	1.198	0.8277

Tukey 95.0% Simultaneous Confidence Intervals
Response Variable Ultimate Load
All Pairwise Comparisons among Levels of Fixation Method
Fixation Method = A subtracted from:



Fixation Method = B subtracted from:



Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

Tukey Simultaneous Tests

Response Variable Ultimate Load

All Pairwise Comparisons among Levels of Fixation Method

Fixation Method = A subtracted from:

Fixation Method	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	224.8	231.0	0.9735	0.6106
C	320.2	266.7	1.2004	0.4821

Fixation Method = B subtracted from:

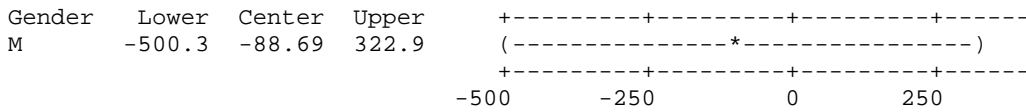
Fixation Method	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	95.36	102.9	0.9270	0.6379

Tukey 95.0% Simultaneous Confidence Intervals

Response Variable Ultimate Load

All Pairwise Comparisons among Levels of Gender

Gender = F subtracted from:



Tukey Simultaneous Tests

Response Variable Ultimate Load

All Pairwise Comparisons among Levels of Gender

Gender = F subtracted from:

Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
M	-88.69	181.9	-0.4875	0.6376

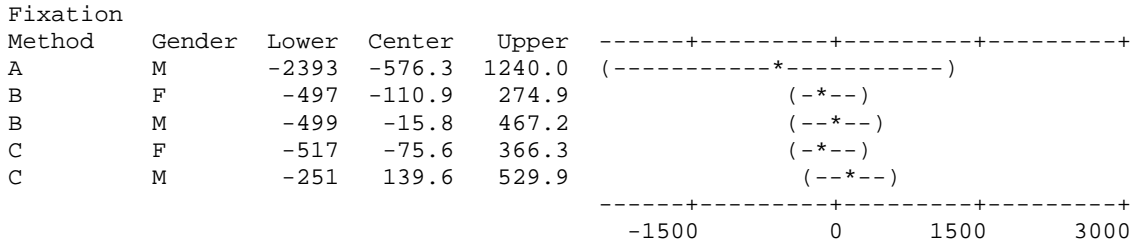
Tukey 95.0% Simultaneous Confidence Intervals

Response Variable Ultimate Load

All Pairwise Comparisons among Levels of Fixation Method*Gender

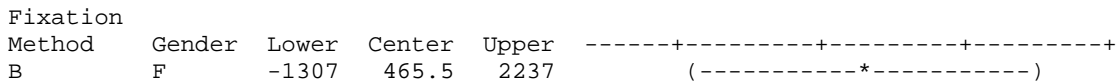
Fixation Method = A

Gender = F subtracted from:



Fixation Method = A

Gender = M subtracted from:



Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

C M 715.9 536.5 1.3345 0.7613

Fixation Method = B
Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	M	95.07	140.7	0.6759	0.9804
C	F	35.30	134.4	0.2627	0.9998
C	M	250.48	126.5	1.9805	0.4189

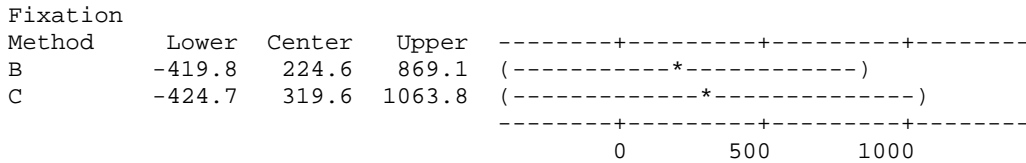
Fixation Method = B
Gender = M subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	F	-59.77	152.4	-0.3923	0.9984
C	M	155.41	156.9	0.9902	0.9101

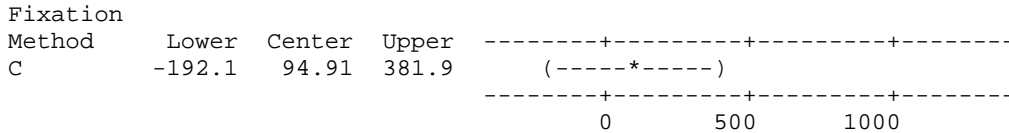
Fixation Method = C
Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	M	215.2	140.7	1.530	0.6565

Tukey 95.0% Simultaneous Confidence Intervals
Response Variable Post-Yield Disp
All Pairwise Comparisons among Levels of Fixation Method
Fixation Method = A subtracted from:



Fixation Method = B subtracted from:



Tukey Simultaneous Tests
Response Variable Post-Yield Disp
All Pairwise Comparisons among Levels of Fixation Method
Fixation Method = A subtracted from:

Fixation Method	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	224.6	230.7	0.9736	0.6105
C	319.6	266.5	1.1992	0.4828

Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

Fixation Method = B subtracted from:

Fixation Method	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	94.91	102.8	0.9235	0.6399

Tukey 95.0% Simultaneous Confidence Intervals
Response Variable Post-Yield Disp
All Pairwise Comparisons among Levels of Gender
Gender = F subtracted from:

Gender	Lower	Center	Upper	
M	-498.5	-87.32	323.8	(-----*-----)

-500 -250 0 250

Tukey Simultaneous Tests
Response Variable Post-Yield Disp
All Pairwise Comparisons among Levels of Gender
Gender = F subtracted from:

Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
M	-87.32	181.8	-0.4804	0.6424

Tukey 95.0% Simultaneous Confidence Intervals
Response Variable Post-Yield Disp
All Pairwise Comparisons among Levels of Fixation Method*Gender
Fixation Method = A
Gender = F subtracted from:

Fixation Method	Gender	Lower	Center	Upper	
A	M	-2387	-572.2	1242.3	(-----*-----)
B	F	-494	-109.1	276.4	(-*-)
B	M	-496	-13.8	468.7	(--*--)
C	F	-516	-74.0	367.4	(--*--)
C	M	-249	141.0	530.9	(--*--)

-1500 0 1500 3000

Fixation Method = A
Gender = M subtracted from:

Fixation Method	Gender	Lower	Center	Upper	
B	F	-1307	463.1	2233	(-----*-----)
B	M	-1088	558.3	2204	(-----*-----)
C	F	-1278	498.1	2274	(-----*-----)
C	M	-1189	713.1	2616	(-----*-----)

-1500 0 1500 3000

Fixation Method = B
Gender = F subtracted from:

Fixation Method	Gender	Lower	Center	Upper	
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Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

Fixation Method = B

Gender = M subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	F	-60.19	152.2	-0.3954	0.9983
C	M	154.80	156.8	0.9873	0.9110

Fixation Method = C

Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	M	215.0	140.5	1.530	0.6564

Appendix C: Statistical Analysis – Anterior-Posterior shear

General Linear Model: Stiffness versus Fixation Method, Gender

Factor	Type	Levels	Values
Fixation Method	fixed	3	A, B, C
Gender	fixed	2	F, M

Analysis of Variance for Stiffness, using Adjusted SS for Tests

Source	DF	Seq SS	Adj SS	Adj MS	F	P
Age	1	10524.9	6152.4	6152.4	8.78	0.041
Fixation Method	2	5837.5	4659.0	2329.5	3.32	0.141
Gender	1	96.7	1017.0	1017.0	1.45	0.295
Fixation Method*Gender	2	3721.9	3721.9	1860.9	2.66	0.185
Error	4	2802.7	2802.7	700.7		
Total	10	22983.7				

S = 26.4701 R-Sq = 87.81% R-Sq(adj) = 69.51%

Term	Coef	SE Coef	T	P
Constant	-116.06	60.12	-1.93	0.126
Age	2.9181	0.9848	2.96	0.041

Unusual Observations for Stiffness

Obs	Stiffness	Fit	SE Fit	Residual	St Resid
5	32.570	32.570	26.470	-0.000	* X
11	0.000	-0.000	26.470	0.000	* X

X denotes an observation whose X value gives it large leverage.

Tukey 95.0% Simultaneous Confidence Intervals

Response Variable Stiffness

All Pairwise Comparisons among Levels of Fixation Method

Fixation Method = A subtracted from:

Fixation Method	Lower	Center	Upper	-----+-----+-----+-----+
B	-63.99	12.14	88.26	(-----*-----)
C	-46.47	107.09	260.66	(-----*-----)

-----+-----+-----+-----+

0 100 200 300

Fixation Method = B subtracted from:

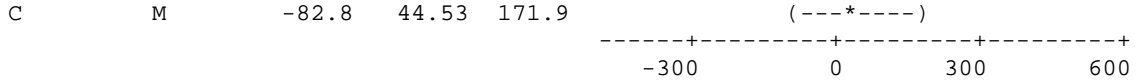
Fixation Method	Lower	Center	Upper	-----+-----+-----+-----+
C	-40.44	94.96	230.4	(-----*-----)

-----+-----+-----+-----+

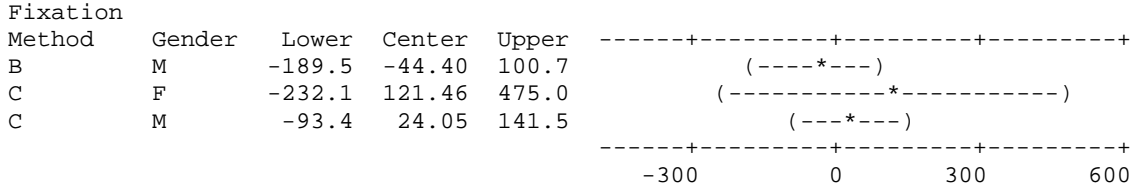
0 100 200 300

Tukey Simultaneous Tests

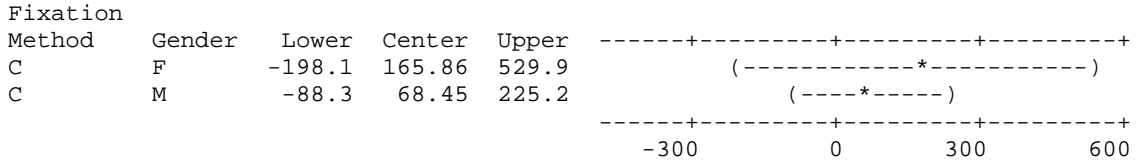
Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens



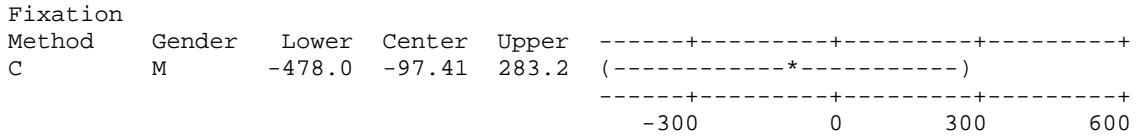
Fixation Method = B
Gender = F subtracted from:



Fixation Method = B
Gender = M subtracted from:



Fixation Method = C
Gender = F subtracted from:



Tukey Simultaneous Tests
Response Variable Stiffness
All Pairwise Comparisons among Levels of Fixation Method*Gender
Fixation Method = A
Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
A	M	27.706	27.35	1.0129	0.8926
B	F	48.189	24.34	1.9795	0.4729
B	M	3.789	32.66	0.1160	1.0000
C	F	169.651	77.96	2.1760	0.4004
C	M	72.238	26.58	2.7173	0.2497

Fixation Method = A
Gender = M subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	F	20.48	26.09	0.7850	0.9564
B	M	-23.92	34.18	-0.6997	0.9722
C	F	141.95	84.28	1.6842	0.5986
C	M	44.53	26.84	1.6593	0.6099

Biomechanical Comparison of Wire Circlage and Rigid Plate Fixation
for Median Sternotomy Closure in Human Cadaver Specimens

Fixation Method = B
Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
B	M	-44.40	30.58	-1.452	0.7063
C	F	121.46	74.51	1.630	0.6232
C	M	24.05	24.76	0.971	0.9065

Fixation Method = B
Gender = M subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	F	165.86	76.72	2.162	0.4052
C	M	68.45	33.04	2.071	0.4378

Fixation Method = C
Gender = F subtracted from:

Fixation Method	Gender	Difference of Means	SE of Difference	T-Value	Adjusted P-Value
C	M	-97.41	80.21	-1.214	0.8138