Managing Sternal Closure with Rigid Fixation
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Background:
• Specialist in cardiac surgery
• Senior physician
• Interest:
  • Valve replacement
  • Lungtransplantation
  • Rigid sternum closure

Note: Dr. Lehmann is a Biomet Consultant
Course Goals
Goals for Today

1) Obtain a understanding of *the bone remodeling process*

2) Discuss how *rigid fixation* impacts bone repair

3) Provide you with the latest information on *sternal closure*

4) Allow you to gain *hands on* experience with rigid sternal fixation

5) Arm you with information that will help you go back to your practice and *personalize the care you provide* for each patient
Introduction
Does This Look Like Your Weekend??

LORENZ
SKILLS ACADEMY

Thoracic Program
The Right Tools Make a Big Difference
The same is true in surgery...

Various Tools for Closure...

- Sternal Sutures / Wire
- Double Wires
- Sternal Band
- Sternal Cables
- Sternal Clamps
- Sternal Plates
So How Do you Know What to Use?

1) Have a deep understanding of the factors that affect bone repair

2) Know your patient’s history / demographics
Don’t Tune Out Yet!

Did You Know...

✓ The sternotomy is the **most common osteotomy** worldwide³.

✓ **You cut more bone** than most orthopedic surgeons.

✓ Bone repair can be the **most painful part** of your patient’s recovery³.

✓ Side effects of poorly repaired bone can result in **complications³, and significant expenses⁴** to your facility.

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Overview of SternaLock® System
SternaLock® Plate & Screw System

• Introduced by Biomet in 2003
• Stabilize & fixate anterior chest wall fractures
  • Rigid fixation for sternal closure
• Plate & screw system
• System specific instrumentation
Sternum: Anatomy
Basic Anatomy of Sternum

- Elongated, flat bone
- Forms middle portion of anterior wall of thorax
- Manubrium support the clavicles
- Composed of three sections
  - Manubrium
  - Body
  - Xiphoid

Advanced Discussion of Sternum

Cortical Outer Shell\textsuperscript{1,2}

- Dense outer surface of bone
- Forms protective layer
- Compact bone
- High resistance to bending & torsion
- Imperative to structure & weight

Sternal Cortical Outer Shell

Cancellous Inner\textsuperscript{1,2}

- Spongy tissue
- Help in formation & growth of bone
- Interconnecting spaces containing bone marrow

Bone Repair Process
Starts with an Injury: Bone Fracture

Tibia / Fibula Fracture\(^1,2\)

- Fractures cortical and cancellous bone
- Causes bleeding of cancellous bone
- Fracture site swells
- Damage to periosteum triggers nerves

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Sternotomy is an Injury...

Sternotomy\textsuperscript{1,2}

- Fractures cortical and cancellous bone
- Causes bleeding of cancellous bone
- Fracture site swells
- Damage to periosteum triggers nerves

## Bone Repair Process

Bone repair process is not rigidly fixated.

### Normal Bone Repair...

<table>
<thead>
<tr>
<th>Stage¹:</th>
<th>Hematoma (Inflammatory)</th>
<th>Soft Callus</th>
<th>Hard Callus</th>
<th>Remodeling</th>
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</thead>
<tbody>
<tr>
<td>Timeframe¹:</td>
<td>1-2 Weeks</td>
<td>2-3 Weeks</td>
<td>4-16 Weeks</td>
<td>17 + Weeks</td>
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<td>* Painful</td>
<td>* Painful</td>
<td>* Less Painful</td>
<td>* Stable</td>
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<tr>
<td></td>
<td>* Fragile</td>
<td>* Fragile</td>
<td>* More Stable</td>
<td></td>
</tr>
</tbody>
</table>

*Note: A patient’s habits and state of health can effect these times*

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1. Permission to utilize photos pending from Orthofix.
Bone Repair Process *(Rigid fixation)*

Rigidly fixated bone undergoes **Direct Bone Repair**...

"Callus-free"

<table>
<thead>
<tr>
<th>Stage&lt;sup&gt;1,4&lt;/sup&gt;:</th>
<th>Hematoma (Inflammatory)</th>
<th>Remodeling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timeframe&lt;sup&gt;1,4&lt;/sup&gt;:</td>
<td>1-2 Weeks</td>
<td>2-4 + Weeks</td>
</tr>
<tr>
<td>Comments&lt;sup&gt;2&lt;/sup&gt;:</td>
<td>* Painful * Fragile</td>
<td>* Stable</td>
</tr>
</tbody>
</table>

**Note:** A patient’s habits and state of health can effect these times

1. Permission to utilize photos pending from Orthofix.
Keys to Direct Bone Repair...

1. Exact Reduction
2. Stable Fixation
3. Adequate Blood Supply
The Break Can Impact Healing...

- Unclean / shattered bone needs to be cleaned up to ensure cancellous bone touches cancellous bone
- Clean break means easier approximation
Stability

- Stability allows the vessels to grow across the fracture
  - Vessels are the key to carrying blood / nutrients
  - If vessels keep breaking due to movement, bone takes longer to heal

- Proper stabilization keeps your great work in place
Stability: Some Motion is Good

**Micromotion is Good**

1. Allows for very small, controlled, motion between two segments
2. Often not “seen” or felt by hand
3. Promotes a controlled build up and break down ultimately leading to strong remodeling

**Macromotion is Bad**

1. Allows for significant, uncontrolled, motion between two segments
2. Able to see and palpate by pressing on adjacent segments
3. Prevents segment from moving past the Callus formation and often results in scared tissue

• Bone repair doesn’t happen overnight!

• Patients need to immobilize the site of fracture to allow for bone repair$^1$
Bone Repair Process *(stable vs. unstable)*

**Stable Bone**

- **30 Days**
  - Hematoma
- **60 Days**
  - Remodeling
- **90 Days**
  - Remodeling

**Unstable Bone**

- **30 Days**
  - Hematoma
- **60 Days**
  - Soft Callus
- **90 Days**
  - Thick Scar

References:
1. Permission to utilize photos pending from Orthofix.
Recap: Keys to Bone Repair

1) Ensure a clean fracture

2) Good bone approximation to facilitate healing
   - Cancellous to Cancellous
   - Cortical to Cortical

3) Stability to allow vessels to grow across fracture
   - Micromotion is good
   - Macromotion is bad

4) Time to allow bone fusion

Side Effects of Bone Non-Union

- Increased pain medication intake by patient¹
- Slower return to work / activity²
- Extended risk of severe infection³
- Patients forget your lifesaving work and only focus on pain


References
Patient Factors that Impact Bone Repair
Osteoporosis

Note: Insufficient quality or quantity of bone is a contraindication of rigid fixation.

- Bone mass is significantly lower than normal
- Bone is weak and brittle – difficult to fixate
- Screws do not anchor as well into thin, weak, osteoporotic bone


Good Quality

Poor Quality
Bone Mass

Figure 1: Bone Mass Lifecycle

- As people age bone mass declines
- Women lose mass faster than men during menopause
- Lower bone mass leads to fragile bone, more difficult to fixate

Smoking

Note: Limited blood supply is a contraindication of rigid fixation.

- Blood vessels constrict approx. 25% of their normal diameter
  - Decreases nutrients to bone
- Bone takes 2 months longer to heal
- Coughing puts large force on sternum
- Typically excluded from FDA trials in orthopedics – failure rate is 4 fold compared to non-smokers

Active Patients

Note: It is imperative for patients to follow post-op instructions given by surgeon

• Patients typically want return to activity / work sooner
  • Drying hair
  • Picking up children
  • Working
  • Golfing
  • Lifting groceries
  • Exercising

• Patients need to immobilize the site of fracture to allow for bone repair¹
Other Factors the Effect Bone Repair...

- Non-steroidal anti-inflammatory drugs (NSAIDs)
  - Aspirin
  - Ibuprofen
  - Naproksen

- Nutritional Status

- Steroid Use

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Recap: Bone Repair

Keys...

- Clean surfaces (no bone wax)
- Controlled vascularized site
- Good approximation of adjacent extremities
- Forces
- Micromotion vs. macromotion
- Time
Recap: Bone Repair

Patient Factors...

- Bone quality
- Smoking
- Patient activity level
- NSAIDs, Steroids & Nutrition
Natural Forces on the Sternum
Breathing & Coughing Forces\(^1\) (sternotomy study)

- Maximum coughing places 150kg of force on sternum\(^1\)
- This equates to 25kg of force across each sternal wire\(^1\)
- At 20kg force, twisted wire starts to untwist\(^1\)
- There is a risk that severe coughing may cause wires to untwist\(^1\)

Fixating the Sternum: Biomechanical Testing
✓ Compare fixation of cadaveric sterna by...
  • Wire circlage (3 peristernal @ manubrium & 5 trans-sternal along body)
  • Rigid plate fixation construct #1 (1 L plate & 2 X plates)
  • Rigid plate fixation construct #2 (1 Box plate & 2 X plates)

✓ Determine which rigid plate construct will provide the strongest and stiffest method of closure

Note> Study conducted by Lanny V. Griffin, Ph.D. – Professor and Chair of Cal Poly Biomedical Engineering Department, et. al (11/3/09)

Note: Bench testing is not necessarily indicative of clinical performance
Methodology

✓ 43 cadaveric models divided into 3 groups...

✓ Several biomechanical parameters evaluated...
  • Stiffness, Yield Load, Post Yield Displacement, Ultimate Load
43 Cadaveric Sternums Tested

Rostro-Caudal Shear Testing

Anterior-Posterior Shear Testing

Lateral Distraction Testing

Other Observations

✓ Under ultimate load, no plate constructs failed
  ✓ Failure occurred when sternum separated from the ribs

✓ Under ultimate load, wire construct failed
  ✓ Failure occurred when wires broke apart

Rigid fixation of the sternum using titanium plates and screws is biomechanically superior to wires.

No statistically significant differences between the 2 plating constructs in lateral distraction testing.

“L” plate configuration statistically superior to “Box” plate configuration in rostro-caudal shear testing.
Fixating the Sternum: Animal Testing
Earlier Bone Healing in Baboons

- 14 skeletally mature baboons underwent standard median sternotomy
  - 7 closed w/ 24-gauge wire circlage
  - 7 closed with thin Vitallium compression miniplates & transverse lag screws
- Sternum harvested @ 4 & 8 weeks
- Clinical stability superior with plates @ 4 weeks
- Rigid fixation resulted in earlier union than wires

Earlier Bone Healing

- Histological evaluations of Manubrium @ 4 weeks post op in Baboons
- Evaluation by Sargeant (1991)

Rigid Fixation of the Sternum
Why have we not evolved to rigid bone fixation like other specialties? *(neuro, ortho, spine, cmf)*

Rigid Fixation

- Phalanges
- Clavicle
- Femur
- Fibula
- Midface
- Radius
- Humerus
- Spine
SternaLock® Technique

1) Sternotomy & bone assessment

2) Measure sternal depth & select screws

3) Reduce sternum

4) Select & contour plates

5) Fixate plates to sternum & complete chest closure
Sternotomy & Bone Assessment

I) Perform midline sternotomy

Notes:
* Ensure down center of sternum
* Use reference points to guide your cut

Reference Points for Sternotomy
II) Expose sternum by reflecting the pectoral muscle
III) Analyze the bone health

Notes:
* Consider risk factors that cause poor bone quality
* How did the bone feel when cut with saw
* Feel the bone with your fingers (solid or soft)
IV) Identify Transverse Fractures

Notes:
* Mark transverse fractures
* When closing do not place screws on / near fractures
V) Carefully Retract the Sternum

Notes:
* Minimize trauma to sternum
* Apply even force along sternal halves to avoid fractures

Apply Even Force
V) Perform Intended Surgical Procedure

* During procedure minimize trauma to sternum
1) Sternotomy & bone assessment

2) Measure sternal depth & select screws

3) Reduce sternum

4) Select & contour plates

5) Fixate plates to sternum & complete chest closure
I) Measure Sternal Depth After Procedure

* Measure at 3 Points (Manubrium, Body & Xiphoid)
* If additional plates used – measure depth at plate location
* Write down the measurements for later use
Measure sternal depth & select screws

Measure at 3 Locations on Sternum...

- Manubrium
- Xyphoid
- Body
II) Select Screw Sizes Using Measurements

Notes:
* Sternal plate is 2mm thick, so must add 2mm & select screw
* Screw will penetrate bone up to the posterior cortex
* Short screws can lead to backout / Long screws can puncture

Measure sternal depth & select screws
Measure sternal depth & select screws

Examples of Various Screw Lengths...

Too Short

Just Right

Too Long
1) Sternotomy & bone assessment

2) Measure sternal depth & select screws

3) Reduce sternum

4) Select & contour plates

5) Fixate plates to sternum & complete chest closure
I) Use Wires to Approximate Sternum

Notes:
* 2 Wires at Manubrium to approximate sternum
* 1 Wire at Xyphoid to approximate sternum
* Sternal halves aligned in lateral, AP and RC directions
* Ensure tight connection (cancellous to cancellous)
Reduce Sternum

II) Use Reduction Forceps to Align Segments

Notes:
* Apply to inferior intercostal spaces to avoid internal mammary
* Do not apply too much force as it will damage the bone
SternaLock® Technique

1) Sternotomy & bone assessment
2) Measure sternal depth & select screws
3) Reduce sternum
4) Select & contour plates
5) Fixate plates to sternum & complete chest closure
Select & Contour Plates

I) Select Plates To Implant

Notes:
* Determine the number of plates to place & location
* Ensure plates will have good space to rest on
* Recommend at least 5 “struts” across the sternotomy
* Do not place non-cuttable sections across sternotomy

Recommended configuration based on biomechanical testing

“L Plate” placed at Manubrium

“X Plate” placed at Body

“X Plate” placed at as low as possible
Select & Contour Plates

II) Clear Excess Tissue From the Bone

Notes:

* Mark where plates will rest with Bovie pen
* Use Bovie pen to remove excess tissue @ plate location
* Do not fully strip the periosteum – important for blood flow

Use Bovie pen to
mark plate location &
clear excess tissue
Select & Contour Plates

III) Contour Plates

Notes:
* Plates should rest flush to the bone – contour to achieve this
* Use plate benders to bend plate as necessary
* Bend each plate to conform to anatomy at site of implantation
1) Sternotomy & bone assessment

2) Measure sternal depth & select screws

3) Reduce sternum

4) Select & contour plates

5) Fixate plates to sternum & complete chest closure
I) Fixate Plates to Sternum

Notes:
* Begin by inserting screw into outer holes – work your way in
* Hold plate flush to the bone while inserting screw
* Do not fully seat the first screw – plate will spin

Drive screw into plate keeping the screw as perpendicular as possible to plate
Examples of improperly fixated Plates...
II) Continue Fixating Plates Until Complete

Notes:
* Place the first plate at the body of the sternum
* Place the second plate as close to the Xyphoid as possible
* Place the final plate at the manubrium
If screws do not gain purchase use Emergency Screws...

2.7 mm Diameter (Emergency)

2.4 mm Diameter (Standard)

Red SternaLock® Emergency Screw
Fixate Plates & Complete Chest Closure

III) Complete Chest Closure

Closing the Chest
Fixate Plates & Complete Chest Closure

If necessary to re-enter...

*Option 1:*
Cut Plate Cross-Section with Double Action Wire Cutters

*Or...*

*Option 2:*
Use Screwdriver to Remove Screws
1) Sternotomy & bone assessment

2) Measure sternal depth & select screws

3) Reduce sternum

4) Select & contour plates

5) Fixate plates to sternum & complete chest closure

Proper Technique is Key!!
Fixating the Sternum: Clinical Study
• Randomized-Controlled Multicenter Study to Evaluate STernotomy Patients for Osteosynthesis and REcovery

• University of Chicago
• Leipzig (Germany)
• UC Davis (CA)
• St. Joseph's (Phoenix, AZ)
• Scott & White (Temple, TX)
• Baptist Memorial (Memphis, TN)
• Tampere University (Finland)

• 7 Sites

• N=432; 216 observational (wire); 216 treatment (SternaLock)

• Primary endpoints: osteosynthesis, pain, return to activity score

• Follow-up at baseline, days 0-10, discharge, 3 wk, 6 wks, 3 mo, 6 mo

Inclusion pre-op (≥3)

- COPD
- Diabetes mellitus
- BMI > 30 kg/m²
- Osteoporosis
- Renal failures
- Chronic steroid use
- Concurrent infection
- Immunosuppression
- Redo sternotomy
- Neurologic dysfunction
Inclusion intra-op

- Bilateral IMA
- Cardio-pulmonary bypass time > 2h
- Transverse fracture
- Off-midline sternotomy
Exclusion

- No contract
- < 18 years
- Pregnant
- Lactation
- CCS Class IV
- NYHA Class IV
- Emergency
- Don’t come to the follow-up
Drop out (n=7)

• 2x bleeding
• Pulmonary embolism
• 2x Bypass failure
• 2x Re mitral valve replacement
<table>
<thead>
<tr>
<th></th>
<th>wire</th>
<th>plates</th>
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<tbody>
<tr>
<td>n</td>
<td>31</td>
<td>29</td>
</tr>
<tr>
<td>age</td>
<td>66.4 ±10 y</td>
<td>66.1 ±7 y</td>
</tr>
<tr>
<td>male</td>
<td>72.4 %</td>
<td>77.4 %</td>
</tr>
<tr>
<td>coronary HD</td>
<td>72.4%</td>
<td>61.3%</td>
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</table>
Sternalock group

- Manubrium
- Reduction wire
- Additional plate can be a box, L, etc
- X-Plate on mid-body
- X-Plate as low as possible
- Xyphoid
- Reduction wire
Wire group

singel wire about periost
1x wire per 10 kg
min. 7 wire
Activity after 3 weeks

Baseline

SternaLock

Wire

<table>
<thead>
<tr>
<th>Activity</th>
<th>Baseline</th>
<th>SternaLock</th>
<th>Wire</th>
</tr>
</thead>
<tbody>
<tr>
<td>General fatigue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole body weakness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feelings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neck pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper back pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shoulder pain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain at rest</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain during coughing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tenderness/irritation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound healing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neck stiffness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Engaging chest incision</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chest incision</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Popping/grating/cracking</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Baseline Wire

3,00

2,50

2,00

1,50

1,00

0,50

0,00
Activity after 6 weeks

- Activity
- General Fatigue
- Whole body weakness
- Waking up night
- Feeling dizzy
- Neck pain
- Upper back pain
- Shoulder pain
- Pain at rest
- Pain during coughing
- Pain during activity
- Tenderness
- Incision
- Wound healing
- Neck stiffness
- Tingling
- Chest Incision
- Chest opening
- Worrying
- Chest opening
- Popping/ grating/ clicking

Baseline
Sternal Lock
Wire

Baseline
Sterna Lock
Wire
Activity after 3 month

- Feeling sleepy
- Neck pain
- Upper back pain
- Shoulder pain
- Pain at rest
- Pain during coughing
- Tenderness/irritation
- Wound healing
- Neck stiffness
- Tugging/chest traction
- Chest incision looks
- Worry/itch chest opening
- Popping/glazed clicking

Baseline
SternaLock
Wire

The graph shows the activity levels for different conditions after 3 months, comparing baseline, SternaLock, and Wire treatments.
CT Scan 3 month

Thoracic Program
CT scan 6 month
<table>
<thead>
<tr>
<th>Infection</th>
<th>Wire</th>
<th>plates</th>
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<tr>
<td>superficial</td>
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<td>1</td>
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<tr>
<td>medistinitis</td>
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<td>0</td>
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<tr>
<td>Instable sternum</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Conclusion

• More activity in first time after operation

• Less pain after operation

• No difference between infection
SternaLock®
Case Studies

Thoracic Program
Thank you

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