Clinical Trials

Restore and The SternaLock Blu Study

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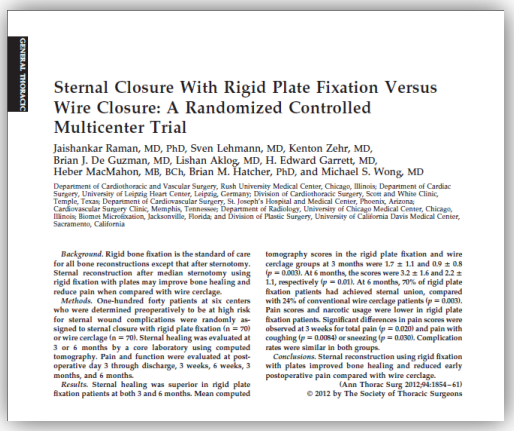
The Restore Study



GENERAL THORACIC

Sternal Closure With Rigid Plate Fixation Versus Wire Closure: A Randomized Controlled Multicenter Trial

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Background. Rigid bone fixation is the standard of care for all bone reconstructions except that after sternotomy. Sternal reconstruction after median sternotomy using rigid fixation with plates may improve bone healing and reduce pain when compared with wire cerclage.

Methods. One-hundred forty patients at six centers who were determined preoperatively to be at high risk for sternal wound complications were randomly assigned to sternal closure with rigid plate fixation ($n = 70$) or wire cerclage ($n = 70$). Sternal healing was evaluated at 3 or 6 months by a core laboratory using computed tomography. Pain and function were evaluated at postoperative day 3 through discharge, 3 weeks, 6 weeks, 3 months, and 6 months.

Results. Sternal healing was superior in rigid plate fixation patients at both 3 and 6 months. Mean computed tomography scores in the rigid plate fixation and wire cerclage groups at 3 months were 1.7 ± 1.1 and 0.9 ± 0.8 ($p = 0.003$). At 6 months, the scores were 3.2 ± 1.6 and 2.2 ± 1.1, respectively ($p = 0.01$). At 6 months, 70% of rigid plate fixation patients had achieved sternal union, compared with 24% of conventional wire cerclage patients ($p = 0.003$). Pain scores and narcotic usage were lower in rigid plate fixation patients. Significant differences in pain scores were observed at 3 weeks for total pain ($p = 0.020$) and pain with coughing ($p = 0.0084$) or sneezing ($p = 0.030$). Complication rates were similar in both groups.

Conclusions. Sternal reconstruction using rigid fixation with plates improved bone healing and reduced early postoperative pain compared with wire cerclage.

(Ann Thorac Surg 2012;94:1854–61)

Title: Sternal Closure with Rigid Plate Fixation Versus Wire Closure: A Randomized Controlled Multicenter Trial

Objective: Evaluate sternal bone healing and pain in patients with multiple risk factors undergoing open heart surgery via a median sternotomy.

Design: Prospective, randomized, controlled multi-center trial

Investigational Device: SternaLock Silver

Configurations: SternaLock: 2 X plates & one L plate at the manubrium; Wires: 1 wire per 10 kg and min of 7 wires peristernal.

Patient Demographics: High Risk Patients

Sites: 6 (USA & Germany)

Patients: 140

Times for follow-up: Pre-op, during hospital stay, 3 & 6 weeks, 3 & 6 months.

Primary Endpoints: Radiographic evaluation of bone healing using CT scans

Secondary Endpoints: Pain (visual analog scale), pain medication (index admission)

Key Results:

- Improved Healing
  - SternaLock Silver had superior healing at both 3 and 6 months
  - At 3 months SternaLock Silver was 15% sternal union vs. 0% with wire
  - At 6 months SternaLock Silver was 70% sternal union vs. 24% with wires
- Reduced early postoperative pain
  - 25% reduction in pain scores and narcotic usage
- Complication rates
  - Similar between groups

Data Details:

- Improved Healing
  - Limited data because the same patients were not scanned at 3 & 6 months.
  - Higher risk patients which could impact healing and lead to lower scores when compared to the SLB Study.
- Similar Complication Rates
  - Majority of the StenaLock Silver's complications occurred due to improper screw length (10/12mm screws) used
  - Patients had multiple co-morbidities and hgih risk for complications
- Pain
  - No correlation between sternal healing and pain due to not scanning the same patient at 3 & 6 months

Surgeons & Institutions

Restore Surgeons	Restore Institutions	City / State
Jaishankar Raman, MD, PhD	Rush University Medical Center	Chicago, IL
Sven Lehmann, MD	University of Leipzig Heart Center	Leipzig, Germany
Kenton Zehr, MD	Scott and White Clinic	Temple, TX
Brian J. DeGuzman, MD	St. Joseph's Hospital and Medical Center	Phoenix, AZ
Lishan Aklog, MD	St. Joseph's Hospital and Medical Center	Phoenix, AZ
Edward Garrett, MD	Cardiovascular Surgery Clinic, Memphis	Memphis, TN
Michael Wong, MD	University of California Davis Medical Center	Sacramento, CA

Resource:
Raman J, Lehmann S, Zehr K, et al. Sternal closure with rigid plate fixation versus wire closure: A randomized controlled multicenter trial. Ann Thoracic Surg. 2012; 94:1854-61.

The SternaLock Blu Study

Title: An Evaluation of Rigid Plate Fixation in Supporting Bone Healing: A Prospective, Multi-Center Trial: Final Study Report

Objective: To evaluate clinical and economic outcomes following sternal closure with either SternaLock Blu or wire cerclage in patients undergoing elective cardiac surgery.

Design: Prospective, randomized, controlled multi-center trial

Investigational Device: SternaLock Blu

Configurations: SternaLock Blu: 2 X plates & one (L, JL, hexagon or box) plate at the manubrium; Wires: min of 6 wires in any configuration per institutional preference

Patient Demographics: Elective Cardiac Surgery Patients

Sites: 12 (USA)

Patients: 236

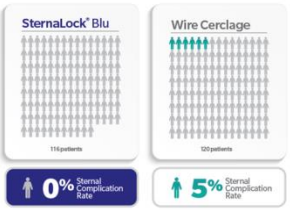
Times for follow-up: Pre-op, during hospital stay, 3 & 6 weeks, 3 & 6 months.

Primary Endpoints: Radiographic evaluation of bone healing using CT scans

Secondary Endpoints: Pain (visual analog scale), pain medication (thru 6 months), Quality of Life (SF-36), Function Outcomes (UEFI), Complications, Health Economics.

Key Results:

- **Improved Healing**
  - Sternal healing was assessed with CT scans by independent radiologists using validated methods.
  - At 3 months SLB was 2.6X higher vs. wires
  - At 6 months SLB was 1.2X higher vs. wires



- **Fewer Sternal Complications**
  - 0% complication rate SLB vs. 5% complication rate wires
  - Reflects all sternal complications over 6 months (vs. “<1%” rate often cited as the 30 day DSWI rate)
  - In a regression analysis, the method of closure was the only predictor of sternal complications.

- **Improved Patient Recovery**
  - 237 total fewer days in rehabilitation and recovery for SternaLock Blu patients compared to wire patients. ✱

Proven Cost Savings

- **Cost Effective Solution**
  - Proven cost savings over 6 months with SternaLock Blu.
  - Increased costs with wire patients primarily due to increased sternal complications and greater outpatient resource utilization
    - (e.g. rehab hospitals, skilled nursing facilities).

Data Details:

- **Improved Healing**
  - **Higher rates of healing and faster healing with SLB**
- **Sternal Complications**
  - **Probability of complications with SLB remains low even with increasing BMI**
  - **Sternal closure was the only factor that was found to be a predictor for complications and infections**
  - **Patients with sternal complications (n=6) required 11 reoperations and 94 days of additional hospital stays**
- **Proven Cost Savings**
  - **Primary drivers of cost savings were cost related to sternal complications and outpatient resource utilization (OPRU) (eg. 237 fewer days)**

Surgeons & Institutions

SLB Study Surgeons	SLB Study Locations	City/State
Keith B. Allen	St. Luke's Mid America Heart Institute	Kansas City, MO
Vinod H. Thourani	Emory University	Atlanta, GA
Yoshifumi Naka	Columbia University Medical Center	New York, NY
Kendra J. Grubb	University of Louisville	Louisville, KY
John Grehan	United Heart and Vascular Clinic	Saint Paul, MN
Nirav Patel	Lenox Hill Hospital, New York, NY	New York, NY
T. Sloane Guy	Temple University, Philadelphia, PA	Philadelphia, PA
Kevin Landolfo	Mayo Clinic, Jacksonville, FL	Jacksonville, FL
Marc Gerdisch	Franciscan St. Francis Health, Indianapolis, IN	Indianapolis, IN
Mark Bonnell	University of Toledo, Toledo, OH	Toledo, OH
David J. Cohen	St. Luke's Mid America Heart Institute	Kansas City, MO
Donald Botta	Florida Hospital	Orlando, FL

Resources

This is a summary of the Study entitled, CR 0712: An Evaluation of Rigid Plate Fixation in Supporting Bone Healing: A Prospective, Multi-Center Trial; Final Study Report CR0712S & CR0712E. Report on file at Zimmer Biomet.

✱SternaLock Blu patients spent a total of 237 total fewer days in rehab hospitals or skilled nursing facilities over 6 months (705 total days for wire cerclage (n=120) vs. 468 total days for SternaLock Blu patients (n=116).