

# The Science Behind Rigid Sternal Fixation

## Abstract

Approximation and rigid fixation of bony structures has been implemented as a means to improve stability and reduce motion, and is an essential factor for successful healing.<sup>1,5</sup> The SternaLock® Sternal Closure System was developed based on these principles as a method of rigidly fixating the sternum following a sternotomy. This paper reviews the development of the SternaLock Sternal Closure System, discusses the key engineering principles governing the function of the device, the mechanical studies that demonstrate how these principles lead to improved performance compared with wire cerclage and the clinical studies that examine how these principles may translate into improved patient benefits.

## Introduction

Each year in the United States, more than 700,000 people undergo open heart surgery via sternotomy. Unlike nearly every other fracture or osteotomy, where rigid fixation is used routinely to increase stability and improve bone union, wire cerclage remains the primary technique for most cardiac surgeons when closing a median sternotomy (Fig. 1). Wire cerclage has been shown to result in significant movement and sternal separation,<sup>2,3</sup> and does not provide adequate stability to support bone.<sup>4,17</sup> This inability to provide stability and achieve sternal union has been associated with complications such as sternal dehiscence, pain, delayed healing or nonunion and mediastinitis.<sup>1,3,5</sup>

To improve post operative recovery, a variety of rigid sternal fixation systems have been introduced. These systems utilize the principles of rigid fixation adopted in other specialties and function by stabilizing the bony segments. This stabilization reduces movement and sternal separation, and it is well known that rigid fixation and mechanical stability promote bone healing.<sup>5</sup> Mechanical studies have shown that rigid fixation of the sternum using plates and screws results in mechanical properties superior to multiple methods of wire closure, including reinforced wiring techniques.<sup>2,3,5</sup> In addition, clinical studies suggest that this mechanical benefit may translate into improved clinical outcomes, including superior bone healing.<sup>4</sup>

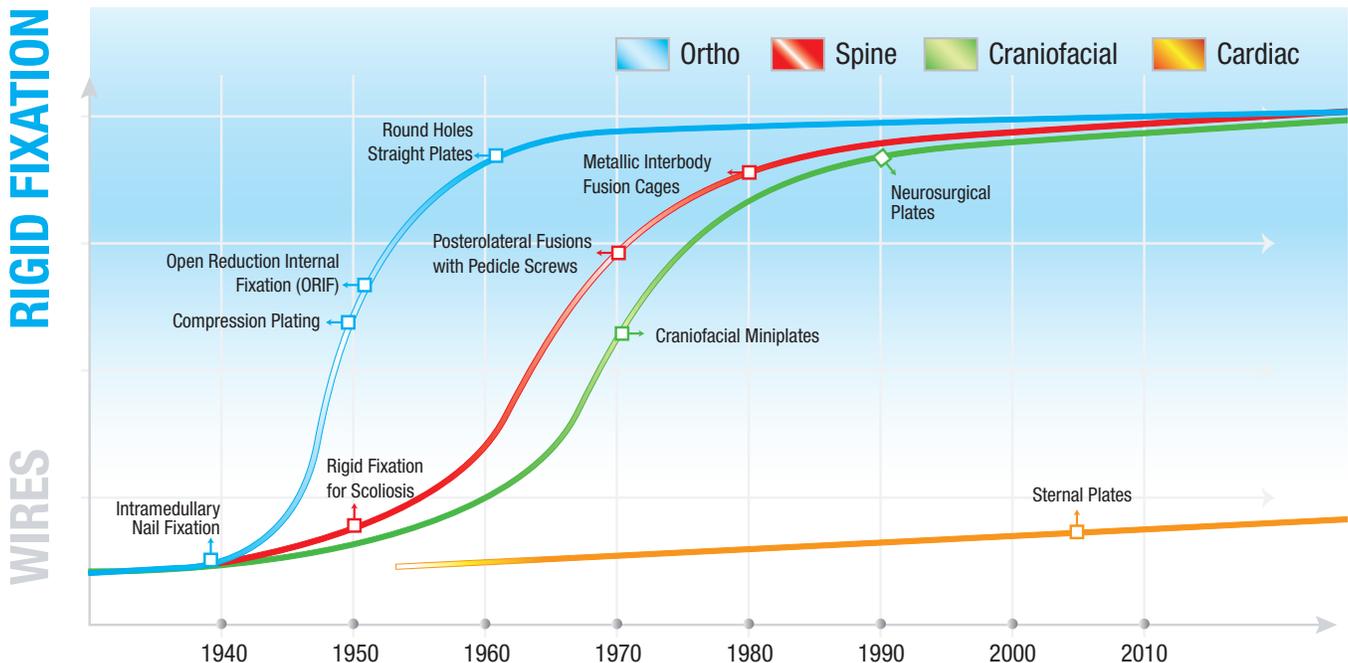
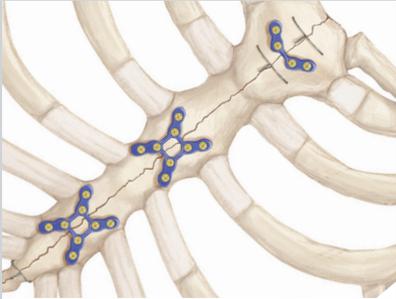


Figure 1. Timeline illustrating the adoption of rigid fixation in other specialties. Despite the adoption of rigid fixation techniques in nearly every other bone, and the numerous advances that have occurred in cardiac surgery over this period, wire closure remains the predominant method of sternal closure.<sup>18,19,20,21</sup>

	<b>Design Feature/ Technical Specification</b>	<b>Images</b>	<b>Rationale/Benefit</b>
<b>SternaLock Blu Plate</b>	<ul style="list-style-type: none"> <li>• 1.6mm Thin Sternal Blu Plates</li> </ul>		<ul style="list-style-type: none"> <li>• Allows plate to be easily contoured to sternum</li> <li>• Limited palpability</li> <li>• Provides adequate strength while allowing for rapid re-entry with wire cutters</li> </ul>
	<ul style="list-style-type: none"> <li>• Multiple Plate Configurations</li> </ul>		<ul style="list-style-type: none"> <li>• Plates for various surgical procedures include midline and mini-sternotomies</li> <li>• Accounts for different sternal anatomies</li> </ul>
<b>Cancellous Bone Screw</b>	<ul style="list-style-type: none"> <li>• Self-Drilling Cancellous Screws</li> </ul>		<ul style="list-style-type: none"> <li>• Screw designed to provide improved fixation in cancellous bone</li> <li>• Screws have low insertion torque and are easy to insert</li> <li>• 2.4mm and 2.7mm diameter options</li> </ul>
	<ul style="list-style-type: none"> <li>• 8-20mm Screw Lengths</li> </ul>		<ul style="list-style-type: none"> <li>• Allows for bicortical purchase in sterna with variable thicknesses</li> </ul>
<b>Screw/Plate Construct</b>	<ul style="list-style-type: none"> <li>• Locking Mechanism</li> </ul>		<ul style="list-style-type: none"> <li>• Locks plate into screw to reduce chance of backout</li> <li>• Multiple leads in screw head allow for rapid locking of screw and plate</li> <li>• Locking threads located only at screw head which prevents plate from lifting away from sternum</li> </ul>

**Table 1:** The design features of SternaLock Blu were engineered to address specific surgeon needs, resulting in a reliable and mechanically sound implant. <sup>6, 7, 8, 9, 10, 11, 12</sup>

## The Development of SternaLock® Blu

### The History of SternaLock

The SternaLock Sternal Closure System (K011076, K033740, and K110574) was initially cleared by the United States Food and Drug Administration in 2001. Since that time, the device has been cleared for use in 45 countries. In July 2011, a second generation system, SternaLock Blu, was launched.

The SternaLock Sternal Closure System has been a joint development effort between cardiac surgeons, plastic surgeons, orthopaedic surgeons and development engineers. The collaborative efforts between these groups resulted in a system that provides improved sternal stability compared with wire cerclage.<sup>2,3,6-13</sup> Additionally, the combined efforts and clinical experience over the last decade have contributed to the development and launch of SternaLock Blu.

### Sound Engineering Principles Govern Product Design and Performance

SternaLock Blu has a number of elements specifically engineered to enhance performance and meet specific surgeon needs. These are highlighted in Table 1.

### Mechanical Studies Demonstrate Superior Strength and Performance and Support an Optimal Product Design<sup>6-13</sup>

Mechanical performance of the SternaLock Sternal Closure System has been evaluated using a combination of bench top studies and Finite Element Analysis.<sup>13, 14</sup> Bench top studies in cadaveric bone allow for the overall mechanical performance of the system to be evaluated and allow for properties such as stiffness and strength to be measured. These types of analyses allow for the determination of how much load a given method of sternal closure can withstand and allow this to be put into a clinical perspective by utilizing physiologic loads such as coughing.

Finite element analysis (FEA) is a method of analyzing mechanical properties through the use of computer modeling. These analyses complement the bench top studies and allow for the evaluation of how load is distributed across a construct. FEA has been used with the SternaLock Sternal Closure System to determine the impact of plate design, screw location and screw length on how load is distributed.

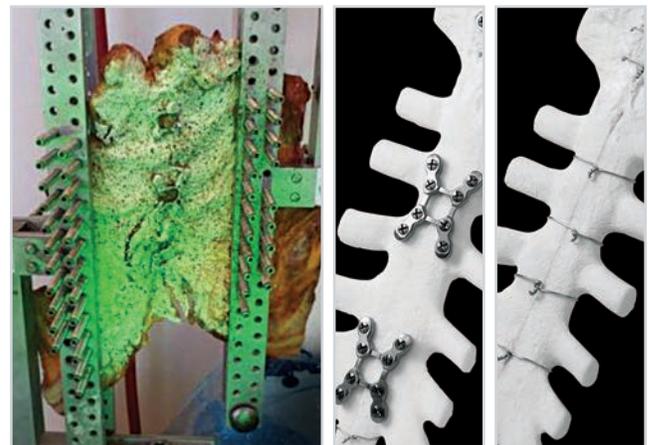
Collectively, FEA and bench top studies have been used to develop a sternal closure system with better mechanical performance compared to wire closure, that is capable of withstanding significant loads likely to be experienced as a result of coughing or movement, and that distribute the load in an optimal manner across the implant and sternum.

## Cadaveric and Biomechanical Studies

A series of cadaveric and biomechanical studies have been conducted to evaluate the mechanical performance of sternal closure using SternaLock plates and various methods of wire closure.<sup>2, 3, 13</sup> These studies have shown:

- Rigid sternal fixation with SternaLock plates results in superior strength and stiffness compared to wire cerclage.<sup>13</sup>
- Reinforced wiring techniques have the least stability of any wiring technique, and result in more movement and separation than simple wire cerclage.<sup>2, 3</sup>
- Closure with multiple wiring techniques results in movement and separation of > 5mm. Studies have shown that separation and bony gaps > 2mm may result in nonunion.<sup>15</sup>

A mechanical study conducted to compare the mechanical properties of wire cerclage with rigid fixation using the SternaLock Sternal Closure System was conducted in human cadaveric sterna (Fig. 2).<sup>13</sup> Thirty-one sterna were tested in lateral distraction, rostro-caudal shear and anterior/posterior shear using a pneumatic test system to determine strength and stiffness.



**Figure 2.** Cadaveric sterna were used to evaluate the mechanical performance of the SternaLock Sternal Closure System and wire cerclage, and demonstrated superior strength and stiffness with rigid plate fixation.

This study demonstrated<sup>13</sup>:

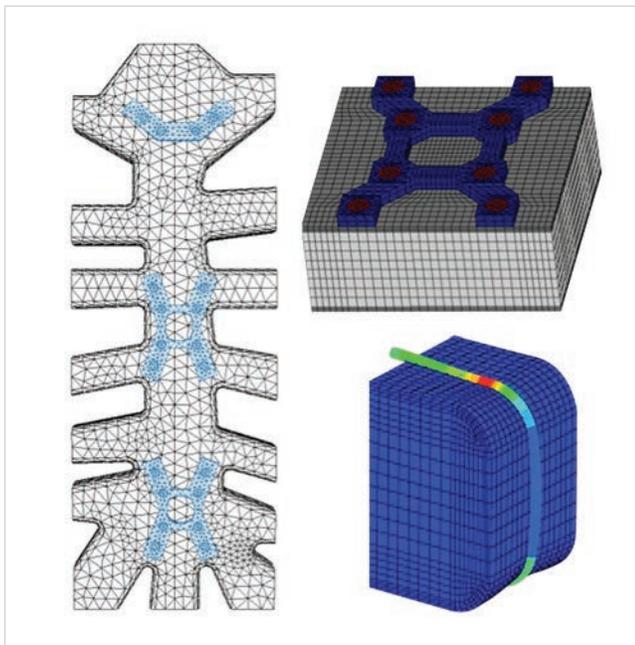
- Greater stiffness and strength was observed for sterna fixed with SternaLock plates compared to wire closure.
- The strength of fixation achieved with SternaLock plates was so strong that failure occurred as a result of rib fractures or intercostal tearing.
- In sterna closed with para-sternal wires, there was wire pull through in 78% of the tested sterna at force values comparable to coughing.

	Plates	Wires	p value
<b>Yield strength (N); Lateral distraction</b>	560	397	<0.05
<b>Yield strength (N); R/C Shear</b>	156	86	>0.05
<b>Stiffness (N/m); Lateral distraction</b>	3190	638	<0.05
<b>Stiffness (N/m); R/C Shear</b>	1482	87	<0.05

**Table 2.** Stiffness and strength of cadaveric sternum closed with SternaLock plates and wires cerclage.<sup>13</sup>

### Finite Element Analysis

A Finite Element Analysis (FEA) study was conducted to further evaluate the mechanical performance of the SternaLock® Sternal Closure System (Fig. 3).<sup>14</sup> A computer model of a sternum was created that contained cortical bone on the anterior and posterior cortex, and an intermediate cancellous layer. The mechanical properties of the bone, thicknesses of the cortical and cancellous layers, amount of force applied, and the direction of loading were varied, to determine how plate design, screw location, and screw length impacted sternal separation and load distribution.



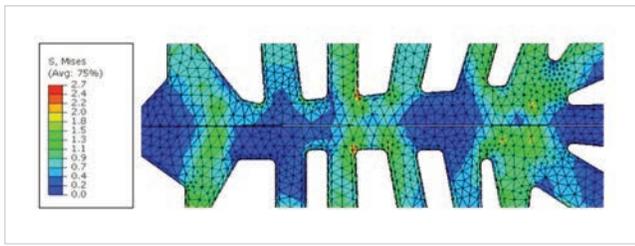
**Figure 3.** Representation of the FEA sternal model with the SternaLock Sternal Closure System and wire cerclage. The model was constructed to allow for various parameters to be adjusted, including the mechanical properties of the bone, variations in the thickness of the cortical and cancellous layers, and the amount and directions of the applied loads.<sup>14</sup>

Parameter	Value(s)	Rational
Direction of Force	<ul style="list-style-type: none"> <li>Lateral Distraction and Rostro-Caudal Shear</li> </ul>	Representative of various activities
Magnitude of Force	<ul style="list-style-type: none"> <li>350N and 175N</li> </ul>	Simulated slight coughing <sup>2</sup>
Bone Strength	<ul style="list-style-type: none"> <li>6, 12, 25 GPa (Cortical bone modulus)</li> <li>0.04, 1.1, 2.2 GPa (Cancellous bone modulus)</li> </ul>	Indicative of patients with both good and bad bone quality
Bone Layers	<ul style="list-style-type: none"> <li>50% penetration of posterior cortical bone</li> </ul>	Bicortical bone of variable thicknesses
Screw Length	<ul style="list-style-type: none"> <li>80% penetration of cancellous bone</li> </ul>	Bicortical vs. unicortical screw purchase

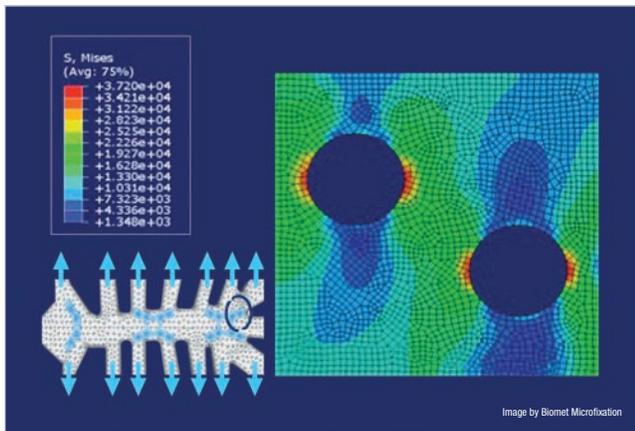
**Table 3.** The parameters in the table were adjusted to evaluate their impact on the mechanical performance and the distribution of load following closure with SternaLock plates or wire cerclage. For this study, force values comparable to light coughing were tested in the model.<sup>2</sup>

### The results from this study illustrated<sup>14</sup>:

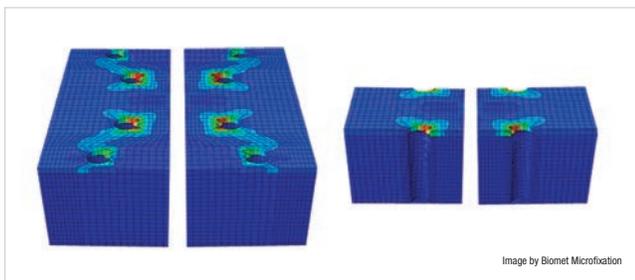
- Sternal separation seen with wire fixation was 48-75 times greater than with rigid plate fixation (Fig. 4).
- Sternal separation seen with SternaLock plates was minimal (< 0.0066 mm). This limited movement, along with the stiffness and strength of SternaLock plates that was observed in the cadaveric study results in a rigid construct with properties known to support bone healing.<sup>17</sup>
- Off-setting the screw locations, such as on an “X” plate, results in a more even distribution of load across the sternum and limits stress gradients (Fig. 5).
- Using bicortical screws results in a more even distribution of load in the anterior and posterior cortical bone, and less stress in the cancellous bone (Fig. 6).



**Figure 4.** Rigid fixation with the SternaLock Sternal Closure System resulted in minimal sternal separation (< 0.0066mm). Closure with wire cerclage resulted in 48-75 times more sternal movement and separation.<sup>14</sup>



**Figure 5.** Offsetting the screw locations in a staggered position, such as on the “X” plate, results in fewer stress gradients along the sternum and a more even distribution of load into the bone.



**Figure 6.** In combination with an anterior plate, bicortical screw purchase results in the majority of load being distributed in the cortical layers, and limited load and stresses seen in the intermediate cancellous bone.<sup>14</sup>

## Clinical History Establishes Benefits of Rigid Sternal Fixation

### Retrospective Studies Establish Low Rates of Sternal Wound Complications in Patients Treated with Rigid Sternal Fixation

A review of the clinical literature supports a low rate of complications in patients treated with the SternaLock Sternal Closure System and other benefits such as improved bone healing.<sup>4,16, 22</sup>

A retrospective study examining the economic impact of using the SternaLock Sternal Closure System in primary closure for patients at high risk for developing sternal wound complications has been conducted. This study compared 33 patients who received the SternaLock Sternal Closure System with 45 patients who received reinforced wiring techniques. This study showed a higher rate of sternal wound complications and a higher cost associated in treating patients who received sternal closure with wires.<sup>16</sup>

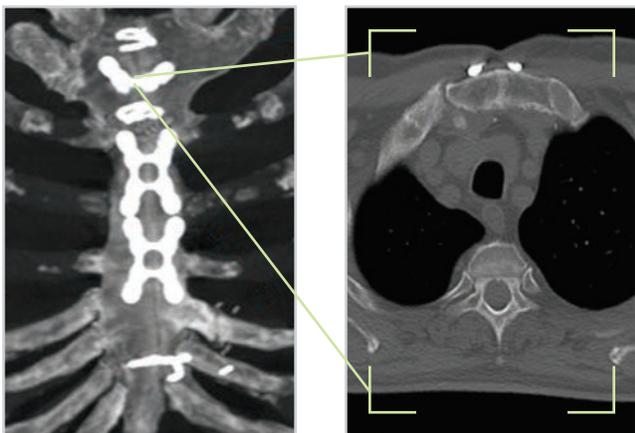
### A Prospective, Randomized Controlled Trial Established Rigid Sternal Fixation Promotes Fusion and Leads to Higher Rates of Sternal Union Compared to Wire Cerclage

In addition to these published studies, Biomet sponsored a prospective, randomized multi-center study to compare outcomes in patients treated with rigid plate fixation using the SternaLock Sternal Closure System to patients treated with wire cerclage.<sup>4, 22</sup> One-hundred forty patients at six centers who were determined pre-operatively 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).

Patient Characteristics	RPF	CWC	p value
Age in years (mean ± SD)	66.3 ± 9.8	64.0 ± 8.9	0.14
Gender (% male)	73	74	1.0
BMI (mean ± SD, kg/m <sup>2</sup> )	31.8 ± 5.5	31.8 ± 4.6	0.98
BMI > 30 (%)	64	70	0.59
Diabetes (%)	69	61	0.48
Renal failure (%)	27	27	1.0
COPD (%)	21	27	0.55

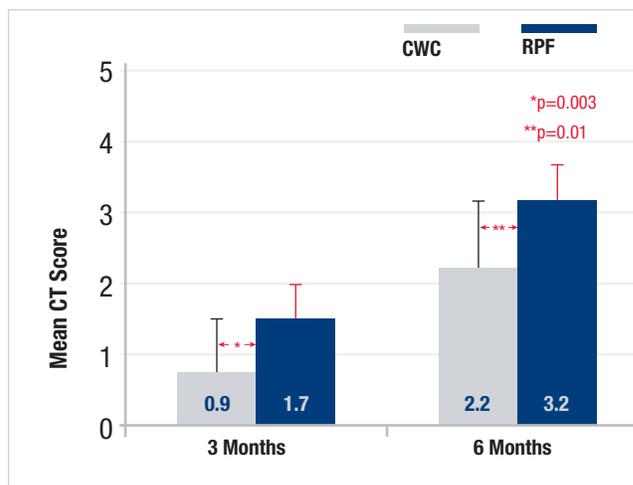
**Table 4.** Patient demographics for wire (CWC) and plated (RPF) patients enrolled in the RESTORE clinical trial.<sup>4, 22</sup>

Sternal bone healing was evaluated in patients using CT scans. Patients were randomized to receive a CT scan at either 3 months or 6 months, and CT scans were analyzed by 2 independent radiologists. Axial CT scan slices were analyzed at five locations along the sternum: at the manubrium, the top of the aortic arch, the aortopulmonary window, the main pulmonary arteries, and the aortic root (Fig. 7). A six-point quantitative scale was used to score osteosynthesis at each of the five locations (0 = no sign of healing, 1 = minimal healing, 2 = mild healing, 3 = moderate healing, 4 = partial synthesis, 5 = complete synthesis (Fig. 8)). A mean score was assigned to each patient who had a CT scan on the basis of an average of consensus scores for the five sternal locations. Sternal union, a binary outcome, was defined as a mean score of  $\geq 3$ .<sup>22</sup>

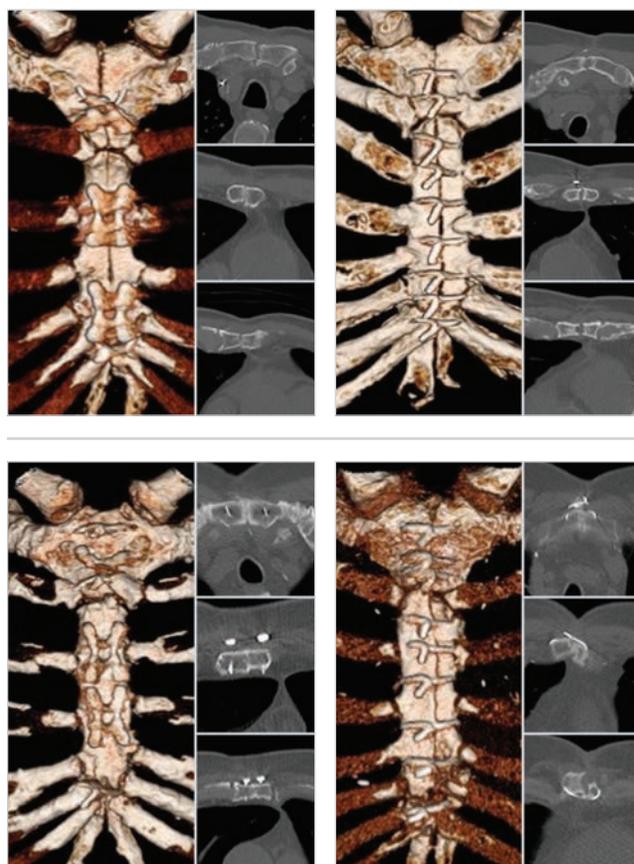


**Figure 7.** Representation of computed tomography scan methodology. Axial slices from five anatomic locations along the sternum from the manubrium to the aortic root were selected for quantitative evaluation of sternal bone healing using a 6 point scale.

This study showed that sternal bone healing was superior in patients who received sternal closure with the SternaLock Sternal Closure System compared to patients who received wire cerclage at both 3 and 6 months (Fig. 9). Mean computed tomography scores in the SternaLock and wire cerclage groups at 3 months were  $1.7 \pm 1.1$  and  $0.9 \pm 0.8$  ( $P = 0.003$ ). At 6 months, the scores were  $3.2 \pm 1.6$  and  $2.2 \pm 1.1$ , respectively ( $P = 0.01$ ) (Fig. 8). At 6 months, 70% of rigid plate fixation patients had achieved sternal union, compared with 24% of conventional wire cerclage patients ( $P = 0.003$ ) (Fig. 8).



**Figure 8.** CT scan evaluation demonstrated significantly greater sternal bone healing in SternaLock patients compared to wire cerclage patients at both 3 and 6 months.



**Figure 9.** Representative computed tomography scans (three-dimensional scan reconstructions and axial images at five locations) for rigid plate fixation and conventional wire cerclage patients at 3 months (top) and 6 months (bottom). These three-dimensional reconstructions and axial images are from patients with computed tomography scores that are representative of the mean values for their respective group.

## Summary

The SternaLock Sternal Closure System has been designed to provide improved mechanical stability and fixation compared to wire cerclage following sternotomy and sternal closure. Mechanical and FEA studies have demonstrated that rigid fixation of the sternum with this system results in less movement and greater stability compared with multiple types of wire closure. This mechanical stability is a prerequisite for bone healing, and a prospective randomized trial demonstrated that

sternal closure with the SternaLock Sternal Closure System led to better sternal bone healing than wire cerclage. These mechanical and clinical studies demonstrate that the engineering principles governing the design of this system translate into improved mechanical performance, and this translates in better bone healing. Additional clinical studies are examining the impact of improved bone healing on other outcomes, such as complication rates, pain, function and quality of life.

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