

# An Innovative Approach for Sternal Closure

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**Purpose.** Midline sternotomy remains the preferred technique for access in cardiac surgery. Application of steel wires has been the preferred method of closure. Because of associated complications, such as superficial and deep infections, as well as bony nonunion complications, an alternative technique is being proposed. The purpose of this study is to evaluate results of a new device for sternal closure.

**Description.** The Sternal Talon (KLS Martin Group, Jacksonville, FL), a lightweight titanium closure device is designed to encircle the sternum, thus yielding a stable closure by effectively distributing the strength of closure over the entire length of the sternotomy. After multiple strength tests demonstrated its superiority over wires, and cadaver tests confirmed its ease of placement, the Food and Drug Administration recently approved the device for its unrestricted use. Eight institutions were chosen to perform initial placements. Patient selection was limited to patients at high risk for sternotomy complications.

**Evaluation.** In 42 patients who underwent placement of the Sternal Talon (KLS Martin Group) after sternotomy, no wound infections or dehiscence, nonunions, or returns to the operating room were observed. Three postoperative deaths were reported, none of which were device related. The device is magnetic resonance imaging compatible and there are no reported problems with computed tomographic scatter or chest roentgenogram visualization.

**Conclusions.** These initial cases prove the safety and efficacy of the Sternal Talon device for sternum closure in high-risk patients and may be regarded as an alternative to conventional wire closure. Future prospective studies are warranted to prove the superiority of the device in terms of long-term stability and sternum union rates, as well as decreased infection rates specifically in the high-risk patient population undergoing sternotomy.

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The most frequently applied approach to the mediastinum in cardiothoracic surgery remains through a median sternotomy. The sternotomy was first described by Julian and colleagues [1] in 1957, and until today it remains the preferred method of access. It provides ease in access and exposure for bypass and valvular surgery. In 2001 alone, nearly 760,000 such operations were performed in the United States, including coronary artery bypass, great vessel repair, mediastinal tumor surgery, repair of congenital defects, and trauma-related injuries [2]. Interestingly, wire closure after sternotomy for sternal stabilization remained standard for the last 50 years, whereas all other associated cardiac techniques have

evolved or have been modified. Common complications that can arise from wire closure include early sternal dehiscence, superficial and deep infections, seromas and hematomas, sternal fractures, and nonunions. Comorbidities that predispose patients to complications include poor nutritional status, osteoporosis, diabetes mellitus, obesity, tobacco use, advanced age, steroid usage, renal failure, prolonged operative time, excessive bleeding, and emergency surgeries.

A known problem that may occur during wire closure is that the amount of force necessary to appose the sternal segments can cause the wires to pull through the bone. This force can increase during powerful coughing episodes by the patient in the immediate postoperative period. Technical issues, such as forced twisting, may

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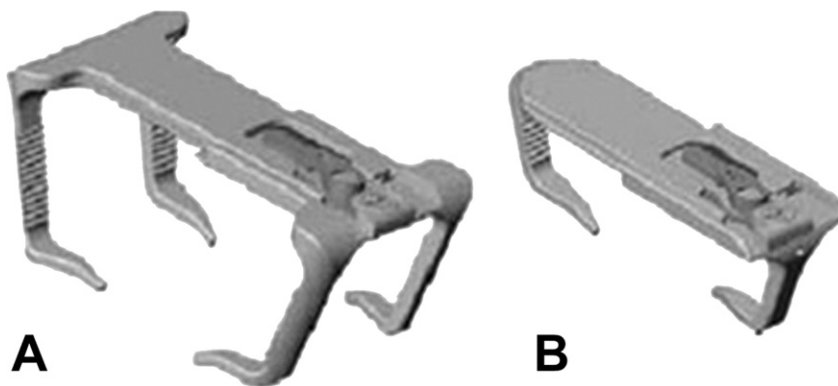
result in weakening or even breakage of the wires during the operation or shortly thereafter. Tightening of the wires by the surgeon is inconsistent and unpredictable. Once wires are tightened, they must be turned into the surrounding soft tissues. This may result in pain and possible bursa formation.

As recognized in other surgical subspecialties such as orthopedic and craniofacial surgery, improvements in methods for bone stabilization have reduced the incidence of complications and facilitated bone healing [2-5]. Song and colleagues [2] reported that in sternal closure patients who have undergone rigid fixation, a significant decrease in the incidence of postoperative wound infections occurs compared with a similar population of patients who have received the standard wire closure technique. Another study has suggested that the use of reinforced sternal closure technique causes no additional risk [6]. Bony fixation has progressed from early use of wire stabilization to plate and screw rigid fixation in the fields of neurosurgery, plastic surgery, and orthopedic surgery. Today, rigid fixation is the accepted standard of practice [5]. The technique is now taking a forefront in the only remaining field that uses wires in the stabilization of bone [2]. This article introduces a new and innovative device (cleared by the Food and Drug Administration) that may be routinely used in high-risk patients for sternal approximation. The Sternal Talon (KLS Martin Group, Jacksonville, FL) is a lightweight, titanium closure device that encircles the sternum and achieves a stable and consistently powerful closure.

### Technology

Use of the Sternal Talon (KLS Martin Group) consists of placing the average of three devices on the sternum. It transfixes the sternum by its legs and feet placed in the intercostal spaces, inserting them around the posterior sternal cortex with the two-mated sections articulated by a locking ratchet mechanism. It completely apposes the sternal segments by compression without violating cortical or cancellous bone, and it requires no screw or wire placement. One possible configuration is two double-legged devices (Fig 1A) and one single-legged device (Fig 1B) centrally placed. Thus, there is flexibility in placement and the device applies in various combinations.

Fig 1. (A) Double-legged and (B) single-legged Talon devices (KLS Martin Group, Jacksonville, FL).



Some surgeons prefer the routine use of single or double wires in conjunction with the Sternal Talon for further apposition of the manubrium. The sternum width is measured to facilitate choosing the correct Sternal Talon size. These measurements are important as wide variations in sternal widths and depths are common (Fig 2A). Using calipers, the width and depth of the device is calculated at each placement position (Figs 2B, 2C). The total sternal width is determined by measuring each side of the divided sternum at the same level and adding them together. These two measurements (from the edge of the intercostal space to the midline) allow for proper selection from 28 available sizes (14 single-legged and 14 double-legged) that measure the anteroposterior thickness of the sternum.

### Technique

In the next step the device is applied (Figs 3A-3C). As many as three stabilizing wires at each pole of the sternum may be used to hold the sternal segments in place. Soft tissues are gently retracted to expose the articulations of the ribs at the sternum. Then using an electrocautery or blunt dissector, a track is created for the Sternal Talon legs to pass around the lateral edges of the sternum (Fig 2A). Once the correct size is selected, one side of the device is rotated to a 45-degree angle, the legs are passed gently through the tracks, and then the device is seated. The second mated portion is placed in the same fashion on the opposite side. All three devices are placed prior to closure. Care should be taken at this point to protect the intercostal vessels and the internal mammary artery. When placed in the correct position, the Sternal Talon legs should remain medial to the internal mammary artery. Prior to placement, the locking mechanism is set at the 3 o'clock position by the assistant to allow ease of closure (Fig 4A). The closing of the device is performed by applying medial pressure to both the male and female portions of the Sternal Talon. Alignment is facilitated by the use of the Sternal Talon's introducing and aligning forceps. Once the devices are aligned, final tensioning is done with the reduction forceps. A "safe" position is etched on the surface of the device indicating mechanical closure (Fig 4B). Proper closure is confirmed, ensuring strength of clo-

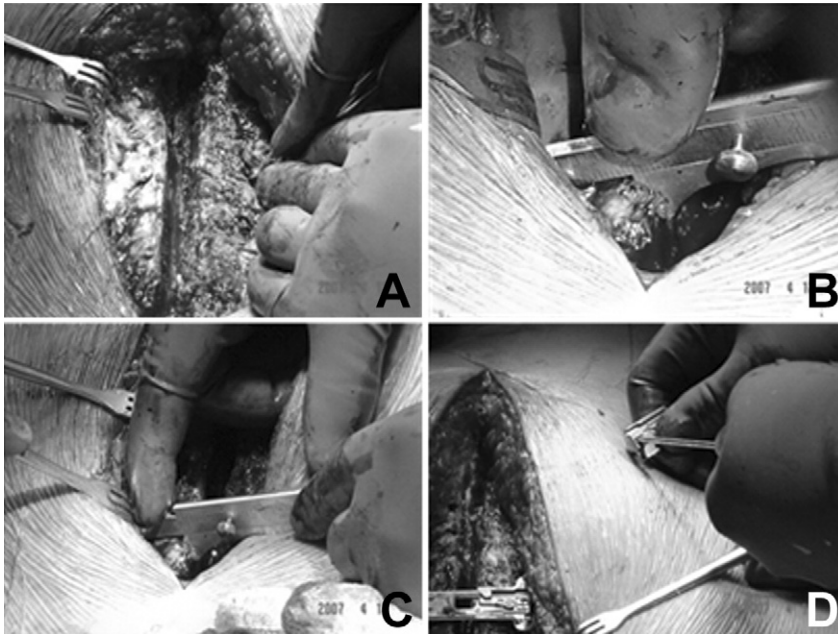


Fig 2. (A) Preparation, (B, C) size selection, and (D) placement of Talon device (KLS Martin Group, Jacksonville, FL).

sure, and the lock is turned to 12 o'clock to prevent disengagement (Fig 4C). For emergent re-entry, the device can be easily removed by turning the screw clockwise to 6 o'clock, which causes the device to disengage. Two alternative methods of rapid disengagement are also available. Final closure may then proceed. An online demonstration is available at <http://www.rapidsternalclosure.com/medical/talon.php>.

The current cost for a single device is \$1,295 and for the double device is \$1,495, according to the manufacturer.

### Clinical Experience

A retrospective data collection and analysis was approved by the Duke Medical Center Institutional Review Board. Data from 42 patients that underwent stabilization

of the sternum with the Sternal Talon was collected and analyzed. Data points included patient age, sex, weight (body mass index), comorbidities, primary diagnosis, and primary procedures at the time of the Sternal Talon placement (Table 1). Cardiovascular risk factors from an Emory University 20-year mortality management study were used to assess patient risk prior to surgery. Cardiac procedures are cited in Table 2.

### Results

Of the 42 patients, 26 were male and 16 were female (age range, 34 to 84 years). Patients were selected to undergo stabilization of the sternum based on the number of risk factors present at the time of surgery. Currently, only patients who have three or more risk factors are eligible to undergo surgery using the Sternal Talon system.

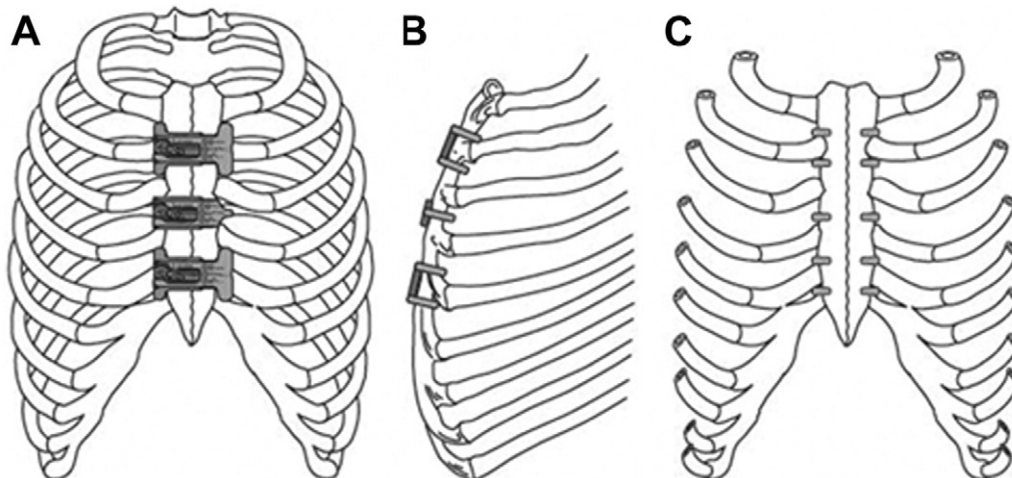


Fig 3. Application of Talon device (KLS Martin Group, Jacksonville, FL). (A) View from anterior, (B) lateral, and (C) posterior.

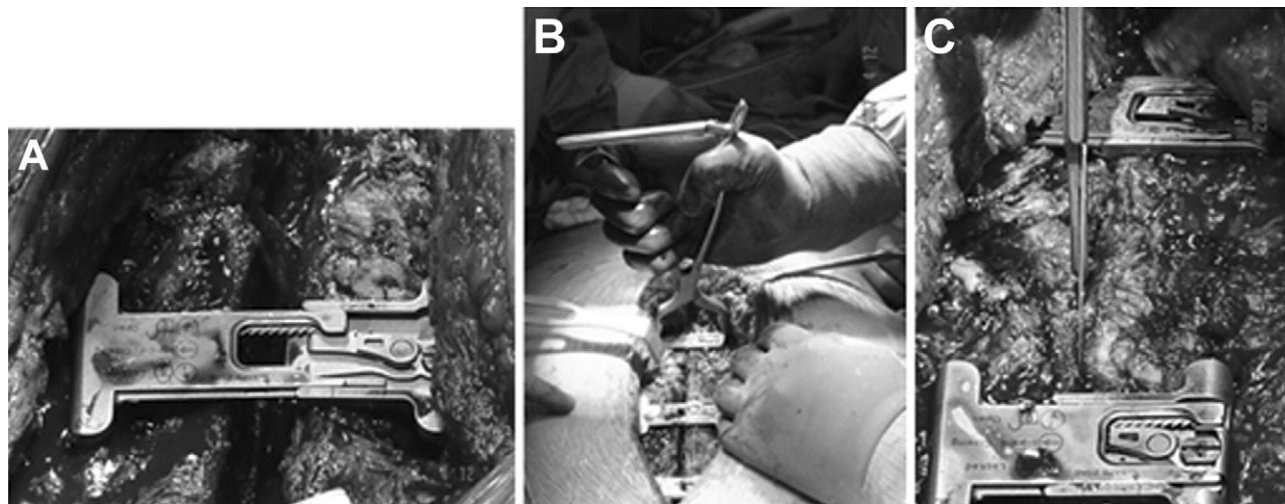


Fig 4. (A–C) Closure of Talon device (KLS Martin Group, Jacksonville, FL).

The main goal of this study is to determine the efficacy and safety of the device. A gradual reduction in time of placement of the devices from approximately 30 minutes to an average time of placement of approximately 8 to 10 minutes was reported. No sternum instability or dehiscence with usage of the Talon system was reported. No directly associated patient deaths were observed. The number of postoperative infections included one reported superficial skin infection, which was successfully treated with oral antibiotics, and no seroma formation. Subcutaneous Blake-type drains (Ethicon, San Angelo, TX) should be used in conjunction with the placement of the Sternal Talon to avoid chest tube holes from catching on the footplate of the device (Table 1).

**Comment**

Traditionally, steel wires are used to secure median sternotomies. Complications resulting in sternal dehiscence can be life threatening, debilitating, and costly. A recent declaration by the Centers for Medicare and Medicaid Services suggests that hospital compensation for sternal mediastinitis procedures should be discontinued, which has placed an emphasis on decreasing the incidence of this devastating complication [6]. A study by Baskett and colleagues [4] demonstrated an increased mortality associated with certain risk factors in patients

undergoing median sternotomies, including obesity, diabetes mellitus, smoking, renal failure, and steroid use. Complications noted with sternal wiring reported in the range of 1% to 4% include problems such as sternal instability, wound infections, and dehiscence, with hematomas or seromas, sternum fractures, and chronic pain that may prevent daily activities.

Attempts to improve sternal wire closure have been reported using cable “figure 8” wires, double wires, and by increasing the numbers of wires [7]. Sternal plating, which provides secure sternal approximation, has been reported for the treatment of sternal nonunion and pain relief. However, the Sternal Talon is the first device designed to apply the principle of rigid fixation for primary use in sternal stabilization. It was designed and developed by surgeons in three subspecialties and has progressed from an early concept of an “L” beam, which was custom made and used screw fixation [8], to its current design with three-position locking ratchets, which is lightweight but solid. Rigid fixation, as a standard principle in orthopedic surgery, is now adopted in cardiothoracic surgery [3].

The early results of sternal fixation with rigid techniques have been reported to be both promising and potentially lifesaving [2, 4]. The authors are presenting a series of 42 patients who underwent sternum stabilization after median sternotomy using the recently developed Sternal Talon system, with its first placement in a patient accomplished in December 2006. The introduction of the Sternal Talon may

Table 1. Patient Demographics

	Range	Mean
Age	34–84	58/12.62 (SD)
Gender	M/26 - F/16	
Weight	112–334 lbs	231/56.30 (SD)
BMI	19.6–46.5	34/7.28 (SD)
Risk factors	Obesity	34/42 (SD)

BMI = body mass index; F = female; M = male; SD = standard deviation.

Table 2. Cardiac Procedures

CABG, 27
Nonunion, 1
MAZE, 2
Thymectomy, 1
Other, 11

CABG = coronary artery bypass graft.

result in future growing confidence in the role of rigid fixation in sternal surgery. The ease of placement could be a key factor in the increased routine use of the device [9, 10].

Future prospective studies are warranted to prove the superiority of the device in terms of long-term stability and sternum union rates, as well as decreased infection rates specifically in the high-risk patient population undergoing sternotomy. Additional advantages in comparison with conventional wire techniques may include improved pain control, thus facilitating more rapid ambulation. If proven, these advantages will help the Sternal Talon system assume an important future role in cardiothoracic surgery as an improvement in sternal closure.

### Disclosures and Freedom of Investigation

The Sternal Talon is manufactured and sold under license to United States Patent numbers: 7,033,377; 6,007,538; 6,217,580; and 6,051,007; with other United States and foreign patents pending. Dr Levin receives royalties from Mavrek, Inc. The authors have full control of the design of the study, methods used, outcome measurements, analysis of data, and production of the written report.

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### Disclaimer

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