Sternal Talon Offers a Solution for Secondary Sternum Osteosynthesis in Patients With Nonunion

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Background. Median sternotomy may be associated with postoperative complications such as nonunion after conventional metal wire closure. The Sternal Talon device (KLS Martin, Jacksonville, FL) has recently been introduced as an alternative for osteosynthesis after median sternotomy and may also be beneficial for patients with persistent sternal nonunion.

Methods. A consecutive series of 24 patients underwent Sternal Talon repair for sternal nonunion or acute mediastinitis, or both, after sternal wire closure. Patient data—including demographics, surgical history, and indication for operation, as well as outcomes—were obtained and analyzed by retrospective chart review.

Results. The average patient age was 61.3 years and 23 patients were men (95.8%). The most common median sternotomy procedure was coronary artery bypass grafting (CABG) in 19 patients (79.2%). Secondary closure using the Sternal Talon was indicated for sternal nonunion or infection, or both, in all patients. Eight patients underwent simultaneous muscle flap procedures during the placement of the Sternal Talon (33.3%). Sternal union was eventually achieved in 23 of 24 patients (95.8%). Subsequent reoperation was required in 4 patients (16.7%).

Conclusions. The data presented suggest that the osteosynthesis using the Sternal Talon device is a safe and effective modality for treating symptomatic sternal nonunion or acute dehiscence associated with infection (mediastinitis.)

(Approximately 760,000 median sternotomies are performed annually in the United States [1]. Closure of the median sternotomy remains a challenge for plastic and thoracic surgeons. Traditionally, metal sternal wires have been used for this purpose, although they may result in complications including nonunion, sternal dehiscence, infection, hematoma, and seroma formation, occasionally leading to patient mortality [2]. The innovative Sternal Talon device (KLS Martin, Jacksonville, FL) provides an improved method for sternal osteosynthesis [3]. By approximation of sternal bone edges using compression without disruption of cortical or cancellous bone, the Sternal Talon produces excellent results with low complication and nonunion rates in primary closure [3]. However, the utility of the device in treating persistent sternal nonunion and sternal dehiscence after wire closure is currently unknown given its recent introduction in the past decade. The goal of this study was to assess the results of secondary closure using the Sternal Talon device, particularly in patients in whom wire closure failed.

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Patients and Methods

Institutional review board approval was obtained from both the University of Pennsylvania Medical Center (UP) and Duke University Medical Center (DU), permitting a combined institutional investigation (DU, Pro00047331; UP, 818662). The study cohort was composed of all patients at either institution with a history of nonunion and secondary Sternal Talon closure between 2009 and 2013. A retrospective chart review was then performed using electronic medical health record systems to obtain patient data, including age, sex, coronary pathologic processes, date of median sternotomy, date of Sternal Talon placement, indication for secondary Sternal Talon closure, number of Sternal Talon devices placed, adjunctive procedures performed during Sternal Talon closure (ie, pectoralis turnover flap), and any subsequent complications or mortality events after Sternal Talon closure. Descriptive statistics were generated and reported, but no statistical analysis was performed because of the infancy of this indication and the small study cohort.
Results

A total of 27 patients were identified from both institutions with an appropriate past medical history involving Sternal Talon placement after failed wire closure. Of these 27 patients, only 24 had sufficient follow-up, including at least 1 postoperative visit, to be meaningfully included in the study (19 patients from DU and 5 patients from UP). The study population included 23 men (95.8%), and the average patient age was 61.3 years. Diabetes mellitus had been previously diagnosed in 7 patients (29.2%), and hypertension in 19 (79.2%) patients, and chronic obstructive pulmonary disease in 2 (8.3%) patients. The most common indication for the initial median sternotomy with wire closure was coronary artery disease requiring coronary artery bypass grafting (CABG) (79.2%). The remaining patients underwent median sternotomies for valve replacement (12.5%), septal defect repair (4.2%), and heart transplantation (4.2%).

The average time from initial wire closure to Sternal Talon placement was 12.6 months (range, 1–34 months). The Sternal Talon was placed in all patients to correct sternal nonunion or sternal dehiscence. One Sternal Talon device only was placed in 2 patients (8.3%), 2 devices were placed in 5 patients (25%), 3 devices were placed in 14 patients (58.3%), 4 devices were placed in 2 patients (8.3%), and 1 patient had 5 Sternal Talon devices placed (4.2%). The number of Sternal Talon devices placed was determined by surgeon judgment related to the defect size and sternal stability. Six patients (25%) had simultaneous unilateral pectoralis major flap coverage performed during the Sternal Talon placement for soft tissue coverage, and 2 patients had bilateral pectoralis major flaps (8.3%), but no other hardware was used for sternal stabilization. Complete demographic information is presented in Table 1.

Overall, 23 of the 24 (95.8%) patients achieved sternal union after Sternal Talon placement, with 1 patient attaining gross sternal stability but experiencing mild painful nonunion immediately inferior to the manubrium. The majority of the study patients healed well postoperatively without any further complications (16 of 24 [66.7%]). However, 4 patients required additional operations between 2 weeks and 4 months after Sternal Talon placement (Table 2). Of these 4 patients, a chest hematoma developed in 1 patient and was successfully evacuated. One patient required removal of 1 of his devices because of exposure of the implant after achieving sternal union. Hardware infection developed in 1 patient 6 months after placement and required removal, but sternal union had been achieved. Finally, 1 patient required removal of his hardware for infection 3 weeks after placement but successfully attained sternal union after debridement and treatment with antibiotics. All 4 of these patients healed appropriately after their second operation with no further issues.

Two patients experienced infectious conditions (1 viral respiratory infection and 1 case of cellulitis) that were adequately treated nonoperatively. Finally, 1 patient had a fistula within the incision line that was of insufficient size to probe, and it healed successfully with silver nitrate treatment. No patients died during the follow-up period of an average duration of 11.7 months, which likely underrepresents the long-term success of Sternal Talon closure given that many patients were discharged on a return-as-needed basis.

Comment

Median sternotomies are among the most common surgical approaches within the scope of thoracic and cardiothoracic surgical interventions. However, these operations require cutting through the sternum to access the thoracic cavity, which presents the challenge of effectively closing the sternotomy. Traditionally, metal
wire sutures are used for this purpose; however, there have been numerous reports regarding complications arising from the fallibility of sternal wire closure [4–7]. Postoperative sternal wound complications and infection represent a major problem in this patient population, with mortality rates reported to be as high as 16% in patients with sternal dehiscence [8]. Patients may also experience complete or partial symptomatic nonunion secondary to poor osteosynthesis with traditional metal wires. Complete nonunion can be difficult to manage and is further classified based on severity as type I, longitudinal nonunion without a transverse component; type II, unilateral nonunion in the transverse dimension; type III, single or multiple bilateral nonunion; and type IV, multiple fractures with missing bone segments and subsequent free-floating fragments [9].

Rigid fixation has been suggested as a superior method for sternal closure with greater rigidity [10], higher rates of sternal union, lower pain scores [11], and quicker recovery [12]. Additionally, sternal plating has demonstrated promise in the correction of prolonged sternal nonunion of all severity types [9]. Given the favorable initial results with primary Sternal Talon closure [3], the high morbidity and mortality of postoperative nonunion and infections after a median sternotomy [8], and the clear benefit of rigid fixation [1, 9], we evaluated the Sternal Talon device for secondary closure of persistent nonunion and mediastinitis after previously failed sternal wire closure.

Preoperatively, patients with open wounds at presentation were treated with vacuum-assisted closure until the surgical procedure. Sternal Talon osteosynthesis was the only closure method used by any of the senior surgeons during the study period and was felt to be the optimal closure method because of its clear advantages (Table 3). When coupled with adequate debridement and the possibility of a vascularized myocutaneous flap for coverage, the authors are unaware of any superior methods for secondary sternal closure, except in the case of severe osteomyelitis or wound infection, in which no intervention is often preferred.

Placement of the hardware is performed by first measuring the size of the sternum to select the appropriately sized Sternal Talon device (Fig 1). Next, the 2 portions of the device are placed on opposing sides of the sternum and are clamped together with the automatic locking mechanism of the hardware. The number of devices required depends on the individual defect. Correct placement is then verified intraoperatively by the surgeon, and routine anteroposterior and lateral radiographs are obtained.

Table 3. Summary of Advantages and Disadvantages of Sternal Talon Hardware

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
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<tbody>
<tr>
<td>Ease of application</td>
<td>High cost</td>
</tr>
<tr>
<td>Low complication rate</td>
<td>Unfamiliar new technology</td>
</tr>
<tr>
<td>Avoids screws</td>
<td>Not suitable for horizontal</td>
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<tr>
<td>(no drilling required)</td>
<td>or comminuted fractures</td>
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postoperatively. No other imaging is recommended, and the hardware is both biocompatible and durable so that routine removal is neither necessary nor recommended. The Sternal Talon device is also designed as a stand-alone method for closure, and additional hardware is not required. However, 1 of the senior surgeons (LSL) has been successfully using horizontal reconstruction plates to stabilize multisegment hemisternum before bridging with the Talon device. It is likely that the Sternal Talon can be combined with many other devices for a synergistic effect, but these options have not been fully explored to date given the recent introduction of the hardware. Additionally because of its infancy, no clear complications or potential difficulties with the hardware have been identified.

In our study, a small cohort of patients who had previously undergone secondary closure with the Sternal Talon device was selected for retrospective review. Some of these patients had been experiencing persistent sternal nonunion for up to 34 months but rapidly improved after the reaproximation of the sternal edges provided by the Sternal Talon technology (Figs 2 and 3). The majority of these patients progressed well and did not require further intervention after the placement of the Sternal Talon. Overall, a 33% complication rate was observed; however, the majority of these events were minor, with only 4 patients requiring serious intervention. Further, when compared with historical controls, only 2 patients experienced mediastinitis (8.3%) after Sternal Talon placement compared with a sternal infection rate of 12.5% reported previously [13]. This finding is amplified by the fact that the previous report included only
patients with noninfectious nonunion, whereas 10 (41.7\%) patients in the current study cohort had active sternal infections at the time of reoperation (4 cases of *Staphylococcus aureus*, 1 case of infection with a diphtheroid, 1 case of *Enterococcus*, and 4 patients with no growth).

The pectoral turnover flap has been previously described as an adjuvant treatment for closing sternal defects [14], and 8 of the included patients underwent this procedure during the placement of the Sternal Talon devices. Of these 8 patients, only 1 patient required reoperation to evacuate a hematoma, and a postoperative fistula developed in 1 patient, suggesting further benefit with pectoralis turnover flaps. Although the population size is insufficient to provide necessary power for statistical analysis, we believe that these preliminary results are promising and warrant the expansion of indications for Sternal Talon to include secondary closure for nonunion or mediastinitis, or both.

Despite the apparent success of the Sternal Talon in this series, the study is subject to certain limitations. The present investigation was designed to use data from existing patients who had already undergone operation, which eliminated the possibility of a prospective methodology. Additionally, the study population was of insufficient size for any meaningful analysis. Although these initial retrospective data demonstrate that the Sternal Talon offers a viable option for nonunion, further rigorous study would be required to demonstrate superiority, ideally in the form of a randomized controlled trial.

In conclusion, Sternal Talon closure is a safe and effective treatment modality for patients with persistent sternal nonunion and infectious dehiscence and should be added to the surgical arsenal for the correction of these conditions.

References

The most common method of sternal closure remains sternal wire, but this is not without problems, especially in heavier patients. Increased sternal displacement forces can cause them to break, migrate through the bone, or loosen, which can lead to sternal instability, infection, and increased pain. The recent study by DeLong and colleagues [1] suggests that using the Sternal Talon (KLS Martin LP, Jacksonville, FL) improves the fixation, thus reducing the risk of sternal complications and resulting in faster recovery.

Nonrigid sternal fixation, such as wire closure, allows for a certain degree of movement of the sternal halves; a variety of wire configurations have been described. Invariably one of the most feared complications is sternal dehiscence or sternal nonunion, especially in osteoporotic patients. Sternal osteosynthesis cannot typically occur with sternal gaps greater than 2 mm; this has been shown to result in significant lateral sternal displacement, leading to a failure rate of 0.5% to 4% [2]. The advantages of sternal wire closure include very low cost and universal familiarity among surgeons worldwide.

Rigid sternal fixation is known to prevent lateral sternal displacement and nonunion. A number of trials have shown that titanium plates can help minimize the mobility of the closure. Known complications include screw loosening due to repetitive movement of the sternum [3].

The Sternal Talon is a relatively new, alternative method of midline sternotomy closure that uses rigid orthopedic-type fixation. The device provides the compressive and locking forces that are both needed to optimally fixate the plate to the bone. Results from the available studies show the Talon system offers improved mechanical properties for rigid sternal fixation without the need for screws. The device has a locking mechanism and can be suited to almost any cardiothoracic patient, including those who have morbid obesity, diabetes, or chronic obstructive pulmonary disease.

The exact role of the Talon in successfully managing transverse sternal fractures is not entirely clear. Other potential barriers for the device's more widespread use include the high cost and uncertain results in highly osteoporotic bone. A larger prospective randomized study is expected to elucidate the Talon’s true incidence of infection and related problems that necessitate another trip to the operating room to remove it.

The study by DeLong and colleagues [1] helps to illuminate some of the values of the Sternal Talon. Despite the small number of patients, retrospective nature of the study, and no adequate follow-up, their work represents an important step that should be expanded upon with comparable studies of a wider variety of closure techniques and a much larger sample.

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References