Clinical Investigation

Nitinol Thermoreactive Clips for Secondary Sternal Closure

in Cases of Noninfective Sternal Dehiscence

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Postoperative sternal dehiscence is a potentially catastrophic sequela to median sternotomy that can cause not only chest-wall discomfort and pulmonary dysfunction but infection, both superficial and mediastinal. Nitinol thermoreactive clips use a novel material in the treatment of sternal dehiscence. We sought to determine whether the use of these clips is an effective remedy for noninfective sternal dehiscence.

From January 2008 through December 2011, we retrospectively studied the data on 10 patients whose sternums had been closed with nitinol thermoreactive clips after the development of noninfective sternal dehiscence. Diagnosis was made on the bases of clinical criteria, chest radiography, and microbiological investigation. There was no control group.

No procedure-related sequelae occurred. There was no recurrent sternal instability and dehiscence, sternal-related hemorrhage, superficial wound infection, or mediastinal infection.

We believe that the use of nitinol thermoreactive clips is a safe, easy, and efficient method of secondary sternal closure for noninfective sternal dehiscence. ***(Tex Heart Inst J 2012;39(4):513-6)***

Key words: *Biocompatible materials; bone wires; postoperative complications; reoperation; retrospective studies; sternotomy, median; sternum/surgery; surgical wound dehiscence/prevention & control/surgery; suture techniques; sutures; thoracotomy/adverse effects*

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Despite the widespread adoption of minimally invasive surgical techniques in recent years, median sternotomy remains the most commonly used operative approach to the heart and great vessels. Postoperative sternal dehiscence is a serious and potentially catastrophic sequela of median sternotomy that can cause not only chest-wall discomfort and pulmonary dysfunction but infection, both superficial and mediastinal.[1,2] The outcome of mediastinal infection is linked to specific predictors.[3]

Noninfective sternal instability develops rarely.[4] It usually occurs within the first 1 or 2 postoperative weeks, before the bone-healing process is complete. Instability can follow the application of excessive mechanical stress and is more likely to occur in patients who have a constitutionally thin sternum or whose bone density has been reduced by osteoporosis.[5] Sternal dehiscence can require surgical revision in the most severe cases, and chronic instability can cause patients discomfort and persistent morbidity. In fact sternal stability is essential for the prevention of surgical wound sequelae.[6] None of the current remedies that use traditional monofilament steel wire seems to be free of the wound complications common in patients at highest risk of impaired healing. Common occurrences are wire fractures and wire cuts (through bone).

As a consequence of primary failure to bond, poor wound healing, or premature overexertion, sternal dehiscence occurs in 0.2% to 5% of patients who undergo sternotomy.[7-11] The preoperative risk factors associated with sternal dehiscence include obesity, chronic obstructive pulmonary disease, osteoporosis, heart failure categorized as New York Heart Association (NYHA) functional class III–IV, immunosuppression, diabetes mellitus, renal insufficiency, and previous sternotomy.[1,7,12,13] Operative risk factors include bilateral internal mammary artery harvesting and the transfusion of excessive volumes of blood.[2,12-14]

Nitinol thermoreactive clips use a novel material to prevent sternal dehiscence. It is characterized by shape memory and super elasticity. These clips become malleable at temperatures under 8 °C and return to their original shape when warmed to body temperature.[15]

In this summary, we review the records of all patients in whom noninfective sternal dehiscence was found after midline sternotomy, and we present the results of our treatment of these patients with thermoreactive clips.

Patients and Methods

Patients. From January 2008 through December 2011, we retrospectively studied the data on 10 patients who had developed noninfective sternal dehiscence. Patients who experienced infectious complications or multiple sternal fractures were excluded (these last were treated with sternal plating or the Robicsek procedure). There was no control group. The ages of the 10 patients in our study group ranged from 62 to 74 years (mean, 68.6 ± 3.7 yr). Nine patients experienced sternal dehiscence after coronary artery bypass grafting, and 1 patient after mitral valve replacement. The diagnosis of sternal dehiscence was made on the bases of clinical criteria, chest radiography (anteroposterior and lateral views), and microbiological investigation. All study data were collected retrospectively, so informed consent was not required. Obesity was defined as a body mass index of 35 kg/m^2 or greater, and chronic obstructive pulmonary disease was defined as forced expiratory volume, during the first second, of less than 80% of predictive value. The criteria for osteoporosis were subjective insofar as they depended on the individual surgeon's evaluation of bone density at the time of surgery. All patients who had cardiac and other comorbidities were medically prepared for surgery in a manner suited to the circumstances.

Preoperatively, 6 patients presented with chronic obstructive pulmonary disease, 2 with obesity, 3 with osteoporosis, 7 with diabetes mellitus, and 5 with heart failure categorized as NYHA functional class III–IV. In all patients, cefazolin was administered for antibiotic prophylaxis just before the induction of anesthesia and was continued for 2 or 3 days postoperatively. The clinical profile of the 10 patients appears in Table I.

After surgery, patients participated in the standard outpatient follow-up program at our institution, which entailed periodic physical examinations and chest radiography (anteroposterior and lateral views).

Materials. Nitinol is a shape-memory alloy (more precisely, in this case, an "intermetallic compound") of nickel and titanium, in which the bonding force is much stronger than in alloy stainless-steel components. At low temperatures (<8 °C), the alloy is highly flexible; at moderate temperature (~27 °C), the alloy begins to recover the "memory" of its original shape; and at the austenite finish temperature of 35 °C or above, it recovers its original shape. Nitinol thermoreactive clips (Nitillium Research SRL; Naples, Italy) are designed for sternal closure (Fig. 1) and are available in 8 sizes, ranging from 22.5 through 40 mm. These clips are available commercially.

Methods. Electrocautery is used to create holes through the intercostal space that enable the clip to attain traction on the sternum. During the course of electrocautery, attention must be given to avoiding the internal thoracic arteries (Fig. 2). To keep the sternum closed until the clips are in place, temporary loops are placed through these holes in the intercostal spaces. When the 2 halves of the sternum are approximated, the distance between the intercostal spaces is measured in order to select the clip size, which must be 7 to 8 mm smaller than the measured size. The clip is then cooled with ice and implanted around the sternum with specific (supplied) forceps. Cooling to a temperature below 8 °C makes the clip highly malleable and easy to situate in the intercostal space (Fig. 3). Finally, the clip is heated with warm water. Should a new sternotomy be required, clips can

TABLE I. Clinical Profile of the 10 Patients

Variable	No. of Pts.
Mean age, yr (range)	68.6 ± 3.7 (62–74)
Male/female	7/3
Age >70 yr	4
Diabetes mellitus	7
Renal insufficiency	0
Bilateral internal mammary artery harvesting	0
NYHA functional class III–IV	4
Osteoporosis	5
Chronic obstructive pulmonary disease	6
Obesity	2
With 1 risk factor	1
With 2 risk factors	4
With 3 risk factors	2
With >3 risk factors	3
Related hemorrhage	0
Recurrent sternal instability and dehiscence	0

NYHA = New York Heart Association

Fig. 1 *Nitinol thermoreactive clip.*

easily be removed by cooling and by using the specific forceps, because the nitinol thermoreactive clip does not integrate with bone.

Results

Postoperatively, the mean follow-up period was 4.2 ± 1.3 months (range, 2–6 mo), and there were no procedure-related sequelae. No instances of recurrent sternal instability and dehiscence, sternal-related hemorrhage, superficial wound infection, or mediastinal infection were reported. Two major respiratory complications, which required prolonged intensive care unit and hospital stay, developed early in the postoperative period.

Discussion

Usually, the sternum is closed with single-passage or figure-8 steel wires. Noninfective sternal dehiscence is clinically characterized by sternal splitting, chest discomfort, and respiratory distress. Mechanical forces play the most important roles in determining this condition. In some patients who have a thin and fragile ("wafer-like") sternum, standard closure with steel wires can lead to dehiscence.[16] Sternal dehiscence is a potentially catastrophic complication, which usually occurs during the initial hospital stay. In most cases, the diagnosis is made radiographically. Displacement or rotation of one or more wires is the most common finding; broken sutures are another possibility.[4]

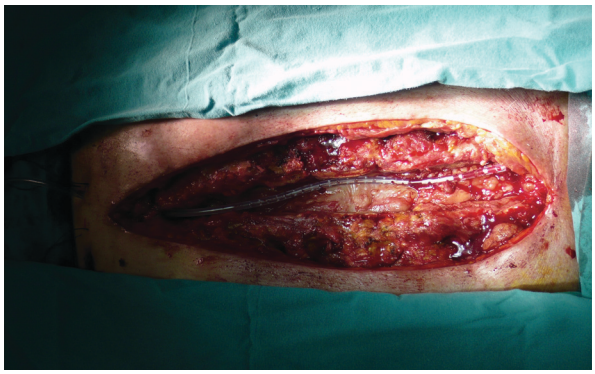

Fig. 2 *To provide traction for the clips, we created holes through the intercostal space by means of electrocautery.*

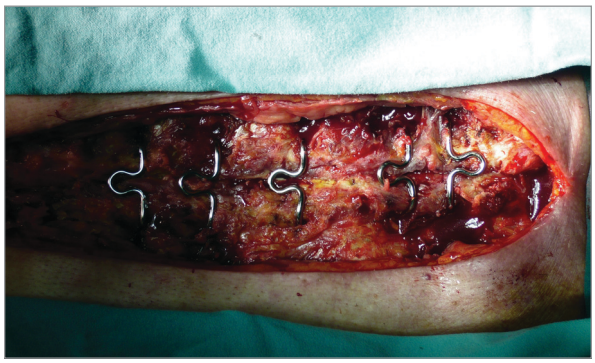

Fig. 3 *The thermoreactive clips are implanted over the sternum while they are cold and easily malleable. As they warm to body temperature (with the immediate application of warm water), they return to their original size and tightly approximate the sternum.*

Nitinol is characterized by shape memory and super elasticity. The clips become malleable at under 8 °C and then return to their original shape when warmed to body temperature.[15] The nitinol thermoreactive clips do not completely surround the sternum, and they are more flexible than steel.[17] At body temperature, the rigidity of the clips means that they can fracture when exposed to high-energy impact above a specific tensile force. Such forces are, however, rarely exerted on the sternum, and, when applied, they also fracture sternal wires and sternal bone itself.

Nitinol thermoreactive alloy also has many advantages over stainless steel, in that it is more stable, less destructive, and more biocompatible. Furthermore, unlike stainless-steel wires, the clips do not integrate with bone; and because they are non-ferromagnetic, the clips are safe to use in magnetic resonance imaging.[15] Nitinol thermoreactive clips have been shown to reduce the incidence of sternal complications.[15,17,18]

When bone quality is poor or there are multiple fractures of the sternum, traditional rewiring can fail and rigid fixation systems can be required for sternal reconstruction. New approaches to sternal reconstruction, derived from experience with orthopedic, plastic, and maxillofacial fixation systems, have recently been introduced. Sternal closure systems that consist of titanium reconstruction plates, cables, and screws perform transverse rib-to-rib stabilization, thereby extending the zone of fixation laterally—beyond the fractured sternum to the ribs, where the bone quality should be better.[19,20]

The thermoreactive clips can be used in patients with a normal sternum or in patients with slight osteoporosis, where steel wires are normally used. In our study, 6 patients with normal sternum were treated with nitinol thermoreactive clips (Fig. 4A). The remaining 4 patients had sternal dehiscence with unilateral single sternal fracture, so nitinol thermoreactive clips were placed obliquely between the intercostal spaces just below the fracture line on the damaged side of the sternum and just above the fracture line on the opposite (nonfractured) side of the sternum (Fig. 4B).

Conclusion

In our small study, the use of nitinol thermoreactive clips was an effective method of treating noninfective sternal dehiscence. This method has several advantages. It enables semi-rigid compression, and therefore provides more physiologic sternal stability than does steel.

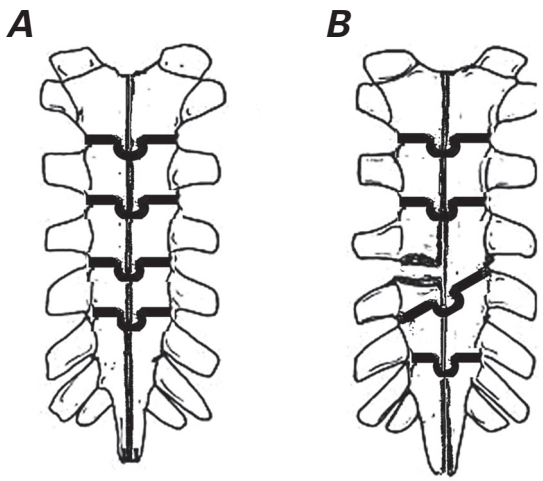

Fig. 4 ***A****) Thermoreactive clips were applied in the usual manner in the 6 patients whose sternum was intact except for dehiscence of the surgical wound.* ***B****) In each of the 4 patients who had both unilateral single sternal fracture and dehiscence of the surgical wound, 1 thermoreactive clip was situated obliquely between the intercostal spaces, just below the sternal fracture on the fracture side and just above the fracture line on the other side.*

Because these clips are thicker than steel wires, they carry a lower risk of cutting sternal bone. These advantages should reduce the incidence of re-dehiscence, in comparison with conventional wire. A nitinol clip has higher biocompatibility than steel; nitinol can be implanted or removed easily and quickly. This clip confers relatively less risk of bleeding than does steel wire, and nitinol is a non-ferromagnetic alloy that ensures magnetic resonance feasibility. We believe that the use of thermoreactive clips is safe, easy, and efficient.

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