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Efficacy of Thermoreactive Nitinol Clip Implantation in Reconstruction of Sternal Dehiscence

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ABSTRACT

Background: Sternal dehiscence is a severe complication of open heart surgery. Reinforced wiring, a system of reinforced sternal closure, fixation of a rigid plate, and implantation of thermoreactive nitinol clips (TRC) are some surgical procedures used. The aim of this study was to evaluate the role of TRC for secondary sternal reconstruction.

Methods: Of 1198 patients who underwent their operations via median sternotomy in 2 separate medical centers, sternal dehiscence was observed in 16 patients overall (1.33%). The mean (SD) age of the patients was 64.06 ± 9.18 years (range, 40-77 years). Sternal dehiscence was diagnosed in all patients between the fifth and 30th postoperative days.

Results: TRC were implanted in all of the patients who developed sternal dehiscence (16 patients). One patient developed severe respiratory failure, became ventilator dependent, and died from pneumonia on postoperative day 24. The other 15 patients were discharged without complications. Postoperative follow-up of the surviving patients revealed adequate and satisfactory sternal stability.

Conclusion: Implantation of TRC is an effective and easy method for fixing the sternum and can be performed rapidly and securely.

INTRODUCTION

During the last 5 decades median sternotomy has been the standard approach in cardiac operations, and cerclage wire fixation is the most common closing procedure [Gummert 2002]. Sternal dehiscence including wound complications and infection occurs in 1% to 3% of patients undergoing cardiac surgery [Borger 1998; Douville 2004]. Recurrent exposure and access to the mediastinum increase the mortality rate up to 15% [Song 2004; Bapat 2008]. Sternal dehiscence is a severe complication in open heart surgery. A multidisciplinary approach involving cardiothoracic surgery, plastic surgery, and consultation with infectious disease specialists is necessary for treating these patients. Reinforced wiring (Robicsek weave), a system of reinforced sternal closure, and fixation of a rigid plate are alternative surgical procedures. The aim of this study was to investigate the use of thermoreactive nitinol clips (TRC), which were specifically designed as an alternative method for sternal fixation for sternal closure in patients with sternal dehiscence.

TRC is a recently deployed sternal closure device being used in cardiothoracic surgery. The nitinol staples clasp the sternum to hold together the edges of the sternal osteotomy permanently and safely. TRC are made of nitinol, a thermoreactive material. Nitinol is an alloy containing nearly equal quantities of nickel and titanium [Ooi 2009]. Nitinol transforms into a soft material during cooling, whereas heating returns nitinol to the previously hard condition. Owing to their malleability, a 10% to 15% deformation in width is possible during coughing or movement, thus preventing bone or clip damage. The clips become malleable at low temperatures (<10°C) and return to their definitive shape at 35°C. The retention of shape memory is due to a crystalline phase change known as "thermoelastic martensitic transformation." During heating, the material converts into its high-strength condition, austenite. Nitinol alloys contain more nickel than stainless steel alloys, and they have been shown to be chemically more stable, less corrosive, and more biocompatible than stainless steel while producing fewer artifacts during magnetic resonance imaging. The clips are available in 8 sizes, ranging from 22.5 mm to 40.0 mm [Negri 2002; Ooi 2009].

TRC are lighter, and their implantation is less traumatic than with common sternal-closure systems. They allow a certain degree of rib cage expansion, and easier removal or faster sternal closure is possible.

In this study, we wanted to evaluate the role of TRC as an option for secondary sternal reconstruction.

MATERIALS AND METHODS

We retrospectively investigated 1198 patients who had

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undergone cardiac surgery via median sternotomy in 2 separate cardiac centers (Gülhane Military Medical Academy, 758 patients between December 2006 and December 2009; Medicana International Ankara Hospital, 440 patients between December 2008 and December 2009). Sternal dehiscence was noted in 16 patients. We reviewed our experience with TRC (Flexigrip; Praesidia, Bologna, Italy). The mean (SD) age was 64.06 ± 9.18 years (range, 40-77 years), the mean EuroSCORE was 4.94 ± 1.73, and the mean body mass index was 29.25 ± 7.15 kg/m2. Two parameters were recognized as risk factors: chronic obstructive pulmonary disease (9 patients) and obesity (body mass index >30 kg/m2, 7 patients). In the first operation, all 16 patients had undergone a standard sternal-closure procedure with steel wires. Sternal dehiscences were diagnosed on the fifth to 30th postoperative days. One of these patients had undergone coronary artery bypass surgery with mitral valve replacement; the remaining 15 patients had undergone only coronary artery bypass grafting. For the acute sternal dehiscence in 14 of these patients, we used TRC without substernal dissection in the secondary sternal reconstruction. Substernal dissection was performed in 2 patients who had a mediastinal infection. Proximal and distal parts of the sternum were brought into close contact with steel wire suture before applying the TRC. Intensive intravenous antibiotic therapy was administered to these patients following aggressive curettage. Vacuum-assisted closure (V.A.C.; Kinetic Concepts, San Antonio, TX, USA) aspiration therapy was used in addition to TRC. No further revision or debridement was required. Tissue cultures were undertaken for microbiological investigations. The type of antibiotic treatment was based on the antibiogram.

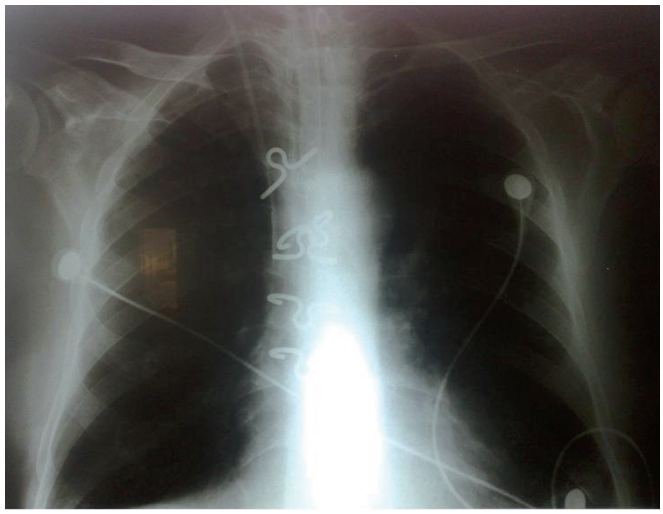
Application Procedure

All patients were prepared as in open heart surgery. The area of the sternal incision was brushed with Betadine solution, and scar tissue was excised. The midline sternotomy incision was opened in a sterile setting. Suture materials and broken steel wires were removed or cleaned up. Three osseal clips were applied on the sternum—2 on the manubrium and 1 near the xiphoid. Holes were treated with electrocautery, and clips were implanted next to the parasternal line. Distances were measured to ascertain the correct clip size. The appropriate clips were cooled in ice water (<10°C) and mounted onto an applicator that splays the clips into an open position. The clips were then applied around the sternum. On rewarming (35°C), the clips returned to their original shape and strength, clasping the sternum together.

RESULTS

The incidence of sternal dehiscence was 1.33% (16 cases in 1198 cardiac operations). Our standard procedure for sternal closure consists of 4 to 5 wires in a figure-8 pattern for cerclage, depending on the sternum length. We used TRC in all 16 dehiscence cases. The mean follow-up period was 58 ± 13 weeks (range, 28-124 weeks). Follow-up was performed either by clinical examination or via a telephone questionnaire. One patient had prolonged intubation because of respiratory failure and died of pneumonia on the 24th postoperative day. The patient did not have mediastinitis.

Closure was successful in all patients, and none required further surgery. No bleeding of the coronary artery graft or the left internal mammary artery was encountered during TRC implantation. Although 3 clips were sufficient to achieve good sternal stability, we used 2 additional clips to achieve a satisfactory result for a patient with multiple fractures of the sternum. In this case, 3 of the clips were used in the same fashion as in the other patients, and the other 2 clips were placed obliquely to fix the fractured bone into position (Figure).



Chest radiograph showing 5 clips implanted in different positions to fix multiple fractured sternal bones.

DISCUSSION

Sternal complications increase patient discomfort and the likelihood of disability and mortality. Inappropriate fixation of the sternotomy line may lead to development of osteomyelitis as well. Multiple sternal fractures may occur in poor-quality bone, especially while wires are pulled during surgery, or during a patient's movements or coughing. Fixation of the sternal bones is necessary in reoperation to reunite the bone and to prevent symptoms and recurrence. Rewiring of the unstable sternum with steel wires may lead to bone fractures, which are associated with recurrent dehiscence. TRC have a wider surface of contact with the bone than steel wires. This property is a great advantage when repairing the sternum, because steel wires may easily cut the bones if they are pulled more than desired. Avlonitis et al used TRC devices in 8 patients with dehiscence who had undergone closure with steel wires in the first operation; these investigators found TRC highly effective [Avlonitis 2008]. The application of TRC has been reported to be easy, nontraumatic, and safe [Negri 2002].

Implantation of 3 clips is generally sufficient to achieve satisfactory sternal stability. An approximation of the correct sternal position is achieved by applying 2 steel wires for traction. In the standard technique, 2 clips are applied on the

manubrium, and 1 clip is applied near the xiphoid. If the sternum is not broken, the existing wires may be tightened. This technique is specifically preferred by surgeons who do not wish to explore the substernal area because of the risk of possible cardiac injury and mediastinal infection [Tocco 2009]. TRC can also be applied between strong wires.

Healing of the superficial wounds can be managed with simple drainage and antibiotic therapy, whereas deep infections (10%-15% of dehiscence cases) require a more complicated strategy [Douville 2004]. This complication remains one with a high rate of morbidity and mortality, despite improvements in antibiotic treatment and sophisticated techniques of wound healing [Bapat 2008]. In addition to open debridement and drainage, sternal-reclosure methods such as V.A.C. therapy or pectoral muscle flap can be useful. V.A.C. therapy can be essential for treating deep sternal-wound infections. Adhesions formed following V.A.C. therapy make mediastinal exploration and rewiring difficult. For this group of patients, TRC can be of great advantage because they do not require substernal tissue exploration. We used V.A.C. therapy in 3 patients, and subsequent TRC implantation was very safe and easily applied.

A well-known and commonly used method in cases of sternal dehiscence is the modified Robicsek technique [Robicsek 1977]. It is also commonly used in high-risk cases during the first operation to prevent the occurrence of dehiscence. The modified Robicsek technique is unquestionably effective. It allows a peristernal approach and may avoid further damage to the sternum (including fractures) compared with standard transsternal wiring. The advantage of TRC in secondary dehiscence cases, however, is the ease of the method and the avoidance of exploration of substernal tissues.

Staged sternal-plate reconstruction has been described as a successful method for cases of sternal dehiscence cases with mediastinitis and a major loss of sternal bone [Huh 2008]. No study has compared the use of TRC versus sternal plates. Indications are different for the 2 closure techniques [Plass 2007]; however, because TRC may be applied semivertically or obliquely, this approach might become popular for these patients in the near future.

The mean cost of implantation per procedure was $550 in our series. The cost varies widely, depending on the number of TRC to be placed. TRC are significantly more expensive than steel wires. Compared with other methods of treatment, the cost of rigid-plate fixation ranges from $700 to $1400 [Song 2004], whereas the cost of a transverse sternal-plating system is approximately $8500 [Huh 2008]. Although health insurance companies in Turkey do not refund the routine costs of TRC use, this procedure can be cost-effective in specific cases of primary closure of osteoporotic, poor-quality, and multiply fractured bones in patients with multiple risk factors and in cases of redo closure [Ooi 2009].

Despite the ease, cost-effectiveness, and safety of their use, TRC have some disadvantages. A case of a fractured TRC has been reported [Broadhurst 2010]. It is not possible to use this technique when the sternal width exceeds the sizes of commercially available clips (22.5-40.0 mm) [Negri 2002]. In the presence of strong adhesions, the efficacy of clip use may decrease, and insertion of the clips can cause serious retrosternal bleeding. Fortunately, we did not encounter such complications.

We also think that performing an emergent sternotomy for a sternum previously fixed with TRC can be challenging and slower than in patients with a rewired sternum. On the basis of our experience, we believe that TRC are not suitable for patients who have chronic dehiscence with sternal pseudarthrosis. Plass et al [2007] share the opinion that TRC cannot develop the necessary force required in pseudarthrosis cases. More recently, however, TRC have been reported to permit sternal resynthesis and to be useful in pseudarthrosis cases [Tocco 2009].

Our study has several limitations. We used TRC for a small number of patients who underwent their operations within a limited time interval, because the costs of this operation are not refunded in our country. The study period could be extended to include more patients.

TRC implantation takes little time. The technique is easy and does not necessitate opening of the chest. It avoids placement of a retractor and further bone fracturing. It is an excellent method that may be used in high-risk patients (chronic obstructive pulmonary disease, osteoporosis, the elderly).

The early results of TRC implantation have shown it to be very effective for stabilizing the sternum. Long-term follow-up is needed to determine the fate of TRC in the sternum. Advantages of TRC use include easy heating and cooling down. They are safe, thick (thereby avoiding cutting the bone), unbreakable, and static, and they do not necessitate substernal exploration. TRC serves as an additional tool for patients who have poor-quality sternal bones, for patients with multiple comorbidities such as chronic obstructive pulmonary disease and osteoporosis, and for patients with complications after sternal closure. They can be placed at different angles (horizontal, oblique, semivertically), and their use accelerates bone healing. These clips have some disadvantages, however, such as increased costs and limited size availability. Furthermore, the formation of intercostal holes, which is a fundamental step in clip placement, may lead to hemorrhage.

The small number of cases described in this report does not allow meaningful statistical comparisons, and therefore this report is of an observational study. Future studies with long-term results and routine application of TRC must be conducted. TRC will serve as an adjuvant tool to the patient with a poor-quality sternum or with high-risk factors for establishing sternal stability after standard heart surgery.

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