

Thermoreactive nitinol clips for re-sternotomy in cases of sternal dehiscence

Sternal ayrışma nedeniyle yapılan tekrar sternotomi ameliyatlarında termoreaktif nitinol klipsler

Sabit Sarıkaya, Fuat Büyükbayrak, Özge Altaş, Onur Yerlikhan, Ali Fedakar, Murat Rabuş, Kaan Kırallı

Department of Cardiovascular Surgery, Kartal Koşuyolu Heart Education and Research Hospital, İstanbul, Turkey

Background: This study aims to evaluate the effectiveness, reliability, advantages, disadvantages and the application technique of the thermoreactive nitinol clips (TRNC) used for sternal closure in patients with sternal dehiscence.

Methods: Between January 2010 and March 2012, we used TRNCs for sternal closure in 24 patients (13 males, 11 females; mean age 67±4 years; range, 53 to 79 years) with sternal dehiscence in Kartal Koşuyolu Yüksek İhtisas Training and Research Hospital, Cardiovascular Outpatient Clinic. All patients with sternal dehiscence after primary cardiac surgery were identified before the hospital discharge. They underwent sternal revision on postoperative 12±3 days (range, 6 to 18 days). Substernal tissues were not dissected in 19 patients whose sternums had been closed with TRNC, while the rest of the patients underwent substernal tissue dissection due to the risk for deep sternal wound infection. Subsequently, high risk tissues with suspected infection were debrided and curated.

Results: A total of 33.3% (n=8) had superficial sternal wound infection, while 4.1% (n=1) had deep sternal wound infection. One patient who underwent substernal dissection during revision surgery developed right atrial injury due to adhesion of giant atrium to the sternum. No in-hospital mortality was observed. No complications of sternotomy including recurrent sternal dehiscence, sternal abscess, mediastinitis or secondary osteomyelitis were reported during the six-month follow-up period.

Conclusion: Early surgical intervention should be considered in patients with sternal dehiscence to break the vicious circle of infection-mechanical disorder-dehiscence and to minimize the risk for mediastinitis. We recommend using TRNCs as the first treatment of choice for sternal closure in patients with sternal dehiscence thanks to its easy and safe utilization during surgery, shorter length of hospital stay, relatively lower cost and patient comfort.

Key words: Deep sternal infection; sternal closure; sternal dehiscence; thermoreactive nitinol clip.

Amaç: Bu çalışmada, sternal ayrışma gözlenen hastaların sternumlarının kapatılmasında termoreaktif nitinol klipslerin (TRNC) etkinliği, güvenilirliği, avantajları, dezavantajları ve uygulama tekniği değerlendirildi.

Çalışma planı: Kartal Koşuyolu Yüksek İhtisas Eğitim ve Araştırma hastanesi Kalp ve Damar Cerrahisi Kliniği'nde, Ocak 2010 - Mart 2012 tarihleri arasında sternal ayrışma gözlenen 24 hastada (13 erkek, 11 kadın; ort. yaş 67±4 yıl; dağılım 53-79 yıl) sternal kapama tekniği olarak TRNC'ler kullanıldı. Tüm hastalarda primer kardiyak cerrahiden sonra oluşan sternal ayrışma, hastanede kaldıkları süre içerisinde tespit edildi. Bu hastalar, ameliyat sonrası 12±3. günde (dağılım, 6-18 gün) sternal revizyona alındı. Sternumu TRNC ile kapatılan hastaların 19'unda substernal dokular diseke edilmezken, beşinde derin sternal yara enfeksiyonu riski açısından substernal dokular diseke edildi. Takiben enfeksiyondan etkilendiği düşünülen riskli dokular debride ve kürete edildi.

Bulgular: Hastaların toplam %33.3'ünde (n=8) yüzeysel sternum yara yeri enfeksiyonu görülürken, %4.1'inde (n=1) derin sternum yara yeri enfeksiyonu saptandı. Revizyon ameliyatı esnasında, substernal diseksiyon yapılan bir hastada, dev sağ atriyumun sternuma yapışmasından dolayı sağ atriyal yaralanma görüldü. Hiçbir hastada hastane içi ölüm görülmedi. Hastaların ameliyat sonrası altı aylık takiplerinde tekrarlayan sternal ayrışma, sternal apse, mediastinit, sekonder osteomyelit gibi sternotomi komplikasyonları görülmedi.

Sonuç: Sternal ayrışma gözlenen hastalarda, enfeksiyon-mekanik bozukluk-ayrışma kısır döngüsünü kırmak ve bununla beraber mediastinit riskini en aza indirmek için erken dönemde cerrahi girişim yapılmalıdır. Ameliyat esnasında TRNC'nin kolay ve emniyetli uygulanması, hastanede yatış süresini kısaltması, nispeten daha az maliyetli olması ve hastalar için konforlu olması nedeniyle, sternal ayrışma gözlenen hastalarda sternal kapamalarda TRNC kullanımını ilk tercih olarak önermekteyiz.

Anahtar sözcükler: Derin sternal enfeksiyon; sternal kapama; sternal dehiscens; termoreaktif nitinol klip.



Available online at
www.tgkdc.dergisi.org
doi: 10.5606/tgkdc.dergisi.2013.7603
QR (Quick Response) Code

Received: August 27, 2012 Accepted: January 03, 2013

Correspondence: Özge Altaş, M.D. Kartal Koşuyolu Yüksek İhtisas Eğitim ve Araştırma Hastanesi Kalp ve Damar Cerrahisi Kliniği, 34846 Cevizli, İstanbul, Turkey.

Tel: +90 216 - 500 15 00 e-mail: dr.ozgealtas@gmail.com

Sternal steel wires were first used by Minton^[1] in 1897 for sternal closure and were made popular by Julian et al.^[2] in 1957. Despite the development of new cardiac operation techniques in recent years, median sternotomy featuring this conventional closure technique is still the most frequently performed procedure.^[3] Recently, new alternatives to steel wires for the closure of sternal dehiscence have been developed which have greatly benefited cardiac surgeons by helping prevent possible serious complications. Early sternal dehiscence, superficial and deep infections, seromas, hematomas, sternal fracture, and sternal nonunion are the most commonly observed sternal wound complications when steel wires are used for closure.^[3] Predisposing factors such as obesity, diabetes mellitus (DM), renal failure, chronic obstructive pulmonary disease (COPD), steroids, advanced age, smoking, use of bilateral internal mammary artery (IMA) play significant role in the formation of sternal wounds.^[4]

Sternal dehiscence, which stems from mechanical defects and/or infection, is a rare complication of median sternotomy (0.5-2.5%).^[5] Sternal dehiscence secondary to mechanical defects develops as a process after asymmetric sternotomy incision while performing sternotomy. It also can be caused by sternal fractures during IMA preparation, the application of excessive force on the sternum via a retractor during the operation, unbalanced straightening of the steel wires, and problems involving the cutting process in the primary operation. In addition, respiratory insufficiency, low cardiac output, re-exploration due to bleeding,^[6] powerful coughing attacks, and aggressive activity can contribute to enhance the pressure of the steel wires on the bone.^[3] Gradually, the sternal wires fail to hold both the left and right hemisterna together, and dehiscence occurs at different levels. This can cause not only chest wall discomfort leading up to pulmonary dysfunction, but superficial and mediastinal infection. As a result, a sternal structure that is more defective and difficult to fix might be encountered than what is found in the primary operation. For the revision of patients with sternal dehiscence, classical and modified Robicsek techniques,^[7,8] sternal plates,^[9] thermoreactive nitinol clips (TRNCs) (Nitalium Research SRL, Naples, Italy)^[4,10] and sternal talon systems^[3] are currently being used (Figure 1).

The aim of this study was to evaluate the effectiveness, reliability, advantages, and disadvantages of the TRNC application technique for the closure of patients with sternal dehiscence.

PATIENTS AND METHODS

From January 2010 to March 2012, we inserted TRNCs for sternal closure in 24 of 56 patients (13 males, 11 females; mean age 67±4 years; range 53-79 years old) who developed sternal dehiscence after the primary operation. The rest of the patients were treated via the Robicsek technique (n=6) or secondary healing with a sternal corset in cases of partial dehiscence (n=20). Six others were referred to the plastic surgery team after vacuum-assisted closure (VAC) reduced the defect. We used no. 6 steel wires (Doğ-San Medical Equipment, Trabzon, Turkey) for the patients in the cardiac operations. The preoperative risk factors (COPD, DM, renal failure, peripheral artery disease, obesity, bilateral IMA usage, etc.) are summarized in Table 1. After the primary cardiac surgery, all patients were observed to have developed sternal dehiscence during their hospitalization period. The preoperative, intraoperative, and postoperative demographic data of the patients who underwent primary cardiac surgery and sternal revision are summarized in Table 2. Preoperative blood and wound cultures along with intraoperative mediastinal tissue and fluid cultures were collected from all patients.

Regarding the first operations, the patients were asked to take a shower approximately 10-12 hours before the operation, and a body trim was done before entering the operating room. We first applied 4% chlorhexidine gluconate (Plasti-med, İstanbul, Turkey) and then 10% povidone-iodine 10%

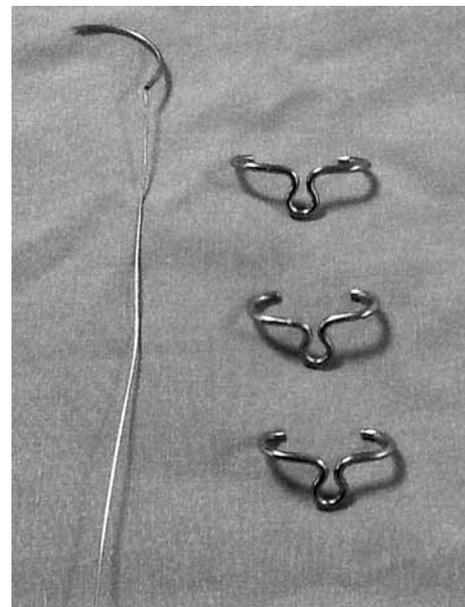


Figure 1. Different size of the nitinol clips to compare with sternal wire.

Table 1. Preoperative and intraoperative risk factors of patients for sternal wound complications (n=24)

	n	%
Chronic obstructive pulmonary disease	15	62.5
Diabetes mellitus	12	50
Obesity (BMI ≥ 30 kg/m ²)	11	45.8
Renal insufficiency	4	16.6
Peripheral vascular disease	7	29.1
Bilateral internal mammary artery	1	4.16

BMI: Body mass index.

(Orbak Kimya, İstanbul, Turkey) to the surgical area to prevent infection. All patients received cefazolin (2 gr.) preoperatively followed by daily doses (4 gr.) until the drains were removed. The patients with positive blood cultures were treated with a combination of vancomycin and amikacin preoperatively because of the risk of mediastinitis before revision operations. Antibiotherapy culture results were then updated again according to the data.

The sternal fixation was initiated with the administration of an average of 7-8 steel wires placed one at a time due to the risk factors causing the sternal wound. The TRNCs were then used to stabilize the sternum during the sternal revision. These were administered in two ways during the

surgical procedure. In 19 patients of the group, nitinol clips were inserted without dissecting any substernal tissue in contrast to other patients (n=5). The primary operations and perioperative values are given in Table 2. A detailed sternal exploration was initially performed, and the level of sternal dehiscence, infection, and sternal fractures were observed visually. The decision regarding whether or not to perform substernal tissue dissection was made according to the degree of infection as judged by our clinical experience. Holes were cut through the, first, second, third, fourth and fifth intercostal spaces by electrocautery, and temporary loop clamps were used to keep the sternum closed until the clips were in place. In the meantime, suitable-sized TRNCs were selected, ranging from 2.25 to 4 cm. Each clip was then exposed to icy saline (below 10 °C) to minimize its flexibility and implanted around the sternum at relevant points. Finally, the clip was heated with hot saline (above 45 °C) so that it could return to its original shape. This practice was applied to the other intercostal distances in order. To determine the proper TRNC size for patients with segmental fractures, the fractured ribs were measured above and below the level of the costochondral joint. Afterwards, the TRNCs were placed longitudinally (Figure 2) to stabilize, the fractured region. For the patients who had their substernal tissue dissected, both hemisterna were brought together after debriding the tissue. Next, the

Table 2. Preoperative, intraoperative and postoperative demographic data for the primary operation (n=24)

	n	%	Mean±SD	Range
Preoperative				
Age			67±4	53-79
Gender				
Female	11	45.8		
Male	13	54.1		
Ejection fraction <30%	2	8.3		
Intraoperative				
Coronary artery bypass grafting	14	58.3		
Valve	7	29.1		
Others	1	4.1		
On-pump	23	95.8		
Left internal mammary artery	13	54.1		
Bilateral internal mammary arteries	1	4.1		
Extracorporeal circulation time (minutes)			86±7	66-104
Aortic cross-clamp time (minutes)			60±3	56-65
Intra-aortic balloon pump	1	4.1		
Postoperative				
Drainage (ml/24 hours)			730±67	700-850
Delirium	7	29.1		
Mechanical ventilation (hours)			14±3	11-29

SD: Standard deviation; EuroSCORE: European system for cardiac operative risk evaluation.



Figure 2. The fractured region was stabilized by thermoreactive nitinol clips.

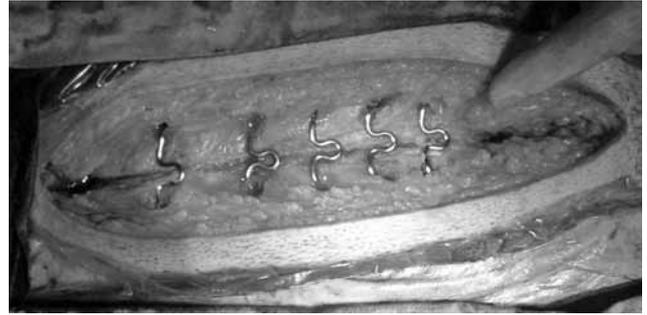


Figure 3. Thermoreactive nitinol clips were placed at intercostal distances without using sternal wires.

TRNCs were placed at intercostal distances without the use of steel wires (Figure 3).

RESULTS

The preoperative and intraoperative risk factors for sternal wounds are presented in Table 1. The patients underwent two surgical operations that consisted of the primary cardiac surgery and the sternal revision operation due to dehiscence. Perioperative and postoperative values are presented in Tables 2 and 3. Patients with dehiscence were operated on postoperatively for sternal revision at 13±4 days (range; 6-17 days). Three intubated patients who underwent sternal revision had been in the intensive care unit (ICU). The substernal tissues were not dissected in 19 of the 24 patients who had TRNCs, and the rest of the patients (n=5) underwent debridement due to the

risk of deep sternal wound infection (DSWI). When the patients were examined clinically, the following results were found: eight (33.3%) were observed to have sternal surgical wound infection (SSWI), one (4.1%) had DSWI, five (20.83%) had a positive blood culture [*Staphylococcus Epidermidis* (*S. epidermis*)] in three patients, methicillin-resistant *S. aureus* (MRSA) in one, and *S. aureus* in another), 10 (41.6%) had high C-reactive protein (CRP) levels (>3.0 mg/L), and 16 (66.6%) displayed elevated leucocyte levels (>10.0x10⁹/L). The VAC system was utilized for the treatment of DSWI in one patient before sternal closure. Additionally, no mediastinitis or mortalities were observed (Table 3). A segmental fracture of the sternum was seen in six patients (25%) at the beginning of the revision. During this procedure, one patient who underwent substernal dissection developed

Table 3. Preoperative, intraoperative and postoperative clinical data of the revision operation (n=24)

	n	%	Mean±SD	Range
Preoperative				
Time of revision (days)			13±4	6-17
Sternal superficial wound infection	8	33.3		
C-reactif protein levels (>3.0 mg/L)	10	41.6		
Leucocyte levels (>10.0x10 ⁹ /L)	16	66.6		
Positive blood culture	5	20.83		
Intraoperative				
Multiple sternal fracture	6	25		
Deep sternal wound infection	1	4.1		
Cardiac injury	1	4.1		
Operation time (minutes)			43±7	35-60
Postoperative				
Extubation time (minutes)			85±57	24-117
Intensive care unit stay (days)			4±2	1-7
Hospital stay (days)			14±6	7-29
Revision	0	0		
Mediastinitis	0	0		
Mortality	0	0		

SD: Standard deviation.

a right atrial injury due to the adhesion of the giant atrium to the sternum. However, no complications (e.g., example sternal base, dehiscence, mediastinitis, or osteomyelitis) were observed in any of the patients at the six-month follow-up. The operation time was 43 ± 7 minutes (range, 35-60 min.), and the extubation time was 85 ± 57 minutes (range 24-117 min.). Furthermore, the duration of stay in the ICU was 4 ± 2 days (range 1-7 days), and the length of hospital stay was 14 ± 6 days (range 7-29 days) (Table 3). The most common problem encountered in the postoperative ICU was respiratory failure. This prolonged the ICU stay, but the issue was resolved by inhaled bronchodilator treatment and physical therapy.

DISCUSSION

Median sternotomy was first described by Minton^[11] in 1887 and still remains the most common surgical approach in cardiac surgery. The most effective method of prevention for sternal dehiscence is proper sternal approximation with adequate immobilization of the sternocostal junctions. The incidence of sternal dehiscence is reported to be 0.5-8%, but this depends on the mechanical defect and type and degree of infection.^[11] Sternal dehiscence is a catastrophic complication that usually occurs during the initial hospitalization period, and all of our patients developed this complication during their hospital stay. Postoperative median sternotomy complications have been detected in as little as four days after the first operation and as much as 32 days afterwards, with an average time of eight days.^[12] More than 40 techniques have been described for the treatment of sternal dehiscence and its complications in the literature, but no optimal method has been found thus far.^[13] Early surgery should be undertaken in patients with sternal dehiscence to avoid the risk of mediastinitis and break the vicious circle of infection, mechanical disorders, and dehiscence. The patients in this study had surgery at 13 ± 4 days (range, 6-17 days) after the primary cardiac operation.

New fixation systems may be required for sternal reconstruction. There have been various apparatuses that have been employed for closing the sternum, such as TRNCs, sternal plates, and talon systems.^[14] Titanium fixation systems for sternal reconstruction require both an expanded zone to do the fixation laterally and better bone quality. The wires for this system are made of stainless steel, whereas those for TRNC are made from a nitillium alloy. In our study, we preferred TRNCs because of their favorable characteristics, elasticity, and shape memory. The clips become malleable at under 8 °C and return to their

original shape when the temperature is above 45 °C. It is maintained that TRNCs provide some advantages over standard wires in terms of sternal fixation:

1. Their surface area is five to seven times larger, which keeps the sternum under pressure. Thus, the bone is less exposed to the risk of being torn.^[10]
2. They can be applied more quickly and easily to the bone without harm because of their thermoreactive characteristics and also may be removed when necessary.
3. They have higher biocompatibility than steel.^[10]
4. Their compatibility with computed topography (CT) scans and nuclear magnetic resonance (NMR) is ideal.^[4]
5. There is less risk of bleeding than with standard wires.^[10]
6. Their elasticity allows for 10-15% flexibility under some conditions, such as intensive coughing or overloading that increases the tension.^[4]

Thermoreactive nitinol clips come in a wide range of sizes (2.25-4 cm), which makes it possible to repair deformities in the sternum, such as a multiple sternal fracture or sternocostal joint dislocation. However, it is not possible to use the TRNC clips when the distance between the intercostal spaces exceeds the clip size. It's better to use them after dissecting retrosternal structures and infected areas in the presence of DSWI in a complicated deformed sternum. Being able to use these clips without dissecting the substernal region is an important advantage. Plass et al.^[10] believed that cohesions in substernal distance limit the applicability of this technique and that the right ventricle and present bypass grafts might get harmed if the TRNCs were implanted in this manner. In our study, the substernal tissues were not dissected in the majority of the patients, but as previously mentioned, one patient (4.1%) did develop a right atrial injury that required suture placement due to the adhesion of the giant atrium to the sternum. Reiss et al.^[15] preferred TRNCs for the closure of the sternum after sternal VAC. They directly applied them without dissecting the cohesions that were present in the substernal distance and encountered no substernal complications in these patients. We only had one patient that underwent sternal closure with TRNC after VAC, and there were no reports of mediastinitis or mortality with that patient or any others in our study. Since TRNC systems do not directly come into contact with the rib bone nor have tissue-to-metal contact, they do not technically affect the sternal blood flow. However,

in other studies during operations that used that the classical Robicsek technique, the intercostal arteries were squeezed by the ring that formed.^[18,16] In addition, bilateral IMA usage also interrupts the sternal blood flow, and these patients have a 5% incidence of sternal wound complications.^[17] For this reason, it should be kept in mind that surgical techniques which interrupt sternal collateral blood flow might also contribute to the development of sternal wound complications.

When our patients were examined with regard to infection, eight had (33.3%) SSWI and one (4.1%) had DSWI. The pathogens found in our study were similar to those that have been reported by others. Blood cultures identified *S. epidermidis* as the primary source, followed by *S. aureus* and MRSA. In the study by Negri et al.^[4] that focused on 1,000 prospective randomized diseases that require cardiac surgery (conventional sternal fixation in 500 patients, sternal fixation by TRNC systems in 500 patients), 14 of the 500 patients who underwent conventional sternal fixation demonstrated infection-free dehiscence, whereas this was true for only one of the 500 patients who had sternal fixation by TRNC ($p=0.002$). Furthermore, nine patients who underwent conventional sternal closure had infected dehiscence, but none experienced this problem with sternal fixation by TRNC ($p=0.007$). However, no difference was observed between the two techniques that affected the development of SSWI or sternal aseptic necrosis.^[6] Furthermore, we observed no dehiscence, SSWI, sternal aseptic necrosis, osteomyelitis, sternal base, mediastinitis or mortality in the patients who used TRNC during follow-up. We believe that the combination of TRNCs with the steel wires used during the first cardiac operations^[4,10] should also be applied to patients with sternal dehiscence.^[18,19] We only used TRNCs without steel wires while performing sternal fixation during the sternal revision operations for dehiscence. There was no mortality or morbidity during the postoperative follow-up stage, and no sternal complications were observed in the routine controls. Therefore, we believe that using TRNCs without steel wires is sufficient for sternal fixation. The hospitalization period for our patients after sternal revision was determined to be 14 ± 6 days (range 7-29 days). Hence, the use of TRNCs provides a dramatic recovery for patients with sternal dehiscence. In addition, the length of hospital stay is shorter, and the hospitalization costs are lower.

Conclusion

If the retrosternal region is not infected in patients with sternal dehiscence, the placement of TRNCs without substernal tissue dissection can be performed

directly. In cases when infection is suspected, we recommend sternal closure with TRNCs accompanied by substernal dissection without the use of steel wires. Therefore, due to improved safety, easy and fast application, less hospitalization time, relatively low cost, and patient comfort, we recommend the TRNC technique, especially for sternal closures in patients with dehiscence.

Declaration of conflicting interests

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Funding

The authors received no financial support for the research and/or authorship of this article.

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