



# THERMOACTIVE NITINOL CLIPS AS PRIMARY AND SECONDARY STERNAL CLOSURE AFTER CARDIAC SURGERY – FIRST EXPERIENCE IN SLOVENIA

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**SUMMARY** – Although there has been a trend towards minimally invasive and sternum-sparing procedures, median sternotomy is still a standard surgical approach in cardiac surgery. Many techniques and innovations for closure of sternal osteotomy have been developed with contradictory results. In this report, we present our first experience with the nitinol-made sternal closure system in the primary, as well as secondary closure of sternal osteotomy. A small series of 20 patients had their sternotomy closed with Flexigrip clips. In one case, the Flexigrip clips were used in secondary wound closure in a patient with deep sternal wound infection after full sternotomy and coronary bypass surgery. After 6-month follow-up, all patients were doing well with their sternums clinically stable and the sternotomy wounds completely healed. In conclusion, Flexigrip clips offered a stable alternative to steel wires in primary, as well as secondary sternal closure. Moreover, in secondary sternal closure, the thermoactive clips offered safety advantages over the standard wire cerclage technique because the need for dissection of the substernal adhesions could be avoided.

**Key words:** *Median sternotomy; Wound closure; Nitinol clips; Surgical wound infection; Cardiac surgery*

## Introduction

Median sternotomy is still the standard and most common surgical approach in cardiac surgery. Despite a trend towards minimally invasive and sternum-sparing procedures, over a million sternotomies are still performed annually worldwide<sup>1</sup>.

The ideal sternal closure technique, as reported by Casha *et al.*<sup>2</sup>, must be able to resist twice the maximum potential stress applied on the sternum to provide proper stability and thus reducing the rates of mortality, morbidity, and the financial burden on healthcare resources. Even though multiple techniques and innovations have been developed in the last decades, the ideal technique is yet to be determined.

Wire cerclage, introduced by Milton in 1897 and popularized by Julian *et al.*<sup>3</sup>, is the standard and most commonly used technique for primary sternal closure. A modification, figure-of-eight shape, is the standard method of sternal closure at our institution. It has been shown that modified wire techniques redistribute shearing forces better than simple single wires and are thus less likely to cut the sternum, therefore decreasing the rates of post-closure complications<sup>4-6</sup>.

Rigid plate fixation may be superior to wire cerclage in ensuring stability and faster sternal healing, thereby reducing postoperative complications, especially in high-risk patients<sup>7-9</sup>. Park *et al.*<sup>10</sup> showed that despite higher initial costs compared to wires and interlocking systems, rigid fixation systems were the most cost-effective technique; however, they have never been widely accepted among cardiac surgeons.

A mix of both previously described techniques, commonly referred to as rigid cerclage in the form of

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sternal clamps, has been introduced in the last decade<sup>11</sup>. Flexigrip (Praesidia srl., Bologna, Italy) is a representative of the thermoactive subgroup of sternal clips, composed of the nickel-titanium alloy, commonly known as nitinol, with a memory effect which acts as a brace holding together sternal osteotomy<sup>12-14</sup>. The Flexigrip sternal closure system consists of nitinol clips and an instrumentation kit, which allows measurement of the correct size of the clip and its insertion. The nitinol clip becomes flexible at temperatures below 10 °C and recovers its shape and firmness when warmed above 25 °C. After measurement and determination of the appropriate size, the clip is cooled in iced water and applied through holes made bilaterally parasternally in the intercostal spaces. In case of a T- or L-shaped ministernotomy, or a broken sternum, it can also be applied longitudinally or diagonally. After insertion, the clip is irrigated with warm water in order to regain its initial shape, size and firmness.

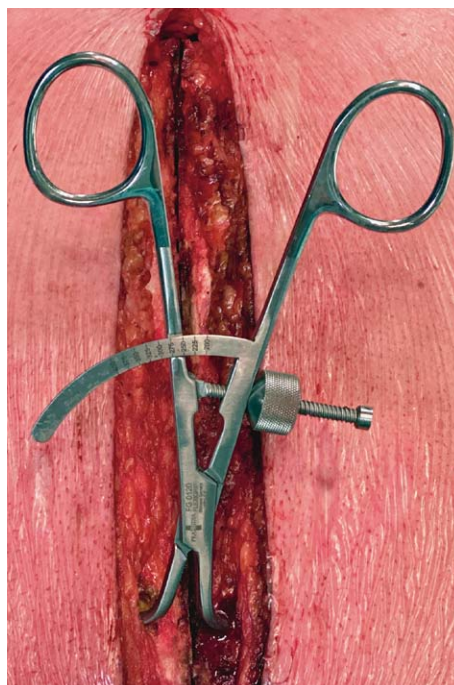
In this report, we present our first experience with the Flexigrip sternal closure system in the primary, as well as secondary closure of sternal osteotomy. To the best of our knowledge, this is the first experience with this system in Slovenia.

## Patients and Methods

At our institution, we started using Flexigrip clips in 2019 as an alternative to complete wire cerclage in primary sternal closure in standard full sternotomies and left upper mini-sternotomy cases.

This report was approved by the institutional medical Ethics Committee and performed in full accordance with the tenets of the Declaration of Helsinki. The need for written informed consent was waived because of the retrospective nature of the analysis.

This small, retrospective observational series included 20 patients who underwent standard full sternotomy or upper right ministernotomy (the latter mostly after aortic valve replacement) between February and March 2019. The patients had their sternotomy closed either with or without a combination of a wire placed in figure-of-eight shape through manubrium and Flexigrip clips. The idea of the initial wire placement is to bring the sternum edges together and allow measurement of the appropriate Flexigrip clip size. The approximation of sternal edges using a sternal wire is not mandatory because it can also be accom-



*Fig. 1. A measuring device is used to determine appropriate size of the nitinol clip. It can also be used to approximate the edges of sternal osteotomy.*

plished using only Flexigrip clips and the measurement instrument (Fig. 1).

In one case, Flexigrip clips were used in secondary sternal closure after the standard cerclage wires had to be removed due to infection of a full standard sternotomy wound two months after a coronary bypass procedure in a female diabetic patient. The patient was treated with initial removal of all osteosynthetic material, necrectomy, antibiotics, and negative pressure wound therapy. At the time of the initial primary osteosynthetic material removal, dense adhesions between the left side of the sternum and upper side of the right ventricle and left internal mammary artery graft had already formed. Once the infection had been eradicated, the Flexigrip system significantly facilitated secondary closure of the sternum because dense and tight adhesions made placement of the cerclage wires difficult. Implantation of the Flexigrip system does not require dissecting adhesions underneath the sternum because insertion of the clips is performed entirely from the upper side of the sternum. Later, negative pressure wound therapy was deployed and the wound was successfully closed. All patients were followed-up for 6 months.

## Results

All 20 patients included in the report had their sternotomy closed using Flexigrip clips with the technique previously described. The results are presented as mean  $\pm$  standard deviation in case of normally distributed data and median (interquartile range) in case of non-normally distributed data. Categorical variables are presented as frequencies (percentages).

The mean age of the patients was  $78.0 \pm 3.1$  years, mean weight  $79.7 \pm 12.5$  kg, and mean body mass index (BMI)  $28.96 \pm 4.79$  kg/m<sup>2</sup>. Six (30%) patients were categorized as overweight (BMI 25–29.9 kg/m<sup>2</sup>) and eight (40%) patients as obese (BMI  $\geq 30$  kg/m<sup>2</sup>), as currently recommended<sup>15</sup>.

Table 1. Patient characteristics (N=20)

Age (years)	78.0 $\pm$ 3.1
Sternotomy type:	
full standard sternotomy	12 (60%)
upper right ministernotomy	8 (40%)
EuroSCORE II	1.34 (1.49)
Weight (kg)	79.7 $\pm$ 12.5
Height (m)	1.66 $\pm$ 0.82
Body surface area (m <sup>2</sup> )	1.87 $\pm$ 0.15
Body mass index (BMI) (kg/m <sup>2</sup> ):	28.96 $\pm$ 4.79
overweight** (BMI 25–29.9 kg/m <sup>2</sup> )	6 (30%)
obese** (BMI $\geq 30$ kg/m <sup>2</sup> )	8 (40%)
ICU stay (days)	1 (1)
Number of patients with >24 h ICU stay	7 (35%)
LoHS (days)	8.5 (3.5)
Female gender	8 (40%)
Diabetes	3 (15%)
COPD	1 (5%)
LVEF $\geq 50\%$	17 (85%)
Urgent surgery	2 (10%)
PAD	4 (20%)
Poor mobility*	2 (10%)
Pulmonary hypertension $\geq 30$ mm Hg	10 (50%)

EuroSCORE II = European System for Cardiac Operative Risk Evaluation; ICU = intensive care unit; LoHS = length of hospital stay; COPD = chronic obstructive pulmonary disease; LVEF = left ventricular ejection fraction; PAD = peripheral artery disease; \*severe impairment of mobility secondary to musculoskeletal or neurological dysfunction; \*\*as defined by the American College of Cardiology/American Heart Association guidelines for the management of overweight and obesity in adults<sup>15</sup>.



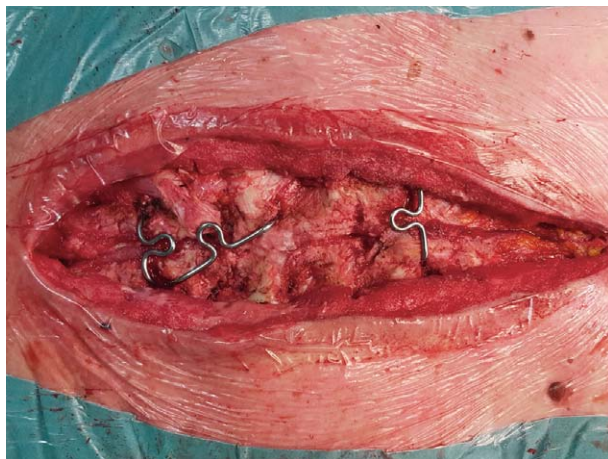
Fig. 2. An example of a standard full-sternotomy closed by using five Flexigrip clips.



Fig. 3. Postoperative chest x-ray showing Flexigrip clips in place.

Twelve (60%) patients underwent standard full sternotomy and eight (40%) patients had upper right ministernotomy. Patient characteristics are presented in more detail in Table 1.

During the 6-month follow-up period, no deaths, deep sternal wound infection, sternal dehiscence, or instability were identified. An example of sternal



*Fig. 4. Secondary closure of full sternotomy with 3 Flexigrip clips after eradication of deep sternal wound infection.*

wound closure and postoperative chest x-ray are shown in Figures 2 and 3.

In addition, we also included one patient with postoperative deep sternal wound infection and firm substernal adhesions two months after a coronary bypass procedure. After eradication of the infection, her sternum was closed with three Flexigrip clips (Fig. 4). At 6-month follow-up, the patient was doing well with the sternum clinically stable and the sternotomy wound completely healed.

## Discussion

The Flexigrip nitinol clips are fast and easy to implant and because of their thickness lower the risk of cutting through the bone, which is especially important in osteoporotic, female, elderly and obese patients<sup>14</sup>. These conclusions have not yet been confirmed by randomized control trials and meta-analyses, which show contradictory results<sup>12-14,16</sup>. According to some studies, they lower the risk of post-sternotomy complications, which make the clips more cost-effective despite their higher initial cost, which is still lower than the cost of rigid plate fixation<sup>14,16</sup>. In our mini-series of 20 patients, we did not encounter any deep sternal wound infection, sternal dehiscence, or instability after Flexigrip nitinol clip implantation. Although only three (15%) patients were diabetic and one had chronic obstructive pulmonary disease, 14 (70%) study patients were categorized as overweight

or obese, showing that Flexigrip clips offered good stability of sternal osteotomy.

Flexigrip has been previously reported as a safe alternative in secondary sternal closure<sup>17</sup>. Deep sternal wound infection (DSWI; mediastinitis and sternum osteitis) after open-heart surgery is a severe complication associated with high mortality, morbidity, prolonged length of hospital stay, need for multiple surgical procedures, and burden on healthcare resources. The incidence of DSWI varies from 0.5% to 5%<sup>18,19</sup>. However, it should not be confused with the postpericardiotomy syndrome<sup>20</sup>. Current management of DSWI (mediastinitis) involves many procedures and the choice of surgical strategies is usually based on the El Oakley and Wright classification<sup>18</sup>. The optimal treatment approach is still a matter of debate. Most commonly, it involves wound and sternal debridement, mediastinal irrigation, followed by drainage and different approaches to sternal closing<sup>20,21</sup>. For a successful treatment outcome, it is also important to remove sternal wires whenever possible<sup>22,23</sup>. All implant-related infections are caused by biofilm forming bacteria on the surface of the material and are difficult to eradicate without complete removal of the foreign material. Treatment with biofilm active antimicrobials (rifampicin and fluoroquinolones) was found successful in DSWI after cardiac surgery in a retrospective study emphasizing the role of implant-associated infection in case of sternal fixation<sup>24</sup>.

In the last years, a vacuum-assisted closure device has been successfully used in the treatment of superficial or deep sternal wound infections, and as a bridge to chest closure with muscle flaps or direct sternal resynthesis<sup>25</sup>. When sternal resynthesis is feasible, thermoactive clips have been shown to be superior to steel wires. One of the most important advantages is their noninvasiveness to the posterior surface of the sternum, especially in cases of severe adhesions to the right ventricle and a concomitant patent internal mammary graft in place. The use of the clips therefore allows sparing of the mediastinal structures from dissection and potential damage<sup>26</sup>. Furthermore, because of their thickness compared to the standard wires, the risk of cutting through the bone is lower.

Although only one patient at our institution underwent secondary sternal closure with Flexigrip clips so far, the nitinol thermoactive clips have proven as a safe and effective alternative to wire placement where

secondary sternal closure with wire cerclage would require dissection of the adhesions on the posterior surface of the sternum.

There have been some concerns regarding the safety and feasibility of Flexigrip clips in case of urgent (or elective) re-sternotomy. However, the clips can be easily and quickly removed after they have been soaked in cold saline (<10 °C) for a few moments, simply using a standard strong needle holder or surgical pliers. For removal of the clips, no special instrumentation kit is therefore necessary. Nonetheless, if there is one available, the same clips can be used for re-closure of the sternum. As nitinol does not integrate into the bone<sup>14</sup>, removal of the clips is fast and easy even many years after the implantation. Finally, because nitinol is a nonferromagnetic alloy, magnetic resonance imaging can be safely undertaken<sup>27</sup>.

There are important limitations of this report which need to be mentioned. First of all, it is a small, retrospective analysis. The selection of patients was at the surgeon's discretion. The incidence of DSWI or sternum instability is by far too low to be adequately evaluated in such a small series. However, the only purpose of this analysis is to report on the first experience using this system at our institution.

In conclusion, considering our initial positive but limited experience, the Flexigrip clips offered a good and stable alternative to steel wires. In secondary sternal closure, the thermoactive clips offered important advantages over the standard cerclage technique, one of the most important being the possibility to avoid dissection of the mediastinal structures from the sternum in case of tight adhesions.

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### Sažetak

## TERMOAKTIVNE NITINOLSKE KOPČE ZA PRIMARNO I SEKUNDARNO ZATVARANJE STERNALNIH OSTEOTOMIJA NAKON KARDIOKIRURŠKIH ZAHVATA – PRVO ISKUSTVO U SLOVENIJI

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Iako postoji trend primjene minimalno invazivnih procedura s očuvanjem sternuma, medijana sternotomija je još uvijek standardni kirurški pristup u kardiokirurgiji. Mnogo je tehnika i inovacija za zatvaranje sternalne osteotomije dosad razvijeno s proturječnim rezultatima. U ovom izvješću iznosimo naše prvo iskustvo sa sustavom sternalnog zatvaranja napravljenog od nitinola u primarnom kao i u sekundarnom zatvaranju sternalne osteotomije. Maloj seriji od 20 kardiokirurških bolesnika sternotomija je bila zatvorena kopčama Flexigrip. Kod jednog bolesnika kopče Flexigrip korištene su za sekundarno zatvaranje rane u slučaju duboke infekcije sternalne rane nakon pune sternotomije i operacije koronarnog premoštenja. Nakon 6-mjesečnog praćenja svi bolesnici bili su dobro, njihovi sternumi su bili klinički stabilni, a rane od sternotomije bile su zacjeljene. Kopče Flexigrip su nudile stabilnu alternativu čeličnim žicama u primarnom kao i u sekundarnom zatvaranju sternuma. Povrh toga, kod sekundarnog zatvaranja sternuma termooaktivne kopče imale su sigurnosne prednosti u odnosu na standardnu tehniku serklaže žicom, jer se mogla izbjeći potreba za disekcijom supsternalnih adhezija.

**Ključne riječi:** *Medijana sternotomija; Zatvaranje rane; Nitinolske kopče; Infekcija kirurške rane; Kardiokirurgija*