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Original Article

Early Sternal Bone Healing after Thermoreactive Nitinol Flexigrip Sternal Closure

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Purpose: Thermoreactive nitinol Flexigrip has been developed to ensure better fixation than conventional wire closure. To verify the advantage of Flexigrip over the conventional wiring, we compared early sternal bone healing on computed tomography (CT).
Methods: A prospective cohort study enrolled the first consecutive 80 patients with wiring and the second consecutive 44 patients undergoing Flexigrip sternal closure. The primary endpoint was sternal healing evaluated quantitatively using a 6-point scale and measured gaps/offsets of the sternal halves at 6 levels on CT scans on the 14th postoperative day. Secondary endpoints included pain scores and sternal complications 1 month after surgery.
Results: Compared with the patients of wiring, those who received Flexigrips showed higher 6-point scores at most sternum levels, less frequent gaps (52% vs 70%, p = 0.04), lower offsets (3.3 ± 0.9 mm vs 4.3 ± 0.7 mm, p <0.001) at the manubrium, and less frequent gaps (25% vs 43%, p = 0.04) and offsets (2.3% vs 24%, p = 0.002) at the middle of sternum. The pain scores and sternal complication rates were similar between both groups.
Conclusion: CT evaluation 2 weeks after surgery revealed that Flexigrip sternal closure showed less gaps and offsets of the sternal halves, suggesting faster sternal bone union when compared to the wiring.

Keywords: Flexigrip, sternal closure, wiring, gap, offset

Introduction

Stainless steel wiring remains the most common method for closing median sternotomy in cardiac and thoracic aortic surgery.[1] It is simple and effective but associated with healing complications such as dehiscence, instability, osteomyelitis, mediastinitis, and surgical site infection (SSI). Despite recent advances in perioperative management, sternal wound complications are reported to occur at 0.5% to 6.1% after cardiac surgery, associated with high mortality up to 47%.[1,2] Inadequate sternum closure may be an important risk factor for sternal wound complications, as well as obesity, diabetes, chronic lung disorder, renal failure, congestive heart failure, old age, osteoporosis, smoking, steroid user, and use of bilateral thoracic arteries.[3–5] Any sternal closure should ensure fixation and stability with symmetric adaptation without any gaps or offsets.

Flexigrip (Praesidia SRL, Bologna, Italy), acting as a brace holding together the sternal osteotomy, has been developed to ensure better fixation and stability than conventional wire closure, with the following advantages with reduced stress on the sternum[6–8]: 1) high thermoreactive elasticity with a memory effect of the special nickel and titanium alloys with wide open “Ω shape” without damaging the sternum and 2) wide contact surface with the sternum (5 to 7 times that of standard

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wiring) with excellent stress distribution. To verify the estimated advantage of Flexigrip, we dared to evaluate very early sternal bone healing with Flexigrip on computed tomography (CT) images after median sternotomy, comparing to the conventional wiring.

Materials and Methods

Study design and patients

This prospective cohort study, considering a learning curve associated with use of the new technology, enrolled the first consecutive 80 patients undergoing sternal closure by the conventional wiring and the second consecutive 44 patients undergoing Flexigrip sternal closure, among those presenting to our department for cardiac surgery through a midline sternotomy between January 2021 and November 2021. Exclusion criteria were those with metal allergies to titanium and nitinol. This study was approved by Institutional Review Board at Fujita Medical University (ID HM20-574; June 30, 2022) with informed consent from each patient, including a study-related radiation by postoperative CT scans.

Sternal closure techniques

The technique for sternal closure with the conventional wiring method included parasternal or transsternal single fixation of 6 stainless-steel wires.

The techniques for sternal closure with Flexigrip, which becomes malleable at <10°C and recovers its shape when placed at >25°C, are as follows[6–8] **(Video 1**; the videos are available online). 1) Four or three holes, according to surgeon's preference, were created with electrocautery bilaterally into the 1st or 2nd, 3rd, and 4th intercostal spaces (ICSs), shaving the tissue on the lateral surface of the sternum. 2) Two stainless-steel wires were placed for the manubrium and one for the 5th ICS. 3) After sternal approximation achieved by temporary fixation of the wires, the accurate size of each ICS were measured using a specific sizer for Flexigrip, ranging between 20 mm and 40 mm by 2.5 mm. 4) The Flexigrip of the selected size was instantaneously cooled with cold (<10°C) saline, allowing its full malleability. 5) The Flexigrip, inserted into the bilateral ICS, was rewarmed with hot (>45°C) saline, allowing its original shape to be restored instantaneously, to achieve bone approximation. 6) The wires at the manubrium and the 5th ICS were finally fixed.

The sternotomy wound was then closed similarly in both groups of Flexigrip and wiring. The muscle layers were closed in a simple interrupted technique using 0 coated polyglactin absorbable sutures. After closing the sternal and muscle layers, the wound was also washed with 500 mL normal saline. Subcutaneous tissue and dermis were closed using 3-0 and 4-0 continuous or intermittent absorbable monofilament sutures, respectively. The incision was covered with a sterile waterproof transparent dressing with an absorbent pad (Opsite Post-Op Visible; Smith & Nephew, Hull, UK), a hydrocolloid dressing (Karayahesive; Alcare Co. Ltd., Tokyo, Japan), or a sterile liquid adhesive made of octyl-2-cyanoacrylate (Dermabond; Ethicon, Somerville, NJ, USA) according to surgeon's preference.

Perioperative management

Body hair was removed using electric clippers after induction of anesthesia. All operative sites were cleaned and disinfected with chlorhexidine alcohol, followed with 10% povidone-iodine. At least 2 minutes later, adhesive iodophor-impregnated plastic incision drapes were applied to the operative field. Surgical hand antisepsis was as follows: the 2-stage or waterless procedure. All stuffs of the operating team were wearing 2 pairs of gloves, the outer of which was changed regularly. Cefazolin was used for antimicrobial prophylaxis against SSI, with an initial dose of 1 g given within 30 minutes of the skin incision and repeated dose for every 4 hours. For methicillin-resistant *Staphylococcus aureus* carriers, 1 dose of 1 g vancomycin was given in the ward and completed within 1 hour before skin incision, followed by a second dose of <4 mg/kg. Before sternal closure, the pericardial cavity and mediastinum were washed with saline of >1000 mL. After surgery, the mediastinal tube drainage was removed when bleeding was <200 ml over a 12-hour period. Blood glucose was checked repeatedly perioperatively. If the glucose value was >160 mg/dL, continuous insulin therapy was initiated, followed by a sliding scale-guided intermittent subcutaneous injection.

Postoperative outcomes measures

The primary endpoint was sternal bone healing evaluated quantitatively on CT scans 2 weeks after surgery. Secondary endpoints included pain scores and sternal complications 1 month after surgery. We also collected the data of the surgical procedures and postoperative data, including intubation duration and drained volume.

CT evaluation

The sternums were evaluated on CT scans, according to the previously reported method.[9–12] To evaluate the

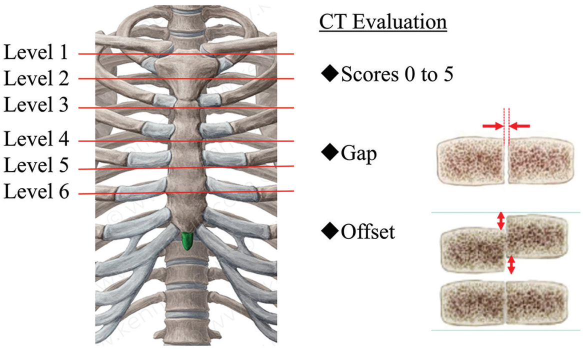


Fig. 1 The left figure shows six levels for evaluating sternal bone healing on CT. The right figure shows the quantitative parameters of the axial sections on CT for evaluating sternal bone healing at each level. CT: computed tomography

entire length of the sternum, 6 axial CT slices from a priori-defined anatomic locations were selected for evaluation, as shown in **Fig. 1**: Level 1 at the caudal edge of the sternoclavicular joint, Level 2 at the caudal edge of the 1st sternocostal joint, Level 3 at the caudal edge of the 2nd sternocostal joint, Level 4 at the caudal edge of the 3rd sternocostal joint, Level 5 at the caudal edge of the 4th sternocostal joint, and Level 6 at the caudal edge of the 5th sternocostal joint. Each location was scored by a 6-point scale (higher scores represent greater healing) with anchors at 0, meaning no unions of the hemisternums; 1, meaning indeterminate; 2, meaning minimal healing with gaps; 3, meaning mild synthesis; 4, meaning moderate synthesis even with some offsets; and 5, meaning complete synthesis. Furthermore, to evaluate sternal healing quantitatively, the gap, defined as an empty space or opening, and offset, defined as a horizontal displacement on the face of the hemisternums, were measured between the right and left hemisternums at each level of the sternum.

Sternal wound complications

Sternal wound complications 1 month after surgery were defined as SSI, according to the nosocomial infection surveillance criteria of the U.S. Centers for Disease Control and Prevention.[13] These definitions require signs of infection over the surgical wound, including purulent drainage and an abscess. Microbiology culture and antibiotic sensitivity or resistance were conducted on chocolate and semisolid agars for both aerobic and anaerobic organisms.

Paint scoring

Pain intensity was measured at our outpatient clinic after discharge, 1 month after surgery, using a 10-cm graduated visual analogue scale ranging from “no pain at all” to “unbearable pain.” The pain scores of 0 to 10 (0, no pain and 10, the worst imaginable pain) were assessed by a nurse blinded to group allocation.[14]

Statistical analysis

Sample size estimation was obtained on the offset value of the hemisternums, one of the primary variables, from our preliminary study. The minimum number of the sample size (33:66) was based on a two-tailed *t* test with a significant level of 0.05, a power of 0.90, and anticipated difference of means/standard deviation of 1.5 mm/1.0 mm, with the sample size of 1:2 (Flexigrip:wiring). Continuous variables were expressed as mean ± standard deviation. Categorical variables were expressed as absolute number (percentage). Statistical analysis comparing the patients of wiring and Flexigrip was performed using Mann–Whitney U test for the continuous variables and the Fisher’s exact test for the categorical variables. A 2-sided p-value of <0.05 was considered statistically significant. All statistical analyses were performed with SPSS 18 software (IBM Corporation, Armonk, NY, USA).

Results

Patient demographics and operative outcomes

Between the groups of wiring and Flexigrip, the baseline characteristics were similar, except for significantly more prevalence of hemodialysis and therefore higher preoperative creatinine levels in the Flexigrip group (**Table 1**). The surgical procedures and postoperative outcomes were also similar between the groups (**Table 2**). There were no recognized complications specifically associated with the Flexigrip placement, including injuries of the internal mammary arteries. There were no differences in overall incidence of sternal wound complications (1.3% of wiring vs 0% of Flexigrip, $p = 0.64$) and in-hospital mortality (1.3% of wiring vs 2.3% of Flexigrip, $p = 0.58$). A 66-year-old female patient of wiring developed a *Pseudomonas aeruginosa* SSI after aortic valve replacement. She underwent debridement and vacuum-assisted closure therapy, followed by rectus abdominis myocutaneous flap after confirming no pathogens. The causes of death in the study patients were non-occlusive mesenteric ischemia 29 days after mitral valve replacement in a 68-year-old male patient on hemodialysis who received Flexigrips and cerebral infarction 106 days after coronary artery bypass grafting

Table 1 Patient demographics

Preoperative variables	Wiring (n = 80)	Flexigrip (n = 44)	*p* value
Age, years	71 ± 9	71 ± 10	0.86
Male, n (%)	55 (69%)	31 (71%)	0.83
Body mass index, kg/m^2	23.2 ± 3.2	23.8 ± 4.6	0.77
Cardiothoracic ratio on X-ray, %	51.2 ± 6.3	51.7 ± 7.0	0.71
Atrial fibrillation, n (%)	10 (13 %)	6 (14%)	0.68
Hypertension, n (%)	63 (79%)	36 (82%)	0.73
Hyperlipidemia, n (%)	49 (61 %)	24 (55%)	0.64
Smoking, n (%)	41 (51%)	27 (61%)	0.59
Chronic lung disease, n (%)	17 (21%)	8 (18%)	0.72
% vital capacity	100.0 ± 14.5	92.2 ± 33.9	0.39
Forced expiratory volume 1.0%	74.9 ± 6.1	74.9 ± 8.6	0.89
Diabetes mellitus, n (%)	27 (34%)	20 (46%)	0.25
HbA1c, %	6.2 ± 1.0	6.2 ± 1.2	0.93
Insulin therapy, n (%)	6 (8%)	2 (5%)	0.71
Liver disease, n (%)	3 (3.8%)	0	0.55
Chronic kidney disease, n (%)	15 (19%)	12 (27%)	0.49
Blood urea nitrogen, mg/dL	19.8 ± 10.2	22.1 ± 12.8	0.57
Creatinine, mg/dL	1.5 ± 2.0	2.4 ± 3.3	0.006
On hemodialysis, n (%)	3 (4%)	8 (18%)	0.016
Peripheral artery disease, n (%)	18 (23%)	7 (16%)	0.49
Past cerebral infarction, n (%)	11 (14%)	5 (11%)	0.79
Echocardiographic LVDd, mm	49.1 ± 8.2	50.9 ± 8.9	0.37
LVDs, mm	35.2 ± 8.7	36.5 ± 10.2	0.43
LVEF	0.54 ± 0.09	0.54 ± 0.12	0.35
Hemoglobin, g/dL	12.9 ± 1.6	12.6 ± 1.5	0.69
Platelet count, ×10^4/μL	19.9 ± 6.0	19.2 ± 7.2	0.33
Serum albumin, g/dL	3.9 ± 0.5	3.9 ± 0.8	0.49
Total bilirubin, mg/dL	0.69 ± 0.34	0.64 ± 0.25	0.51
Total cholesterol, mg/dL	172 ± 44	169 ± 40	0.44
Triglyceride, mg/dL	136 ± 84	121 ± 74	0.29

HbA1c: hemoglobin A1c; LVDd: left ventricular end-diastolic dimension; LVDs: left ventricular end-systolic dimension; LVEF: left ventricular ejection fraction

with wiring sternal closure in an 82-year-old male patient with bullous pemphigoid treated with prednisolone.

Flexigrip use

As shown in **Fig. 2**, 44 patients underwent sternal closure with Flexigrip; there were 9 patients (20%) with 4 devices into the 1st, 2nd, 3rd, and 4th ICSs, while 35 patients (80%) with 3 devices into the 2nd, 3rd, and 4th ICSs. The sizes of the used Flexigrip were 29.0 ± 4.7 mm for the 1st ICS (n = 9), 21.9 ± 3.4 mm for the 2nd ICS (n = 44), 22.1 ± 2.7 mm for the 3rd ICS (n = 44), and 24.2 ± 4.5 mm for the 4th ICS (n = 44). It was easy to apply the Flexigrip with a learning curve, especially regarding creation of the parasternal holes and sizing.

Pain scoring (Table 2)

The pain intensity levels 1 month after surgery, evaluated by the 11-point visual analog scale, were similar between the patient groups of wiring (4.6 ± 1.2) and Flexigrip (4.3 ± 1.1) without any significance ($p = 0.64$).

CT evaluation (Table 2 and Video 2)

The CT scans on the 14th postoperative day showed significantly higher 6-point scores (greater healing of the sternum) at Levels 2, 3, 4, and 5 in the patients of Flexigrip than in those of wiring, while the scores were similar at Levels 1 and 6 between both groups. At Level 1, the gaps of the hemisternums were less frequently observed in the patients of Flexigrip than in those of

Table 2 Operative and postoperative outcomes

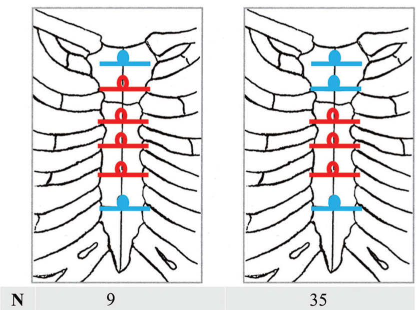
Variables	Wiring (n = 80)	Flexigrip (n = 44)	*p* value
Surgical procedures			
Coronary, n (%)	33 (41%)	20 (45%)	0.26
Bilateral ITAs use	2 (6%)	1 (5%)	0.78
Valve, n (%)	12 (15%)	12 (27%)	0.83
Thoracic aorta, n (%)	35 (43%)	11 (25%)	0.79
Combined, n (%)	29 (36%)	10 (23%)	0.85
Urgent or emergency, n (%)	8 (10%)	4 (9%)	0.82
Re-operation, n (%)	2 (2.5%)	1 (2%)	0.76
Off-pump, n (%)	10 (13%)	4 (9%)	0.35
Operation, min	389 ± 114	364 ± 89	0.20
Cardiopulmonary bypass, min	193 ± 70	176 ± 72	0.18
Cardiac ischemia, min	137 ± 63	139 ± 50	0.36
Lowest body temperature, °C	28.0 ± 5.2	29.6 ± 4.8	0.17
Postoperative outcomes			
Intubation duration, hours	28 ± 42	22 ± 31	0.35
Drained volume, mL			
On the day of surgery	372 ± 184	350 ± 161	0.54
On the 1st POD	359 ± 162	343 ± 144	0.66
On the 2nd POD	243 ± 163	218 ± 149	0.57
On the 3rd POD	128 ± 94	115 ± 103	0.80
On the 4th POD	98 ± 117	92 ± 102	0.82
On the 5th POD	93 ± 79	110 ± 60	0.76
Drain placement, days	3.8 ± 0.7	3.5 ± 0.7	0.54
ICU stay, days	3.7 ± 2.1	3.5 ± 1.8	0.37
Blood transfusion	61 (81%)	35 (80%)	0.74
Red blood cells, units	5.9 ± 3.6	5.7 ± 3.3	0.66
Fresh frozen plasma, units	3.4 ± 2.8	3.1 ± 2.2	0.47
Platelet concentrate, units	9.3 ± 11.9	8.5 ± 10.7	0.39
Lowest hemoglobin, g/dL	8.9 ± 1.0	9.0 ± 0.8	0.75
Lowest platelet count, $\times 10^4/\mu L$	5.7 ± 3.3	6.1 ± 2.5	0.41
Reoperation for bleeding, n (%)	0	0	1.00
Sternal wound infection, n (%)	1 (1.3%)	0	0.64
In-hospital death, n (%)	1 (1.3%)	1 (2.3%)	0.58
Pain scoring	4.6 ± 1.2	4.3 ± 1.1	0.64
Sternal healing scores on CT	2.3 ± 0.8	3.3 ± 0.9	<0.001
Level 1	1.9 ± 0.9	2.4 ± 1.2	0.077
Level 2	2.4 ± 0.8	2.9 ± 0.9	0.031
Level 3	2.7 ± 0.8	3.8 ± 0.7	<0.001
Level 4	3.0 ± 0.7	3.7 ± 0.7	<0.001
Level 5	3.3 ± 0.6	3.7 ± 0.6	0.039
Level 6	2.9 ± 0.6	3.2 ± 0.7	0.07
Gap between the hemisternums	1.1 ± 1.7	0.4 ± 1.2	0.001
Level 1	57 (72%)	23 (52%)	0.04
gap, mm	3.4 ± 1.8	3.2 ± 1.5	0.48
Level 2	34 (43%)	11 (25%)	0.04
gap, mm	3.1 ± 1.3	2.7 ± 0.8	0.48
Level 3	19 (24%)	1 (2.3%)	0.002
gap, mm	2.1 ± 0.8	3.1	0.21

(Continued)

Table 2 (Continued)

Variables	Wiring (n = 80)	Flexigrip (n = 44)	*p* value
Level 4	8 (9.6%)	2 (4.5%)	0.47
gap, mm	3.5 ± 1.0	2.7 ± 1.2	0.35
Level 5	4 (4.5%)	0	0.33
gap, mm	3.8 ± 0.5	0	–
Level 6	7 (9%)	0	0.11
gap, mm	2.3 ± 0.9	0	–
Offset of the hemisternums	1.0 ± 1.6	0.4 ± 1.1	0.004
Level 1	25 (31%)	13 (29%)	0.84
offset, mm	1.4 ± 2.1	3.3 ± 0.9	0.014
Level 2	30 (31%)	6 (14%)	0.007
offset, mm	3.3 ± 1.4	2.8 ± 1.2	0.38
Level 3	23 (29%)	3 (6.8%)	0.005
offset, mm	3.0 ± 0.9	3.3 ± 0.3	0.39
Level 4	16 (20%)	3 (6.8%)	0.06
offset, mm	2.7 ± 0.8	1.8 ± 1.1	0.21
Level 5	14 (18%)	2 (4.2%)	0.08
offset, mm	2.5 ± 0.7	2.0 ± 1.1	0.45
Level 6	6 (8%)	4 (9%)	0.74
offset, mm	3.5 ± 0.5	3.9 ± 0.3	0.27

ITAs: internal thoracic arteries; POD: postoperative day; ICU: intensive care unit; CT: computed tomography



	N	Size, mm
1st ICS	9	29.0 ± 4.7
2nd ICS	44	21.9 ± 3.4
3rd ICS	44	22.1 ± 2.7
4th ICS	44	24.2 ± 4.5

Fig. 2 The sternal closure methods using Flexigrip and the sizes of the used Flexigrips. Blue indicates stainless wires and red indicates Flexigrips. ICS: intercostal space

wiring (52% vs 70%, $p = 0.04$) with the similar values, while the offsets were similarly observed in both groups with significantly lower values in the patients of Flexigrip than in those of wiring (3.3 ± 0.9 mm vs 4.3 ± 0.7 mm, $p < 0.001$). At Levels 2 and 3, both gaps and offsets of the hemisternums were less frequently observed in the patients of Flexigrip than in those of wiring (25% vs 43%, $p = 0.04$ and 24% vs 2.3%, $p = 0.002$) (14% vs 31%, $p = 0.007$ and 6.8% vs 29%, $p = 0.005$) with the similar values. At Levels 4, 5, and 6, neither gaps nor offsets of the hemisternums were significantly different between both groups, although the patients of Flexigrip showed no gaps at Levels 5 and 6 and a less tendency in frequency of offsets of the hemisternums than those of wiring.

Discussion

Our main finding is that Flexigrip sternal closure presented less gaps and offsets of the hemisternums on CT images 2 weeks after surgery via median sternotomy, suggesting faster and better sternal healing in comparison to the conventional wiring, although there were no differences in sternal complications. This is the first report of CT evaluations of the sternal closure with Flexigrip, a nitinol clip composed of thermoreactive alloy of nickel and titanium with a memory effect, according to the previously reported method.[9–12] Stacy et al.[9] have established their simple system of quantitatively evaluating sternal healing on CT scans with high inter- and intraobserver reliability. Using this evaluation system, Raman et al.[10] and Allen et al.[11,12] reported that sternal closure with rigid plate fixation (SternaLock; Zimmer Biomet, Jacksonville, FL, USA) resulted in improved sternal healing compared with wire closure.

The continued use of wiring for sternal closure after median sternotomy may be due to low cost. However, it does not adequately prevent movement dehiscence, causing sternal complications.[15] Alternative fixation devices have been used to avoid sternal dehiscence, including Flexigrip,[6–8] titanium plates,[10–12] and ZIPFIX cables (DePuy Synthes, West Chester, PA, USA),[16] although a systematic review[17] suggested that any new sternal closure methods make little difference to prevent sternal complications when compared to the standard wiring closure.

As for Flexigrip, Negri et al.[6] showed a lower risk of sternal wound complications with Flexigrip in a randomized trial comparing 500 patients each with Flexigrip and sternal wires. Bejko and colleagues[7] also reported that the overall incidence of sternal wound complications was significantly lower in the group of Flexigrip than in the group of wiring by a propensity matched analysis of 464 patients of each group. Nikolaidis et al.[8] reported that mortality related to sternal wound complications was 8% in 884 patients with wires, whereas 0% in 235 patients with Flexigrip. In contrast, Srivastava et al.[18] reported no difference in sternal wound infection rates between Flexigrip and wiring by a propensity matched analysis of 356 obese patients of each group with lower incidence of diabetes. Although our study, which was not propensity matched but prospective, showed no difference in the incidence of sternal complications, it showed less gaps and offsets on postoperative CT images in the patients with Flexigrip. To verify the estimated advantage of Flexigrip over the conventional wiring, we dared to compare very early (2-week) sternal bone healing on CT scans. Our results may support the findings of the previous reports[6–8] of more excellent clinical outcomes of Flexigrip than wiring. Recently, Elsayed et al.[19] demonstrated that the patients diagnosed with deep sternal wound infection early (≤30 days) after cardiac surgery have increased mortality than those with late onset (>30 days) infection, speculating a greater aggressiveness of the early onset infection. Therefore, early osteosynthesis (solid bony union) with Flexigrip, as demonstrated in our study, is strongly desired to prevent early onset of sternal infection.

It may be desirable to add a 6-month or more follow-up to our data. However, several investigators have already showed clinical usefulness of Flexigrip to reduce wound complications after surgery.[6–8] According to Praesidia SRL, the sales record was about 200000 units of Flexigrip as of February 2019. Therefore, there may be no need of longer follow-up reports now. Rather, we evaluated the patients with Flexigrip at 2-weeks after surgery in this study, in order to obtain the CT imaging evidences for reported lower incidence of sternal complications with Flexigrip.

Although most predictors for sternal complications, including female gender, diabetes mellitus, and obesity, are unmodifiable, the method of sternal closure is modifiable. Inadvertent paramedian sternotomy inhibits optimal approximation and alignment of the sternal edges, optimal bone healing, and chest wound stability.[19] As demonstrated in our study, Flexigrip may be useful for optimal approximation and alignment of the sternal edges to produce bone healing and chest stability. Especially, improved bone union was achieved at the manubrium when the method of closure was the same wiring in this region in both cohorts of Flexigrip and wiring. The reason for such preferable effect on the manubrium may be less stress to produce sternal dehiscence by Flexgrip-induced more tight, rigid, and optimal approximation of the sternal edges of the body of the sternum.

Because of increasing age, frailty, comorbidities including osteoporosis, and complexity of the surgery, increasing numbers of patients are at high risk for sternal instability and wound complications after cardiac surgery. Some recommend a rigid plate[10–12] fixed to the sternum with screws. It may be inadequate for patients with osteoporosis or unhealthy bone, because the bone must be healthy for the screw to be properly fixed. In contrast, Flexigrip can be used safely for those with severe osteoporosis based on less stress to the sternum by its wide open “Ω shape” with high thermoreactive elasticity and wide contact surface with the sternum, as evidenced by the report by Sarıkaya et al.[20] that Flexigrip is useful to treat sternal dehiscence in reoperations. Of course, appropriate sizing for each ICS is quite important to take advantage of Flexigrip.

An additional benefit of Flexigrip may be less restriction immediately after surgery, based upon our finding of earlier sternal bone union with Flexigrip. Most institutions recommend the resumption of driving after 4 to 8 weeks.[21] They also have the routine prescription with restrictions on the use of the upper limbs for 6 to 12 weeks.[22] The rationale for these restrictions is to promote solid osteosynthesis by minimizing the forces and avoiding micromotion between the sternal edges. Such seriously limited lifestyle may result in substantial negative ramifications on the patients’ life, associated with increased emotional stress and a negative impact on employment, work, and economic status. These restrictions may be moderated by the application of Flexigrip.

Study limitations

First, although justified statistically, study groups were small to account for any major differences and to perform any propensity score matching. Second, a single institution research could have added sampling bias. Third, it was difficult to strictly blind the radiologists reading the CT scans as to Flexigrip group allocation, despite the CT evaluation of sternal healing by a previously validated method.[9–11,16] Fourth, we included 9 patients with the 1st ICS Flexigrip. Although it may be important to investigate the significance of the 1st ICS Flexigrip, we did not compare CT scans between those with and without the 1st ICS Flexigrip. Fifth, we did not undergo an economic evaluation, which is imperative for a new medical device, because the Flexigrip is not reimbursed currently in Japan yet. As for costs, Bejko et al. compared the actual hospital costs, including costs of the Flexigrip (€80 each) and the steel wires (€20 for each pack with 6 wires) in a propensity score-matched cohort.[7] They concluded that Flexigrip closure offered a €510864 cost saving compared with standard steel wiring, due to a lower incidence of sternal complications with Flexigrip. Our results of earlier sternal bone union, synthesis, or healing on CT scans may complement the advantages of such cost-effective Flexigrip.

Conclusions

Evaluation on CT images 2 weeks after surgery revealed that Flexigrip sternal closure showed less gaps and offsets of the sternal halves, suggesting faster sternal bone union, synthesis, or healing when compared to the conventional wiring.

Disclosure Statement

All authors received no external research fundings, except for the Flexigrips used in the study, which were supplied free of charge from Praesidia SRL, Bologna, Italy, via Nippon BXI, Inc., Tokyo, Japan. Both companies were not involved in the conduction/design of this study as well as in analysis and interpretation of the results. All authors have nothing to disclose with regard to conflict of interest and commercial support.

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