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ORIGINAL ARTICLE

ZipFix Versus Conventional Sternal Closure: One-Year Follow-Up

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Background The present study aimed to compare postoperative complications commonly revealed after sternotomy closure by new sternal ZipFix™ (Synthes GmbH, Oberdorf, Switzerland) implant and conventional steel wire.

Methods Among the initial 360 subjects, 326 patients enrolled in this randomised control trial who were candidates for cardiac surgery from April 2014 to March 2015. After the surgery, the sternal closure was randomly done with poly-ether-ether-ketone (PEEK) based sternal ZipFix (ZF) on the sternal body (n = 168) or with conventional wires (CWs) (n = 158). Patients were followed postoperatively as well as 1, 3, 6, and 12 months after discharge regarding postoperative complications such as pain severity, dehiscence, and infection including incisional infections (superficial or deep), and organ/space infection (mediastinitis or osteomyelitis).

Results The mean age of the ZF and CW groups were 63.58 ± 10.9 and 62.42 ± 7.1 years, respectively ($p = 0.262$). In addition, there was no significant difference between the two groups' baseline characteristics ($p > 0.05$). Our study showed higher mean pain severity score in the conventional closure group compared with ZipFix closure group at all study time points ($p < 0.001$). Infection was seen in 2.76% of the overall participants with no significant difference of incisional and organ infection between the two groups throughout the study. After 1-month follow-up, five patients in the CW group had sternal dehiscence whereas no patients in ZF had dehiscence ($p < 0.001$).

Conclusions Our trial demonstrates greater clinical advantages in terms of pain and sternal dehiscence post surgery by using sternal ZipFix compared to conventional steel wire.

Keywords Sternum • Closure • Steel wire • Poly-ether-ether-ketone

Introduction

Closing the sternum after median sternotomy using conventional stainless steel wires has been accepted as a gold-standard conventional method for more than half a century [1]. Its easy use and low cost makes this method an acceptable option for sternal closure [2]. Despite the common application of this device in patients undergoing median sternotomies, there are some limitations accompanying its use, including dehiscence, thus requiring possible reoperation

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[3]. In this regard, some new techniques and devices have been recently developed to minimise the aforementioned complications. One of the recent incorporated devices is sternal ZipFix™ implant, a biocompatible poly-ether-ether-ketone (PEEK) cable-tie-based sternal closure device (Synthes GmbH, Oberdorf, Switzerland) [4]. This technique has some potential benefits, including its flexibility and easy handling, its facility in closing the sternum with high stability, high biocompatibility, and low risk of glove puncture [5]. It is believed that this new device reduces sternal closure known complications and enables a higher sternal fusion. Based on some case reports on the use of this new technique [6], it seems that the use of this method and its combination in hybrid sternal closure techniques with stainless steel wires and Sternal ZipFix can result in favourable surgical outcomes as well as no dehiscence or sternal instability. However, few studies are available on investigating lowering postoperative pain, local infection or dehiscence following use of sternal ZipFix™. Hence, the present study aimed to compare postoperative complications commonly revealed after sternotomy closure by sternal ZipFix™ technique and conventional method.

Material and Methods

Patients

This non-blinded, randomised control trial study included 326 patients who were candidates for cardiac surgery and underwent median sternotomy from April 2014 to March 2015 at Mehr and Javad al Aemeh hospitals, Mashhad, Iran. The exclusion criteria were preexisting autoimmune diseases, connective tissue disorders and sternal infection. Patients were randomised 1:1, using simple randomisation with table of random number by computer, Group A for digits 0–4 and group B for digits 5–9. A statistician undertook the randomisation process once the patient was admitted and the surgeon was informed which method to use with a sealed envelope when surgery began. Sternal closure was performed with either ZipFix (DePuy Synthes GmbH, Oberdorf, Switzerland), a biocompatible poly-ether-ether-ketone (PEEK) cable tie (intervention group) or with conventional steel wire (control group). The study endpoint was to compare the frequency of infection and dehiscence as well as pain severity post sternotomy in the intervention and control groups. Written informed consent was obtained from all participants.

All patients received 1 gr intravenous (IV) cephalothin every 6 hours at the time of induction until chest tube removal. Moreover, patients undergoing on pump coronary artery bypass grafting also received 1 gr IV amikacin at the time of intubation and 24 hours after.

Surgical Technique

A single surgeon performed all the conventional median sternotomies and the sternal closures in either group. In each group, two stainless steel wires were placed through the manubrium. Then, in the control group, wires were placed through the sternal intercostal spaces to coapt the sternum. Similarly, in the intervention group, ZipFix were placed around the sternum through intercostal spaces with the help of a needle at their tips. The needle is then removed, cable ties tightened and any redundant flaps cut off. Sutures were placed at intercostal levels 3, 4, and 5, in each group. The soft tissue and skin were closed in a routine manner in both groups. Postoperative care was identical in both groups.

In the intensive care unit, patients were extubated when they were awake, haemodynamically stable, arterial blood gases met the criteria for extubation, and no significant bleeding from the chest drains was detected. Patients were discharged from the intensive care unit when they were off inotropes and the chest drains had been removed.

Follow-Up

After discharge, patients were followed postoperatively as well as 1, 3, 6, and 12 months after discharge regarding postoperative complications including pain severity, dehiscence, incisional infections (superficial or deep), and organ/space infection (mediastinitis or osteomyelitis).

The diagnosis of incisional and organ/space infection was made according to the Guideline for Prevention of Surgical Site Infection [7]. Incisional infections are divided into superficial and deep infections. Superficial wound infections refer to those involving only skin and subcutaneous tissue (Superficial Surgical Site Infection (sSSI)). Deep infections refer to those involving deeper soft tissues of the incision (Deep Surgical Site Infection (dSSI)) and Organ/Space SSI involved any part of the anatomy (e.g., organ or space) other than incised body wall layers that were opened or manipulated during an operation. All suspicious subjects for infection were identified by the surgeon in follow-up visits and were referred to a single infection specialist for confirmation and determination of the infection type. Patient's pain at cough was measured by the use of a 0–10 visual analog scale (VAS). The surgeon asked patients to score their current, worst and best pain experienced in the past 24 hours, postoperatively and in follow-ups. The average of the three scores was considered for each patient.

In our study, the assessment and diagnosis of sternal dehiscence was made based on clinical findings of sternal click or evidence of sternal instability during respiration or coughing.

Statistical Analysis

The sample size was calculated using sample size formula (4). We considered $\alpha = 0.05$ and power = 80% with 152 subjects on each group. Considering the probability of exclusion and loss of follow-ups in each group, 177 subjects in each group were considered for this study. For statistical analysis, results were presented as mean ± standard deviation (SD) for quantitative variables and were summarised by absolute frequencies and percentages for categorical variables. Categorical variables were compared using chi-square test or Fisher's exact test when more than 20% of cells with an

expected count of less than 5 were observed. Continuous variables were compared using t test and/or non-parametric Mann-Whitney test whenever the data did not appear to have normal distribution. All statistical analysis was performed using SPSS software (version 21.0, SPSS Inc., Armonk, NY, USA).

Results

A total of 360 subjects were initially studied, six were excluded, 17 were missing and 11 deaths were detected and the remaining completed our follow-ups at 1, 3, 6 and 12 months (Figure 1). In 168 patients the sternum was closed with ZipFix and 158 patients were closed using conventional wires.

Baseline characteristics of subjects are shown in Table 1. The mean age of the ZipFix and Conventional wire closure groups were 63.58 ± 10.9 and 62.42 ± 7.1 years, respectively ($p = 0.262$). In addition, no significant difference was revealed between the ZipFix and Conventional groups in gender distribution and average body mass index (BMI) as well as cardiovascular risk factors. Despite the greater overall risk factors for dehiscence in the ZipFix group including chronic obstructive pulmonary disease (COPD) and diabetes mellitus (DM), this difference was not significant ($p > 0.05$).

Operation types included coronary artery bypass grafting (CABG) (175 patients), solitary valve procedures (86 patients), combined procedures (CABG and valvular procedures) (46 patients), aortic operations (17 patients) and other procedures (two patients). Intraoperative data including cardiac pulmonary bypass (CPB) time, clamping time, sternal closure time and total operation time were similar between the groups ($p > 0.05$) (Table 2). Mean hospital length of stay was similar between the groups ($p = 0.435$).

The prevalence of postoperative superficial infection was revealed in 1.19% of patients in the ZipFix closure group and in 2.53% of patients in the control group 1 month after discharge ($p = 0.369$). After 3-month follow-up, superficial infection of one patient in the control group remained whereas no patient in ZipFix closure group had superficial infection ($p = 0.303$). Deep infection was found in one patient in the conventional closure group ($p = 0.303$) who was seen treated at the 3-month follow-up visit. Mediastinitis and osteomyelitis were found in one patient in the control group at 1 and 3-month follow-ups, respectively ($p = 0.303$).

Dehiscence was not found in the ZipFix group at any study time points, though 3.16% (5 of 158 patients) in control group had dehiscence 1-month after surgery ($p < 0.001$). Among five patients with dehiscence at 1 month, two had clinically significant dehiscence which required reoperation and the remaining three had mild dehiscence who were planned for a conservative treatment of a longer chest support application. All these five patients' dehiscence resolved at 3-month follow-up except one patient who had used chest support which required reoperation for the un-healed lower sternal dehiscence. The patient whose dehiscence remained in the control group, had a BMI > 40.

Our study showed higher mean pain severity score in the conventional closure group compared with the ZipFix

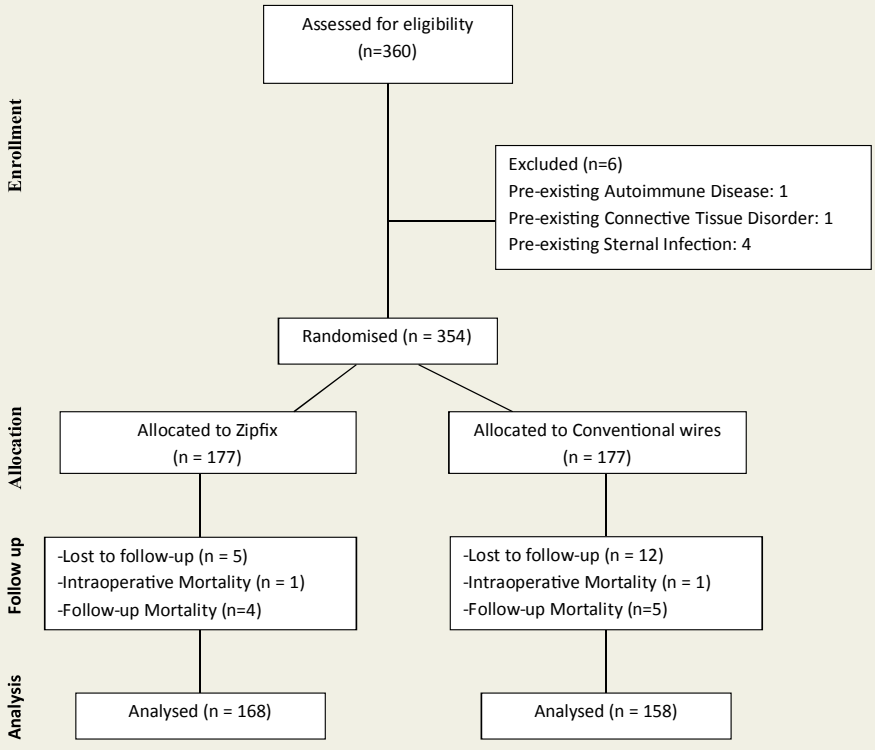

Figure 1 Consort flow chart.

Table 1 **Baseline characteristics and medical history.**

Characteristics	ZipFix closure (n = 168)	Conventional closure (n = 158)	p-Value
Male gender	96 (57.73)	98 (62.02)	0.432
Age, year	63.58 ± 10.91	62.42 ± 7.1	0.262
BMI, kg/m^2	28.99 ± 4.75	29.59 ± 4.84	0.264
Diabetes mellitus	81 (48.21)	63(39.87)	0.13
Dyslipidaemia	87 (51.79)	67 (42.41)	0.091
Hypertension	108 (64.29)	95 (60.13)	0.440
COPD	15 (8.93)	12 (7.59)	0.664
Coronary artery disease	119 (70.83)	116 (73.42)	0.604
Heart failure	11 (6.55)	7 (4.43)	0.404
Neurovascular disease	13 (7.74)	10 (6.33)	0.621
Renal failure	20 (11.9)	23 (14.56)	0.481
Current smoking	111 (66.07)	95 (60.13)	0.267
Peripheral vascular disease	14 (8.33)	7 (4.43)	0.149

Abbreviations: BMI, Body Mass Index; COPD, chronic obstructive pulmonary disease.

closure group at all study time points (Table 3) ($p < 0.001$). There was, however, no difference in the trend for the change in pain severity between the two groups within follow-up times ($p = 0.283$) (Figure 2).

Discussion

Wiring with stainless steel has been known to be the standard technique for sternal closure following median sternotomy since 1957 due to its simplicity and strength [1]. However, major sternal complications such as dehiscence, mediastinitis, osteomyelitis, and surgical site infections resulted in the introduction of several other techniques or devices for sternal closure to reduce the aforementioned complications.

Other strategies such as polyethylene terephthalate ribbon, nylon bands, jacketed steel wires, and steel bands have been applied but have not been widely adopted, possibly due to the complexity of application and increased incidence of accompanying infection up to life-threatening mediastinitis [8–11].

Closure with rigid-plate fixation system has been demonstrated to be structurally superior to standard wire closure,

Table 2 **Intra and postoperative variables.**

Variable	ZipFix (n = 168)	Conventional Wire (n = 158)	p-Value
Double IMA graft (%)	15 (8.93)	10 (6.33)	0.380
With CPB (%)	133 (79.17)	130 (82.28)	0.479
CPB time (min)	60.08 ± 13.71	62.27 ± 12.67	0.135
Clamping time (min)	41.99 ± 11.34	44.12 ± 10.09	0.075
Operation time (min)	195.44 ± 14.16	200.57 ± 30.13	0.054
Closure time (min)	8.81 ± 1.29	9.08 ± 1.62	0.092
Procedures (%)			
CABG only	94 (55.95)	81 (51.27)	0.398
Valve only	42 (25)	44 (27.85)	0.561
Combined	20 (11.9)	26 (16.46)	0.239
Repair of diseased Aorta	10 (5.95)	7 (4.43)	0.538
Other	2 (1.19)	0 (0)	0.170
Hospital stay (day)	6.14 ± 2.03	6.31 ± 1.97	0.435

Abbreviations: IMA, internal mammary artery; CPB, cardiopulmonary bypass; CABG: coronary artery bypass grafting.

Table 3 Postoperative complications.

Item	Postoperatively	1 month later	3 months later	6 months later	12 months later
Superficial infection					
ZipFix	0 (0.0)	2 (1.19)	0 (0.0)	0 (0.0)	0 (0.0)
Conventional	0 (0.0)	4 (2.53)	1 (0.63)	0 (0.0)	0 (0.0)
p-Value	–	0.369	0.303	–	–
Deep infection					
ZipFix	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conventional	0 (0.0)	1 (0.63)	0 (0.0)	0 (0.0)	0 (0.0)
p-Value	–	0.303	–	–	–
Mediastinitis					
ZipFix	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conventional	0 (0.0)	1 (0.63)	0 (0.0)	0 (0.0)	0 (0.0)
p-Value	–	0.303	–	–	–
Osteomyelitis					
ZipFix	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conventional	0 (0.0)	0 (0.0)	1 (0.63)	0 (0.0)	0 (0.0)
p-Value	–	–	0.303	–	–
Dehiscence					
ZipFix	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Conventional	0 (0.0)	5 (3.16)	1 (0.63)	0 (0.0)	0 (0.0)
p-Value	–	<0.001	0.303	–	–
Pain severity					
ZipFix	3.50 ± 1.70	1.60 ± 1.22	0.40 ± 0.75	0.30 ± 0.55	0.30 ± 0.55
Conventional	5.20 ± 1.56	2.20 ± 1.39	0.80 ± 0.82	0.70 ± 0.72	0.70 ± 0.72
p-Value	<0.001	<0.001	<0.001	<0.001	<0.001

but adds operative time and costs and is problematic during emergent re-entry [12,13].

The ZipFix System is based on the cable-tie principle providing a larger implant-to-bone contact through the intercostal space, which enables rigid fixation for use in primary sternal closure especially in patients at risk. Compared with steel wires, these cable-tie bands provide effective bone fixation and they showed a reduction in postoperative pain and length of postoperative hospital stay [14,15]. The ''soft and smooth'' material adapts perfectly to the bone and provides a large device-to-bone contact for better force distribution and for avoiding bone cut through. In an emergency situation, the ZipFix bands are easily cut by scissors.

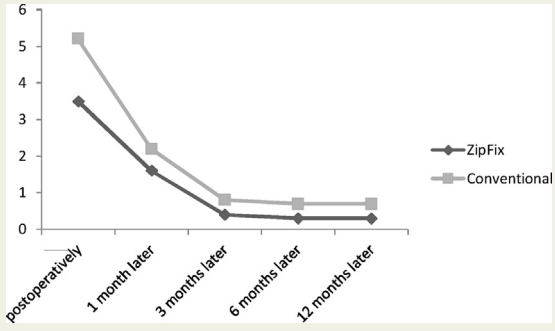

Figure 2 Trend of the changes in pain severity score within follow-up time.

We used this newly developed device at our institution with satisfactory and superior results in comparison to wire suture closure and without increasing the risk of device-related complications when compared with the literature [11,16]. This technique is fast, reliable and safe, easy to use and has great potential to serve as an alternative for traditional wire closure.

Initial examinations on comparing ZipFix with stainless steel cerclage showed its superiority with regard to its clinical safety and postoperative complication. Moreover, compared with wires, these steel bands not only provided effective fixation, but they demonstrated a reduction in postoperative pain and length of postoperative hospital stay [11,17].

Several studies have investigated the use of various techniques to reduce the most post-sternal closure life-threatening complication, being deep infection SSI. It is reported that deep infection SSI occurs in 4% of patients undergoing median sternotomy, yet its occurrence contributes to 14–47% mortality [8]. In this study, the rate of reported deep infection SSIs in both groups was satisfying throughout the

follow-ups with a single patient treated for deep infection SSI in the control group. Moreover, superficial SSI in a study by Heilmann et al. [18] was reported to be 3.3%, whereas in our study 1.8% of the total subjects faced sSSI. Although the occurrence of dSSI and sSSI was less when using ZipFix, the influence was not significant. Our study demonstrates a neutral impact of the sternal ZipFix system in patients regarding sternal infection and showed no significant effect with regard to the 'overall' sternal infection for the biocompatible ZipFix sternal closure system and conventional wiring. This is in line with the previously reported study by Melly et al. [4]. Reports on the impact of ZipFix on infection after cardiac surgery are still lacking. Although devices that lead to rigid and safe osseous coaptation and fixation have been shown to promote earlier union and primary healing [12], we did not succeed in demonstrating a significant decrease in postoperative sternal infection, which, theoretically, should be expected by reducing the number of patients with sternal dehiscence followed by secondary infection.

Sternal dehiscence is another complication of median sternotomy and is closely related to sternal wound infection and occurs due to the osteoporosis, pulmonary obstructive disease and force-imposing activities such as coughing. It occurs with an incidence rate of 0.3–8% and leads to 40% mortality and morbidity [11,19]. It has been demonstrated that rigid sternal fixation could decrease the incidence of sternal dehiscence and related sternal wound complications [11]. In our study after 1-month follow-up, five patients in the CW group had sternal dehiscence whereas no patients in ZF had dehiscence at 1-month follow-up ($p < 0.001$). This significant reduction in sternal dehiscence rate is considered a major achievement of the sternal ZipFix system.

Pain is another complication of median sternotomy and its prevalence varies widely in different studies, with observed numbers from 11 to 56%. Nevertheless, the prevalence of patients reporting severe and disabling pain is about 2–10% [20]. Few studies have demonstrated novel material to facilitate sternal closure and hence reduce the associated pain [8,10]. It was previously reported that the use of a biocompatible bone adhesive for sternal closure significantly reduces pain at coughing post-surgery and up to 2-weeks after surgery [10]. Early clinical results suggested that Figure 8 FlatWire provides excellent stability, which result in significantly diminished postoperative pain at discharge [21].

Our study showed significantly higher mean pain severity scores in the conventional closure group compared with the ZipFix closure group at all study time points during 1-year follow-up. We believe that improved early sternal stability may reduce postoperative pain, decrease the need for analgesics, improve chest wall mechanics and breathing, and motivate early mobility with rapid hospital recovery [22].

Although there have been several efforts and innovations to improve the sternal closure technique, the ideal methods have yet to be found. An ideal technique should consider a device that imparts appropriate mechanical properties, biocompatibility, radiopacity, removability when necessary, and cost-effectiveness [23].

Nowadays, this new ZipFix technique is successfully applied in many clinical settings. However, despite its high clinical efficacy and minimal complications, its cost is considerably higher than conventional devices, leading to its limited use [24,25]. However, with its use, the risk for reoperation can be totally reduced leading to overall cost-effectiveness.

Despite this study being the first with follow-ups to compare the efficacy and complications of Zipfix with conventional steel wire, we believe the low incidence of infection made our study underpowered to detect any significant difference in infection between our two groups. Therefore, we suggest future studies to consider a larger sample size and higher risk patients.

Conclusion

In our study, comparing early and long-term postoperative complications following the use of ZipFix technique and conventional methods resulted in lower postoperative complications as well as considerably lower pain severity.

Acknowledgment

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