AZJCVS
AZerbaijan Journal of CardioVascular Surgery

AZJCVS 2024;5(1):18-22
DOI: 10.5455/azjcvs.2024.01.01

Original Article

Comparison of the short and medium term efficacy of ortholox UHMWPE sternal cerclage band system and figure-of-8 wire sternum closure technique in patients at risk for sternal dehiscence

Erdinc Eroglu[1], Ahmet Acipayam[2], Alptekin Yasim[1], Mehmet Acipayam[1]

[1]Kahramanmaraş Sütçü İmam University, Faculty of Medicine, Department of Cardiovascular Surgery Department, Kahramanmaraş, Türkiye

[2]Kahramanmaraş Sütçü İmam University, Faculty of Medicine, Department of Throracic Surgery, Kahramanmaraş, Türkiye

Received: 01 March, 2024
Accepted: 25 March, 2024
Published: 27 March, 2024

Corresponding Author: Erdinc Eroglu
Kahramanmaraş Sütçü İmam University, Faculty of Medicine, Department of Cardiovascular Surgery Department, Kahramanmaraş, Türkiye
Email: erdinc046@hotmail.com

CITATION
Eroglu E, Acipayam A, Yasim A, Acipayam M. Comparison of the short and medium term efficacy of ortholox UHMWPE sternal cerclage band system and figure-of-8 wire sternum closure technique in patients at risk for sternal dehiscence. AZJCVS. 2024;5(1):18-22.

Abstract

Aim: In this retrospective study, it was aimed to compare the short and medium term efficacy of Sternal Cerclage Band System and Figure-of-8 wire closure technique in open heart surgery patients with risk for sternal dehiscence.
Material and Methods: In total, 320 open heart surgery patients with risk for sternal dehiscenceattempting to Kahramanmaraş Sütçü İmam University Medical Faculty Hospital between 28.12.2017 and 11.12.2021were subjected to this restrospective study. Since the study is retrospective, randomization and randomization procedures are not in question.The patients included in the study were divided into 2 groups as Steel Wire (standard procedureFigure 8 wiretechnique), and the Sternal Cerclage (sternum was closed with the Ortholox® Sternal Cerclage Band System). Baseline characteristics and outputs of patient groups were compared.
Results: Age and body mass index (BMI) means were significantly higher in Cerclage Band group ($p<0.05$). 53.8% of Cerclage Band group and 38.1% of Steel Wire group had obesity, and the difference was significant ($p<0.05$). Diabetes mellitus (DM) rate was 36.3% in Steel Wire group and 48.4% in Cerclage Band with statistically significant differences ($p<0.05$). In Cerclage Band group, 42.5% of patients were smoker, whereas 3.8% of Steel Wire group were smokers ($p<0.05$). Length of hospital stay, sternal stability and infection after surgery rates were similar between patient groups with statistically insignificant differences ($p>0.05$).
Conclusion: Although there are differences between Cerclage Band and Steel Wire, results and outputs were similar, and showed that Sternal Cerclage Band System is a safe and useful technique in open heart surgery patients with risk for sternal dehiscence.

Keywords: Sternal cerclage band system, sternal dehiscence, figure-of-8

INTRODUCTION

Sternotomy is a common procedure used in open heart surgery. Following the procedure, the sternum is often closed using either the U or Figure 8 Wireapproach or a straightforward single stitch using steel wire. The wire method is a widely used, low-cost technique that is simple to apply, fast, and tool-free. It is also conveniently accessible and regarded as quite safe (1). Over forty methods have been created, including torque-adjustable tensioners, several types of metal and polymer bands, hook-screw plates, and hand tools that ensure wire tension (2). Cardiothoracic surgeons have been accessing the heart using median sternotomy since 1957. While sternal separation or separation is a rare (0.5-2.5%) consequence following median sternotomy, its death rate ranges from 10% to 40%. Osteomyelitis, wound infection, and separation are linked to sternal instability. During the first two weeks, separation typically happens (3). In addition, sternal separation puts pressure on the patient, results in extended hospital stays necessitating plastic surgery, and has a major financial impact on the healthcare system (4). This is particularly true when there is an extra wound infection. Various surgical techniques have been devised to avert this consequence (3). It may be argued that the most popular technique in the literature is the one of fully reciprocating and bonding with steel seams one by one or in the Figure 8 Wire.

The Steel Wire closure method has been recognized as the standard procedure for sternal closure due to its cost-effectiveness. However, because the wires pierce the sternum's cortical layers, there is a risk that the patient would move inappropriately, which could result in sternum separation (5). Figure-of-8 Wire, which were designed as an alternative to the traditional one-by-one

wire, are used to reduce this risk (6). In cases when closure has failed, sternal 8-shape wires have been utilized both frequently and as a first rescue technique. In addition to limiting lateral and longitudinal motions, the Figure-of-8 wire arrangement distributes sternal stress across a larger region than a single suture (8-11). In addition to these benefits, the sternal Figure-of-8 wire design has significant drawbacks. The product's sternum may experience metal corrosion as a result of using metal as a production raw material. This is the first of three potential issues.

The purpose of this retrospective study was to evaluate the short- and long-term efficacy of the Figure-of-8 wire closure technique—which is used to close the sternum in patients undergoing open heart surgery who are at risk for sternal dehiscence—and the Ortholox® Ultra-high-molecular-weight polyethylene (UHMWPE) Sternal Cerclage Band System (Ortolog Medikal Sanayi ve Ticaret A.Ş., Ankara, Türkiye).

MATERIAL AND METHODS

This study included patients who underwent open heart surgery with median sternotomy (opening the sternum) between 2017 and 2022 and who satisfied the inclusion/exclusion criteria. Two groups of 160 patients each were created from the patients. Group 2 is made up of patients whose sternums were closed using the Ortholox® UHMWPE Sternal Cerclage Band System, while Group 1 is made up of patients whose sternums were closed using steel wire following open heart surgery (standard procedure Figure-of-8 wire approach). A comparison was made between the two groups' efficacy in sternal fixation, and the automated system, postoperative physical examination, and Posteroanterior lunggraphy were used to gather patient data. The study was approved by Kahramanmaraş Sütçü İmam University Faculty of Medicine Clinical Research Ethics Committee with the decision number 02 dated 16.11.2022 in accordance with theprinciples of the Declaration of Helsinki.

Study Groups

The study comprised patients who underwent open heart surgery with a median sternotomy as well as male and female patients aged 30-85 who applied from a single center to the Cardiovascular Surgery and Thoracic Surgery Clinic. The trial comprised 320 patients in total.The patients included in the study were divided into 2 groups. Group 1; After open heart surgery, the sternum was closed with Steel Wire (standard procedure Figure-of-8 wire technique), and Group 2 wasthegroup in which the sternum was closed with the Ortholox® UHMWPE Sternal Cerclage Band System.

Statistical Analysis

MedCalc® Statistical Software version 19.7.2 (MedCalc Software Ltd, Ostend, Belgium) was used to conduct the statistical analysis. Shapiro-Wilk test was used to test the normality of continuous variables. The mean, standard deviation, median, and minimum-maximum are used to present descriptive statistics. In order to describe categorical variables, frequency analysis was used. To compare the categorical variables, the Chi-Square and Continuity Correction tests were used due to linearization deviations (12). The Mann Whitney U test was used to compare non-normally distributed variables.

RESULTS

Age and body mass index (BMI) means were significantly higher in Cerclage Band group ($p<0.05$). 53.8% of Cerclage Band group and 38.1% of Steel Wire group had obesity, and the difference was significant ($p<0.05$). Diabetes mellitus (DM) rate was 36.3% in Steel Wire group and 48.4% in Cerclage Band with statistically significant differences ($p<0.05$). In Cerclage Band group, 42.5% of patients were smoker, whereas 3.8% of Steel Wire group were smokers ($p<0.05$). Gender, revision and type of surgery differences between patient groups were statistically insignificant ($p>0.05$) (Table 1).

Table 1. Baseline characteristics of patient groups and difference analysis results

	Steel wire (n=160)	Cerclage band (n=160)	All patients (n=320)	p
Gender n (%)				
Female	63 (39.4)	71 (44.4)	134 (41.9)	0.365[a]
Male	97 (60.6)	89 (55.6)	186 (58.1)	
Age				
Mean±SD	58.5+14	63.1+14.5	60.8+14.4	0.002[b]
Med (min-max)	60 (16-85)	64 (18-95)	62 (16-95)	
BMI (kg/m²)				
Mean±SD	29+4.7	30.9+6.8	30.0+6	0.029[b]
Med (min-max)	28.4 (17.7-45.3)	30.3 (17.9-50.1)	29 (17-7-50.1)	
Obesity				
Yes	61 (38.1)	86 (53.8)	147 (45.9)	0.005[a]
No	99 (61.9)	74 (46.3)	173 (54.1)	
Smoke n (%)				
Smoker	6 (3.8)	68 (42.5)	74 (23.1)	<0.001[c]
Non smoker	154 (96.3)	92 (57.5)	246 (76.9)	
Comorbidities n (%)				
COPD	3 (1.9)	7 (4.4)	10 (3.1)	0.335[c]
DM	58 (36.3)	76 (48.4)	74 (23.1)	0.028[a]
Revision				
Yes	4 (2.5)	-	4 (1.3)	0.123[d]
No	156 (97.5)	160 (100)	316 (98.8)	
Type of surgery				
CABG	84 (52.8)	73 (45.6)	157 (49.2)	0.302[a]
AVR	13 (8.2)	16 (10)	29 (9.1)	
MVR	3 (1.9)	8 (5)	11 (3.4)	
Combined	53 (33.3)	58 (36.3)	111 (34.8)	
TVR	2 (1.3)	4 (2.5)	6 (1.9)	
ASD	4 (2.5)	1 (0.6)	5 (1.6)	

a: Pearson Chi-Square, b: Mann-Whitney U, c: continuity correction, d: Fisher's Exact Test, SD: standard deviation, CABG: coronary artery bypass grafting, AVR: aortic valve repair, MVR: mitral valve repair, TVR: tricuspid valve regurgitation, ASD: an atrial septal defect

Length of hospital stay, sternal stability and infection after surgery rates were similar between patient groups with statistically insignificant differences (p>0.05) (Table 2).

Table 2. Length of hospital stay, strenal stability and infection outputs of patient groups and difference analysis results

	Steel wire (n=160)	Cerclage band (n=160)	All patients (n=320)	p
Length of hospital stay				
Mean±SD	4.6+3.1	3.8+2.5	3.9+2.6	0.436[a]
Med (min-max)	3.5 (2-12)	3 (0-16)	3 (0-16)	
Sternal stability				
Stable	145 (90.6)	152 (95)	297 (92.8)	0.194[b]
Unstable	15 (9.4)	8 (5)	23 (7.2)	
Infection				
Yes	8 (5)	8 (5)	16 (5.0)	p>0.05
No	152 (95)	152 (95)	304 (95.0)	

a: Mann-Whitney U, b: continuity correction, SD: standard deviation

DISCUSSION

Significant morbidity and mortality following median sternotomy can be caused by issues with infection control and sternal bone repair (14). A number of conditions, including diabetes, obesity, and extended hospital stays, can raise the risk of infection (14). The short-and medium-term effectiveness of the Ortholox UHMWPE Sternal Cerclage Band Systemand the Figure-of-8 wire sternal closure technique was compared in patients at risk of sternal dehiscence in this retrospectively structured study (Figure 1).

Figure 1. A sternal closure using ortholox UHMWPE sternal cerclage band system

The study's main focus was on the infection and sternal stability data. In 92.8% of the patients, sternal stability was attained; in the Steel Wire group, this percentage was 90.6%, and in the UHMWPE Cerclage Band group, it was 95%. In 7.2% of the patients overall, sternal stability was unstable; however, in the Steel Wire group, this incidence was 9.4%, and in the UHMWPE Cerclage Band group, it was 5%. There was no statistically significant difference between the Steel Wire and UHMWPE Cerclage Band groups when the findings were evaluated.

The Ortholox® Sternum closure system (Figure 2) is a band system made of UHMWPE fibers that secures the sternum in a straight, U, or diagonal shape with a proprietary locking block (15,16). It is applied swiftly and easily because to its straightforward instrumentation. The rib cage can expand under control thanks to this dynamic compression process, giving stable stability. By absorbing the loads brought on by the patient's daily motions, coughing, or sneezing after surgery, it serves as a shock absorber. Without the need for wire cutting scissors or plaque removal instruments, it can be simply removed with a scalpel on the operating table in an emergency (Figure 3).

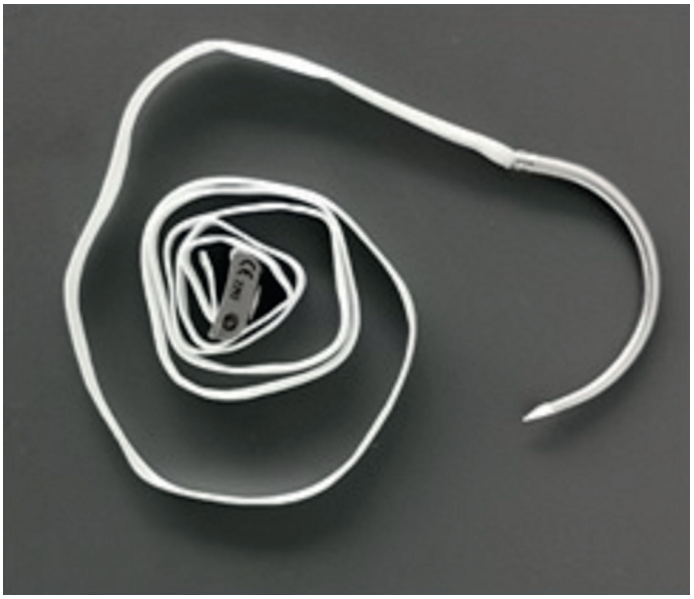

Figure 2. Ortholox® UHMWPE sternal closure system

Figure 3. Ortholox® sternal closure system application surgical instruments

In our study, 58.1% of the patients in the study were male, and 41.9% of the patients were female. Sixty-three of the 134 female patients received steel wire, whereas 71 of them received

UHMWPE Cerclage Bands. Regarding patients who were male, Steel Wire was utilized in 97 out of 186 cases. In 89 patients, the UHMWPE Cerclage Band was employed. Gender differences were statistically insignificant.

Patients' mean age was 60.8 years. The UHMWPE Cerclage Sternal Band group saw an increase in this rate from 58.5 in the Steel Wire group to 63.1. Studies using statistics revealed that the patients in the Steel Wire group were younger than those in the UHMWPE Cerclage Sternal Band group. Age is one of the known factors associated with inadequate early healing, according to the literature (17-18). In comparison to the Steel Wire group of the UHMWPE Cerclage Sternal Band product, the statistically significant data indicated above is determined to be successful.

Obese patients had a higher risk of wound infection and sternal separation following heart surgery (19,20). Compared to the patients in the Steel Wire group, the UHMWPE Cerclage Band group's obesity levels were statistically higher. Furthermore, compared to patients in the Steel Wire group, patients in the UHMWPE Cerclage Sternal Band group smoke more. This rate stayed at 6 patients in the Steel Wire group but reached 68 patients in the UHMWPE Cerclage Band group. 246 patients did not smoke, compared to 74 smokers overall. Obesity and a high body mass index are well-known risk factors for several postoperative wound healing issues.It may be concluded that, in individuals at risk for sternal dehiscence, excessive usage of UHMWPE Cerclage Sternal Band is statistically significant more effective than Steel Wire. This is especially true for patients with a high body mass index and obesity.

Chronic obstructive pulmonary disease (COPD) and diabetes mellitus were contrasted as important comorbidities. Regarding COPD, there was no statistically significant difference between the groups; however, individuals with Diabetes Mellitus were found to be substantially more prevalent in the UHMWPE Sternal Cerclage Band group. Of the procedures, 157 involved a Coronary Artery Bypass Graft, 111 involved a Combination, 29 involved replacing the Aortic valve, 11 involved replacing the Mitral valve, 6 involved replacing the Tricuspid valve, and 5 involved fixing an Atrial Septal Defect. The types of surgeries done did not statistically differ between the groups. Comparing the postoperative hospital stays of the two groups revealed no differences.

In 297 cases, sternal stability was obtained; however, in 23 patients, it remained unstable. Stability was attained in 152 (95%) of the patients in the UHMWPE Cerclage Band group when compared between the groups. Eight individuals (5%) could not reach stability. Within the Steel Wire cohort, 145 patients (90.6%) attained stability, whereas 15 patients (9.4%) did not reach stability. Under these circumstances, a statistical comparison between the Steel Wire group and the other group revealed no differences in terms of sternal stability.

152 patients in the Steel Wire group did not have an infection, whereas 8 patients had an infection when the infection data were analyzed. There were 8 patients with infection in the UHMWPE Sternal Cerclage Band group, compared to 152 patients without infection. There was no discernible statistical difference between them. The study's findings demonstrated to us the UHMWPE Sternal Cerclage Band System's effectiveness and safety. Ortholox® UHMWPE Sternal Cerclage Band System can be safely utilized in patients at risk for sternal dehiscence, as evidenced by the lack of a substantial difference between them and Steel Wire, which is frequently used for sternal stability and infection. Based on these results, it is possible to say that no significant statistical data was determined according to the cost effectiveness evaluation since both groups did not require additional operative time.

CONCLUSION

As a conclusion of this study, the Ortholox® UHMWPE Sternotomy Closure System, which is the subject of the study, offers a fast and reliable solution to determine the appropriate method to perform sternal fixation most effectively in patient groups. It has been observed that physicians prefer to use the Ortholox® UHMWPE Sternotomy Closure System in patients with the highest risk of wound healing, such as COPD, obesity, high BMI and diabetes, against complications that may ocur due to sternal dehiscence case experiences. Although both closure methods had no difference in terms of postoperative hospitalization. It became clear that the Ortholox® UHMWPE Sternotomy Closure System was an effective alternative to the Figure-of-8 wire closure technique in open heart surgery patients at risk of sternal dehiscence. Although there was no statistical difference between the two groups, it was observed that there was approximately a 50% difference in terms of sternal stability between the group using the Ortholox® UHMWPE Sternotomy Closure System and the group using the Figure-of-8 wire closure technique.

Future Perspective

In a retrospective study, it can be said that the Ortholox® UHMWPE Sternotomy Closure System is reliable and effective against comorbidity factors such as COPD, high BMI, obesity and diabetes in patients at risk of sternal dehiscence after open heart surgery. However, the success and effectiveness of the Ortholox® UHMWPE Sternotomy Closure System requires to support with further study.

Conflict of Interests: The authors declare that there are no conflict of interests.

Financial Disclosure: The authors declare that there is no financial support.

Ethics Committee Approval: The study was approved by Kahramanmaraş Sütçü İmam University Faculty of Medicine Clinical Research Ethics Committee with the decision number 02 dated 16.11.2022 in accordance with theprinciples of the Declaration of Helsinki.

REFERENCES

1. Kukulski L, Krawczyk A, Pacholewicz J. Retrospective analysis of the impact of sternum closure technique on postoperative comfort and rehabilitation. Kardiochir Torakochirurgia Pol. 2018;15:233-7.
2. Karigyo CJT, Pesarini A. A simple modification of the conventional figure-of-eight sternal closure technique. Braz J Cardiovasc Surg. 2019;34:406-11.
3. Casha AR, Yang L, Kay PH, Saleh M, Cooper GJ. A biomechanical study of median sternotomy closure techniques. Eur J Cardiothorac Surg. 1999;15:365-9.
4. Riess FC, Awwad N, Hoffmann B, Bader R, Helmold HY, Loewer C, et al. A steel band in addition to 8 wire cerclages reduces the risk of sternal dehiscence after median sternotomy. Heart Surg Forum. 2004;7:387-92.
5. Okutan H, Tenekeci C, Kutsal A. The reinforced sternal closure system is reliable to use in elderly patients. J Card Surg. 2005;20:271-3.
6. Vo TX, Juanda N, Ngu J, Gawad N, LaBelle K, Rubens FD. Development of a mediansternotomysimulation model forcardiacsurgerytraining. JTCVS Tech. 2020;2:109-16.
7. Jensen CJ, Schnur M, Lask S, Attanasio P, Gotzmann M, Kara K, et al. Feasibility of the figure-of-8-suture as venous closure in interventional electrophysiology: one strategy for all?. Int J Med Sci. 2020;17:965-9.
8. Qiu F, Wang S, Jin X, Wu X, Zhou J. Clinical evaluation of titanium-alloy bands for sternal closure after median sternotomy: single-center experience. Contrast Media Mol Imaging. 2022;2022:8622498.
9. Razafimanjato NNM, Tsiambanizafy GO, Ravelomihary TDN, Rakotovao HJL, Hunald FA. Successful surgical repair of a sternum cleft using composite mesh: a case report and new technical note. Afr J Thorac Crit Care Med. 2021;27:10.7196/AJTCCM.2021.v27i2.103.
10. Krauze A, Fus-Kujawa A, Bajdak-Rusinek K, Żyła-Uklejewicz D, Fernandez C, Bednarek I, et al. Impact of local delivery of allogeneic chondrocytes on the biological response and healing of the sternum bones after sternotomy. Sci Rep. 2023;13:15971.
11. Wang D, Camp CL, Werner BC, Dines JS, Altchek DW. Figure-of-8 reconstruction technique for chronic posterior sternoclavicular joint dislocation. Arthrosc Tech. 2017;6:e1749-53.
12. Yılmaz K, Turanlı M. A multi-disciplinary investigation of linearization deviations in different regression models. AJPAS. 2023;22:15-9.
13. Kirmani BH, Jones SG, Malaisrie SC, Chung DA, Williams RJ. Limited versus full sternotomy for aortic valve replacement. Cochrane Database Syst Rev. 2017;4:CD011793.
14. Hancock HC, Maier RH, Kasim A, Mason J, Murphy G, Goodwin A, et al. Mini-sternotomy versus conventional sternotomy for aortic valve replacement: a randomised controlled trial. BMJ Open. 2021;11:e041398.
15. Takahara S, Sasaki K, Saito T, Sakuma K, Fujiwara H, Yoshioka I, et al. Clinical assessment of efficacy of poly-L-lactide sternal pin on sternal stability and post-operative pain: a prospective randomized trial in cardiovascular surgery. J Thorac Dis. 2022;14:76-89.
16. Dell'Amore A, Congiu S, Campisi A, Mazzarra S, Zanoni S, Giunta D. Sternal reconstruction after post-sternotomy dehiscence and mediastinitis. Indian J Thorac Cardiovasc Surg. 2020;36:388-96.
17. Shin YC, Kim SH, Kim DJ, Kim DJ, Kim JS, Lim C, Park KH. Sternal healing after coronary artery bypass grafting using bilateral internal thoracic arteries: assessment by computed tomography scan. Korean J Thorac Cardiovasc Surg. 2015;48:33-9.
18. Endo D, Yamamoto T, Kajimoto K, Matsushita S, Dohi S, Shimada A, et al. Coronary artery bypass grafting in patients with chronic kidney disease: chronic kidney disease has an independent adverse effect on the long-term outcome of coronary artery bypass grafting. Biomed Res Int. 2022;2022:4994970.
19. Lamm P, Gödje OL, Lange T, Reichart B. Reduction of wound healing problems after median sternotomy by use of retention sutures. Ann Thorac Surg. 1998;66:2125-6.
20. Ata EC, Beyaz MO. Sternum Dehiscence: A Preventable Complication of Median Sternotomy. Heart Surg Forum. 2020;23:E599-605.