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Fibrin-Coated Collagen Fleece Seems to Prevent Sternal Instability after Cardiac Surgery: A Matched Pair Data Analysis

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Abstract

Background To examine if fibrin-coated collagen fleece (Tachosil) interferes with bone and wound healing when it is used on the cut surface of the sternum after median sternotomy.

Methods A total of 25 patients with osteoporotic sternal disorders were treated with fibrin-coated collagen fleece at the cut surface of the sternum after median sternotomy (therapy group). We compared the occurrence of impaired wound healing and sternal instability, reoperation rate, and 30-day mortality with a control group of 25 case-matched patients. After matching for age, gender, and risk factors for sternal instability (diabetes mellitus, osteoporosis, body mass index, nicotine consumption), both groups were comparable.

Results Sternal instability occurred in one (4%) patient in the study group and in five (20%) patients in the control group. Impaired wound healing occurred in one (4%) patient in the therapy group and two (8%) patients in the control group. Reoperation was necessary in four (16%) patients in the therapy group and 6 (24%) patients in the control group. The 30-day mortality occurred in six (24%) patients in the therapy group and four (16%) patients in the control group.

Conclusions The use of fibrin-coated collagen fleece on the cut surface of the sternum in patients with osteoporosis does not impair bone and wound healing. Furthermore, it seems to result in less sternal instability. A larger prospective study is necessary to verify the results of this explorative study.

Keywords
- sternal instability
- fibrin-coated collagen fleece
- bone healing
- wound healing

Introduction

Sternal instability is a serious complication occurring in 0.25 to 7% of patients after cardiac surgery.[1–3] In patients suffering from osteoporosis, the incidence of sternal instability rises up to 14%.[4] Reoperation for sternal instability, prolonged hospital stay, and a mortality rate between 5 and 30%, as well as rising costs, are the consequences. Osteoporosis, diabetes mellitus, use of bilateral mammary artery, and obesity are known risk factors for sternal instability and wound disorders.[1,5–9]

Fibrin-coated collagen fleece is routinely used to achieve hemostasis in all types of surgery.[10–13] It can also be used to stop bleeding from cancellous bone. Nevertheless, so far, there are no data on the influence of fibrin-coated collagen fleece on bone and wound healing when used on the cut surface of the sternum after median sternotomy.

The aim of this study was to examine if fibrin-coated collagen fleece interferes with sternal stability and wound healing after median sternotomy.

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Materials and Methods

All patients ($N = 25$) who were treated with fibrin-coated collagen fleece on the cut surface of the sternum between 2006 and 2011 were included in the study (therapy group). In all 25 patients, osteoporosis, defined as abnormal bone structure with thinning of the sternum and rarefication of cancellous bone, was found intraoperatively.

Baseline, intra-, and perioperative data of all 25 treated patients were compared retrospectively with 25 patients in a case-matched control group. The patients in the control group were known to suffer from osteoporosis preoperatively since diagnosis had been previously confirmed.

Noninfectious impaired wound healing (NIWH) was defined as a superficial wound dehiscence without signs of infection. Noninfectious sternal instability (NISI) was defined as sternal dehiscence with palpable crepitation without signs of infection. Superficial sternal wound infection (SSWI) was defined as warming, reddening, and superficial dehiscence of the sternal wound without sternal instability. Deep sternal wound infection (DSWI) was defined as wound secretion, deep dehiscence with sternal instability.

Surgery was performed in a standardized manner by the same surgeon (P. R.) in all patients of both groups.

Median sternotomy using a saber saw was performed after skin incision and transection of the subcutaneous tissue by diathermia. Different cardiac procedures were performed using cardiopulmonary bypass. At the end of surgery, sternal stabilization was achieved with eight single steel wires (stainless steel) in a standard manner. Before closure of the sternum by the implanted wires, a 9.6×4.8 cm fibrin-coated collagen fleece (Tachosil, Takeda, Konstanz, Germany) was cut longitudinally in two halves (9.6×2.4 cm), and each of the halves, with the fibrin-coated layer directing toward the cut surface, was pressed on one cut surface of both sides of the sternum for 2 minutes. Tachosil is waterproof and airtight and is completely resorbed within 13 weeks. Then, sternal steel wires were twisted with the two pieces of Tachosil between the two halves of the sternum. Vicryl single bottom sutures (Ethicon) were used for subcutaneous tissue closure. Skin closure was performed by intracutaneous running suture (4×0 Ethilon, Ethicon).

Data Analysis

Patients were stepwise matched according to the following factors: gender, osteoporosis, diabetes mellitus, and nicotine consumption. In the second step, patients were matched for age (±6 years). In the third step, patients were matched for body mass index (BMI) (±3 kg/m^2). In the last step, patients were matched for time frame of operation.

Statistical analysis was performed with SPSS (version 19, IBM Corp., Armonk, New York, United States). Average, median, minimum, and maximum, as well as percentiles and standard deviation were calculated for metric data. Categorical variables were compared using Fisher's exact test. Significance was assumed at $p \leq 0.05$. A trend to significance was supposed at $p < 0.2$. Mann–Whitney U test was used for the analysis of not normally distributed, unrelated parameters. Logistic regression analysis was used to quantify relationships between treatment modality (therapy group vs. control group) and adverse outcomes. Odds ratio were calculated.

The study protocol was approved by our university's Local Ethics Committee (vote 206/11).

Results

There were no differences between both groups regarding baseline characteristics with the exception of the predicted risk of mortality and priority of surgery (►**Table 1**). Especially, the known risk factors for sternal instability (diabetes

Table 1 Baseline characteristics

	Therapy group ($N = 25$)	Control group ($N = 25$)	p-Value
Age (mean)	74	71	0.586
Male	3 (12%)	3 (12%)	1.000
Female	22 (88%)	22 (88%)	1.000
IDDM	11 (44%)	12 (48%)	1.000
SSRI	2 (8%)	0	0.490
Height (cm) (mean)	164 ± 8	161 ± 9	0.321
Weight (kg) (median)	70	70	0.662
BMI (kg/m^2) (median)	27	26	1.000
Nicotine	6 (24%)	5 (20%)	1.000
Osteoporosis	25 (100%)	25 (100%)	1.000
BIMA	0	2 (8%)	0.490
Anticoagulation therapy	10 (40%)	9 (36%)	1.000
Peripheral vascular disease	1 (4%)	4 (16%)	0.349
Cortisol medication	0 (0%)	2 (8%)	0.490
ASA 3	17 (68%)	22 (88%)	
ASA 4	7 (28%)	2 (8%)	0.181
ASA 5	1 (4%)	1 (4%)	
Elective	11 (44%)	22 (88%)	
Urgent	6 (24%)	1(4%)	0.004
Emergent	8 (32%)	2 (8%)	
EuroSCORE I (points)	10 ± 3	8 ± 4	0.034

Abbreviations: ASA, American Society of Anaesthesiologists classification; BIMA, bilateral internal thoracic arteries; BMI, body mass index; EuroSCORE, European system for cardiac operative risk evaluation; IDDM, insulin-dependent diabetes mellitus; SSRI, selective serotonin reuptake inhibitor.

Note: There were no differences between groups in baseline characteristics, except urgency of operations and predicted mortality (EuroSCORE I).

Table 2 Surgical procedures and perioperative data

Operation	Therapy group ($N = 25$)	Control group ($N = 25$)	p-Value
CABG	11	11	
AVR	5	10	
MVR	4	1	
TVR	0	2	
Heart tumor	1	0	
Aortic surgery	4	1	
ECC (minutes) (median)	103	103	
Operation time (minutes) (median)	222	205	0.541
LOS (days) (median)	16	16	0.719
LOS ICU (days)	7	5	0.611
CRP max (mg/L)	193.6 ± 76.2	230.5 ± 123.3	0.240

Abbreviations: AVR, aortic valve replacement; CABG, coronary artery bypass grafting; CRP, C-reactive protein; ECC, extracorporeal circulation; LOS, length of stay; LOS ICU, length of stay intensive care unit; MVR, mitral valve reconstruction; TVR, tricuspid valve reconstruction.

mellitus, BMI, osteoporosis, nicotine consumption, use of bilateral internal mammary artery (BIMA) grafts, and cortisol therapy) were not different. In the therapy group, there were more urgent (24 vs. 4%) and emergent (32 vs. 8%) patients than in the control group ($p = 0.004$).

Surgical procedures and perioperative data are shown in ►**Table 2**. In the therapy group, there were less aortic valve replacements (AVRs) and more mitral valve replacements and aortic operations. Operation time (OP), length of stay (LOS), and length of stay in intensive care unit were similar in both groups.

Sternal instability occurred in 6 (12%) of the 50 patients (►**Table 3**). The mean time interval from surgery until the occurrence of sternal instability was 15 days (range: 7–21 days; median: 18). Five of those six patients were reoperated on, and one of the patients with sternal instability died before reoperation. Of the six patients with sternal instability, two had a DSWI (one in each group) and four had an NISI (all in the control group).

There were less sternal instabilities in the therapy group ($N = 1$; 4%) than in the control group ($N = 5$; 20%; $p = 0.19$). The odds ratio for sternal instability was 0.17 (95% confidence interval [CI]: 0.018–1.5) in the therapy group (►**Fig. 1**).

We observed 10 (20%) cases of impaired wound healing. There were more cases in the control group ($N = 6$; 24%) than in the therapy group ($N = 4$; 16%; $p = 0.73$).

From those 10 patients, 6 patients had NIWH and 4 had wound infections: 2 SSWI (one in each group) and 2 DSWI (one in each group). These four patients needed wound revision (►**Table 4**). The other six patients were treated conservatively. The odds ratio for NIWH in the therapy group compared with the control group was 0.46 (95% CI: 0.0076–2.8) and that for infectious wound healing impairment was 1 (95% CI: 0.36–2.8) (►**Fig. 1**). In addition, the mean C-reactive protein level was lower in the therapy group than in the control group (not significant), showing that there is no increased inflammatory reaction caused by the use of fibrin-coated collagen fleece (►**Table 2**).

Of out 50 patients, 10 had a reoperation (20%): 4 patients were in the therapy group (16%) and 6 in the control group (24%). The difference was not statistically significant ($p = 0.73$).

The reasons for reoperations were sternal instability in five (50%; three NISI and two DSWI) patients, bleeding in two (20%) patients, SSWI in two (20%) patients, and pericardial effusion in one (10%) patient. Data of the patients who were reoperated on are shown in ►**Table 4**.

The odds ratio for reoperation in the therapy group compared with the control group was 0.6 (95% CI: 0.15–2.47) (►**Fig. 1**).

The predicted mortality calculated by the European system for cardiac operative risk evaluation (EuroSCORE) I was higher in the therapy group (10 ± 3 vs. 8 ± 4 points; $p = 0.034$; 22.5 vs. 15.4%). Total 30-day mortality in our study was 12% (16% [$N = 4$] in the therapy group and 8% [$N = 2$] in the control group), which was lower than the predicted mortality but reasonable for the high-risk collective (►**Table 5**). Only one

Table 3 Data of all patients suffering from sternal instability after the index procedure

Patient	Group	Age	Sex	Procedure	Urgency	Time interval to occurrence (days)	LOS ICU	Mortality	BMI	DM
1	Therapy	67	F	MVR	Urgent	21	34	No	33.5	Yes
2	Control	52	M	CABG	Elective	19	9	No	34.7	No
3	Control	59	F	AVR	Elective	10	11	Yes	23.1	No
4	Control	71	F	AVR	Emergent	18	25	No	27	Yes
5	Control	77	F	CABG	Urgent	7	13	No	27.5	No
6	Control	82	F	CABG	Elective	19	27	No	19.5	Yes

Abbreviations: AVR, aortic valve replacement; BMI, body mass index; CABG, coronary artery bypass grafting; DM, diabetes mellitus; LOS ICU, length of stay intensive care unit; MVR, mitral valve reconstruction.
Note: One patient in the therapy group and five in the control group had sternal instability.

	Treatment		Control			
Parameter	Events	Total	Events	Total	OR	95%-CI
Re-Operation	4	25	6	25	0.60	0.15-2.47
Infectious wound healing impairment	2	25	2	25	1	0.36-2.8
Non-infectious wound healing impairment	2	25	4	25	0.46	0.0076-2.8
Sternal Instability	1	25	5	25	0.17	0.018-1.5
Mortality	4	25	2	25	2.19	0.36-13.22
Expected Mortality	5.55	25	3	25	1.57	0.37-6.61

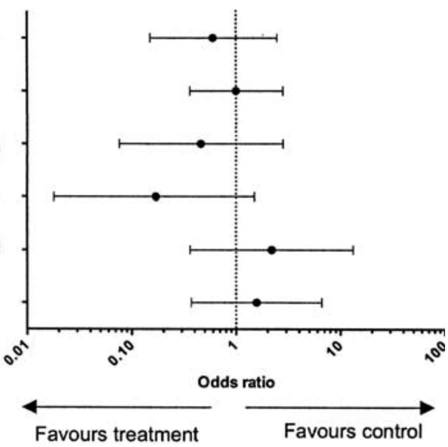

Fig. 1 Odds ratio.

patient who died suffered from an NISI. This patient was in the control group. The patient was a 59-year-old woman, who died after elective AVR at day 11 due to septic multiorgan failure. Preoperative EuroSCORE was 3.

The other five patients died because of cardiogenic shock (7th day), septic shock (25th day), lung embolism (2nd day), and pneumonia (23rd and 28th day). The EuroSCORE of the five patients has been higher than the average (between 11 and 13 points). None of these five patients had sternal instability (►**Table 5**). The odds ratio for mortality in the therapy group was 2.19 (95% CI: 0.36–13.22). The odds ratio for the predicted mortality in the therapy group was 1.57 (95% CI: 0.37–6.61).

Discussion

Median sternotomy is the standard approach in cardiac surgery. Bleeding from the cut surface of the sternum is difficult to treat and might be a reason for reoperation. Sutures and diathermia are not really suitable to stop such bleedings. The most common treatment is the use of bone wax, which itself might compromise the bone healing.[14–16] Fibrin-coated collagen fleece is a treatment option for the management of bone bleedings. There is no published experience with fibrin-coated collagen fleece used on the cut surface of bones so far.

It is well known that foreign material in surgical wounds, such as sutures, vascular clips, vascular prostheses, pacemakers and others implants, can lead to impaired wound healing and wound infections.[17,18] Even though fibrin-coated collagen fleece, used to achieve hemostasis or prevent adhesions, is completely resorbed, it is a foreign material in a surgical wound and might influence wound healing and cause wound infection. We hypothesized, therefore, that the use of fibrin-coated collagen fleece impairs sternal stability, wound healing, and the occurrence of wound

Table 4 Reoperation

Patient	Group	Day of first reoperation	Reason for reoperation	Procedure	No. of reoperation	LOS ICU
1	Therapy	14	Bleeding	Hematoma evacuation	1	86
2	Therapy	21	DSWI	VAC and omentum plasty	4	34
3	Therapy	0	Bleeding	Hematoma evacuation	1	7
4	Therapy	8	SSWI	Wound debridement	1	37
5	Control	19	NISI	Sternal restabilization	1	9
6	Control	25	Pericardial effusion	Pericardial fenestration	1	10
7	Control	6	SSWI	Wound debridement	1	2
8	Control	7	NISI	Sternal restabilization	1	13
9	Control	19	DSWI	VAC and pectoralis plasty	9	27
10	Control	18	NISI	Sternal restabilization	1	25

Abbreviations: DSWI, deep sternal wound infection; LOS ICU, length of stay intensive care unit; NISI, noninfectious sternal instability; SSWI, superficial sternal wound infection; VAC, vacuum-assisted closure.
Note: Four patients in the therapy group and six in the control group needed reoperation.

Table 5 Risk factors and reasons for death

Patient	Group	Age	Sex	Procedure	Euro SCORE (points)	Reoperation	Sternal instability	Day of mortality	Cause of mortality
1	Therapy	41	M	CABG	12	No	No	7	Cardiogenic shock
2	Therapy	71	F	CABG	11	No	No	25	Septic shock
3	Therapy	55	F	Pulmonary embolectomy	13	No	No	2	Right heart failure
4	Therapy	74	F	CABG	12	No	No	28	Pneumonia
5	Control	59	F	AVR	3	No	Yes	11	Septic multiorgan failure
6	Control	83	F	CABG	13	No	No	23	Pneumonia

Abbreviations: AVR, aortic valve replacement; CABG, coronary bypass grafting; EuroSCORE, European system for cardiac operative risk evaluation.
Note: Four patients in the therapy group and two in the control group died.

infections after median sternotomy in cardiac surgery when used on the cut surface of the sternum. To verify this hypothesis, we analyzed the data of 25 consecutive patients with fibrin-coated collagen fleece on the cut surface of the sternum after median sternotomy.

Sternal instability after median sternotomy is a serious complication after cardiac surgery, containing the risk of sternal infection and mediastinitis, which is a major cause of morbidity and mortality.[19] In patients above 65 years of age suffering from osteoporosis, sternal instability appears in up to 14% after median sternotomy. For this reason, our patients represent a high-risk collective for sternal instability and wound infections, and our results ($n = 6$; 12%) are in accordance with the literature.[20]

Surprisingly, our data show that the use of fibrin-coated collagen fleece on the cut surface of the sternum does not impair sternum stability after median sternotomy. There was only one sternum instability in the therapy group but five in the control group. Even though there is no statistical difference in this end point, there is a trend toward worse results in the control group concerning sternum instability ($p = 0.19$). This means that the use of fibrin-coated collagen fleece could probably even decrease the risk of sternal instability in this high-risk group.

Noninfectious wound disorders also occurred in more cases in the control group than in the therapy group (four vs. two), but sternal wound infections were equal in both groups (one SSWI and one DSWI each). These results demonstrate that the use of fibrin-coated collagen fleece on the cut surface of the sternum did not impair wound healing in terms of infection.

No mortality has been caused by sternal instability or wound healing in either group. Only one patient from the control group who died had noninfectious sternum instability 10 days after surgery. Unfortunately, she expired at day 11 after surgery due to septic multiorgan failure before the revision of the sternum could be performed (►**Table 3**).

The overall mortality in our high-risk therapy group was 12%, which is high in comparison with a normal patient collective but lower than the predicted mortality for our patient group (19%, EuroSCORE I).

The higher mortality rate in the therapy group compared with the control group (►**Table 3**) is mainly explained by the significantly higher predicted risk profile of this group arising from EuroSCORE I (22.5 vs. 15.4%; $p = 0.026$) and the differences in the baseline characteristics (more urgent and emergent procedures in the therapy group). The actual mortality in both groups was lower than predicted (12 and 8%).

The all-cause reoperation rate was also high (20%; 10/50 patients), which is mainly explained by the risk profile of the patients and the type of surgery. Of the patients, 88% were female, all suffered from osteoporosis, and 48% had insulin-dependent diabetes mellitus. This is the reason why our collective had a high risk of sternal instability and wound infections. Only 44% of the procedures were coronary artery bypass grafting and 56% of the operations were valve or aortic surgery. Consequently, the vast majority (7/10) of reoperations had to be performed because of sternal instability (4/10) and wound disorders (3/10). The remaining reoperations were rethoracotomies for bleeding (2/10) and for pericardial effusion (1/10) (►**Table 4**).

Of these reoperations, there were more which occurred in the control group compared to the therapy group. From the six reoperations in the control group, three had to be performed due to sternal instability. From the four reoperations in the therapy group, only one was due to sternal instability. Of course, the difference was statistically not significant ($p = 0.73$) due to the low patient numbers. Two further patients of each group were reoperated due to wound healing impairment.

Similar to the sternal instability data, the results show that the use of fibrin-coated collagen fleece on the cut surface of the sternum does not increase the risk of reoperation.

Our results lead to a hypothesis change in such a way that the use of fibrin-coated collagen fleece on the cutting surface of the sternum prevents sternal instability and impaired wound healing after median sternotomy in a high-risk population. To confirm this hypothesis, a larger prospective randomized follow-up study is in preparation. The study presented here will be used for calculation of the required number of cases in the study. Besides the benefits for the patients, the economic aspect is also of great interest. The question whether the costs of the fibrin-coated collagen fleece balance the expenses saved on reoperations has to be analyzed. Furthermore, the patient collective who benefits from the treatment with fibrin-coated collagen fleece has to be defined.

Conclusion

Our hypothesis that fibrin-coated collagen fleece impairs sternal stability, wound healing, and the occurrence of wound infections after median sternotomy is not supported by our data. Furthermore, our data show that fibrin-coated collagen fleece could probably even prevent sternal instability and reoperations due to sternal complications. In summary, we could show that fibrin-coated collagen fleece can be used on the cut surface of the sternum for controlling bone bleeding without increasing wound disorders, sternal instability, and mortality. A larger prospective study is necessary to investigate this assumption.

Limitations

Even though both groups were accurately matched, the retrospective, nonrandomized character of the study and the small number of patients are relevant limitations. Due to the retrospective character of the study, there were no bone density measurements available to objectify osteoporosis. Osteoporosis was taken as given, when thinning of sternum and rarefication of cancellous bone was seen intra-operatively in the therapy group and when the diagnosis of osteoporosis was known preoperatively in the control group. In addition, bone healing was not confirmed by computed tomography (CT) scan postoperatively.

There might be a selection bias because the decision regarding the use of fibrin-coated collagen fleece has been made by the surgeon during the operation. However, this bias would have led to inclusion of patients at an even higher risk in the therapy group and more wound healing impairment would have been expected in those patients treated with collagen fleece. Furthermore, as only one surgeon performed all operations, consistency in this decision-making can be assumed.

Conflict of Interest
None declared.

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