

## The Impact of a Microbial Sealant to Reduce Surgical Site Infections in High Risk Cardiac Surgery Patients

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### Abstract

**Introduction:** Post-sternotomy infection is a serious cause for morbidity and mortality after cardiac surgery. The goal of this study was to evaluate the impact of a microbial sealant on post-sternotomy infections in high risk patients undergoing cardiac surgery.

**Methods:** Between January 2006 and July 2008 a total of 291 consecutive patients underwent cardiac surgery with a Fowler score of at least 10, which indicates high risk patients to develop surgical site infection (SSI). Patients were divided into a control group (n=132) receiving standard institutional preoperative care and a microbial sealant group (n=159) received additionally a microbial skin sealant. Pre- and peri-operative characteristics were examined for both groups. The clinical end-point of this study was freedom of post-sternotomy infection.

**Results:** Follow up was 100% completed. The preoperative risk score of the control and the microbial sealant group were similar, respectively  $15.5 \pm 4.0$  and  $15.2 \pm 3.8$  ( $p=0.513$ ). Comparing pre- and peri-operative characteristics of both groups, significant higher rates of carotid artery disease ( $p=0.022$ ) and diabetics ( $p=0.046$ ) were found in the microbial sealant group. All other pre- and peri-operative characteristics were similar for both groups. The clinical end-point however, showed a significant decrease of SSI in the microbial sealant group 2.5% (n=4) versus the control group 7.6% (n=10), ( $p=0.045$ ).

**Conclusions:** This study showed that the additional use of a microbial sealant to standard institutional preoperative preparation reduces statistically significant the risk for surgical site infection in high risk patients undergoing cardiac surgery.

**Keywords:** Surgical site infection; Cardiac surgery; Microbial skin sealant; Infection prevention

### Introduction

Surgical site infection (SSI) is a serious complication after cardiac surgery. The frequency of post-sternotomy infection range between 2% and 15%, associated with increased morbidity and mortality [1,2]. Mortality rates in patients infected with methicillin-resistant *Staphylococcus aureus* (MRSA) are as high as 74% [3]. Mekonto-Dessap et al. [4] examined the mortality rate of patients with post-sternotomy mediastinitis, at 30 days postoperatively, by MRSA and Methicillin-Susceptible *Staphylococcus aureus* respectively, 40% and 15% [4]. In 41 patients reassessed 3 years after surgical treatment, the mortality rates were 74% and 21% respectively. In addition to the destructive impact on individual patients, there is a potential financial impact on treating SSI starting from superficial wound infection, and major mediastinitis can even double the total cost for surgery [5].

Generally an intact skin withstand microbial invasion by cell-mediated immunity as well as antibodies and therefore microorganisms cannot past the keratinized layers of the epidermis. In addition, the relative dryness of the skin limits growth of the "normal" skin flora [6]. There is a complex ecosystem between the microbes, presented on the skin or within the human body, and the total number of host cells. The microbes however far extend the number of host cells. Microorganisms that constitute the normal skin flora include, in addition to *Staphylococcus aureus* and coagulase-negative staphylococci (CoNS) chiefly *Staphylococcus epidermidis*-*Propionibacterium acnes*, gram-negative bacilli, micrococci, and *Corynebacterium spp* [7]. Microbial sealant can decrease the penetration of bacteria into the surgical site during surgery which was proven in several previous studies [8-10].

This study evaluates the effects and contribution of a microbial sealant on high risk patients for SSI after cardiac surgery.

### Patients and Methods

#### Patient selection

High risk patients for SSI in cardiac surgery are patients suffering from obesity (body mass index  $>30$ ), diabetes, age, re-operation, chronic obstructive pulmonary disease, emergency surgery, peripheral or cerebral vessel disease, hypertension, hypercholesterolemia, renal impairment, immunosuppressive treatment, congestive heart failure, cardiogenic shock, decrease left ventricular ejection fraction ( $EF <40\%$ ) [11-17] these clinical predictors for SSI are incorporated in the Fowler score [18], which was initially used for coronary bypass patients. High risk patients were identified as patients with a score above 10 which would predict a probability having a SSI of 3.1%.

A total of 291 adult patients were identified on high risk for SSI

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undergoing on-pump cardiac surgery from January 2006 till July 2008 at the Department of Cardiovascular Surgery of the Charity Hospital, by a single surgeon (PMD). Standard institutional preoperative care was performed in 132 patients (control group) and 159 patients (microbial sealant group) received additionally InteguSeal® (Kimberly Clark Health Care, Atlanta, Georgia, USA).

SSI were registered and recorded at the German Nosocomial Infection Surveillance System (Krankenhaus Infections Surveillance System, KISS) [19]. The participation on this surveillance was approved by the Institutional Board on the Ethics of Clinical Studies. All data were de-identified and accorded to patient pre-, peri- and post-operative data. Pre-operative preparation was standardized [7], as well as peri-operative management was performed as published in the past [20].

## Clinical endpoint

This clinical study end-point was freedom of superficial or deep SSI in accordance with the Centers for Disease Control and Prevention [21]. Superficial SSI was defined as treated with or without vacuum assisted closure (VAC) therapy with closed sternum before discharge and/or readmission within 30 days of surgery. Infection was documented by at least one of the following: 1) purulent drainage, with or without laboratory confirmation, from the superficial incision; 2) organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision; 3) at least one of the following signs of symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, *unless* incision is culture-negative; or 4) diagnosis of superficial incision SSI by the surgeon or attending physician. Deep SSI/mediastinitis was defined as infection of the surgical site treated with VAC therapy before discharge and/or readmission within 30 days of surgery if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operation. Infection was documented by at least one of the following: 1) purulent drainage from a drain that is placed through a stab wound into the organ/space; 2) organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space; 3) an abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathology or radiologic examination; or 4) diagnosis of organ/space SSI by the surgeon or attending physician.

## Statistical Analysis

Data were analyzed using SPSS software (version 13.0; SPSS, Inc., Chicago, IL, USA). Categorical variables were analyzed using Chi-square. Continuous variables were analyzed with Student's t test. A *p*-value of less than 0.05 was considered to be significant on two-tailed testing.

## Results

### Patient selection

The pre-operative SSI risk stratification of Fowler was  $15.2 \pm 3.8$  for the microbial sealant group and  $15.5 \pm 4.0$  for the control group which was statistic not significant different ( $p=0.513$ ). The resulting predicted SSI risk was 6.4% for the microbial sealant group and 6.4% for the control group.

### Patient characteristics

Characteristics of patients receiving microbial sealant pre-

treatment ( $n=159$ ) and controls ( $n=132$ ) are shown in (Table 1). The mean age of the patient-cohort was  $68.6 \pm 10.9$  years (range, 26 to 89 years). In the microbial sealant group there were significantly more patients suffering from diabetes (44.0% vs. 32.6%,  $p=0.046$ ) and highly significant increased number of patients suffered from carotid artery disease (19.5% vs. 9.8%,  $p=0.022$ ) were more common among patients receiving microbial sealant pretreatment than in controls (Table 1). In both groups more than 40% suffered pre-operatively an acute myocardial infarction.

Surgical characteristic showed no differences within both groups on the priority of the procedure performance. In both groups more than 30% of the patients underwent an emergency procedure. The number of patients undergoing coronary bypass surgery were similar presented in both groups respectively 66.7% in the microbial sealant group and 58.3% in the control group ( $p=0.143$ ). The number of anatomizes in both groups were also similar  $2.2 \pm 0.9$  and  $2.2 \pm 0.8$  in the microbial versus control group ( $p=1.000$ ). Surgical details of the surgical procedures are shown in table 2. There were statistically significant

**Table 1:** Pre-, peri-, and postoperative characteristics of patients and surgery. Data are n (%) unless otherwise indicated.

	Microbial skin sealant group (n=159)	Control group (n=132)	<i>p</i> -value
Age (years), mean $\pm$ SD	68.3 $\pm$ 7.7	69.0 $\pm$ 8.6	0.465
<b>Gender</b>			
Male	107 (67.3)	88 (66.7)	
Female	52 (32.7)	44 (33.3)	
Hyperlipidaemia	129 (81.1)	117 (88.6)	0.078
Arterial hypertension	157 (98.7)	131 (99.2)	0.674
COPD	28 (17.6)	34 (25.8)	0.091
Diabetes mellitus	70 (44.0)	43 (32.6)	0.046
Peripheral artery disease	40 (25.2)	33 (25.0)	1.000
Carotid artery disease	31 (19.5)	13 (9.8)	0.022
Cardiovascular accident	22 (13.8)	15 (11.4)	0.528
Renal failure	37 (23.3)	35 (26.5)	0.523
LV ejection fraction, mean $\pm$ SD	42.4 $\pm$ 14.8	42.3 $\pm$ 14.3	0.954
Congestive heart failure	71 (44.7)	49 (37.1)	0.194
Acute myocardial infarction	69 (43.4)	55 (41.7)	0.766
<b>Priority of procedure</b>			
Elective	101 (63.5)	85 (64.4)	0.877
Urgent/emergency	58 (36.5)	47 (35.6)	
<b>Perfusion time</b>			
<100 min	95 (59.7)	75 (56.8)	0.614
$\geq$ 100 min	64 (40.3)	57 (43.2)	

COPD, chronic obstructive pulmonary disease; LV, left ventricular; SD, standard deviation

**Table 2:** Details of surgical procedure.

Variable	microbial sealant group (n=159) n;%	control group (n=132) n;%	<i>p</i> -value
<b>Type of surgery</b>			
CABG	50 (31.4)	35 (26.5)	0.357
Valve procedure	22 (13.8)	38 (28.8)	0.002
Other single procedures	9 (5.7)	5 (3.8)	0.457
CABG + valve procedure	41 (25.8)	31 (23.5)	0.651
Other combined procedures	37 (23.3)	23 (17.4)	0.220
<b>Reoperation</b>			
CABG	10 (7.5)	15 (9.1)	0.214
Valve procedure	14 (10.7)	9 (5.3)	0.532

**Abbreviations:** CABG; coronary artery bypass grafting

more valve procedures performed in the control groups compared with the microbial sealant group (28.8% vs. 13.8%;  $p=0.002$ ). Total concomitant procedures, however were more common performed in the control group compared with the microbial sealant group (88 patients vs. 54 patients,  $p=0.014$ ).

## Incidence of SSI

At the clinical end point of the study, SSI was recorded for 2.5% ( $n=4$ ) of patients in the microbial sealant group compared with 7.6% ( $n=10$ ) in the control group, which was a statistical significant reduction ( $p=0.045$ ) (Figure 1). Moreover, there was a reduction of over 50% of SSI in the microbial sealant treated group compared with the predicted SSI risk based on patient's characteristics noticed which was 6.4%. Microbiological examination showed that all patients were free of MRSA at screening. The microbial group showed 4 patients with SSI, including MSSA ( $n=1$ ), MRSA ( $n=1$ ), *Staph. epidermidis* ( $n=1$ ) and *Enterobacter cloacae* ( $n=1$ ). In the control group there were MSSA ( $n=1$ ), MRSA ( $n=1$ ), *Staph. epidermidis* ( $n=5$ ), *Pseudomonas aeruginosa* ( $n=2$ ) and *Enterococcus faecalis* ( $n=1$ ).

## Discussion

Surgical site infections are the most common hospital acquired infection for patients after surgery which has a morbidity and mortality. The incidence for SSI is depending on the co-morbidity of the patient. Some risk factors can be reduced or optimized, depending if elective surgery is performed. On the other hand surgeons have also the possibility to optimize the operative condition. It has been reported that off-pump coronary bypass surgery can reduce SSI. Sedrakyan et al. [22] showed in a meta-analyzes that wound infections could be reduced by 48% at the same risk as compared with on-pump surgery (RR, 0.52; 95% CI, 0.37 to 0.74). Risk difference analyzes showed 40 SSI prevented per 1000 coronary bypass surgeries with an off-pump approach. Other studies showed the used mammary artery during coronary bypass surgery have superior patency rates of >90% up to 15 years of follow-up [23]. Therefore it is preferred to use the mammary artery if needed both; however, the disadvantage is the reduction of blood supply of the sternum. Therefore a study of Peterson et al. [24] suggested to prepare the mammary artery skeletonized and not as a pedicle. This study showed the reduction of deep SSI in skeletonized mammary artery harvesting were less likely to develop superficial or

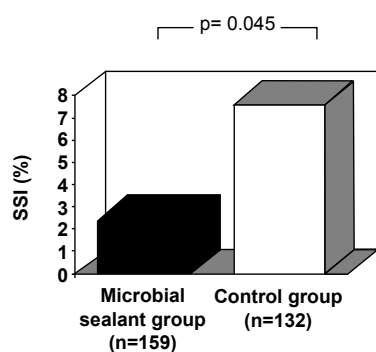
deep sternal wound infection compared with pedicle harvesting (5.1% vs. 22.2%;  $p=0.03$ ).

The incidence of SSI during cardiac surgery accords also to the specific procedure which needs to be performed. Lepelletier et al. [25] studied this influence and showed different SSI risk for patients undergoing coronary artery bypass surgery and valve surgery, respectively 3.9% versus 1.6%. Multivariate analyzes showed that coronary artery bypass grafting with the use of mammary artery was an independent risk factor associated with SSI. This study showed a statistically significant lower rate on patients with valvular procedures in the microbial sealant group compared with the control group, respectively 13.8% and 28.8% ( $p=0.002$ ). Therefore the patients of the microbial sealant group were from the interpretative variable at a high risk to develop SSI. Although the inclusion criteria in this study showed similar risk for SSI, which was developed for coronary bypass surgery patients, this was not recognized in this predictor score.

Sharony et al. [26] showed by performing a partial sternotomy compared with standard full sternotomy also a reduction of mediastinitis respectively, (0/160 vs. 8/337;  $p=0.05$ ). Due to these surgical technique modifications it was possible to reduce SSI. The main source of microbes responsible for SSI is the endogenous flora, which can contaminate the surgical site [7,27]. Therefore new skin tools are investigated to reduce the surgical wound contamination by the endogenous skin flora. In this study we showed in high risk patients to develop SSI a microbial sealant which allows the transient and residual flora no longer to contaminate the surgical site. Although these patients had a high risk to develop a SSI, by including this microbial sealant there was a reduction of up to 70% of SSI in a similar patient population operated at the same hospital with a comparable risk profile. In another study performed by all surgeons of our institute including more than 3,200 patients there were high significant reduction of superficial SSI and mediastinitis seen during follow-up and over years [28].

Waldow et al. [29] studied in a single-centre investigation using two prospective registries to evaluate the prophylactic effect of an antimicrobial sealant on the incidence of mediastinitis. This study however has several limitations as pointed out previously [30]. First of all the title is misleading and incorrect since they found a difference between the microbial sealant and control group for development of SSI, respectively 2.3% and 3.2%. This is statistically not significant however these are different values per se. The study endpoint was 30 days, however CDC guidelines [21] recommend the use of 1 year in case of foreigner body implantation which is generally done in valve surgery or aortic surgery. The number of patients in this study which were only followed for 30 days, instead of 1 year, was almost 50% in both groups, respectively 232/502 in the control group and 238/496 in the microbial sealant group. Therefore the data of this study used at 30 days are not this final data for SSI. The number of mediastinitis in this unselect patient population was for both groups higher as expected in Germany which is today below 1.4% for full sternotomy [31] or 1.1% [32] which is more than double in the study of Waldow. Patient characteristics show also that both patient populations are at lower risk, shown by the limited number of patients with female gender, limited body mass index, limited mammary artery use, especially both mammary arteries in only 2.6% of the patient population. The number of patients in these studies on SSI needs to be much higher to allow significant differences as well as the follow up time should be correct. Therefore the data of this study needs to be carefully studied and have limited impact.

A prospective, randomized, controlled clinical trial of Iyer et al. [33] used a microbial sealant treatment at the donor site of a patient. The



**Figure 1:** Incidence of surgical site infection (SSI) in patients undergoing coronary artery bypass graft surgery who were treated with a microbial sealant group compared with the control group. The incidence of SSI was statistically significantly lower in the microbial sealant group than in the control group (2.5% vs. 7.6%,  $p=0.045$ ).



other donor site of the same patient was the control. After 47 patients were reviewed, the study was stopped, since there was a significant reduction of SSI at the donor site with a microbial sealant (1/47; 2.1%) in contrast with the control group (12/47; 25.5%) ( $p=0.001$ ). This trial demonstrated a serious reduction of the SSI at the donor site, however was not used at the chest.

In conclusion, this study shows due to the use of a microbial skin sealant in cardiac surgery the rate of SSI can be significantly reduced.

## Limitation

Limitations of this study is that this study was not a randomized multi-center study but more a “real world patient collection”, which shows more about daily live situation. The use of patients by a single surgeon it was performed to decrease bias in the patient’s collection, however there is of course another possibility by doing so to create new bias. Both patient groups were different in some characteristics; however the patients in the microbial sealant group were at any time at higher risk to develop SSI. Sufficient randomized studies are needed.

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