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Effect of Three Wound Dressings on Infection, Healing Comfort, and Cost in Patients With Sternotomy Wounds*: A Randomized Trial

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Effect of Three Wound Dressings on Infection, Healing Comfort, and Cost in Patients With Sternotomy Wounds*

A Randomized Trial

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Study objective: To compare three dressing types in terms of their ability to protect against infection and promote healing, patient comfort, and cost-effectiveness.

Design: Prospective, randomized controlled trial.

Setting: Major metropolitan, academically affiliated, tertiary referral center.

Patients: Seven hundred thirty-seven patients were randomized to receive a dry absorbent dressing (n = 243) [Primapore; Smith & Nephew; Sydney, NSW, Australia], a hydrocolloid dressing (n = 267) [Duoderm Thin ConvaTec; Mulgrave, VIC, Australia], or a hydroactive dressing (n = 227) [Opsite; Smith & Nephew] in the operating theater on skin closure.

Results: There was no difference in the rate of wound infection or wound healing between treatment groups. The Primapore dressing was the most comfortable and cost-effective dressing option for the sternotomy wound. Duoderm Thin dressings were associated with increased wound exudate (p < 0.001), poor dressing integrity (p < 0.001), more frequent dressing changes (p < 0.001), more discomfort with removal (p < 0.05), and increased cost (p < 0.001).

Conclusions: In the context of no additional benefit for the prevention of wound infection or the rate of wound healing for any of the three dressing products examined, dry absorbent dressings are the most comfortable and cost-effective products for sternotomy wounds following cardiac surgery.

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Key words: cardiac surgery; sternotomy incision; wound dressing

Abbreviations: CI = confidence interval; LOS = length of stay; SICU = surgical ICU; SWI = sternal wound infection; VAS = visual analog scale

Delayed sternal wound healing and sternal wound infections (SWIs) are a major cause of morbidity and mortality in patients after cardiac surgery. The frequency of this complication is generally low, between 0.7% and 3.3%. However, incidences up to 9.7% have been reported with prolonged post-discharge surveillance. Potential sequelae of infection at this surgical site include wound dehiscence, mediastinitis, pericarditis, osteomyelitis, and endocarditis, with an associated mortality of between 14% and 47%. The specific difficulties associated with the management of sternotomy wounds relate to the location of the incision and the risk of wound contamination and irritation. Endogenous sources of infection include nasal Staphylococcus aureus, vomit, and pulmonary secretions. Environmental sources of infection include endotracheal intubation equipment, monitoring wires, pacing cables, and invasive catheters.

The ideal wound dressing should maintain a moist environment, enable gaseous exchange, protect from secondary infection, allow ongoing assessment, and be comfortable, cost-effective, and able to be removed without causing trauma. The evidence for the relative effectiveness of any dressing type in the context of sternotomy wound healing is at best sparse and contradictory, with very few comparative clinical studies.
trials. Allen compared hydroactive and hydrocolloid dressings to determine their ease of use and effectiveness in terms of patient comfort and ability to accommodate exudate. The dressing that best met these criteria was hydroactive (Opsite Post-Op; Smith & Nephew; Sydney, NSW, Australia). In contrast, Wickblad and Anderson compared a hydrocolloid (Duoderm; Convatec; Mulgrave, VIC, Australia), a hydroactive (Cutinova hydro; Smith & Nephew), and gauze and tape dressing. The hydrocolloid and gauze and tape proved to be similar in terms of wound-healing rate, wound culture results, clinical utility, and patient comfort. The hydroactive dressing, Cutinova hydro, was the least effective. The authors recommended gauze and tape as the dressing of choice in relation to cost, comfort, and ease of assessment. Research examining the effectiveness of dressing products for surgical incisional sites other than the sternum has focused on patient reports of pain, comfort, and wound infection. These studies have, however, been limited by small sample size, quasi-experimental design, poorly defined outcomes, and dressing protocols.

Guidelines for the prevention of surgical site infection recommend closed surgical wounds be covered for 24 to 48 h. At this time, hemostasis is achieved and a fibrin scab formed to seal the wound. The impact of incisional wound management protocols on sternotomy healing and subsequent infection, however, is not clear. The absence of empirical evidence to demonstrate the effectiveness of one dressing over another together with low infection incidence has resulted in high variability in the types of dressings used in this context and a low priority in seeking to determine the best approach to sternotomy wound management on the trajectory of wound outcomes. The aim of this study was to determine the most effective dressing protocol for median sternotomy wounds following cardiac surgery by addressing the following question: Is there a difference in rate of healing, infection, reports of comfort, and cost for patients with dry absorbent (Primapore; Smith & Nephew), hydroactive (Opsite; Smith & Nephew), or hydrocolloid (Duoderm Thin; Convatec) dressings?

**Materials and Methods**

**Sample and Setting**

From September 1999 to November 2001, consecutive patients undergoing cardiac surgery who required a median sternotomy incision in a major metropolitan teaching hospital in Melbourne, Australia, were invited to participate in the study. Patients were excluded from the study if they were unable to provide written consent, were immunosuppressed, or were under the care of one surgeon who did not wish to have his patient participate in the study. Approvals for the conduct of this study were obtained from the relevant ethics, scientific, and research committees at the hospital and University.

**Research Design**

A prospective, randomized study was designed to compare the incidence of infection and rate of healing of the sternotomy incision, along with patient comfort and cost for each dressing type. Randomization was stratified equally across two operating theaters and was achieved using opaque envelopes. Patients were randomly assigned to one of three treatment groups by the circulating nurse on the commencement of sternal skin closure. Dressing protocols for each group adhered to customary clinical practice in the study setting. The dry, absorbent dressing group received the Primaore dressing, which was removed on postoperative day 2. Once the wound dressing was removed, the wound was cleansed with normal saline solution and left exposed. The hydrocolloid (Duoderm Thin) group and the hydroactive (Opsite) group dressings remained in situ until postoperative day 5, the expected day of hospital discharge. In the presence of continued exudate, patients in the dry absorbent group had their dressings replaced with gauze and tape. Patients in the hydrocolloid (Duoderm Thin) or hydroactive (Opsite) dressing groups with continued exudate on day 5 had their wounds assessed and dressed according to their surgeon’s request.

**Procedure**

Consecutive, eligible patients were asked to consent to the study by the cardiothoracic resident medical officer during the presurgery assessment. Patients were transferred directly from the operating theater to the surgical ICU (SICU) with a copy of the appropriate color-coded dressing protocol and an information sheet in the front cover of their medical record. Demographic data for both participating and nonparticipating patients was collected on the operative day (day 0) on admission to the SICU. From postoperative day 1 to day 5, daily data collection and wound assessment were conducted at 3 PM. When stable, patients were transferred from the SICU directly to the cardiothoracic ward. To ensure adherence to the study protocol by nurses caring for enrolled patients, information sessions were conducted at regular intervals for the duration of the study for staff in the operating theaters, preadmission clinic and ward, the SICU, and the cardiothoracic ward. Patients were followed up either through the outpatient department or telephone survey approximately 4 weeks after discharge from the hospital.

**Measurement**

The sternotomy wound survey devised by the research team was completed for all enrolled patients. The instrument had three sections. Section 1 elicited prerandomization patient information, demographic data, and medical and operative information. Section 2 contained end point measures, and section 3 elicited follow-up information. At follow-up, patients were questioned concerning their experience with pain, tenderness, redness, swelling, discharge or ooze from the chest wound; and whether they had sought medical attention or had antibiotic therapy initiated by their local doctor.

**Outcome Measures**

SWI. SWI was classified according to the guidelines provided by the Centers for Disease Control and Prevention. SWIs were...
either superficial, involving skin and subcutaneous tissues, or deep, involving muscle, bone and/or mediastinum, in conjunction with one of the following: excision of wound tissue, a positive wound culture finding, or treatment with antibiotics.\textsuperscript{15} Diagnosis of surgical site infection for cardiothoracic patients was the responsibility of the cardiothoracic unit registrar. Weekly reports were submitted to the cardiothoracic unit database coordinator. In addition, the medical team and nursing unit manager conducted a monthly audit of patient-related complications. Unit data were cross-checked with the infection control database of the hospital to ensure correct patient identification. Potential indicators of wound infection, exudate, and dressing integrity were measured daily. Exudate comprised four categories: purulent, blood, hemoserous, or serous. Exudate was swabbed for microscopy if present beyond the first 48 postoperative hours or earlier if infection was suspected. Dressing integrity included three categories: suture line exposed, poorly sealed (imperfect covering of the suture line with the potential for organism entry), or well sealed.

**Wound Healing:** Wound healing was measured by assessing both wound approximation and skin integrity. Approximation had four categories: total, partial (<2 cm of superficial separation), moderate (>2 cm of superficial separation), and dehiscence (complete separation of layers). Surrounding skin integrity had three categories: normal (pink, no redness), inflamed (heat, redness, swelling), or macerated within a 2.5-cm border of the incision. The presence or absence of necrotic tissue was also noted.

**Patient Comfort:** Four 10-cm visual analog scales (VASs) were used to measure perceptions of dressing awareness, movement limitation, comfort with dressing changes, and overall satisfaction. The VAS had three anchors, at 0 cm, 5 cm, and 10 cm.

**Cost:** Cost calculations represent the number of dressings required for each treatment group as determined by the frequency of required dressing changes and cost per dressing.

**Data Collection**

Blinding of data collectors to treatment was not feasible, as six clinical nurses from the cardiothoracic ward were responsible for data collection from patient admission to follow-up. Interrater reliability between data collectors was established by repeated observation of 10 patient wounds. The initial agreement between data collectors was 80% for exudate detection, 90% for approximation, and 100% for surrounding skin integrity. This procedure was repeated with 10 new patient wounds until there was 100% agreement between all data collectors. Both interrater and intrarater reliability checks were conducted at regular intervals for the duration of the study. Margolis et al.\textsuperscript{16} studied the sensitivity and specificity of interobserver agreement in the context of healed chronic wounds, by untrained observers, and found interobserver reliability was 0.68 (95% confidence interval [CI], 0.66 to 0.70), sensitivity was 0.84 (95% CI, 0.81 to 0.90), and specificity was 0.92 (95% CI, 0.85 to 0.97). They concluded that the reliability and validity of judgments of wound healing were satisfactory, permitting the use of observation in clinical investigations.

**Data Analysis**

All analyses were performed on the basis of intention to treat. Differences in categorical variables were compared using the \( \chi^2 \) test. Continuous variables were compared using the \( t \) test for independent samples (two-tailed). Where distributions were skewed and logarithmic transformations did not increase normality, nonparametric tests—the Mann-Whitney \( U \) test and the Kruskal-Wallis test—were performed. Consequently, medians are reported instead of means, and the measures of dispersion are the 25th and 75th percentile ranks of the distribution; \( p < 0.05 \) was considered statistically significant. Power analysis to calculate sample size was based on wound healing, as the incidence of sternal wound infection at the participating hospital was 3.1% between 1996 and 1997. Wikblad and Anderson\textsuperscript{12} found a 30% incidence of partially healed sternotomy incisions in 169 patients. We chose to adopt a more conservative approach and anticipated a 15% difference in healing rate. To detect this based on a significance criterion of 0.05 confidence and power of 90%, a total of 174 patients were required for each treatment group. The data were analyzed using statistical software (SPSS Version 10.1; SPSS, Chicago, IL).

**Results**

From September 1999 to November 2001, 1,197 patients underwent cardiac surgery and 737 patients (61.6%) were recruited into the study. Reasons for exclusion were patient refusal to enter the study (\( n = 18, 3.9\% \)), inability of patients to understand the implications of the study (\( n = 21, 4.6\% \)), inability or insufficient time to obtain patient consent before the procedure (\( n = 302, 65.6\% \)), and the patients’ surgeon not participating in the study (\( n = 119, 25.9\% \)). Differences in baseline characteristics demonstrated that nonparticipating patients (\( n = 460 \)) were younger (64.5 ± 11.7 years vs 66.1 ± 10.8 years; \( p < 0.05 \)) [mean ± SD], more likely to be smoking on hospital admission (\( n = 51, 11.1\% \) vs \( n = 57, 7.7\%; p < 0.05 \)), and had a greater incidence of pre-existing renal impairment (\( n = 40, 8.7\% \) vs \( n = 46, 6.2\%; p < 0.05 \)) than participants (\( n = 737 \)). This suggests these patients had higher preoperative acuity and tended to bypass the preadmission clinic.

Two hundred forty-three patients (33%) were randomized to the dry absorbent dressing (Primapore), 227 patients (30.8%) to the hydroactive dressing (Opsite), and 267 patients (36.2%) to the hydrocolloid dressing (Duoderm Thin). The prerandomization and operative characteristics of patients allocated to the three treatment groups are shown in Tables 1, 2, respectively. End point measures are shown as means with SD, or frequencies and percentages in Table 3. Relevant between day differences will be discussed.

**Wound Infection**

There were 21 patients (2.9%) with SWIs, and there was no difference in incidence associated with any particular treatment group. Patients with SWIs had an increased incidence of preoperative steroid use (\( p = 0.001 \)), sternal mobility (\( p = 0.006 \)), inflammation (\( p = 0.001 \)), and exudate (\( p = 0.001 \)), and required more frequent dressing changes (\( p = 0.006 \)). Patients in the Primapore dressing...
group were least likely to have an exuding wound. The presence of exudate during day 1 to day 5 was associated with poorly sealed dressings (p = 0.001).

During the study, 219 dressings on 151 patients (20.5%) sealed inadequately.

The median preoperative length of stay (LOS) for patients with an SWI was 1 day (range, 0 to 6 days), compared to a median of 1 day (range, 0 to 2 days) for patients without an SWI (p = 0.013). The median postoperative LOS was 7 days for patients without an SWI (range, 5 to 8 days), compared with a median of 11 days for patients with an SWI (range, 7.75 to 19.5 days; p = 0.001).

Wound Healing

One patient in each dressing group did not have total wound approximation by day 5. An obese elderly patient (0.1%) presented with a superficial separation of the distal 3 cm of the sternal suture line on postoperative day 5. This patient, randomized to the Primapore dressing group, was smoking just...
prior to hospital admission for coronary artery bypass graft surgery, had a mobile sternum, and type II diet-controlled diabetes. There was a slight hemose-rous exudate, and the suture line was approximated and reinforced with Steristrips 3M Health Care; Thornleigh, NSW, Australia) and a dry dressing. A superficial sternal wound infection was diagnosed, treated with antibiotics, and resolved by follow-up. Seven patients (0.9%) had a 2-cm partial separation of the layers of their sternal wound suture line during days 1 to 5 that was not associated with dressing type. At follow-up, six of these wounds were healed and one patient treated with Opsite dressing had a deep SWI.

Surrounding skin integrity was normal in >90% of patient wounds in each dressing group. Wound inflammation was most frequently detected on postoperative days 3, 4, and 5 in 8 patients (1.1%), 7 patients (0.9%), and 15 patients (2.0%), respectively. No necrotic tissue was identified on any patient wounds.

**Patient Comfort**

The comfort measure comprised patient reports of dressing awareness, movement limitation, comfort with removal, and level of satisfaction. Mean scores from days 1 to 5 inclusive revealed the majority of patients in all groups were not aware of their dressing, did not find the dressing limited their ability to move, and were very satisfied with the dressing they had received. Since the dry absorbent group had their dressings removed on the second postoperative day, specific comparisons of patient comfort were focused on day 1 and day 2 data. On postoperative day 2, patients found the Opsite dressing impacted on their ability to move without feeling limited (p = 0.04). When a dressing change was required on postoperative day 1, patients in the Duoderm Thin dressing group were more uncomfortable (p = 0.038) than those with Primapore or Opsite dressings. Despite this discomfort, patients with a Duoderm Thin dressing were more satisfied with their dressing on postoperative days 1 (p = 0.027) and 2 (p = 0.022).

**Cost**

The standard available dressings used to obtain adequate coverage of the sternal suture line were an 8 × 20-cm Primapore dressing costing AU$ 0.52, a 6 × 20-cm Duoderm Thin dressing costing...
AU$ 3.93, and an 8 × 20-cm Opsite dressing costing AU$ 1.59. Duoderm Thin was the most expensive dressing product, with a median cost of AU$ 3.93 (range, AU$ 3.93 to AU$ 7.86). Dressing cost was calculated according to the number of dressings patients required by day 5. Dressings were changed if poorly sealed before day 2 for patients treated with the Primapore dressing or before day 5 for patients treated with either Duoderm Thin or Opsite dressings. The number of dressing changes patients required was associated with the presence of exudate (p = 0.001). As expected, patients with poorly sealed dressings had their dressing changed more frequently (p = 0.001) after surgery. The frequency of dressing changes and associated costs for each treatment group are summarized in Table 3. The most expensive dressing overall was Duoderm Thin, representing both the higher initial cost of the dressing and the high number of patients requiring replacement dressings in the 5 postoperative days (49.8%) when compared to the Opsite group (28.8%).

Follow-up

Eighty-six percent (n = 632) of the randomized patients were available for interview after being discharged from hospital. Of those patients unavailable for follow-up, 52 patients (7.1%) were followed up as private patients in the surgeons’ rooms, 3 patients (0.4%) were transferred to another hospital, 4 patients (0.5%) had died as inpatients, and 44 patients (6.0%) did not attend their follow-up appointment. Time to follow-up was calculated from the day of surgery to the day of follow-up interview (median, 37.0 days; range, 33 to 47 days). The median time between surgery and discharge from hospital for the total sample was 7.0 days (range, 5 to 8.5 days). At follow-up, 578 patient wounds were healed (91.5%) and 54 wounds (8.5%) were not. Of the 54 patients (8.5%) who did not have a healed sternal wound at follow-up, 10 patients (18.5%) had received diagnoses of deep SWIs while inpatients. There were no differences between treatment groups in the frequency of unhealed wounds at follow-up (Primapore, n = 14, 30.4%; Duoderm Thin, n = 16, 34.8%; Opsite, n = 16, 34.8%).

Discussion

There were no differences in the rate of SWI or healing between treatment groups in this study. The majority of patients were not aware of their wound dressing, did not feel their movement was limited by their dressing, and were very satisfied with the dressing they had received. Patients reported the least discomfort with dressing removal when treated with a dry absorbent dressing, and this dressing type was also the most cost-effective.

Overall, the incidence of wound infection was low (2.9%), and 52% of the wound infections were superficial wound infections. Approximately 95% of patients had complete wound approximation, and > 90% had uncompromised surrounding skin integrity in the first 5 days after surgery, regardless of dressing type. Findings of previous studies have also demonstrated little variation in dressing effectiveness in relation to infection and healing.11–17,19 In the context of incisional wounds, highlighting the important role of operative wound closure in instigating primary tissue repair and wound healing.20 The inability to demonstrate specific dressing effectiveness is related to the nature of the wound itself, where healing is taking place by primary intention.17 The purpose of surgical wound closure is to protect underlying structures from contamination and infection. Dressing products placed over surgical incisions aim to stimulate superficial epithelialization and should be cost-effective.19 It is of note that 48% of wound infections were deep infections that are more likely to be associated with preoperative and intraoperative factors rather than specific dressing.

This study combined direct observation and the Center for Disease Control and Prevention6 indicators to diagnose sternal wound infection. Although the overall incidence of infection was low, the study trends reveal the repeated cycle of inflammation, exudate, and poor dressing integrity for patients treated with products that aim to maintain occlusion. It was not possible to determine associations between SWI and dressing application techniques and frequent dressing changes. It is quite possible that the development of superficial SWI may be associated with compromised wound integrity following repeated removal and reaplication of dressings. In addition, infection may occur as a result of suboptimal aseptic technique. Controlled clinical studies that evaluate the impact of dressing application techniques on wound healing and infection are recommended.

Limitations

When treated with Primapore dressings, patients experienced the least discomfort with dressing removal and were most satisfied with the wound dressing. Patients were more aware of Opsite dressing, which they believed limited their movement. Why patients treated with Duoderm Thin dressings were more satisfied with their dressing on days 1 and 2, in the context of more frequent dressing changes, is difficult to explain. The reliability of VASs used to measure dressing comfort has not been tested and in
this setting may not have been adequately sensitive to variations in comfort. Interestingly, many patients also commented that since they had not experienced other dressing products, they did not have a point of reference to make judgments about their level of satisfaction with a particular dressing. The Duoderm Thin dressing is tinted to resemble the skin, and perhaps greater satisfaction was associated with its subtlety and greater esthetic appeal. Barnes claimed patient satisfaction increases with a reduction in visibility of the wound and wound dressing.

Data were only collected for the first 5 postoperative days, where the day of surgery was day 0. This time interval was selected because routine patients are generally independent and preparing for discharge on postoperative day 5. Given the late presentation of wound infection, it may have been useful to continue data collection until and beyond patient discharge. However, the median presentation time of wound infection (38.5 days; range, 34 to 43 days) was after patients were discharged from the hospital and also exceeded time to follow-up as recommended by the Centers for Disease Control and Prevention.

Clinical Implications and Conclusions

Enhancement of postoperative incisional wound healing is a nursing priority regardless of the surgical procedure. In the context of cardiac surgery, however, the morbidity and mortality associated with sternal wound infection emphasizes the importance of wound management practices that are based on the best available evidence. Despite the abundance of wound dressing products available, there is little empiric evidence to guide product choice for site-specific incisional wounds. Hydrocolloid dressings are promoted for use in chronic wounds; while this does not exclude them from use on surgical incisions, their specific properties may not provide the optimal environment for healing in this situation. In the context of no additional benefit for the prevention of wound infection or the rate of wound healing for any of the three dressing products examined, dry absorbent dressings are the most comfortable and cost-effective dressing product for the sternotomy wound following cardiac surgery.

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References

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