

# A Prospective Two-armed Trial Assessing the Efficacy and Performance of a Silver Dressing Used Postoperatively on High-risk, Clean Surgical Wounds

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## Abstract

Surgical site infections (SSI) are a known complication of surgery. Silver-containing wound treatments are popular, despite the lack of evidence of SSI reduction. A two-armed study was conducted between July 2007 and November 2008 to evaluate the efficacy and ease of use of a postoperative silver dressing. In the first arm of the study, patients undergoing clean general, vascular, orthopedic, and neurosurgical procedures were allocated to receive a postoperative silver dressing (POSD) or a standard dressing of nonstick gauze under a fluid occlusive dressing. Outcome variables included the incidence of antibiotic initiation for SSI, clinical signs of infection, and leukocyte counts. The second arm of the study was a prospective case series designed to evaluate the performance and handling characteristics of the POSD. One-hundred-ninety-nine (199) patients (mean age 59.2 [range 21–94] years) were enrolled in the first arm of the study. Three out of 99 (3%) patients in the POSD and six out of 100 (6%) control group patients received antibiotic therapy for SSI ( $P = 0.498$ ). Differences in the percentage of patients with clinical signs of infection following surgery also were not statistically significant (POSD:  $n = 24$ , 24.2%; control:  $n = 30$ , 30%;  $P = 0.426$ ). In the second arm, 34 out of 36 patients rated the study dressing easy to apply in (94%), and no pain on removal was noted in 38 out of 57 (66.7%) assessments. No patients in the dressing performance cohort developed an SSI. Prospective, randomized, controlled clinical studies with large sample sizes are warranted to evaluate the efficacy and cost-effectiveness of the POSD.

**Keywords:** clinical study, surgical site infection, dressings, silver dressing

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More than 30 million surgeries are performed in the United States every year.<sup>1</sup> The incidence of hospital-associated infections is 1.7 million, with surgical site infections (SSI) comprising approximately 20% of these cases.<sup>2–4</sup> SSI are a particular concern and a noteworthy cause of morbidity and mortality. One study estimated 14% to 16% of annual hospital-associated infections can be attributed to SSI, with only urinary tract infections reported more frequently.<sup>3–6</sup> SSIs are a particular focus of

quality improvement initiatives given their substantial role in postoperative morbidity and mortality.<sup>7,8</sup>

Data from the Study on the Efficacy of Nosocomial Infection Control (SENIC) and National Nosocomial Infections Surveillance system (NNIS) show the annual cost for SSI in 1998 was estimated to be more than \$1.6 billion<sup>9,10</sup>; more recently, SSIs were recognized to potentially cost upward of \$3.5 billion in the United States, demonstrating the ever-increasing cost of medical care is further exacerbated by the

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cost of complications that can follow interventions.<sup>11</sup> These costs are often the result of prolonged hospital stays (postoperative site infection can double the length of stay in surgical patient populations) and prolonged treatment with intravenous antibiotics.<sup>9,12,13</sup> A recent multicenter, retrospective, matched case-control study<sup>14</sup> of almost 500 patients showed development of a SSI after abdominal surgery can double the length of stay and increase healthcare expenditures 2.5-fold.

One proposed solution to the rate of postsurgical infections is to change management of the wound in the perioperative period. A Cochrane review<sup>15</sup> published in 2004, examining preoperative antiseptic skin solutions, revealed the heterogeneity of the studies rendered it impossible to conclude results in efficacy and SSI prevention. Currently, no care recommendation for the incision exists past this point. The 1999 Centers for Disease Control and Prevention (CDC) guidelines<sup>6</sup> recommend covering a surgical wound with sterile dressing for 24 to 48 hours postsurgery.

Dressings and topical agents containing silver have been used for decades for their antimicrobial properties. One *in vitro* study<sup>16</sup> that examined silver delivery via nanoparticles embedded on a dressing demonstrated silver can safely be used as a wound dressing. Childress et al<sup>17</sup> showed in a matched control cohort study on patients undergoing clean, lower extremity revascularization procedures that silver dressings significantly decreased the incidence of cellulitis and antibiotic use ( $P = 0.016$ ). Using prospective, controlled studies, Fong et al<sup>18</sup> and Percival et al<sup>19</sup> showed silver dressings successfully reduced clinical SSI and wound bacterial rates, respectively. Fong<sup>18</sup> demonstrated silver to be effective *in vivo* in a controlled trial where one group of burn patients received “standard therapy” (in this case, chlorhexidine washes) and the other received an application of silver dressing daily. Although it was a relatively small trial (70 patients), the results showed patients using the silver dressing had a shorter length of stay and a decreased incidence of infection and antibiotic use (55% and 57% versus 10.5% and 5.2%, respectively). Percival et al’s<sup>19</sup> *in vitro* study showed silver alginate significantly decreased the growth of methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *Enterococci* (VRE), and *Candida*.

Acticoat Post-op (Smith & Nephew Wound Management Inc, St Petersburg, FL) is an immediate postoperative silver dressing (IPOS) (per package insert). The dressing consists of a nanocrystalline, silver-coated polyurethane layer; a white polyurethane foam pad; and an adhesive-coated, waterproof polyurethane film layer composite. The composite dressing is designed to act as an antimicrobial to the bioburden that may exist in the wound and to provide a barrier to external penetration by bacteria; it enables the wearer to shower and bathe normally. The dressing also is designed to conform well to the skin surface, be comfortable to the wearer, and maintain a moist wound environment. The 15- to 20-nm silver nanocrystals are manufactured to undergo extended release,

### Key Points

- The authors compared the use of a silver-containing postoperative dressing to a gauze-based dressing in 199 patients undergoing a variety of clean surgical procedures.
- In a second, noncontrolled study, dressing usage characteristics were evaluated.
- No significant differences between the two dressings in clinical signs of infection or antibiotic initiation for surgical site infection were observed.
- The majority of patients rated the dressing as comfortable.
- Controlled clinical studies with large sample sizes are needed to further evaluate the efficacy and cost-effectiveness of this silver-containing postoperative dressing.

and the dressing provides a large surface area for antimicrobial activity.<sup>20-22</sup>

The purpose of this two-armed study was to evaluate the effect of a postoperative silver dressing (POSD). The first arm of the study was a prospective, controlled, single-center study to compare the use of a POSD to use of nonadherent gauze and a moisture-occlusive outer dressing. The second arm of the study was a descriptive, multicenter study to evaluate performance and acceptability in terms of comfort, dressing conformability, ease of application and removal, associated pain, fluid retention, management of exudate and secretions, and POSD durability using a similarly defined but separate patient population deemed high risk for developing an SSI following primary closure in clean surgical procedures.

### Methods

Both studies were conducted between July 2007 and November 2008. Approval to conduct the studies was obtained from St. Luke’s-Roosevelt Hospital’s Institutional Review Board. Patients were informed about the study by an investigator or subinvestigator involved in the study before operation, and consent forms were signed at this time.

#### First arm.

**Setting and patients.** The first arm of the study was conducted at a tertiary care medical center. Patients who were at least 18 years of age, scheduled for an NNIS-defined clean surgical procedure, and deemed at high risk for SSI<sup>3,22-25</sup> were eligible for inclusion in the study, including patients undergoing vascular, general, orthopedic, plastic, and neurosurgical procedures. “High risk” was defined by patients’ demographic characteristics and medical history, including patients with long leg incisions, diabetes mellitus, obesity, and implanted foreign bodies such as mesh or hardware. Exclusion criteria included patients who were pregnant,

had signs of local infection at the planned surgical site during enrollment, undergoing treatment with systemic antibiotics for a systemic infection, or had a known sensitivity to any evaluation product or to silver products. Using systematic probability sampling, patients were alternately assigned to be managed with the POSD or control dressing. As on many days, multiple patients were randomized — every other patient randomized sequentially to one or the other group.

**Procedure.** All participants underwent preoperative sterile skin preparation with povidone iodine solution per the standard protocol at the authors' institution during the time of the study. All patients received intravenous Gram-positive antibiotic coverage within 1 hour of incision per the preoperative protocol. The closure of individual incision sites (sutures or staples) was not standardized but performed according to standard local protocol and as determined by the operating surgeon. The POSD or control dressing then was applied. The POSD was applied in accordance with the manufacturer's instructions. Participants were evaluated in the hospital for up to 7 days postoperatively.

**Study variables.** Basic patient information and medical history were obtained preoperatively by the operating surgeon and his/her associates. Patients were followed for their hospital course, and hospital charts were maintained. Any event with documentation involving signs of wound infection or problems with the patient during the course of hospitalization and follow-up visits was recorded. The postoperative time course was at the schedule of the primary surgeon. Postoperatively, wounds were assessed by staff members conducting the study for any signs of infection using an ordinal (present/not present) scale, including erythema, edema, drainage, tenderness, and increased temperature. Readmission for SSI was monitored by aggressive outpatient follow-up (see Results).

The **primary endpoint** was the administration of oral or parenteral antibiotics prescribed for clinical diagnosis of infection of the target wound. The provision of antibiotics for unrelated infections (such as for a urinary tract infection or pneumonia) was recorded but not considered an outcome variable. **Secondary endpoints** included clinical signs of infection (which may or may not have prompted initiation of antibiotics) and leukocyte count ( $WBC > 12,000$ ). Clinical signs of infection at the wound site included increased edema, erythema, necrotic debris, delayed healing, pain/tenderness, increased serous or purulent exudate, change in color of the wound bed, the presence of friable or abnormal granulation tissue, pus, and malodor.<sup>6,26</sup>

#### Second arm.

**Dressing performance and handling.** The second arm of the study was conducted at three different centers among patients admitted to the hospital postoperatively and was designed to evaluate the performance and handling characteristics of the POSD during typical postoperative use. All patients deemed eligible to participate were considered

using the same inclusion criteria described previously, using convenience sampling over a fixed (1 week) period of time.

The POSD was allowed to remain in place for up to 7 days postoperatively or removed earlier if clinically needed or required by the local hospital protocol. Because this was a subjective "ease-of-use study," no specific wound variables were recorded. Dressing performance and handling were assessed at each postoperative visit: patients and physicians were asked to rate comfort, dressing conformability, ease of application and removal, associated pain, fluid retention, management of exudate and secretions, and durability using a five-point ordinal rating scale where 1 = not acceptable and 5 = excellent.

The standard study period was 3 weeks or six dressing changes, whichever came first. Evaluation was terminated sooner if the surgical incision closed or if a dressing was no longer required. Patients were seen in the physician's office after discharge from the hospital, and the mean number of days from hospital discharge to follow-up visit was recorded in the clinical research form (CRF). All data were recorded in hard copy CRFs as well as the patient's charts (as source documents). Adverse events and device problems were recorded as they occurred.

#### Data analyses.

**Statistical considerations for controlled study.** A study sample size of 200 patients was based on an estimated control primary endpoint rate in high-risk populations of 25%.<sup>27,28</sup> The authors anticipated a 15% absolute (60% relative) wound complication rate reduction based upon previously published data with a similar dressing.<sup>17</sup> The study was powered to 0.8, with an alpha of 0.05. The control event rate was presumed to be 0.25, with a treatment event rate of 0.15. This was a single-center study that used the higher utilization postoperative antibiotic threshold as a primary endpoint.<sup>29</sup> The sampling interval randomization occurred independently for each type of surgical procedure (ie, general-vascular, neurosurgery, and orthopedic surgery).

All significance tests were two-sided. *P* values are quoted, and 95% confidence intervals were generated where appropriate. The data were analyzed as an intent-to-treat analysis with the set defined as all patients who underwent a clean surgical procedure.

The following outcomes were analyzed by the above method utilizing SAS package 9.1 (Cary, NC): initiation of postoperative antibiotics for target wound, signs of clinical infection, surgical incision site closure, hospital readmission for SSI, total additional length of stay resulting from a SSI over all follow-up assessments, total number of dressings applied by dressing type, and size summed over all assessments.

Fisher's exact test was used to test for a difference in the primary and secondary analyses between patients that received POSD versus control, as well as to test for a difference in the rate of surgical site closure between the POSD and control.

**Table 1. Patient characteristics**

Patient details	Silver dressing n (%)	Control dressing n (%)	Total n (%)
Male	51 (51.5%)	43 (43%)	94 (47.2%)
Female	48 (48.5%)	57 (57%)	105 (52.8%)
Age (mean)	59.9	58.4	59.2
Caucasian	49 (49.5%)	49 (49.5%)	98 (49.5%)
Black	34 (34.3%)	30 (30.3%)	64 (32.3%)
Hispanic	14 (14.1%)	18 (18.2%)	32 (16.2%)
Asian	2 (2%)	2 (2%)	4 (2%)

**Table 2. Dressing use in surgical procedures**

Surgical procedure	DRESSING		Total n (%)
	Silver dressing n (%)	Control dressing n (%)	
General-Vascular	14 (14.1%)	18 (18%)	32 (16.1%)
Neurosurgery	36 (36.4%)	33 (33%)	69 (34.7%)
Orthopedic	49 (49.5%)	49 (49%)	98 (49.2%)
Overall	99 (100%)	100 (100%)	199 (100%)

Adverse events were stratified as adverse event, serious adverse event, investigational device-related adverse event, serious investigational device-related adverse event, unanticipated adverse event, or a serious unanticipated event.

*First arm.* In addition to the statistical considerations stated, the sampling interval was 1:1 regardless of the type of surgical procedure. All patients were hospitalized postoperatively and all had a minimum of two in-hospital postoperative dressing-wound analyses. For analysis purposes, the surgical procedures were stratified into categories. General and vascular surgery procedures are grouped together because the procedures were performed by the same surgeon. Daily blood draws allowed examination of leukocyte count; any count above 12,000 was noted as significant and a potential sign of active infection.

*Second arm.* Data from all patients who underwent a postoperative assessment and at least one POSD application were

included in the analysis. Because this arm was noncomparative, no statistical application was employed in its analysis.

## Results

**First arm.** The first arm of the study included 199 patients, mean age 59.2 (range 21–94) years, 105 (53%) female. Of those, 99 received the POSD and 100 received the control dressing. Participants identified themselves as Caucasian (98, 50%), Black (64, 32%), Hispanic (32, 16%), and Asian (4, 2%). No statistical differences were found between the two dressing groups with respect to demographic and baseline variables (see Table 1). Surgical procedures included 32 general-vascular, 69 neurosurgical, and 98 orthopedic cases (see Table 2). All 199 patients received appropriate preoperative prophylactic antibiotics.

Forty-nine percent (49%) of participants in both groups had their wounds closed with sutures. Other methods of closure included surgical staples in both arms of the study. Ten patients (10, 5%) were lost to long-term follow-up after discharge. However, because the primary endpoint was initiation of postoperative antibiotics in the hospital setting, all patients were included in analysis because they all had a minimum of two data points available. No statistically significant difference was found between the percentage of patients receiving antibiotic therapy in the POSD (3%) compared to the control dressing (6%) groups (95% CI -16.7 - 7.1%,  $P = 0.498$ ) (see Table 3).

No significant differences in the percentage of patients with clinical signs of infection following surgery were seen between the POSD (24, 24.2%) and control (30, 30%) dressing groups ( $P = 0.426$ ). Interestingly, this demonstrated that not every patient who showed clinical signs of infection was prescribed intravenous antibiotics (3% in IPSOD group and 6% in SOC group). Pre-discharge leukocyte counts were similar between the two dressing groups; 21.6% of patients in the group POSD had a leukocyte count  $>10.8$  k/uL, while 24% of patients in the control group had a leukocyte count  $>10.8$  k/uL.

The average patient follow-up time was 7 (range 3–14) days for both groups. Two patients (2%) in the control dressing group were readmitted to hospital due to a SSI, both of whom required an additional procedure. No patients in the POSD were readmitted to the hospital or required an additional procedure due to a SSI. The average number of dressings used during hospitalization was 2.6

**Table 3. Incidence of intravenous antibiotic administration**

Surgical Procedure	Antibiotic use: silver dressing group n (%)	Antibiotic use: control dressing group n (%)	Total n (%)
General-Vascular	0/14 (0%)	2/18 (11.1%)	2/32 (6.3%)
Neurosurgery	0/36 (0%)	1/33 (3%)	1/69 (1.4%)
Orthopedic	3/49 (6.1%)	3/49 (4.9%)	6/98 (5.1%)
Overall	3/99 (3%)	6/100 (6%)	9/199 (4.5%)



(SD 1.3) POSD versus 3.1 (SD 2.0) in the control group (not significant—ns), and the mean length of stay for the POSD group was 7.6 days (SD 4.5) compared to 8.1 days (SD 4.9) for the control group (ns).

**Second arm.** The second arm of the study evaluated the performance and handling characteristics of the POSD dressing. POSD was applied to 36 patients in a nonrandomized prospective fashion. The participants' median age was 51.5 (range 30–85) years; 24 (67%) were female. In this arm, the majority of patients (31, 86%) were treated as outpatients. Seventeen patients (47%) underwent cardiovascular surgery, 10 (28%) had plastic surgery, five (14%) underwent orthopedic surgery, and four (11%) underwent various other procedures. Twenty-five patients (69%) completed the study and no longer required the POSD due to appropriate incision healing, five (14%) were discharged from hospital without complete closure of the surgical incision, and six (17%) were withdrawn early from the study. Of the six participants withdrawn from the study, three missed their follow-up assessment, two did not keep the POSD in place for at least 3 days, and one was unable to obtain a POSD due to a supply shortage at the treating center and therefore had to rely on an alternate dressing.

Following the initial postsurgical assessment, 32 patients (89%) received at least one further dressing change assessment. Eighteen patients (50%) had only one application of the dressing, 10 (28%) had two applications, and eight (22%) had three applications. Reasons for dressing change included routine assessment (37 out of 57 cases, 64.9%), strikethrough (one, 1.8%), saturation with strikethrough at a routine change (one, 1.8%), independent dressing change (12, 21%), dressings changed by the hospital staff before patient discharge (five, 9%), and patient removed the POSD (one, 1.8%).

The median length of evaluation was 8 days. Median application time for each dressing per patient was 2.6 days.

All patients who underwent a postoperative assessment and at least one POSD application ( $n = 36$ ) were included in the data analysis set. Patient comfort, dressing conformability, ease of application and removal, associated pain, fluid retention, management of exudate and secretions, and durability were considered. Dressing application was rated very easy (32 out of 35, 91.4%) and easy (three out of 35, 8.6%) at the postsurgical assessment. The product was found to conform well in 34 out of 36 (94.4%) postsurgical assessments. The remaining two cases were plastic surgery patients where the dressing did not fit appropriately into the inframammary fold incision site. Fifty-seven (57) dressing changes took place overall, and the comfort of the dressing was rated as either very comfortable (46 out of 57, 80.7%) or comfortable (11 out of 57, 19.3%). No pain was noted upon dressing removal at 38 assessments (66.7%), mild pain at 18 (31.6%), and moderate pain at only one dressing change (1.8%).

In 32 out of 33 cases (97%), the clinician rated the POSD as acceptable for the indication. There was no evidence of infection at any of the assessments. At the majority of assessments (64 out of 93, 68.8%), no exudate was noted and only slight exudate in 27 out of 93 (29%) participants. In the one reported case of dissatisfaction with the product, the clinician was dissatisfied with the durability and absorbance capacity of the dressing. Of note: the patient had significant levels of exudate and bleeding resulting from his hip surgery.

## Discussion

The level of bacterial burden in a wound is the most significant risk factor for SSI, and this has been significantly reduced by modern surgical techniques and the use of prophylactic antibiotics.<sup>30-33</sup> Since the introduction of routine prophylactic antibiotic use, infection rates in NNIS system hospitals were reported to be 2.1% clean, 3.3% clean-contaminated, 6.4% contaminated, and 7.1% dirty.<sup>32-34</sup> Patients with long leg incisions, diabetes mellitus, obesity, and foreign bodies such as implanted mesh and hardware have been deemed to be at high risk for SSI.<sup>23,24,35</sup>

A trend toward a higher SSI rate in the control (6%) versus the POSD (3%) cohort was noted; however, this difference was not found to be statistically significant ( $P = 0.721$ ). Similarly, more patients in the control dressing group (30%) showed one or more signs of infection versus the POSD group (24.2%). The latter demonstrates that while some target wounds may have developed one or more signs indicative of infection, these were not deemed clinically significant infections and, thus, they were not treated with antibiotics. In practice, for example, a wound may have serous drainage or erythema that resolves spontaneously; these are considered noninfected wounds, which negates the need for treatment.

Given the actual use of postoperative antibiotic of 4.5% across both cohorts and the clinical effect rate of 50%, a properly powered study would require nearly 3,000 evaluable patients. As noted from previous studies, it may be best in the future to focus on clean surgical wounds in a more tightly defined cohort of patients, such as persons undergoing groin incisions for vascular surgery.<sup>36</sup> This would allow for a smaller sample size; however, such a population is difficult to accrue prospectively, as noted in an ongoing trial from Brigham and Women's Hospital.<sup>37</sup>

In the second arm of the study dedicated to dressing performance characteristics, clinicians rated POSD as “easy” or “very easy” to apply and remove. Patients rated the dressing comfortable to wear. Likewise, during removal, the majority of patients found the polyurethane backing film caused little or no pain. Instances where slight pain was recorded may have been incisional. The performance study also showed the dressing was an effective, safe, and acceptable treatment for surgical incision sites until closure of the wound is ensured in this population, with some limitations.

The two studies were combined in an effort to define both efficacy and performance characteristics. The randomized trial provided some information regarding performance but suffered from a small sample size, which also was affected by a much lower event rate than anticipated. The noncontrolled portion of the study suffered from its lack of a comparison group. In particular, some clinicians commented it was difficult for accurate product assessment with no comparison aside from their prior experience with different dressings in other patients. Bilateral surgeries, such as reduction mammoplasties, could represent a source of comparison for plastic surgeons. However, insight was gained in outpatient wear times (median 2.6 days) and number of median dressing changes required (1.5).

### Limitations

A number of factors hindered statistical assumptions. First, limited patient follow-up in this study possibly contributed to undocumented SSIs. The CDC describes a median presentation time to wound infection of 38.5 days.<sup>6</sup> This seems long compared to the experience in the authors' practice, and the shorter duration of this study may have affected the findings. Therefore, a study with longer follow-up may be warranted. In addition, because most postoperative dressings are removed within the first 7 to 14 days after surgery, such a distant event window may not be affected by the dressing choice.

Second, after complete data analysis, it was apparent the initiation of postoperative antibiotics occurred less frequently than did the documentation of potential signs of postoperative infection. In other words, infection may have developed in some patients but was not always treated. Thus, the surrogate marker utilized in this study (the initiation of antibiotics) caused the actual (or potential) event rate (the occurrence of infection) to be documented considerably less often than the anticipated, an unexpected finding. One study demonstrated at least 2 days of parenteral postoperative antibiotic usage was the best marker by which to discriminate between infected and uninfected patients, with a sensitivity of 81%, a specificity of 95%, and a positive predictive value of 61% for detecting infection.<sup>38</sup> In addition, antibiotics were used twice as often as the observation of clinical signs of an SSI (16% versus 8%).

The diagnosis of SSI in a closed surgical wound is challenging because symptoms are often variable and diagnostic tests nonspecific.<sup>39</sup> Generally, there is a low symptom threshold for starting postoperative patients on intravenous antibiotics, because a delayed diagnosis may lead to reduced function, increased morbidity, and the need for more complex surgery, often involving multiple procedures. Interestingly, current findings did not correlate with the earlier findings of antibiotic initiation as a reliable surrogate marker for SSI. Therefore, if all postoperative wounds had been biopsied and quantitatively cultured rather than relying on a surrogate marker, current results may have differed.

Third, the POSD itself may have impacted the appearance of the incision site and therefore interfered with accuracy of SSI reporting. *In vitro* and animal studies have demonstrated POSD is an effective antimicrobial against a wide range of microbial and fungal pathogens.<sup>22,40-43</sup> It also has been shown to be an effective antimicrobial agent and barrier against methicillin-resistant strains of *S. aureus*.<sup>44,45</sup> Nanocrystalline silver dressing also has been shown to be anti-inflammatory, with decreased periwound erythema and improved subjective scores of wound appearance.<sup>46</sup> In addition to diminished periwound erythema, it is possible the dressing itself may provide more compression than a gauze-type dressing, which may lead to decreased edema at the wound site. The method of closure was not controlled in this study; surgeons were allowed close wounds at their discretion, using suture or staples. Nonuniformity in this part of the study could have influenced the results.

Finally, the surgical group with the highest anticipated rate of SSI was underenrolled in this study. Interestingly, the SSI reduction rate seen in this small subset of patients with long leg incisions was 50%, below the previously published rate for this surgical group. Childress et al<sup>17</sup> evaluated IPOSD in 216 patients corresponding to 248 lower extremity revascularization procedures and found the IPOSD group to have a 5% complication rate compared to a 16% complication rate in patients treated with standard therapy, signifying a complication reduction or clinical effect rate of 64%.

### Conclusion

Despite the limitations of these studies, the data suggest the POSD evaluated may provide a safe and effective dressing alternative for postoperative wound care. This prospective study found patients undergoing clean surgical procedures who were at high risk for developing an SSI had a lower 30-day rate of antibiotic treatment (4.5%) when the incision was covered with a POSD rather than a control dressing. Although it has a substantially higher per unit cost than commonly used gauze dressings, the POSD was well liked by clinicians and patients. However, it is hard to justify its widespread use based on the variables studied. Large, prospective, randomized, controlled clinical studies are needed to evaluate the efficacy and cost-effectiveness of this dressing for various high-risk surgical patients. ■

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