

Role of Surgical Dressings in Total Joint Arthroplasty: A Randomized Controlled Trial

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Abstract

We conducted a randomized controlled trial to compare efficacy of an occlusive antimicrobial barrier dressing and a standard surgical dressing in patients who underwent primary total joint arthroplasty. Two hundred sixty-two patients were randomized to receive either an occlusive dressing or a standard dressing. Wounds were closed in identical fashion. Outcomes included wound complications, dressing changes, and patient satisfaction.

With use of occlusive dressing (vs standard dressing), wound complications (including skin blistering) were significantly ($P = 0.15$) reduced; there were significantly ($P < .0001$) fewer dressing changes; and patient satisfaction was significantly ($P < .0001$) higher.

Use of occlusive dressings can reduce wound complications and promote wound healing after total joint arthroplasty.

Wound complications (eg, delayed wound healing, blisters, prolonged drainage) have been reported in up to 30% of patients who undergo elective total joint arthroplasty (TJA).¹⁻⁶ Wound complications increase resource utilization, lengthen hospital stays, and increase costs.⁷⁻⁹ Prolonged wound healing and persistent wound drainage are also harbingers of both superficial and deep surgical site infections.⁵⁻¹¹

In several studies, wound complications after TJA were the primary reason for hospital readmissions.¹²⁻¹⁵ As part of the Patient Protection and Affordable Care Act, hospitals will be penalized by the Centers for Medicaid & Medicare Services for unplanned hospital readmissions within 30 days after TJA. It is imperative, then, to reduce the risk factors and complications associated with surgical site infections to decrease unplanned readmissions.

Historically, little attention has been given to the role of surgical dressings and the effect of dressings on wound healing. Although many subspecialties (eg, cardiothoracic surgery, gen-

eral surgery) have reported benefits in using occlusive dressings, adoption in TJA has been slow.¹⁶⁻¹⁸ At our institution about 5 years ago, we began using an occlusive silver-impregnated barrier dressing based on preliminary data from studies showing benefits of occlusive dressings in TJA.^{19,20}

We conducted a study to determine if use of occlusive antimicrobial barrier dressings decreases rates of wound complications in TJA. We had 3 research questions: Compared with standard surgical dressings, are occlusive dressings associated with decreased rates of wound complications after TJA? Is there a difference in number of dressing changes required between the 2 dressing types? Is satisfaction higher for patients with occlusive dressings than for patients with standard dressings?

Patients and Methods

This randomized controlled trial (RCT) was reviewed and approved by the Institutional Review Board at Carolinas Healthcare. Patients were randomized by the research staff using a parallel, 1:1 allocation method. The randomization table was generated using a random number generator.

An a priori sample size estimate was made using a 2-tailed Fisher exact test with a .05 level of significance. Based on a study by Clarke and colleagues,²¹ we estimated the incidence of wound problems at 3% in the occlusive dressing (study) group and 13% in the standard dressing (control) group. We determined that 260 participants (130 per group) would be needed to achieve 80% power. We considered a 15% attrition rate for a total enrollment goal of 300 study participants (150 per group).

Between December 2010 and January 2013, patients presenting for either primary total hip arthroplasty (THA) or primary total knee arthroplasty (TKA) were recruited to participate in the study. Eligibility criteria (Table 1) were reviewed, and patients were enrolled by the senior surgeons, Dr. Springer, Dr. Beaver, Dr. Griffin, and Dr. Mason. All eligible participants who provided informed consent were randomized to receive either an occlusive antimicrobial barrier dressing (Aquacel Ag, ConvaTec) or standard surgical dressing (Primapore, Smith & Nephew). The occlusive dressing (Figure 1) consists of an outer barrier layer of hydrocolloid and a central island of hydrofiber, which absorbs and locks in any wound

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Figure 1. Occlusive dressing.



Figure 2. Standard dressing.



Figure 3. Occlusive dressing with strike-through.



Figure 4. Standard dressing with strike-through.

exudate within the fibers and prevents the creation of an overly moist wound environment that can lead to skin maceration and wound breakdown. In addition, the hydrofibers are embedded with ionic silver, which is released only at the site of wound exudate, or drainage; thus, there is no continuous exposure of the entire wound to silver. The standard dressing (Figure 2) consists of a central island of gauze enclosed in low-allergy acrylic adhesive tape.

Table 1. Eligibility Criteria

Inclusion Criteria

Patient is willing and able to understand, sign, and date the study-specific patient informed consent form to volunteer to participate in the study.

Patient is between 18 and 90 years of age at time of surgery.

Patient presents for primary total hip arthroplasty performed through a posterior or posterior-lateral surgical approach or presents for total knee arthroplasty.

Patient is psychosocially, mentally, and physically able to comply with study requirements, including postoperative clinical and radiographic evaluations and questionnaire completion.

Exclusion Criteria

Patient presents for revision total hip or total knee arthroplasty.

Patient has topical hypersensitivity or allergy to a disposable component (eg, ionic silver, polyurethane film) of the dressing system.

Patient has a systemic or local active dermatologic disease (eg, eczema, psoriasis, skin cancer, scleroderma, chronic urticaria) that might interfere with surgical site evaluation.

Patient's participation in another clinical trial may affect participation in this study.

Patient's insurance coverage is not included in our care partner's list of payers.

Patient resides outside our care partner's geographical coverage area.

All surgical dressings were placed over a closed incision in a sterile environment in the operating room after the procedure. The groups' wound closures were identical.

A posterior approach was used for all THAs. The deep fascia was closed with a running barbed suture (Quill, Angiotech), the deep subcutaneous tissue with No. 1 Vicryl suture (Ethicon), and the superficial subcutaneous layer with 2-0 Vicryl suture. A running 3-0 Monocryl stitch (Ethicon) was placed in the subcuticular layer and was followed with a skin adhesive (Dermabond, Ethicon). A closed suction drain, removed on postoperative day (POD) 1, was used for all THAs.

A standard medial parapatellar arthrotomy was used for all TKAs. The arthrotomy was closed with a running barbed suture, the deep subcutaneous tissue with No. 1 Vicryl suture, and the superficial subcutaneous layer with 2-0 Vicryl suture. A running 3-0 Monocryl stitch was placed in the subcuticular layer and was followed with a skin adhesive. A closed suction drain was also used. In addition, a compressive wrap was placed over the dressing in the operating room and was removed the next morning. During the hospital stay, the surgical site was evaluated daily with a standard wound evaluation form.

In the standard dressing group, the bandage was removed for wound evaluation on POD 2, and the dressing was changed every other day during the hospital stay. The dressing was also changed as needed for wound drainage (Figure 3) or other minor wound-healing concerns.

In the occlusive dressing group, the dressing design allowed the dressing to remain in place for about 7 days. It was removed by a home health nurse during a visit closest to but not before the 7-day mark. In addition, it was changed at surgeon discretion if there were concerns about wound drainage or wound healing. For the occlusive barrier, wound drainage was evaluated by strike-through of drainage on the back side of the dressing (Figure 4). If more than 50% of the dressing was saturated, the bandage was changed and the wound evaluated. If there were no immediate concerns about wound complications (eg,

Aquacel® Ag Surgical Dressing vs. Standard Dressing Postoperative Skin Assessment FORM 5
Page 1 of 1

TO BE COMPLETED AT EVERY WOUND/DRESSING CHECK

OC#: _____ Name: _____
 Study ID#: _____ Area: Knee Hip Side: Right Left
 Dressing Change Date ____/____/____ Time: _____
 Dressing Change: Yes, Time: _____ No, Reason: _____
 Number of Dressing Changes: _____

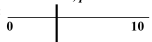
Skin Reaction Assessment
 Exudate, Amount, Type, Color

<input type="checkbox"/> None	<input type="checkbox"/> Serous	<input type="checkbox"/> Yellow
<input type="checkbox"/> Scant (<10%)	<input type="checkbox"/> Serosanguineous	<input type="checkbox"/> Tan
<input type="checkbox"/> Small (10%-25%)	<input type="checkbox"/> Purulent	<input type="checkbox"/> Green
<input type="checkbox"/> Medium (26%-50%)	<input type="checkbox"/> Foul Odor	<input type="checkbox"/> Whitish
<input type="checkbox"/> Large (>50%)		<input type="checkbox"/> Other _____

Surrounding Skin, Wound Margins

<input type="checkbox"/> Within normal limits	<input type="checkbox"/> Open wound margins
<input type="checkbox"/> Blisters	<input type="checkbox"/> Papules
<input type="checkbox"/> Closed wound margins	<input type="checkbox"/> Rash
<input type="checkbox"/> Infection	<input type="checkbox"/> Redness
<input type="checkbox"/> Macerated	<input type="checkbox"/> Swelling
<input type="checkbox"/> Other _____	<input type="checkbox"/> Wound Dehiscence

Was the wound treated? N Y, describe treatment _____

For the question below, please mark the line where your rating falls.
 Example: 

With respect to the patient's wound dressing please rate the amount of difficulty you had changing the dressing.

No Difficulty _____ Extreme Difficulty


Study Staff
 Comments: _____

Study Staff Signature: _____ Date: _____
 PI Signature: _____ Date: _____

Aquacel® Ag Surgical Dressing vs. Standard Dressing Postoperative Patient Satisfaction VAS FORM 4
Page 1 of 1

TO BE COMPLETED AT EVERY WOUND/DRESSING CHECK

OC#: _____ Name: _____
 Study ID#: _____ Area: Knee Hip Side: Right Left
 Dressing Change Date ____/____/____ Time: _____

For each question below, please mark the line where your rating falls.
 Example: 

Please answer the following questions with respect to your wound dressing

1. Please rate the pain you experience during the dressing change
 No Pain _____ Worst Pain Imaginable
2. Please rate your satisfaction with your ability to perform personal hygiene activities.
 Completely Unsatisfied _____ Completely Satisfied
3. Please rate your satisfaction with your ability to change clothes.
 Completely Unsatisfied _____ Completely Satisfied
4. Please rate your satisfaction with your ability to sit comfortably.
 Completely Unsatisfied _____ Completely Satisfied
5. Please rate your satisfaction with your ability to sleep comfortably.
 Completely Unsatisfied _____ Completely Satisfied

Patient Comments:

Patient Signature: _____ Date: _____

Figure 5. Wound assessment form.

Figure 6. Patient satisfaction form. Abbreviation: VAS, visual analog scale.

infection, blistering), a new occlusive dressing was placed. Because the occlusive dressing was waterproof, patients in the study group were able to shower immediately after surgery. In the control group, patients were allowed to shower if the surgical dressing was kept dry, as the bandage was not waterproof.

Per the study protocol, all patients were discharged home and followed by a single home health agency. Mean hospital stay was 3 days (range, 0-8 days), which did not differ significantly between groups ($P = .133$). All home health nurses were trained in evaluation of postsurgical wounds and were aware of the study requirements. The nurses visited all patients 3 days a week until the scheduled 4-week postoperative follow-up with the treating physician or physician assistant. At each visit, the nurse evaluated the wound and surrounding skin using a standard wound document. Dressings were changed based on the criteria we have described. Concerns about wound status (eg, drainage, blistering, erythema) prompted removal of the dressing for further evaluation. The physician was notified of concerns about wound healing, which prompted an office visit for evaluation. The dressing remained in place for a minimum of 7 days but in all cases was removed as close to 7 days as possible, depending on the scheduled nursing visits. Once uneventful wound healing was complete, no further dressing was required. A final wound evaluation was conducted by the surgeon at the 4-week postoperative evaluation.

The primary outcome measure was wound complication (dichotomous variable). Wounds were assessed by describing the amount, type, and color of exudate (Figure 5). The appearance of the wound margins and the surrounding skin was also assessed. Because wounds could not be directly visualized in the occlusive dressing group, drainage (indicated by strike-through) was used as a measure of possible wound complications, prompting removal and full evaluation.

Secondary endpoints included additional wound treatment or surgical procedures for wound complications, number of dressing changes, and patient satisfaction. Patients completed a satisfaction questionnaire at each wound assessment (Figure 6). Using a visual analog scale (VAS), they rated their satisfaction with their ability to perform activities of daily living (personal hygiene, change clothes, sit comfortably, sleep comfortably), drawing a line on the VAS at a point between 0 (totally unsatisfied) and 100 (totally satisfied) for each satisfaction measure. This line was measured and recorded by the study coordinator. The 4 satisfaction measures were averaged for a composite satisfaction measure.

All statistical analyses were conducted using SAS Version 9.2 (SAS Institute). Standard univariate descriptive statistics (means, standard deviations, frequencies, proportions) were calculated and reported. Differences in mean values for con-

tinuous data were assessed with independent t test or Wilcoxon rank sum test. Chi-square test and Fisher exact test were used to determine differences between groups for categorical or dichotomous variables. A significance level of .05 was used for all statistical tests.

Results

The 300 patients who consented to participate in the study were randomized to receive either occlusive dressing or standard dressing. After randomization, 38 patients (15 occlusive, 23 standard) were withdrawn from the study (Table 2), leaving a final dataset of 262 patients, 141 in the occlusive group (67 THAs, 74 TKAs) and 121 in the standard group (49 THAs, 72 TKAs). There were no differences in proportion of THAs or TKAs, age, sex, or body mass index between the occlusive and standard groups (Table 3).

Table 2. Reasons for Study Patient Withdrawal

Reason	Dressing Group, n	
	Occlusive	Standard
Medical reason	1	2
Patient decision	2	1
Canceled surgery	2	10
Not discharged home	2	2
Outside home health catchment area	2	4
Surgery scheduled at non-study hospital	3	0
Incorrect dressing placed	3	3
Lost to follow-up	0	1

Table 3. Patient Demographics

Demographic	Dressing Group		P
	Occlusive	Standard	
Mean (SD)			
Age, y	62.09 (12.09)	62.92 (10.25)	.55
Body mass index	31.17 (6.11)	30.94 (5.43)	.75
Sex, n (%)			.61
Men	65 (46.15%)	52 (42.98%)	
Women	76 (53.90%)	69 (57.02%)	

Table 4. Patient Satisfaction Scores

Measure	Dressing Group, mean (SD)		P
	Occlusive	Standard	
Personal hygiene activities	94.19 (10.39)	79.21 (25.93)	<.0001
Change clothes	93.10 (10.88)	83.86 (20.88)	<.0001
Sit comfortably	91.11 (11.60)	82.33 (21.91)	.0001
Sleep comfortably	89.16 (15.36)	79.66 (23.26)	.0002

There were statistically significantly ($P = .015$) fewer wound complications in the occlusive dressing group (10%) than in the standard dressing group (22%). Blisters at or around the wound site were reported in significantly ($P = .026$) fewer patients with occlusive dressing (1/141, 0.7%) than standard dressing (7/121, 6%). Additional wound care was required in 9 patients (7% in the standard group and 6 patients (4%) in the occlusive group ($P = .27$). Two patients (1.7%) in the standard group were readmitted for treatment of wound dehiscence; no one in the occlusive group was readmitted to the hospital or had to return to the operating room for treatment of a wound complication. The difference was not statistically significant ($P = .13$). There were also no significant ($P = .81$) differences in rate of wound complications between THA and TKA patients.

There were statistically significantly ($P < .0001$) fewer dressing changes in the occlusive dressing group. Mean number of dressing changes was 0.14 (median, 0; interquartile range, 0-0) in the occlusive group and 2.8 (median, 2; interquartile range, 1-3) in the standard group.

Compared with patients in the standard dressing group, patients in the occlusive dressing group reported significantly higher satisfaction scores. Mean overall patient satisfaction score was 92 in the occlusive group and 81 in the standard group ($P < .0001$). Patients in the occlusive group were more satisfied with their ability to take care of their personal hygiene, to change clothes, and to sit and sleep comfortably (Table 4).

Discussion

Wound complications after TJA are common, occurring in up to 30% of patients,¹⁻⁶ and are associated with development of superficial and deep surgical site infections, increased resource utilization, and longer hospital stays.⁵⁻¹¹ Although the role of surgical dressings has received little attention in TJA practice, other subspecialties have found that occlusive barrier dressings can reduce wound complications and promote wound healing.^{16,17} Mitotic cell division and leukocyte activity, which are critical in wound healing, increase under occlusive dressings. This cellular activity is disrupted with every dressing change, delaying wound healing (biological activity takes 3-4 hours to resume).²² In addition, occlusive dressings increase hypoxia, which promotes angiogenesis and accelerates wound healing.²³

Despite being a prospective RCT, this study had several limitations. Because of the need to evaluate wounds and obvious differences between the 2 dressings (eg, color, ability to shower), it was not possible to blind the patient or surgeon to the dressing used. When rating satisfaction, patients were not able to directly compare the 2 dressings. The primary endpoint of the study was the complication rate; however, the deep periprosthetic infection rate may be a superior endpoint and would require a much larger study. Although we assumed that wound complications may be harbingers for periprosthetic infections, no patient in either group developed periprosthetic infection. Therefore, we cannot conclude that surgical dressings play a role in reducing infections. In addition, as the standard dressing was changed on POD 2 (per standard protocol) and the occlusive dressing could remain in place for up to 7 days, there

was a selection bias in the evaluation of the number of dressing changes. However, given the characteristics of the standard dressing (eg, tape, gauze, nonocclusive), leaving it in place after POD 2 is not optimal. Therefore, we would expect to see a difference in the number of dressing changes. We think this comparison remains valid, as occlusive dressings were changed when there were indications of wound problems (eg, excessive drainage [strike-through], surrounding erythema, blistering). With an average of less than 1 dressing change in the occlusive group, we think this is a surrogate for uneventful wound healing and decreased wound complication, and our data support this. It is also important to test both dressing durability and patient tolerance for wearing a single dressing for 7 days.

Our RCT results showed that, compared with a standard dressing, an occlusive antimicrobial dressing was associated with a significant decrease in overall wound complications and blisters. These findings are similar to those of other studies of occlusive dressings in a number of surgical subspecialties.^{16,18} In an RCT of 200 patients who underwent elective and nonelective hip and knee surgery and were randomized to either absorbent perforated dressing with adhesive border (Cutiplast, Smith & Nephew) or Aquacel (ConvaTec) covered with vapor-permeable dressing (Tegaderm, 3M), Ravenscroft and colleagues²⁰ found that Aquacel-plus-Tegaderm was 5.8 times more likely than Cutiplast to produce an uncompromised wound. Similarly, in an RCT of hydrofiber (Aquacel) and central pad (Mepore, Mölnlycke) dressings after primary THA and TKA, Abuzakuk and colleagues¹⁹ found significantly fewer dressing changes (43% vs 77%) and blisters (13% vs 26%) in the hydrofiber group than in the pad group.

Hopper and colleagues²⁴ compared 50 consecutive patients treated with modern dressings (Aquacel) with 50 historical control patients treated with traditional surgical dressings (Mepore). Blisters developed in 20% of the patients in the traditional group and 4% of patients in the modern group ($P = .028$). The authors concluded that adverse outcomes of wound healing can be minimized with modern dressings.

A recent retrospective study by Cai and colleagues²⁵ evaluated the incidence of acute periprosthetic infection (≤ 3 months after surgery) with use of occlusive (Aquacel) and standard dressings. Incidence of acute periprosthetic infection was 0.44% in the occlusive group and 1.7% in the standard group ($P = .005$). Incidence of wound-healing problems was not evaluated.

Our second aim in the present study was to evaluate the number of dressing changes required. There were significantly fewer dressing changes in the occlusive dressing group than in the standard dressing group. Therefore, wear time (amount of time a single dressing remains in place) was substantially longer for the occlusive group. In the study by Hopper and colleagues,²⁴ wear time was significantly shorter for the traditional dressing than for the modern dressing (2 vs 7 days; $P < .001$), and the traditional dressing required more changes (3 vs 0; $P < .001$).

These findings are important for several reasons. Standard surgical dressings often require frequent changes. If left in

place, they create an excessively moist wound environment that promotes blistering and delays wound healing. However, frequent dressing changes expose the wound and increase the risk for surgical site infection.²⁶ A barrier dressing left in place from time of surgery prevents bacteria from entering and contaminating a healing wound. A study by Clarke and colleagues²¹ demonstrated higher skin colonization rates for patients who had dressings changed on POD 1 than for patients who had their first dressing change on POD 6.

Our third study aim was to evaluate patient satisfaction with surgical dressings. The orthopedic literature has little on this topic.²³ Blisters and other wound complications can negatively affect satisfaction.^{2,3} Our data showed significant improvement in satisfaction, particularly regarding sterility and hygiene.

Other surgical subspecialties have found similar improvement in patient satisfaction with occlusive barrier dressings. In an RCT of 88 pediatric patients, Rasmussen and colleagues²⁷ found that patients reported significantly less pain during changes of an occlusive adhesive dressing (Duoderm, ConvaTec) than during changes of a conventional Steristrip (3M) plus Cutiplast. According to the authors, the occlusive wound dressing seemed to minimize the physical and psychological trauma to the infant or child and lessen disruption of the child's and the parents' daily routines, because the children could be bathed immediately after surgery.

Our study did not specifically address cost. Cai and colleagues²⁵ estimated that, if the Aquacel dressing were routinely used in every hip and knee arthroplasty, it would add about \$27 million in cost. However, this must be balanced by the cost of managing infection after TJA. In the United States, at an estimated \$50,000 to \$100,000 per case and an annual incidence of 1% to 2%, the low-end cost for the treatment of periprosthetic infection would be \$500 million.²⁸ Cai and colleagues²⁵ found a 4-fold reduction in periprosthetic infection when use of occlusive dressings was implemented. In addition, wound complications remain the number one reason for hospital readmission after TJA.^{12,13} Cost of hospital readmission, as well as financial penalties to institutions for unplanned readmission for wound complications, must be considered.

Conclusion

Our RCT results demonstrated that use of occlusive antimicrobial barrier dressings (vs standard surgical dressings) significantly reduced wound complications and dressing changes and improved overall patient satisfaction. These findings are similar to those in the literature on TJA and other surgical subspecialties. We conclude that occlusive surgical dressings reduce wound complications after TJA.

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