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## Aquacel Surgical Dressing Reduces the Rate of Acute PJI Following Total Joint Arthroplasty: A Case-Control Study.

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10 **Abstract**

11           An effort to prevent PJI has led to the development of antimicrobial dressings that  
12 support wound healing. We sought to determine whether Aquacel Surgical dressing  
13 independently reduces the rate of acute PJI following TJA. A single institution retrospective  
14 chart review of 903 consecutive cases who received the Aquacel Surgical dressing and 875  
15 consecutive cases who received standard gauze dressing was conducted to determine the  
16 incidence of acute PJI (within 3 months). The incidence of acute PJI is 0.44% in the Aquacel  
17 dressing group compared to 1.7% in the standard gauze dressing group ( $P = 0.005$ ). Multivariate  
18 analysis revealed that use of Aquacel dressing was an independent risk factor for reduction of PJI  
19 (odds ratio of 0.165, 95% confidence interval: 0.051–0.533). Aquacel Surgical dressing  
20 significantly reduces the incidence of acute PJI.

21

22 **Introduction**

23 Periprosthetic joint infection (PJI) is one of the most dreaded complications that occur  
24 after total joint arthroplasty (TJA). PJI is reported to occur in 1%–4% and 0.59%–2% of patients  
25 who have undergone total knee and hip arthroplasty, respectively [1,2]. The infection causes  
26 physical, emotional, and financial strain to patients and their families as well as an immense  
27 monetary burden to hospitals and our economy. The annual nationwide cost to control infection  
28 is approximately \$250 million. The cost of treating an individual PJI can be in excess of \$50,000  
29 and if the offending organism is antibiotic resistant, i.e. MRSA, that cost can surpass \$100,000  
30 [3,4]. Additionally, perioperative mortality associated with PJI can be 10 times greater than with  
31 primary TJA [5,6].

32 Eradication of infection often requires additional surgery and is distressful for both the  
33 treating physician and patient. While there are numerous possible causes for PJI, a few important  
34 risk factors related to the wound itself have been identified including wound drainage and  
35 superficial wound infections [7]. The traditional approach to wound care consists of a simple  
36 dressing that could be removed after 1 or 2 days with the idea that the wound re-epithelializes  
37 during that time and can then be left uncovered.[8]. Among efforts to prevent the occurrence of  
38 PJI, commercial dressings have been developed to optimize wound healing, seal wound drainage  
39 and have antimicrobial properties [9]. In contrast to the conventional use of standard gauze  
40 bandages, these dressings feature antimicrobial linings and have shown to decrease surgical site  
41 infection rates [10].

42 The Aquacel Ag Hydrofiber dressing is an antimicrobial dressing that consists of a  
43 weaved cellulose center that contours to the skin to eliminate dead space, absorbs exudates,  
44 releases ionic silver to reduce microbial activity and supports wound healing [11]. Furthermore,

45 the dressing seals the wound and prevents seepage of drainage beyond the dressing perimeter.  
46 The objective of this study was to evaluate the effect of using this dressing on the occurrence of  
47 acute PJI in patients undergoing TJA. We hypothesized that the Aquacel Ag Hydrofiber dressing  
48 would support healing following surgery and possibly reduce the rate of acute PJI.

49

## 50 **Methods**

51 Prior to initiation of the study, institutional review board approval was obtained. Using  
52 our computerized joint arthroplasty database, 950 consecutive patients who underwent primary  
53 total hip or total knee arthroplasty between October 2010 and March 2012 and received the  
54 Aquacel dressing were identified. A list of 950 consecutive patients who received standard  
55 dressings and who were admitted to the hospital before implementing systematic use of the  
56 Aquacel dressing from April 2007 to August 2010 was generated in a similar fashion. To allow  
57 for consistency in the use of the new dressing, data from the initial 6 weeks when Aquacel  
58 dressing was utilized were omitted. Exclusion criteria included hip hemiarthroplasty,  
59 unicompartmental knee arthroplasty, TJA for fracture treatment, conversion TJA, and revision  
60 TJA. Each case was reviewed to verify the exclusion criteria and collect demographic  
61 information, medical comorbidities, intraoperative parameters and development of acute PJI. The  
62 latter was defined as PJI occurring within 3 months of surgery based on the new definition  
63 criteria established by the Musculoskeletal Infection Society [12]. After eliminating patients  
64 based on the exclusion criteria, 903 patients with hip (392), knee (508) or hip and knee (3)  
65 arthroplasties were retained in the Aquacel group and 875 patients with hip (376) or knee (499)  
66 arthroplasty in the standard dressing group. The Aquacel dressing was applied on the surgical  
67 site in sterile conditions in the operating room and kept in place for 5 days postoperatively.

68 Standard dressing application consisted of sterile xeroform and gauze applied over the incision  
69 site in the operating room and wrapped in an ace bandage that remained in place for 2 days  
70 postoperatively.

71 In addition to the application of the Aquacel Surgical dressing, changes in clinical  
72 practice during the study period included the use of dual intravenous antibiotic prophylaxis with  
73 vancomycin and cefazolin (vs. cefazolin alone previously) and systematic irrigation with dilute  
74 betadine before wound closure. These changes occurred 9 and 4 months before the end of the  
75 study period respectively. A total of 37 patient-related and procedure-related risk factors were  
76 taken into account in a multivariate analysis model where the dependent variable was the  
77 development of acute PJI (Table 1). Statistical analyses were performed using R version 2.15.1  
78 (R Foundation for Statistical Computing, Vienna, Austria).

79

## 80 **Results**

81 The prevalence of acute PJI was lower in the Aquacel group (0.44%) compared to the  
82 standard dressing group (1.71%). Bivariate analysis conducted with Fisher's test first showed this  
83 to be statistically significant ( $P = 0.005$ ). A backward stepwise logistic regression model retained  
84 7 independent risk factors for PJI (of 37 variables), including the use of Aquacel dressing, with  
85 an independent odds ratio of 0.165 (95% confidence interval: 0.051–0.533). Other independent  
86 significant risk factors for infection were as follows: older age, higher body mass index, smoking  
87 status, thyroid disease, liver disease and history of steroid treatment (Table 2). Notably,  
88 utilization of vancomycin prophylaxis and betadine irrigation were not shown to be significant  
89 independent protective factors for acute PJI.

90

91 **Discussion**

92 PJI is a major healthcare concern with mental, physical and financial burden on affected  
93 patients. With projected exponential increases in its incidence and costs, and the predicted  
94 reforms of healthcare reimbursement, prevention of this complication is gaining more  
95 importance [13]. Wound healing problems and superficial surgical site infections have  
96 consistently shown to be determining risk factors for the development of PJI [14,15]. Thus,  
97 addressing these specific issues may prevent the occurrence of deep infection. The Aquacel  
98 dressing has several features that could positively affect the wound environment: it sequesters  
99 fluid to avoid tissue maceration, while at the same time releasing a gel that maintains a relatively  
100 humid environment; it is also completely impermeable, preventing bacteria from entering the  
101 wound site from the outside environment and maintaining hypoxia in the wound, which has been  
102 shown to enhance healing and cellular immunity through the up-regulation of hypoxic-inducible  
103 factors [16]. The addition of silver provides antimicrobial activity [17].

104 The use of the Aquacel dressing in TJA has previously been shown to create less need for  
105 dressing changes, thus decreasing burden on healthcare personnel, diminishing superficial wound  
106 problem, and avoiding delays in hospital discharge due to wound healing issues [18]. As the first  
107 study to correlate Aquacel dressing with acute PJI, our results show that this dressing is an  
108 effective measure to significantly reduce the occurrence of acute PJI after TJA, when compared  
109 to standard dressings with gauze and tape. In our series, it independently reduced the rate of  
110 acute PJI approximately sixfold.

111 The cost of one standard Aquacel dressing at our institution is \$39.05. The cost to treat a  
112 PJI has been variably estimated to range from \$50,000 to over \$100,000 [13]. A standard taped  
113 surgical gauze dressing costs approximately \$5.00. Therefore, the additional cost per case for an

114 Aquacel dressing is about \$34.00. Infection after TJA has been reported to have an incidence  
115 ranging from 1.0% to 2.0% [4]. In the United States., there are over 1,000,000 TKAs and THAs  
116 performed annually [19]. Assuming the lowest cost (\$50,000) of PJI treatment and the lower  
117 incidence (1%) of reported PJI, the annual costs to manage PJI in the United States likely exceed  
118 \$500,000,000. The cost of using an Aquacel dressing routinely in the United States after TJA  
119 would add approximately \$27,000,000 in cost. If the reported fourfold reduction in PJI noted in  
120 our study is accurate, the cost of PJI management in the United States could be reduced by at  
121 approximately \$375,000,000 with use of an Aquacel dressing. Therefore, the additional cost  
122 associated with routine use of the Aquacel dressing after TJA can be readily justified.

123         We recognize several limitations to our study, such as, principally, its retrospective  
124 design on a cohort of consecutive patients. Nonetheless, we were able to include a relatively  
125 large number of subjects and all changes in practice, as well as potential confounding factors,  
126 were taken into account in a multivariate model to ascertain the independent protective effect of  
127 the Aquacel dressing. Our main concern was the confounding effect of intravenous vancomycin  
128 prophylaxis and dilute betadine irrigation, two practices we implemented based on recent  
129 supportive evidence in the literature [20,21]. However, these two factors did not reach a  
130 significant effect on the development of PJI in our current study. This lack of significance is  
131 possibly due to the limited number of subjects involved since these two practices were  
132 introduced at our institution relatively late in the study period. Finally, our main outcome  
133 measurement consisted of PJI occurring within 3 months of surgery. We elected to use the 3-  
134 month minimum follow-up, in compliance with the recent recommendations of the Center for  
135 Disease Control and Prevention, which uses this period to determine if an infection occurring  
136 after surgery could be directly attributed to that procedure or not [22].



137           Despite the aforementioned limitations, this case-controlled study demonstrated that the  
138 Aquacel Ag Surgical wound dressing with ionic silver significantly reduced the incidence of  
139 acute PJI in our cohort of patients. Its systematic use suggests that it would be an effective  
140 measure to prevent the occurrence of acute PJI following TJA and thus diminish the significant  
141 healthcare costs and patient morbidity of PJI.

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224 Table 1 - List of patient-related and procedure-related factors included in the first step of the  
 225 logistic regression model  
 226

Demographic factors	Age Gender BMI
Procedure-related factors	Joint Bilateral procedure OR time Transfusion need Type of anesthesia Length of stay Aquacel dressing Dilute betadine irrigation
<u>Comorbidities</u>	Smoking status Frequent alcohol drinking History of MI Congestive heart failure Peripheral vascular disease Cerebro-vascular disease Dementia Chronic pulmonary disease Connective tissue disease Coronary artery disease Peptic ulcer disease Liver disease Diabetes mellitus Chronic renal disease Malignancy (history, active disease or metastatic disease) Rheumatoid disease Hypertension Dyslipidemia Thyroid disease Psychiatric disease Anemia Dysrhythmia History of DVT or PE GERD History of steroid treatment ASA

227  
 228 ASA = American Society of Anaesthesiologists physical status classification, BMI= Body Mass  
 229 Index, DVT = Deep Vein Thrombosis, GERD = Gastro-Esophageal Reflux Disease, MI =  
 230 Myocardial Infarction, OR = Operating Room, PE = Pulmonary Embolism.

Table 2 - Table 2. Factors included in the final logisticregression model with independent oddsratios and 95% confidence intervals

	<b>Odds Ratio (95% confidence interval)</b>	<b>p-value</b>
<b>Aquacel® dressing use</b>	0.17 (0.05 – 0.53)	0.003
<b>Age</b>	1.09 (1.03 – 1.14)	0.002
<b>Body mass index</b>	1.10 (1.03 - 1.19)	0.006
<b>Former Smoker</b>	3.02 (1.12-8.12)	0.029
<b>Thyroid disease</b>	3.71 (1.42 – 9.67)	0.007
<b>Liver disease</b>	7.03 (1.43-34.60)	0.017
<b>History of systemic steroid treatment</b>	22.22 (1.83 – 269.45)	0.015