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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

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