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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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ABSTRACT

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

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

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

The Aquacel Ag Hydrofiber dressing is an antimicrobial dressing that consists of a weaved cellulose center that contours to the skin to eliminate dead space, absorbs exudates, releases ionic silver to reduce microbial activity and supports wound healing [11]. Furthermore, the dressing seals the wound and prevents seepage of drainage beyond the dressing perimeter. The objective of this study was to evaluate the effect of using this dressing on the occurrence of acute PJI in patients undergoing TJA. We hypothesized that the Aquacel Ag Hydrofiber dressing would support healing following surgery and possibly reduce the rate of acute PJI.

Methods

Prior to initiation of the study, institutional review board approval was obtained. Using our computerized joint arthroplasty database, 950 consecutive patients who underwent primary total hip or total knee arthroplasty between October 2010 and March 2012 and received the Aquacel dressing were identified. A list of 950 consecutive patients who received standard dressings and who were admitted to the hospital before implementing systematic use of the Aquacel dressing from April 2007 to August 2010 was generated in a similar fashion. To allow for consistency in the use of the new dressing, data from the initial 6 weeks when Aquacel dressing was utilized were omitted. Exclusion criteria included hip hemiarthroplasty, unicompartmental knee arthroplasty, TJA for fracture treatment, conversion TJA, and revision TJA. Each case was reviewed to verify the exclusion criteria and collect demographic information, medical comorbidities, intraoperative parameters and development of acute PJI. The latter was defined as PJI occurring within 3 months of surgery based on the new definition criteria established by the Musculoskeletal Infection Society [12]. After eliminating patients based on the exclusion criteria, 903 patients with hip (392), knee

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(508) or hip and knee (3) arthroplasties were retained in the Aquacel group and 875 patients with hip (376) or knee (499) arthroplasty in the standard dressing group. The Aquacel dressing was applied on the surgical site in sterile conditions in the operating room and kept in place for 5 days postoperatively. Standard dressing application consisted of sterile xeroform and gauze applied over the incision site in the operating room and wrapped in an ace bandage that remained in place for 2 days postoperatively.

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

Results

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

Table 1
List of Patient-Related and Procedure-Related Factors Included in the First Step of the Logistic Regression Model.

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
Comorbidities	Smoking status
	Frequent alcohol drinking
	History of MI
	Congestive heart failure
	Peripheral vascular disease
	Cerebrovascular 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
	Dysrythmia
	History of DVT or PE
	GERD
	History of steroid treatment
	ASA

ASA = American Society of Anaesthesiologists physical status classification; BMI = body mass index; DVT = deep vein thrombosis; GERD = gastroesophageal reflux disease; MI = myocardial infarction; OR = operating room; PE = pulmonary embolism.

Discussion

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

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

The cost of one standard Aquacel dressing at our institution is $39.05. The cost to treat a PJI has been variably estimated to range from $50,000 to over $100,000 [13]. A standard taped surgical gauze dressing costs approximately $5.00. Therefore, the additional cost per case for an Aquacel dressing is about $34.00. Infection after TJA has been reported to have an incidence ranging from 1.0% to 2.0% [4]. In the United States., there are over 1,000,000 TKAs and THAs performed annually [19]. Assuming the lowest cost ($50,000) of PJI treatment and the lower incidence (1%) of reported PJI, the annual costs to manage PJI in the United States likely exceed $500,000,000. The cost of using an Aquacel dressing routinely in the United States after TJA would add approximately $27,000,000 in cost. If the reported fourfold reduction in PJI noted in our study is accurate, the cost of PJI management in the United States could be reduced by at approximately $375,000,000 with use of an Aquacel dressing. Therefore, the

Table 2
Factors Included in the Final Logistic Regression Model With Independent Odds Ratios 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

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additional cost associated with routine use of the Aquacel dressing after TJA can be readily justified.

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

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

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ORIGINAL ARTICLE
Reconstructive

Aquacel Surgical Dressing after Thigh Lift: A Case–Control Study

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Background: The postoperative dressing in patients undergoing thigh lift is often difficult, not very resistant to movement, and uncomfortable for the patient, and often exposes surgical site to infection, maceration, or delay in wound healing.
Methods: We included 40 patients in a case–control crossover study with no period effects, who were treated both by Aquacel Surgical and a traditional wound dressing. Surveys with a 10-point scale evaluation were used to assess nontraumatic removal level, ease of application, adhesion, and strength of the 2 treatments. We reported the number of days necessary for wound healing, the number of infection cases, and wound-related complications. Costs of the 2 medications were also considered. Ten days after surgery, patients answered a questionnaire with 6 multiple-choice questions to assess comfort, pain at dressing change, pruritus, strength, and number of dressing changes.
Results: Compared with controls, surveys revealed Aquacel Surgical to be less traumatic to remove, easier to apply, and to be more adherent and stronger. Significant acceleration of the wound healing was also evident with Aquacel Surgical compared with the traditional dressing. Nonsignificant differences were reported about the risk of infection and wound-related complications between the 2 treatments. A statistical analysis of costs revealed that Aquacel Surgical is significantly more expensive than the traditional medication.
Conclusion: We recommend the use of Aquacel Surgical in all the surgery procedures where the risk of wound dehiscence and maceration is high. *(Plast Reconstr Surg Glob Open 2016;4:e863; doi: 10.1097/GOX.0000000000000750; Published online 15 September 2016.)*

Body-contouring surgical procedures are intended to correct skin excess and skin ptosis in patients who have undergone major weight loss, restoring a proper elasticity to the tissues. These procedures include brachioplasty, tummy tuck, torsoplasty, buttock lift, and thigh lift.[1]

In our department, thigh lift is the second most requested surgical procedure in ex-obese body-contouring surgery. This procedure is followed by a high rate of minor complications that include wound dehiscence, infection, and hypertrophic scars.

The postoperative dressing in patients undergoing thigh lift is often difficult, not very resistant to movement, and uncomfortable for the patient. The lack of effectiveness of traditional dressing with sterile gauze and a patch exposes the surgical site to infection, maceration, or a delay in wound healing.

The study aims to demonstrate the effectiveness, durability, and patient's comfort of the surgical dressing, AQUACEL Surgical (ConvaTec Inc., Greensboro, N.C.), compared with traditional wound dressing.

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MATERIALS AND METHODS

Patients

The study was conducted in the Department of Reconstructive and Aesthetic Plastic Surgery at the University Hospital Città della Salute e della Scienza, Turin, Italy, during the period from May 2013 to July 2014. We included 40 patients who performed thigh lift in a case–control crossover study with no period effects (8 men and 32 women; age between 18 and 60 y; mean age, 39 y; average body mass index, 27.6).

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Fig. 1. Aquacel Surgical dressing composition. Copyright © ConvaTec Italia S.r.l. Reprinted with permission.

The exclusion criteria were diabetes, smoking, and vascular diseases. All the patients had undergone bariatric surgery (25 vertical banded gastroplasty and 15 gastric bypass).

Liposuction was not performed contextually with the thigh lift. All surgical incisions were positioned in the inguinal crease, extended anteriorly 1 to 2 cm over the pubis level and posteriorly arriving at the gluteal fold. The average removal of excess tissue was about 350 g; mean wound length, 27 cm; mean weight loss, 30 kg. In all the patients, tubular drains were positioned. The suture was performed using Vicryl 2/0, Monosyn 3/0, and metal staples. The same surgeon closed both thighs for each patient.

Dressing Application and Composition

At the end of the procedure, in the operating room, a dressing with sterile gauze and patch was put on a thigh, selecting it randomly; on the other one, Aquacel Surgical was positioned. This dressing is composed of hydrofibra in combination with hydrocolloid. The core is made of aquacel that is a hydrofiber enriched with silver ions; the border is a hydrocolloid sheet. Aquacel provides absorbent and antimicrobial properties. The hydrocolloid border is water proof and transpirable (Fig. 1).

Postoperative Treatment

Dressing change was performed after 5 days for the thigh where Aquacel Surgical was positioned. On the other thigh, the dressing was changed every day. At each dressing change, surveys with a 10-point scale evaluation were used to assess nontraumatic removal level, ease of application, adhesion, and strength of the 2 treatments. We reported the number of days necessary for wound healing, the number of infection cases, and wound-related complications. Costs of the 2 medications were also considered. All the patients wore a restraining sheath that was held in place for a month after surgery.

Ten days after surgery, patients answered a questionnaire with 6 multiple-choice questions to assess comfort, pain at dressing change, pruritus, adhesion and strength of the dressing, and number of dressing changes.

Data Analysis

This is a case–control crossover study with 2 dependent (paired) samples with no time period effects. Differences of quality characteristics between the Aquacel Surgical and the traditional dressing were evaluated using 2-tail matched pair t tests at a level $\alpha = 0.05$. Wound-healing speed and costs of complete treatments were evaluated using an exact sign 2-tailed (nonparametric) test at a level $\alpha = 0.05$. The proportion of infections and wound-related complications were evaluated using Fisher's exact test at a level $\alpha = 0.05$.

The study was approved by the ethics committee of our institution and was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

RESULTS

Descriptive statistics of quality measures of the 2 dressings are summarized in (Table 1). The frequency distribution graphs of quality evaluation variables are in (Fig. 2): black bars for Aquacel Surgical and gray bars for the traditional dressing.

Matched pair t tests revealed significant differences ($P < 0.001$) between the 2 treatments for quality measures (Table 2). The dressing change was about 3 to 4 points less traumatic on average ($|t| = 30.048$) and about 4 points easier ($|t| = 29.835$) on average with Aquacel Surgical than with the control traditional dressing. The medication remained in loco, adhesive to the skin in each of the patients in the 5 days: the adhesion and strength were about 4 to 5 points better on average with Aquacel Surgical than with traditional dressing ($|t| = 23.845$) (Fig. 3).

Table 1. Descriptive Statistics of Quality Measures of the Study Paired Samples

Variable	N	Minimum	Maximum	Median	Mean	SD
Nontraumatic removal level (higher = less traumatic)						
Aquacel Surgical	40	4.000	9.000	7.000	6.600	1.277
Traditional dressing	40	1.000	5.000	3.000	2.875	1.067
Ease of application (higher = easier)						
Aquacel Surgical	40	4.000	9.000	7.000	6.625	1.295
Traditional dressing	40	1.000	5.000	3.000	2.850	1.001
Adhesion and strength (higher = better)						
Aquacel Surgical	40	4.000	9.000	7.000	6.825	1.174
Traditional dressing	40	1.000	5.000	3.000	2.625	0.979
No. days for wound healing						
Aquacel Surgical	40	5.000	7.000	5.000	5.325	0.526
Traditional dressing	40	7.000	14.000	11.000	10.700	1.728

N is the sample size of each group. All but the last variable is evaluated by doctors in a 10-point scale.

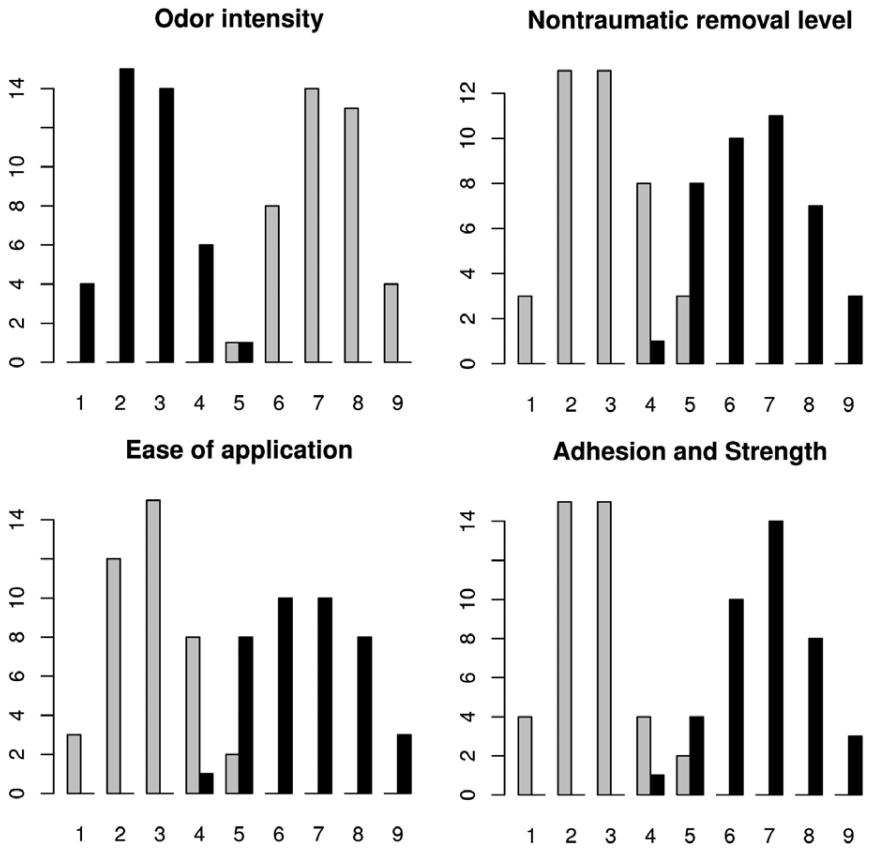

Fig. 2. Frequency distribution graphs of quality measures variables (evaluated with a 10-point scale). *Black*: Aquacel Surgical; *gray*: traditional dressing.

Table 2. Paired *t* Test Statistics for the Quality Measures of the 2 Medications, with df = 39

Variable	|*t*| Value	*P*
Nontraumatic removal level	30.048	<0.001
Ease of application	29.835	<0.001
Adhesion and strength	23.845	<0.001

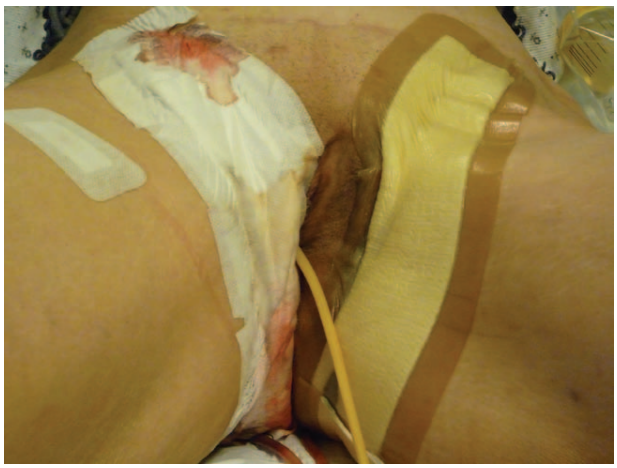

Fig. 3. One day after operation. Dressing with sterile gauze on the right thigh and Aquacel Surgical on the left thigh.

The number of days for wound healing exhibits a different distribution depending on the treatment (Fig. 4), and also the SDs are very different (0.526 and 1.728 for Aquacel Surgical and the traditional dressing, respectively) as reported in (Table 1). For these reasons, an exact sign 2-tailed test (nonparametric) was performed to compare the differences of number of days for wound healing in the 2 treatments.[2] Aquacel Surgical elicited a statistically significant median acceleration (about 5–6 d less) for a complete healing compared with the control medication ($P < 0.001$) (Fig. 5).

Statistical analysis[3] revealed no significant differences between the risk of infection and wound-related complications with the 2 treatments. Four of 40 subjects had infections with the traditional dressing and none with Aquacel Surgical ($P = 0.116$, Fisher's exact test), whereas 4 of 40 subjects had wound-related complications with Aquacel Surgical compared with 5 of 40 subjects with the traditional dressing ($P = 1$, Fisher's exact test).

In Italy, the unitary cost of Aquacel Surgical dressing is 9.89 euros, whereas the unitary cost of a traditional dressing is 38 cents. Aquacel Surgical needs to be replaced every 5 days and the traditional dressing twice a day. In our sample, all the patients needed 1 replacement of Aquacel Surgical, and the total expenditure with this medication was 19.78 euros. On the contrary, the time for a complete recovery and the number of required changes of the tradi-

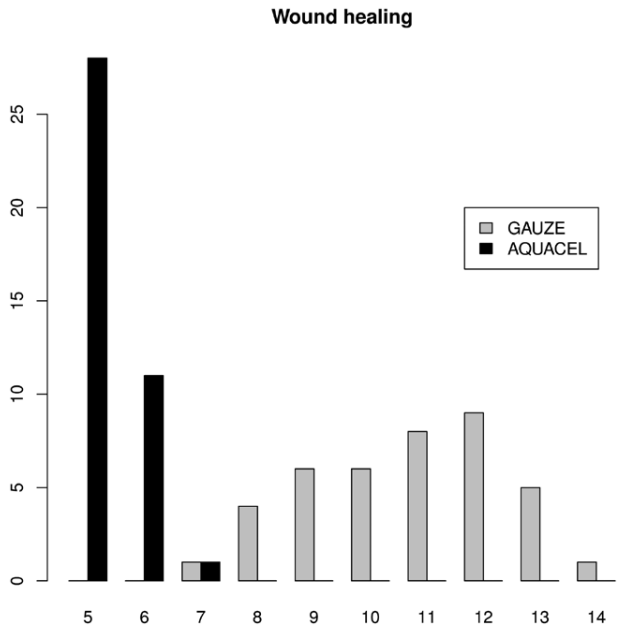

Fig. 4. Distribution graph of the number of days for healing with the 2 medications: Aquacel Surgical (*black*) and the traditional dressing (*gray*).

tional dressing led to a higher variability of costs with this medication (Table 3).

Because neither the distributions of costs are normal nor the distribution of the differences of cost is symmetric (test statistic = 1.4313, $P = 0.1524$[4]), we performed an exact sign 2-tailed test to compare the 2 treatment costs at a level $\alpha = 0.05$. The test revealed a statistically significant median higher cost with Aquacel Surgical (about 11–12 euros more expensive for a complete medication treatment) compared with the control treatment cost of medication ($P < 0.001$).

We analyzed the data gathered from the questionnaires completed by the patients. Thirty-six patients reported that the dressing change, in the thigh where Aquacel Surgical was not positioned, was more painful. Four patients did not report any change in pain between the 2 dressings. Twenty-four patients referred less pruritus in the thigh where Aquacel Surgical was positioned. Sixteen patients did not notice any difference in terms of pruritus.

All the patients reported more comfort during dressing application, a longer duration, and total atraumaticity during the dressing change with Aquacel Surgical.

DISCUSSION

Among the various surgical procedures of body contouring, thigh lift is definitely most at risk of surgical site infection.[5] What predisposes this type of procedure to the risk of infection is the anatomical site involved and the difficulty of medication that creates a greater facility to contamination. The dressing change is often difficult and unstable.

The advanced wound dressing Aquacel Surgical consists of an association between hydrofibra enriched with silver ions and hydrocolloid. The hydrocolloid part is composed of a layer of gelling material adherent to a semipermeable film. The hydrocolloid creates a moist

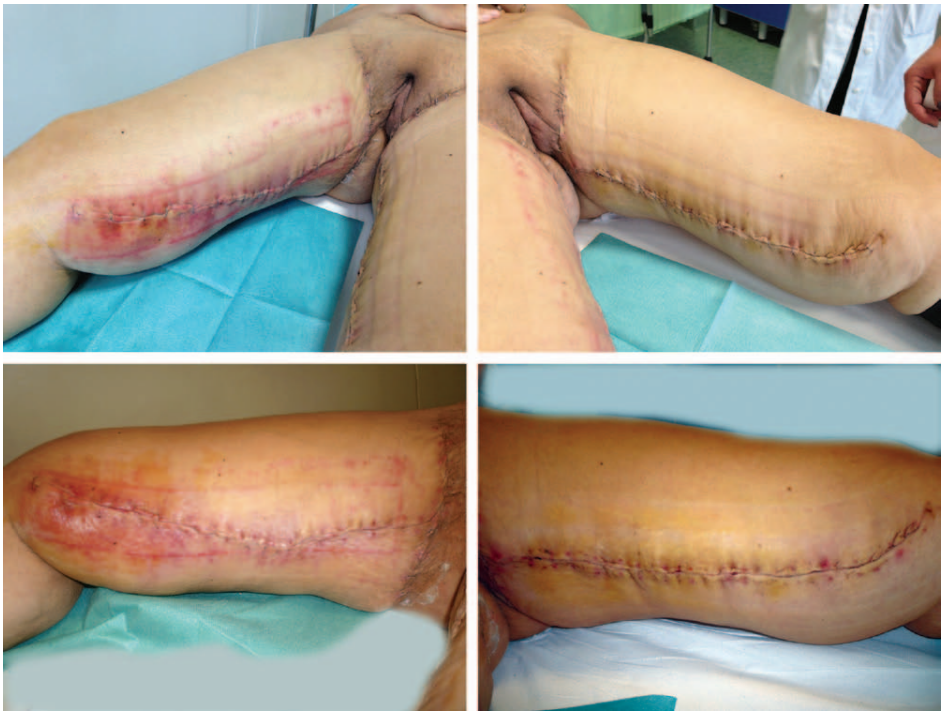

Fig. 5. Five days after operation at dressing change. On the left thigh after dressing with sterile gauze; on the right thigh after dressing with Aquacel Surgical.

Table 3. Statistical Description of the Cost of a Complete Treatment with the Traditional Medication (in Euros)

Cost	N	Minimum	Maximum	Median	Mean	SD
Traditional dressing	40	5.32	10.64	8.36	8.13	1.313

environment for optimal wound healing, as it promotes angiogenesis, increases the number of dermal fibroblasts, and increases the amount of synthesized collagen.[6] Furthermore, the formation of gel during the use of the dressing makes removal nontraumatic and easy. It is believed that the moist environment without oxygen protects the nerve endings giving pain reduction.[7] The ability of hydrocolloids to retain moisture helps soften and rehydrate any necrotic tissue. Hydrocolloid also acts as a barrier against viruses and bacteria (methicillin-resistant *Staphylococcus aureus*, hepatitis B virus, and HIV1), where integrity of the dressing is preserved, and in the absence of leakage or infiltration.[8–10] Therefore, it gives benefits in high contamination areas. Because of this property, the vesical catheter can be removed in less time, preventing urinary tract infections. Hydrofibra is a sterile dressing, made from soft hydrocolloid fibers (sodium carboxymethylcellulose). Thanks to its particular structure, it retains exudate within the hydrofibers, preventing the propagation and reducing the risk of maceration of surrounding skin. The combination of silver ions adds antimicrobial properties.[11]

Dressing change twice daily or daily for the control group is a weak part of the study, but the dressing in the control group was changed because it got dirty or wet very frequently because of the anatomical area. We could not avoid it. Aquacel Surgical retains exudate within the hydrofibers, preventing the propagation so the dressing does not get wet. Dressing change frequency may have also influenced tendency to report more pain in the control group.

This is not a blinded study. Wound healing was assessed in terms of days needed to gain a complete wound healing. In this group of patients, we did not have a high rate of infection and wound dehiscence. In our opinion, this was also due to the exclusion criteria: diabetes, smoking, and vascular diseases. Maybe in a higher number of samples with patients presenting this comorbidity, differences would have been much more evident between the treated thigh and the control one.

The Aquacel Surgical combines the effectiveness of hydrofibra and hydrocolloid. We think that this wound dressing allows the skin to regenerate quickly without any complication such as dehiscence or superficial infection.

CONCLUSION

From the results of our study, we can confirm that Aquacel Surgical seems to be more comfortable and easier to manage for the patient, durable, waterproof, and nontraumatic at dressing change. We recommend the use of Aquacel Surgical in all the surgery procedures where the risk of wound dehiscence and maceration is high.

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PATIENT CONSENT

Patients provided written consent before their inclusion in the study.

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Clinical Study

AQUACEL® Ag Surgical Dressing Reduces Surgical Site Infection and Improves Patient Satisfaction in Minimally Invasive Total Knee Arthroplasty: A Prospective, Randomized, Controlled Study

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The use of modern surgical dressings to prevent wound complications and surgical site infection (SSI) after minimally invasive total knee arthroplasty (MIS-TKA) is lacking. In a prospective, randomized, controlled study, 240 patients were randomized to receive either AQUACEL Ag Surgical dressing (study group) or a standard dressing (control group) after MIS-TKA. The primary outcome was wound complication (SSI and blister). The secondary outcomes were wear time and number of dressing changes in the hospital and patient satisfaction (pain, comfort, and ease of use). In the intention-to-treat analysis, there was a significant reduction in the incidence of superficial SSI (0.8%, 95% CI: 0.00–2.48) in the study group compared to 8.3% (95% CI: 3.32–13.3) in the control group ($p = 0.01$). There were no differences in blister and deep/organ-space SSIs between the two groups. Multivariate analysis revealed that AQUACEL Ag Surgical dressing was an independent risk factor for reduction of SSI (odds ratio: 0.07, 95% CI: 0.01–0.58, $p = 0.01$). The study group had longer wear time (5.2 ± 0.7 versus 1.7 ± 0.4 days, $p < 0.0001$) and lower number of dressing changes (1.0 ± 0.2 versus 3.6 ± 1.3 times, $p < 0.0001$). Increased patient satisfaction ($p < 0.0001$) was also noted in the study group. AQUACEL Ag Surgical dressing is an ideal dressing to provide wound care efficacy, patient satisfaction, reduction of SSI, and cost-effectiveness following MIS-TKA.

1. Introduction

Periprosthetic joint infection (PJI) is a severe complication and occurs in 1-2% of patients after total knee arthroplasty (TKA) [1]. Recently, a study of primary causes of revision TKA found that PJI comprised 14.5% of total revision and 26.8% of cases if revision was performed within one year after index operation [2]. One risk factor related to PJI is superficial wound complication, including surgical site infection (SSI), prolonged wound discharge, and skin blisters [3]. Therefore, prevention of superficial wound complications is necessary after TKA.

Minimally invasive surgery (MIS) has gained popularity in TKA with the advantages of shortened wound length, decreased rehabilitation period, and quicker return to work compared to standard TKA [4]. MIS-TKA also has higher wound complications, which are related to greater tension on wound edges during surgery [5]. Therefore, an improved wound care modality is essential. In our institution, the standard dressing care after MIS-TKA is an antimicrobial dressing (Sofra-Tulle®, Royal Chem. & Pharm. Co., Ltd., Kaohsiung, Taiwan) on the inner layer and gauzes with tape on the outer layer. However, patients often complained of pain during dressing change and discomfort during knee range-of-motion exercise after surgery by the use of gauze dressings [6]. Furthermore, skin blistering and infection are common problems because postoperative movement around the knee joint causes friction between the skin and traditional gauze [7].

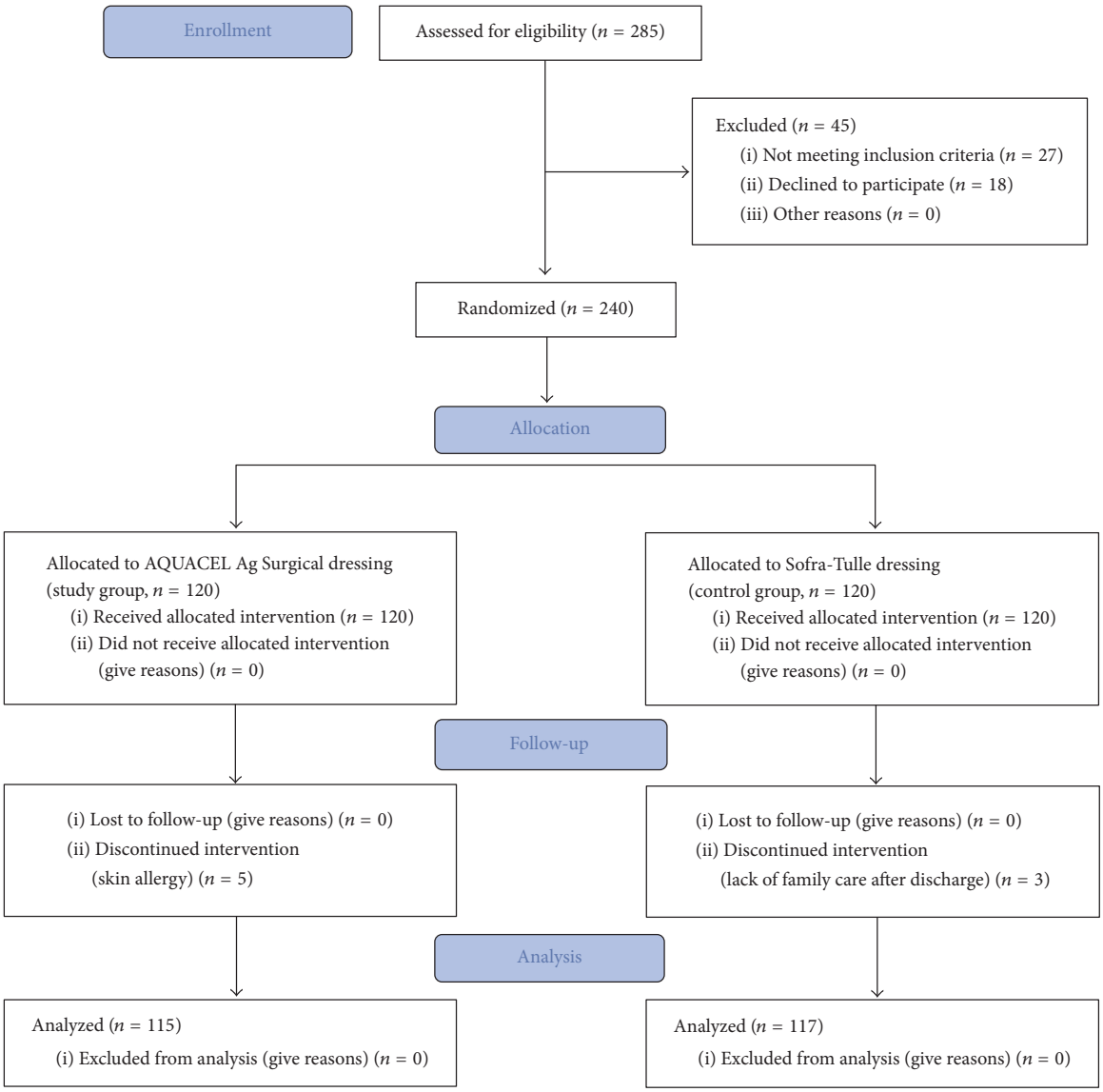

Figure 1: CONSORT flow diagram showing enrollment and exclusion through the trial phase.

AQUACEL Ag Surgical dressing (ConvaTec Inc., Greensboro, North Carolina, USA) is a modern dressing. The dressing comprises a core hydrofiber layer containing ionic silver that absorbs exudates to form a cohesive gel and provides antimicrobial protection and an adhesive hydrocolloid backing that fully protects the wound. Both hydrofiber and hydrocolloid layers are extensible to accommodate skin movement during postoperative physiotherapy and prevent blistering [9]. Few comparisons of the AQUACEL Ag Surgical dressing and the standard dressing have been reported on traditional TKA [11–13], and the literature on MIS-TKA is sparse.

We hypothesized that AQUACEL Ag Surgical dressing would have a significant improvement in the efficacy of wound care, patient satisfaction, and surgical site infection compared with standard dressings after MIS-TKA.

2. Materials and Methods

A prospective, randomized, controlled trial was conducted involving a consecutive series of patients undergoing primary MIS-TKA at a single institute between October 2013 and September 2014. Written informed consent was obtained from all patients before their participation in the study. The present study was approved by the institutional review board of our institution and was registered in the public ClinicalTrials.gov registry (NCT02445300). All patients were enrolled in accordance with the Consolidated Standards of Reporting Trials (CONSORT) (Figure 1).

Inclusion criteria included the patients who were scheduled for primary unilateral MIS-TKA in the study period. The indication for TKA was severe osteoarthritis of the

knee. Exclusion criteria included patients with condition or comorbidity that could compromise wound healing, including varicose vein, peripheral vascular disease, smokers, poor nutrition, receiving immunosuppressive medications, corticosteroid abuse, and chronic skin disease around the knee (e.g., psoriasis and chronic eczema). Patients who *had* had prior knee replacement, an osteotomy, or a fracture of the ipsilateral knee were also excluded. Therefore, 285 patients were enrolled. Twenty-seven patients were further excluded due to the condition or comorbidity that could compromise wound healing. Eighteen patients who declined to participate were also excluded from the study. Finally, 240 patients were randomized to receive either AQUACEL Ag Surgical dressing (study group) or Sofra-Tulle dressing (control group) after MIS-TKA. A computer-generated randomization schedule was used to assign participants to treatment using a block size of 8 (1 : 1 ratio) (Figure 1).

Before the study, 240 opaque sealed envelopes were numbered randomly from 1 to 240 by means of a computer-generated method: 120 envelopes containing 3 pieces of AQUACEL Ag Surgical dressing (9 cm × 25 cm) and 120 envelopes containing 10 pieces of Sofra-Tulle dressings (10 cm × 10 cm). All patients received unilateral primary MIS-TKA under general anesthesia. A pneumatic thigh tourniquet was inflated to a pressure of 300 mmHg before the incision and deflated at the end of surgery after skin closure. All wounds were closed with interrupted skin stitches.

All patients received minimally invasive surgery by the same surgeon. All TKAs were cemented using the same type of prosthesis (NexGen, Legacy, Posterior-Stabilized Prosthesis; Zimmer, Warsaw, IN). A mini-midvastus approach for TKA was employed, as described by Haas et al. [14]. The skin incision was made along the medial aspect of the patella to the medial border of the mid-to-distal tibial tubercle. The patellar components were all resurfaced. There was no local infiltration of local anesthetic. A suction drain was inserted at the end of the operation and was removed two days after the operation. At the end of skin closure, a sealed envelope was opened to notify the surgeon of the closure method. The dressing was applied to the wound in the operating theater by the surgeon. All patients received oral Factor Xa inhibitor as deep vein thrombosis prophylaxis for 14 days. A standard postoperative rehabilitation protocol was applied to all patients, including the use of continuous passive motion of the knee and muscle strengthening exercise immediately after surgery. All patients were taught by a physical therapist to get out of bed with walker support on the first postoperative day.

The study group used AQUACEL Ag Surgical dressing. The indications for removal of the AQUACEL Ag Surgical dressing were leakage beyond the hydrocolloid exterior layer and more than 50% saturation of the hydrofiber inner layer [9]. If there were no indications to change the dressing, it was changed at the day of discharge, usually the 4th or 5th postoperative day (POD), and the wound remained covered for 7 days except for exudates across the dressing. Then, a new AQUACEL Ag Surgical dressing was applied at home until the first visit at the clinic. The control group used Sofra-Tulle dressing, which is an antimicrobial dressing formed by a fabric of leno weave impregnated with white soft paraffin containing 1% framycetin sulphate. The standard dressing consisted of a Sofra-Tulle dressing on the inner layer covered with gauze on the outer layer and was occlusive with tapes over the whole surface of the standard dressing. The indication for removal of the standard dressing was wound drainage on the dressing. If the wound was not soiled, it was changed on the day of discharge. After being discharged from the hospital, the family conducted the dressing change according to the removal criteria for each dressing.

2.1. Outcomes Measurements. The primary outcome measure was wound complication, including surgical site infection (SSI) and blister. Wound complication was assessed *at* each dressing change. SSI was defined based on the recent recommendations of the Centers for Disease Control and Prevention (CDC) and divided into superficial SSI (only involving skin and subcutaneous tissue) within 3 months after surgery, deep SSI (involving below the fascia), and organ-space SSI (involving the joint) within 1 year after surgery [15]. The secondary outcome was patient satisfaction about the dressings. Patient satisfaction was evaluated by three parameters (pain, comfort, and ease of use) on the day of the first postoperative visit. Pain was evaluated with the use of a visual analog scale (VAS), with 0 representing "no pain" and 10 representing "severe pain" [16]. The pain severity was reported by the patient during dressing removal. The comfort and ease of use were classified as excellent, good, fair, or poor [17]. Wear time of the dressing and number of dressing changes in the hospital were also recorded. All the patients completed the outcome evaluation.

2.2. Statistical Analysis. An a priori sample size was estimated using a 2-tailed Fisher exact test with a 0.05 level of significance. Based on the study conducted by Burke and colleagues [9], we estimated the incidence of wound complication at 4.8% in the study group and 17.7% in the control group. We determined that 204 participants (102 per group) would be needed to achieve 80% statistic power. Expecting a 15% attrition rate, a total of 240 patients were enrolled (120 per group).

The categorical data were summarized as an absolute value and percentage. The continuous data were presented as mean and standard deviation. Independent samples t-test was used to compare the continuous variables and the chi-squares test was used to compare the categorical variables. Wound complication rates and patient satisfaction were expressed by calculation of proportion and a 95% confidence interval (CI). The primary prespecified analysis was an intention-to-treat analysis. The intention-to-treat population included all 240 patients who underwent randomization. We also performed a prespecified per-protocol analysis. The per-protocol population included patients in both groups who had used the same dressings throughout the study. Multivariate logistic regression was used to determine whether AQUACEL Ag Surgical dressing was an independent predictor for surgical site infection. The multivariate logistic regression incorporated the following demographics: age, sex, BMI, ASA, and comorbidities. A 5% statistically significant level was prescribed ($p < 0.05$). All data were

Table 1: Demographics of the patients.

	AQUACEL Ag Surgical (study dressing)	Sofra-Tulle (control dressing)	p value
Age (years), mean ± SD	70.3 ± 7.5	70.1 ± 7.1	0.85
BMI (kg/m^2), mean ± SD	27.8 ± 4.6	27.7 ± 4.4	0.86
Sex F/M, n	85/35	91/29	0.38
ASA, n (%)			0.19
I	12 (10.0)	10 (8.3)	
II	65 (54.2)	53 (44.2)	
III	43 (35.8)	57 (46.7)	
Diabetic, n (%)	23 (19.2)	18 (15.0)	0.39
Chronic kidney disease, n (%)	9 (7.5)	11 (9.2)	0.64
Cardiovascular, n (%)	17 (14.2)	14 (11.7)	0.56

SD: standard deviation; BMI: body mass index; F: female; M: male; ASA: American Society of Anesthesiologists.

Table 2: Surgical site infection and blistering estimated according to intention-to-treat and per-protocol analysis in patients treated with AQUACEL Ag Surgical dressing and control dressing.

Wound complications	AQUACEL Ag Surgical (study dressing) (dropouts, n = 5)		Sofra-Tulle (control dressing) (dropouts, n = 3)	
	ITT analysis	PP analysis	ITT analysis	PP analysis
Blistering, % (95% CI)	2.5 (0.00–5.33)	1.7 (0.00–4.17)	5.0 (1.04–8.96)	5.1 (1.07–9.18)
Superficial SSI, % (95% CI)	0.8 (0.00–2.48)	0.9 (0.00–2.59)	8.3 (3.32–13.3)	8.5 (3.41–13.7)
Deep/organ-space SSI, % (95% CI)	0	0	0.8 (0.00–2.48)	0.9 (0.00–2.55)

SSI: surgical site infection; CI: confidence interval; 95% CI: 95% confidence interval; ITT: intention-to-treat; PP: per-protocol.

analyzed with the use of MedCalc software (version 17.4, Ostend, Belgium).

3. Results

A total of 240 patients underwent randomization (Figure 1). Five patients had skin allergies after application of AQUACEL Ag Surgical dressing and were switched to standard dressing. Three patients in the control group refused to participate in the study after allocation due to the lack of family care after discharge and then switched to use AQUACEL Ag Surgical dressing. All 240 patients were included in the intention-to-treat analysis, whereas 115 of 120 patients (95.8%) in the study group and 117 of 120 patients (97.5%) in the control group were included in the per-protocol analysis. No patients were lost during two-year follow-up.

The basic demographic data were similar between the two groups (Table 1). The length of hospital stay did not differ significantly between the two groups (6.3 ± 1.1 versus 6.6 ± 1.4 days, $p = 0.02$). Patients in the study group had a longer mean wear time (5.2 ± 0.7 days) than those in the control group (1.7 ± 0.4 days, $p < 0.0001$). The mean number of dressing changes prior to discharge was significantly lower in the study group (1.0 ± 0.2 times) than in the control group (3.6 ± 1.3 times, $p < 0.0001$).

Of the eight dropouts, only one patient developed blisters in the study group. None of these dropouts developed surgical site infection. In the intention-to-treat analysis, the incidence of blistering was lower in the study group at 2.5% (3/120, 95% CI: 0.00–5.33) compared to 5.0% (6/120, 95% CI: 1.04–8.96) in the control group ($p = 0.31$). The incidence of superficial SSI in the study group was statistically significantly lower at 0.8% (1 of 120, 95% CI: 0.00–2.48) compared to 8.3% (10 of 120, 95% CI: 3.32–13.3) in the control group ($p = 0.01$). One patient developed deep SSI in the control group (0.8%, 95% CI: 0.00–2.48), but no patients had deep or organ-space SSI in the study group ($p = 0.32$) (Table 2). The multivariate logistic regression revealed that AQUACEL Ag Surgical dressing was an independent risk factor for PJI with an odds ratio (OR) of 0.07 (95% CI: 0.01–0.58, $p = 0.01$).

The patient satisfaction is shown in Table 3. The mean VAS pain score was lower in the study group compared with the control group when the dressing was removed (1.1 ± 0.7 versus 3.6 ± 1.2, $p < 0.0001$). In the study group, most patients experienced excellent comfort when the dressing was in place (67.8% versus 31.6%, $p < 0.0001$) and during removal (74.8% versus 42.7%, $p < 0.0001$). Excellent ease of use was rated higher in the study group compared with the control group during application of the dressing (92.2% versus 35.0%, $p < 0.0001$) and removal of the dressing (95.7% versus 40.2%, $p < 0.0001$).

4. Discussion

AQUACEL with or without silver-impregnated dressing has been shown to be an effective dressing to significantly reduce

Table 3: Patient satisfaction.

	AQUACEL Ag Surgical (study dressing)	Sofra-Tulle (control dressing)	p value
Pain (VAS)			
Dressing removal, mean ± SD	1.1 ± 0.7	3.6 ± 1.2	<0.0001
Comfort (excellent), % (95% CI)			
Dressing in place	67.8 (59.1–76.5)	31.6 (23.0–40.2)	<0.0001
Dressing removal	74.8 (66.7–82.8)	42.7 (33.6–51.8)	<0.0001
Ease of use (excellent), % (95% CI)			
Ease of application	92.2 (87.2–97.2)	35.0 (21.5–38.3)	<0.0001
Ease of removal	95.7 (91.9–99.4)	40.2 (31.2–49.2)	<0.0001

VAS: visual analog scale; SD: standard deviation; 95% CI: 95% confidence interval.

the occurrence of acute PJI [11], blister formation [10], and SSI [8, 9] after total joint arthroplasty compared to other adhesive dressings in previous studies (Table 4). In a case-control study by Cai et al. [11], the incidence of PJI was lower in the AQUACEL Ag Surgical dressing group compared to the standard gauze dressing group (0.44% versus 1.7%, p = 0.005). They found that the use of AQUACEL Ag Surgical dressing was an independent risk factor for reduction of PJI (OR: 0.17, 95% CI: 0.05–0.53). Dobbelaere et al. [12] compared three innovative wound dressings to each other and to a standard dressing after total knee arthroplasty. The innovative wound dressings were Opsite Post-Op Visible® (Smith & Nephew Advanced Wound Management, Hull, UK), AQUACEL Surgical®, and Mepilex® Border (Mölnlycke Health Care, Gothenburg, Sweden). The standard wound dressings were Zetuvit® (Paul Hartmann AG, Heidenheim, Germany), immediately applied after TKA, followed on the first postoperative day by Cosmopor® E (Paul Hartmann AG, Heidenheim, Germany). They found no infection in all patients with the use of these three innovative wound dressings. Springer et al. [13] also reported 0% SSI with the use of AQUACEL Ag Surgical dressings in total hip and knee arthroplasty, but they could not conclude that AQUACEL Ag Surgical dressings played an important role in reducing SSI. Our study agreed that AQUACEL Ag Surgical dressing is an independent risk factor for reduction of SSI following MIS-TKA (OR: 0.07, 95% CI: 0.01–0.58). The silver-containing dressing has been proven to fight against commonly encountered wound pathogens, including antibiotic-resistant bacteria such as methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant enterococci, aerobic and anaerobic bacteria, and yeasts in an in vitro study [18]. Upon hydration of exudates, the hydrofiber dressing responds to changes in wound fluid and silver ions are continuously made available during dressing wear time, which reduced SSI in the clinical study. However, we did not find differences in blister formation between the two types of dressings. We considered two reasons. First, our cases were performed using minimally invasive surgery, which avoided eversion of the patella and dissection of the lateral skin flap of the knee [14]. Therefore, the blood supply of the skin flap around the knee may be less compromised. Second, the standard dressing used in our study has nonadherent properties. In previous reports comparing modern and traditional dressings [8–10], the traditional dressing was an adhesive dressing (Mepore®; Mölnlycke Health Care, Norcross, Georgia), which caused increased skin blister formation compared to nonadherent dressings [19].

Our study also showed that AQUACEL Ag Surgical dressing had increased patient satisfaction in terms of pain, comfort, and ease of use compared to standard of care. However, five patients in the study group dropped out of the study because they had skin itching and erythema after application of the AQUACEL Ag Surgical dressings. According to Dobbelaere et al. [12], skin irritation and redness were not found in the AQUACEL Ag Surgical group, but 12.9% of the patients experienced these reactions in the conventional dressing group. They also found that AQUACEL Ag Surgical dressing had better scores for pain, freedom of movement, and general comfort compared to the conventional dressing. In a prospective randomized clinical trial, hydrofiber dressing with ionic silver was better for managing pain, overall comfort, wound trauma upon dressing removal, exudate handling, and ease of use compared to povidone-iodine gauze for the treatment of open surgical and traumatic wounds [17]. Similar results were reported when hydrofiber dressing was applied for chronic leg ulcerations [20]. The reasons for better patient satisfaction in AQUACEL Ag Surgical dressing are attributed to the hydrofiber layer and hydrocolloid layer. The individual fibers in hydrofiber dressings are fine and flexible. The hydrocolloid layer is skin-friendly and comfortable during body movement [21]. With those two characteristics, the AQUACEL Ag Surgical dressing is extensible to accommodate skin movement during physiotherapy and that is associated with reduced blistering after TKA.

The cost of one AQUACEL Ag Surgical dressing at our institution is US$15. A standard taped gauze dressing costs nearly US$1. Therefore, the additional cost for an AQUACEL Ag Surgical dressing is about US$14 per case. In Taiwan, there are approximately 25 thousand TKAs performed annually. The cost of using an AQUACEL Ag Surgical dressing routinely after TKA would add approximately *US$350,000* in cost. Infection after TKA has been reported with an incidence ranging from 1.0% to 2.0% [1]. The cost to treat a PJI has been estimated to range from *US$13,000* to over *US$23,000*

Table 4: Comparison of reported literatures on AQUACEL with or without silver-impregnated dressing following total joint arthroplasty.

Study	Design	Dressing	Number of patients	Surgery	Wear time (days)	Dressing change (number)	Blister (%)	SSI (%)
Clarke et al. (2009) [8]	Prospective	Folded AQUACEL and hydrocolloid dressing	242	TKA and THA	3.7	1.5	2	1
Burke et al. (2012) [9]	Prospective randomized	AQUACEL and hydrocolloid dressing	62	27 TKAs 35 THAs	—	1	4.8	0
Hopper et al. (2012) [10]	Prospective	AQUACEL Surgical	50	25 TKAs 24 THAs 1 RTHA	7	0	4	4
Cai et al. (2014) [11]	Case-controlled	AQUACEL Ag Surgical	903	508 TKAs 392 THAs 3 TKAs + THAs	—	—	—	0.4
Dobbelaere et al. (2015) [12]	Prospective randomized	AQUACEL Ag Surgical	29	29 TKAs	—	0.67	6.9	0
Springer et al. (2015) [13]	Prospective randomized	AQUACEL Ag Surgical	141	74 TKAs 67 THAs	—	0.14	0.7	0
This study	Prospective randomized	AQUACEL Ag Surgical	115	115 MIS-TKAs	5.2	1	1.7	0.8

TKA: total knee arthroplasty; THA: total hip arthroplasty; RTHA: revision total hip arthroplasty; SSI: surgical site infection.

in Taiwan [22]. In the Taiwan *study*, the annual low-end cost for the treatment of PJI would be *US$3.25 million* assuming the lower incidence of reported PJI and lower cost of PJI treatment. If the reported thirteenfold reduction in SSI noted in our study is correct, the cost saving would be reduced to *US$3 million* with the use of an AQUACEL Ag Surgical dressing compared to the control dressing in PJI management using the lower estimate. In the United States, the use of AQUACEL Ag Surgical dressing can result in fourfold reduction in SSI, and thus the cost of PJI management would be reduced at approximately *US$375 million* [11].

We have acknowledged some limitations in this study. First off, allocation concealment was performed using opaque envelopes. However, the differences in the dressing sizes would most certainly mean that those involved in administering the intervention dressings were not blinded and would be aware of upcoming assignments. Moreover, patients were not capable of comparing the 2 dressings when ranking satisfaction. Second, our control group used Sofra-Tulle dressing, which has improved characteristics in wound care such as nonadherent properties and antimicrobial effects rather than simple gauzes accompanied with tapes. Third, the patient's family conducted the wound care after discharge from the hospital. Wound complications may increase if inadvertent wound care is performed. In addition, the indications for early dressing change in both groups were somewhat subjective and there should be a selection bias in the evaluation of the number of dressing changes. Finally, the patient satisfaction assessment did not use a validated tool and patients were not able to compare the two dressings directly.

5. Conclusion

Our prospective, randomized, controlled trial demonstrated that the use of AQUACEL Ag Surgical dressing contributes *favorably* to both the clinical efficacy and the cost-effectiveness for managing wound care that is associated with minimally invasive total knee arthroplasty.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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