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Complications - Infection

Single vs Repeat Surgical Skin Preparations for Reducing Surgical Site Infection After Total Joint Arthroplasty: A Prospective, Randomized, Double-Blinded Study

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ABSTRACT

Background: Preventing surgical site infection (SSI) after total joint arthroplasty (TJA) is a high priority and is partly linked to the efficacy of surgical site preparation solutions (SPSs) in reducing the number of pathogens on the skin before incision. The aim of this study is to investigate the effectiveness of SRS reapplication after draping to reduce the incidence of SSI after TJA.
Methods: Six hundred patients undergoing primary TJA between 2010 and 2011 at a single institution were recruited and randomly assigned to one of 2 groups. The patients in the intervention group (n = 300) received SPS that included alcohol and povidone-iodine before draping and an additional SPS by iodine povacrylex and isopropyl alcohol before application of the final adhesive drape, whereas the patients in the control group (n = 300) received a single SPS with alcohol and povidone-iodine before draping. Randomization was performed by an opaque envelope, and the rates of SSI and blistering were compared between groups.
Results: Five seventy-seven patients completed the study and were included in the final analysis. There was a significant reduction in the incidence of superficial SSI for the intervention group (1.8%, 5 of 283) compared to the control group (6.5%, 19 of 294, $P = .02$). There were 2 (0.7%, 2 of 294) deep incisional SSIs in the control group, and 2 (0.7%, 2 of 283) organ-space SSIs in the intervention group ($P = 1.00$). In addition, skin blistering was lower in the intervention group (3.5%, 10 of 283) vs the control group (6.5%, 19 of 294), but this difference also did not reach statistical significance ($P = .13$).
Conclusion: Reapplication of an SPS after draping and before the application of iodophor-impregnated incisive draping resulted in a significant reduction in the rate of SSI in patients undergoing elective TJA.

It is estimated that more than 500,000 surgical site infections (SSIs) occur each year in the United States, at a rate of 2.8 per 100 operations [1]. SSI after total joint arthroplasty (TJA) can lead to prolonged hospitalization, increased morbidity and mortality, and higher costs [2,3]. Therefore, SSIs after TJA can be a devastating complication with an immense psychological and economic burden for the patient and the health care system [4,5].

Although the etiology of SSI is multifactorial, the ability to prevent bacterial proliferation at the incision site is an important factor for preventing wound-related complications [6]. Skin preparation in the operating room before surgery is routinely implemented worldwide in daily clinical practice [7]. Povidone-iodine [8] or chlorhexidine [9] have generally been used for skin antisepsis, with the recommendation of using these antimicrobial solutions with alcohol [10]. In orthopedic surgery, studies in patients undergoing shoulder [11] or foot and ankle surgery [12] have demonstrated that chlorhexidine with alcohol was effective in reducing bacterial counts at the site of surgery compared to other surgical preparation solutions. The rationale behind skin preparation is the attempt to reduce the number of resident bacteria at the site of incision, recognizing that true sterilization of the surgical site is impractical [13]. Therefore, the prevention of SSI is dependent on

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a balance between the bioburden of infective agents at the incision site and the immune threshold of the host to handle the given bioburden. Thus, it is reasonable to assume that effective reduction of bioburden may result in a lower incidence of SSI.

Numerous strategies are available to reduce bioburden which relate to the operating room environment, such as decreasing operating room traffic; wearing clean scrub attire and wearing sterile gowns and gloves; and preoperative patient optimization, such as skin cleansing before surgery by applying a skin preparation solution [14-17]. Traditionally, patients receive a skin preparation solution, draping of the surgical site occurs, and the surgery proceeds. However, contamination of the surgical site may arise during draping, after the initial surgical preparation solution has been applied and dried. No study to date has evaluated the utility of applying a second surgical site preparation solution after draping for reducing SSI.

Thus, the hypothesis of this study was that repeating skin antisepsis after the standard draping process and before the application of iodophor-impregnated incise drapes can reduce the rate of SSI.

Materials and Methods

A prospective, randomized, single-blinded clinical trial was conducted between March 2010 and November 2011 at a single institution. Institutional review board approval was obtained, and every patient was consented to participate in the study. The trial was registered on ClinicalTrials.gov (NCT01097135). A total of 899 patients undergoing primary TJA were assessed for eligibility. Subjects aged between 18 and 80 years who underwent primary, unilateral TJA and were willing to provide written informed consent were included in this study. Excluded patients were those who were allergic to iodine or iodophors, patients undergoing revision TJA, TJA for trauma-related reasons, bilateral TJA, or unicompartmental TJA. Based on the exclusion criteria, 299 patients were excluded for the following reasons: 33 patients did not meet the inclusion criteria, 250 declined to participate, and 16 for other reasons.

A total of 600 patients were then consented and randomized for the clinical trial by a research coordinator. Three hundred patients were assigned to each arm of the study. Of these patients, 23 subjects did not qualify for the analysis; 15 subjects canceled surgery, 7 withdrew consent after consenting initially, and 1 died during their postoperative stay in the hospital because of cardiac arrest. Of the 577 who qualified for the analysis, 283 were in the intervention group and 294 were in the control group (Fig. 1). The patients in the 2 groups were similar with respect to demographic characteristics and type of surgery (Table 1).

Randomization and Masking

Enrolled patients were stratified into 4 groups according to the location of surgery (knee vs hip) and treatment group (intervention

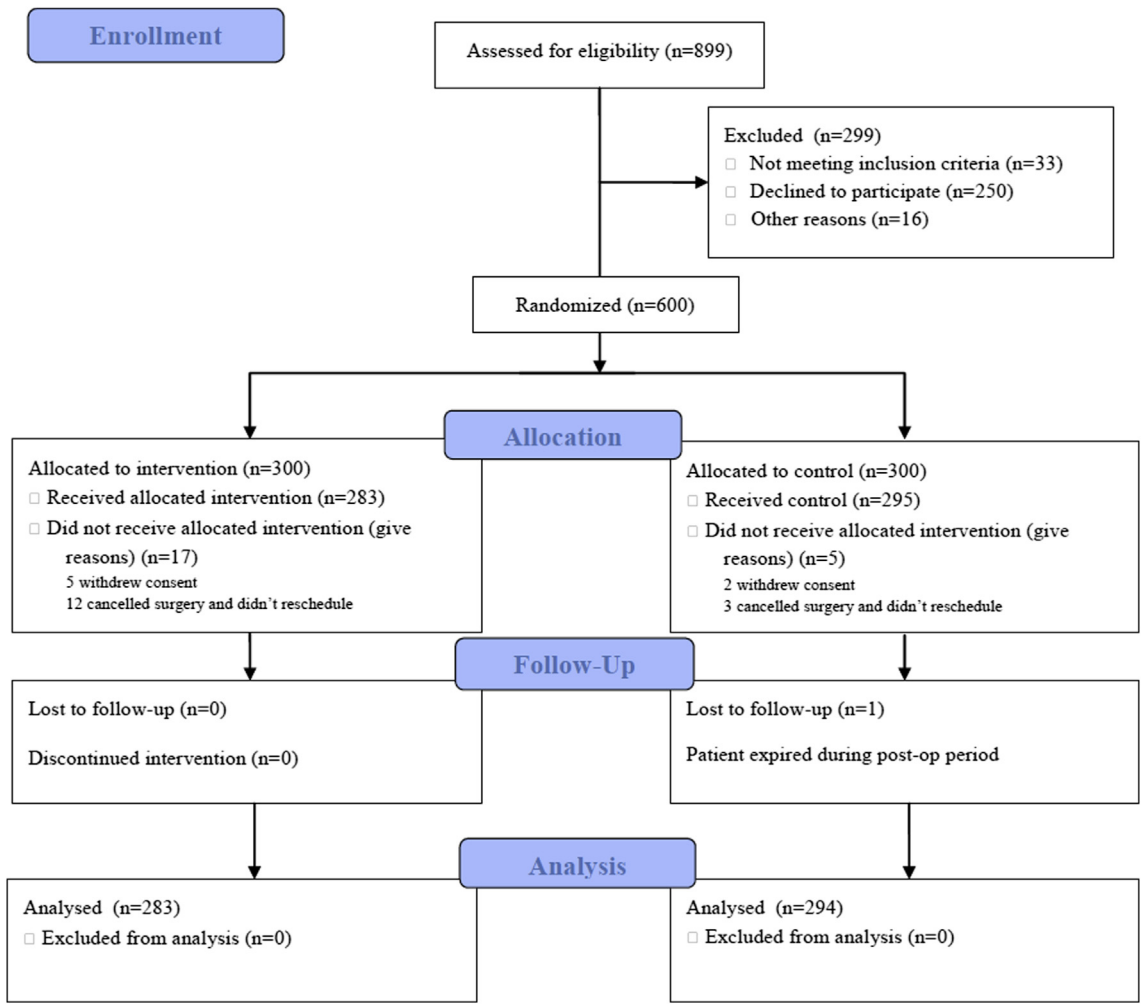

Fig. 1. CONSORT study flow diagram.

Table 1
Demographic Data.

Demographic Parameter	Control Group (N = 294, %)	Experiment Group (N = 283, %)	*P* Value
Gender			.32
Female	52.6	56.9	
Male	47.4	43.1	
Race			.53
White	239 (81.3)	239 (84.5)	
African Americans	5 (1.7)	0 (0.0)	
Asian	51 (17.3)	45 (15.9)	
Other	1 (0.3)	0 (0.0)	
Age (y), mean (SD)	60.4 (9.3)	61.1 (9.8)	.16
BMI (kg/m^2), mean (SD)	30.7 (5.7)	31.1 (6.5)	.20
ASA classification			.17
Class I	5	8	
Class II	108	84	
Class III	181	191	
CCI	0.4 ± 0.9	0.5 ± 1.0	.17
Diabetes	34 (11.6)	44 (15.5)	.18
Joint			1.00
Hip	149 (50.7)	144 (50.9)	
Knee	145 (49.3)	139 (49.1)	

SD, standard deviation; BMI, body mass index; ASA, American Society of Anesthesiology; CCI, Charlson Comorbidity Index.

vs control) with 150 patients in each group. Identification numbers for subjects undergoing total knee arthroplasty (TKA) began with the number "1" and for subjects undergoing total hip arthroplasty (THA) with the number "2," followed by a consecutive series of 3 digits according to the order in which they were enrolled. Randomization occurred on the day of surgery using a sealed envelope, prelabeled method.

Patient Management

Preoperatively, and whenever necessary, all patients had the hair around the incision site clipped and skin cleaned with a 2% chlorhexidine wipe on the day of the surgery by a nurse in the short procedure unit. All patients received 1 g of intravenous cefazolin if they weighed ≤70 kg and 2 g of intravenous cefazolin if they were >70 kg. If a patient had a documented allergy to penicillin or cephalosporins, they were given 1 g of vancomycin. These prophylactic antibiotics were continued 24 hours after surgery. All patients received surgery in operating rooms equipped with a laminar flow system. All patients included in this study received the standard preparation of skin with betadine and alcohol before draping. This was a 3-step process, in which 7.5% povidone-iodine scrub was first applied, followed by 10% iodine paint, and finally 75% isopropyl alcohol.

In the control group, standard draping was applied once the skin was dry from the surgical preparation solution. Standard draping for TKA consisted of application of a sterile impervious stockinette to the extremity to cover the tourniquet, a sterile half sheet below the extremity, a sterile impervious U-drape, an extremity drape, and a self-adherent elastic wrap around the foot and ankle. The impervious stockinette was cut, the surgical site was marked, and an iodophor-impregnated incise drape (Ioban 2; 3M, St. Paul, MN) was applied. Standard draping for THA consisted of the application of a sterile impervious stockinette to the extremity below the level of the incision, a sterile half sheet below the extremity, a sterile impervious U-drape, a second sterile U-drape, and a bar drape above the incision site. A self-adherent elastic wrap was applied to cover the stockinette, the surgical site was marked, and an iodophor-impregnated incise drape (Ioban 2; 3M) was applied.

In the intervention group, standard draping was applied after the skin was dry; then, a repeat skin antisepsis using iodine povacrylex (0·7% available iodine) and isopropyl alcohol, 74% w/w DuraPrep (3M), was performed over the incision site. The skin was allowed to dry before an iodophor-impregnated incise drape was applied (Ioban 2). The difference in intervention groups is demonstrated in Figure 2. Although the use of flammable liquids such as isopropyl alcohol and the iodine povacrylex-isopropyl alcohol combination can be a fire hazard in the operating room, no such events happened during the course of this study.

Postoperatively, both patient groups received a standard nonadherent dressing, gauze, and an abdominal pad. TKA dressings were secured with a compressive wrap, and THA dressings were secured with a medical-grade foam tape. Dressings were removed on postoperative day 1 and assessed for blistering by nurses who were blinded to the intervention performed. Blistering was defined as the development of a fluid-filled sac under the epidermis of any size (Fig. 3). Blinding was performed to remove the potential bias of evaluating for blisters while knowing the purpose of the intervention.

Patients in the control group were followed for an average of 37.5 (±23.0) months, whereas patients in the intervention group were followed for an average of 39.7 (±23.9) months. Postoperatively, the surgical wound was assessed for signs of infection. The attending physicians were blinded to the intervention of the patients who returned to clinic for follow-up at 1-month, 6-month, and 1-year intervals. Our primary end point of SSI occurrence was recorded. SSI was diagnosed and categorized based on hematologic, microbiologic, and physical examination reports by investigators blinded to the subjects' treatment group. These patients were placed into the following categories: superficial, deep, and organ-space SSIs using the Centers for Disease Control guidelines for infectious complications [7]. Superficial SSI was defined as wound problems or drainage above the level of the fascia, whereas deep SSI was defined as wound problems below the level of the fascia and organ-space SSI were infections involving the joint.

Statistical Methods

A previous study on patients undergoing lumbar spine surgery found a 32% colonization rate at wound closure using DuraPrep, compared to a 6% colonization rate after the first preparation, for a difference of 26% [13]. As a conservative estimate, the difference between event rates in the control and intervention groups was estimated to be 20%. For a 2-sided statistical comparison, with a type I error rate of 0.05 and power of 0.80, a sample size of 240 per group was considered appropriate. The recruitment was increased to 300 per group to allow for 20% attrition.

For statistical analysis, Fisher's exact test for 2-by-2 contingency tables was used to compare event rates between the control and intervention groups. Fisher's test was appropriate for this analysis because of the small event counts (usually <5) in the 2 groups. Wilcoxon tests were performed to compare American Society of Anesthesiologist and Charlson Comorbidity Index scores. Risk ratios (RRs) and their 95% CIS were calculated. When there were no events in either or both groups, 0.5 was added to each cell before the RR and CI calculations. All analyses were performed in R 3.0.2 (R Foundation for Statistical Computing, Vienna, Austria).

Results

There were a total of 29 SSIs in the entire group of patients (5.0%). The cumulative incidence of SSIs (superficial, deep, and organ space) in the intervention group was lower, albeit not statistically significantly at 3.2% (9 of 283) compared to 6.8%

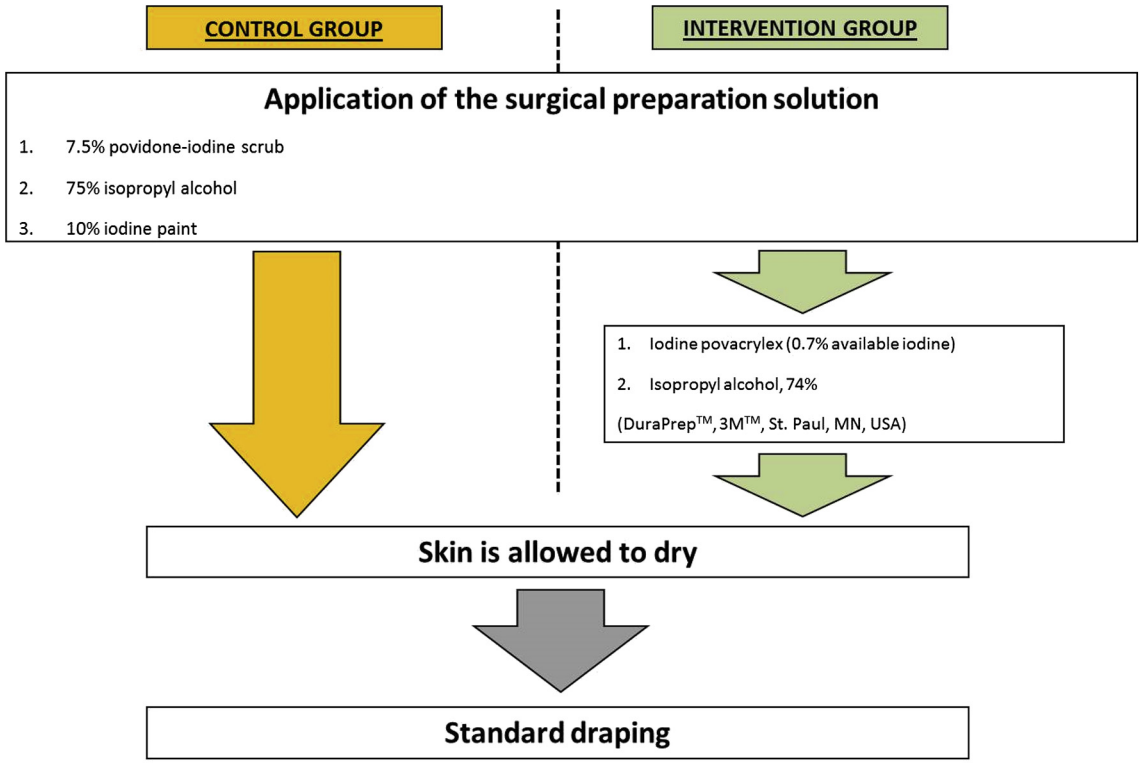

Fig. 2. Control and intervention groups.

(20 of 294) in the control group ($P = .12$). The incidence of superficial SSI in the intervention group was statistically significantly lower at 1.8% (5 of 283) compared to 6.5% (19 of 294) in the control group ($P = .015$, RR: 3.4, 95% CI: 1.18-11.96). The 5 superficial SSIs in the intervention group included cellulitis (2 patients), persistent wound drainage (2), and purulent drainage (1). The 19 superficial SSIs in the control group included cellulitis (6 patients), persistent wound drainage (2), purulent drainage (5), and superficial infection as defined by the treating surgeon (6; Table 2).

There were 2 cases of organ-space SSI in the intervention group (0.7%) and 2 cases of deep SSI in the control group (0.7%; $P = 1.00$, RR: 0.96, 95% CI: 0.13-6.92). Also, the observed incidence of skin blistering was lower in the intervention group at 3.5% (10 of 283) vs 6.5% (19 of 294) in the control group, but the difference was also not statistically significant ($P = .13$, RR: 1.88, 95% CI: 0.82-4.62; Table 3).

The findings were similar when the patients were stratified by the type of joint. Within THA patients (n = 293), patients in the intervention group had lower superficial SSI (2 of 144, 1.4%) than those in the control group (9 of 149, 6.0%, $P = .06$), lower deep/organ space SSI (intervention: 1 of 144, 0.7%; control: 2 of 149, 1.3%; $P = 1.00$), and less blistering (intervention: 1 of 144, 0.7%; control: 3 of 149, 2.0%; $P = .62$). The results were relatively similar in TKA patients (n = 284), as the intervention cohort had lower superficial SSI (3 of 139, 2.2%) than the control cohort (10 of 145, 6.9%, $P = .09$), less blistering (intervention: 9 of 139, 6.5%; control: 16 of 145, 11.0%; $P = .21$), and 1 deep/organ space SSI (intervention: 1 of 139, 0.7%; control: 0 of 145, 0.0%; $P = .49$). However, none of these results were significantly different (Table 4).

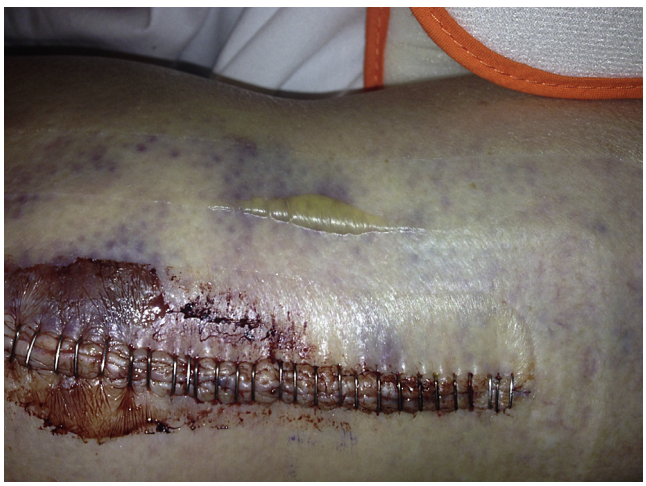

Fig. 3. An example of blistering on a total knee replacement patient.

Table 2
Superficial Surgical Site Infections (SSIs) in Patients Who Did and Did Not Receive the Application of an Additional Surgical Skin Preparation Solution After Standard Draping.

Superficial SSIs	Control (N = 294)	Intervention (N = 283)	RR (95% CI)	*P* Value
Cellulitis	6	2	2.93 (0.78-10.96)	.29
Persistent drainage	2	2	0.96 (0.13-6.92)	1.00
Purulent drainage	5	1	4.88 (6.78-35.11)	.22
SSI (by surgeon)	6	0	8.78 (0.11-693.71)	.12
Total	19/294 (6.5%)	5/283 (1.8%)	3.4 (1.18-11.96)	.015

RR, risk ratio.

Table 3
Blistering and Deep/Organ-Space Surgical Site Infections (SSIs) in Patients Who Did and Did Not Receive the Application of an Additional Surgical Skin Preparation Solution After Standard Draping.

Events	Control (N = 294)	Intervention (N = 283)	RR (95% CI)	*P* Value
Deep/organ-space SSIs	2/294 (0.7%)	2/283 (0.7%)	0.96 (0.13-6.92)	1.00
Blistering	19/294 (6.5%)	10/283 (3.5%)	1.88 (0.82-4.62)	.13

Discussion

Reducing the risk of SSI after TJA is beneficial, as infection results in increased patient morbidity, need for readmission, prolonged hospitalization, and increased costs [3]. The use of preoperative skin preparation in surgical patients is considered an essential practice for preventing SSI [18,19], as encouraged by the Hospital Infection Control Practices Advisory Committee [7]. It is not known if repeat skin preparation in surgical procedures may reduce the risk of SSI further. Thus, this study sought to evaluate the reduction in SSIs by repeating skin antisepsis after the standard draping process and before the application of iodophor-impregnated incise drapes in patients undergoing elective, primary TJA.

Prior studies have evaluated the efficacy of specific surgical site preparation solutions to prevent SSI. In general surgery, patients undergoing clean-contaminated cases who were randomly assigned to chlorhexidine-alcohol (4.2%) had a lower rate of superficial SSI within 30 days than patients who received povidone-iodine alone (8.6%) [20]. A study among patients undergoing urological surgery found that chlorhexidine-alcohol was more effective than povidone-iodine at reducing skin bacterial cultures, with no urethral or genital skin complications [21]. In clean surgical cases, 2 Cochrane reviews demonstrated that chlorhexidine may result in a lower rate of SSI compared to alcohol-based povidone-iodine paint, but these findings were based on only a few studies in the literature [6,22,23].

Within orthopedics, studies have focused on other areas of the body, including foot and ankle [12], shoulder [11], and spine [13]. In TJA patients, studies have demonstrated that skin preparation techniques are effective for preventing infections [24], although good skin preparation techniques must be applied to prevent SSI [25]. With regard to specific surgical solutions in TJA, a study was performed in which patients were randomized to receive either an iodophor-in-alcohol solution or an aqueous iodophor scrub applied for 5 minutes, followed by an aqueous iodophor paint solution [26]. The solutions were found to equally reduce the amount of bacteria at the surgical site, whereas the iodophor-in-alcohol solution improved skin adhesion to the drapes. A similar study was conducted in which TJA patients were randomized to receive either iodine povacrylex (0.7% available iodine) and isopropyl alcohol, 74% w/w (DuraPrep; 3M) or a povidone-iodine–impregnated skin preparation tray (Allegiance, Cardinal Health, Dublin, OH) [27]. The results demonstrated that these groups had similar bacterial contamination, but the liftoff of the drapes was less in the iodine povacrylex (0.7% available iodine) and isopropyl alcohol, 74% w/w group. Although these studies have focused on the solution used to provide antisepsis, no study has evaluated the use of a second surgical skin preparation to reduce the bacterial burden after draping, as was performed in this study.

This prospective, randomized control trial is the only trial that has evaluated the second application of a surgical site preparation solution after draping and before iodophor-impregnated drapes for reduction of SSI and blistering in TJA. Previous studies evaluating surgical site preparation have focused on a single application and compared different preparation solutions, rather than the number of preparation solutions used for decolonizing the skin before surgery. Thus, our study recommends the use of a second skin preparation solution after draping to reduce the bioburden of bacteria on the surgical site and reduce the likelihood of developing a SSI.

There were a few limitations to this study. This study did not evaluate for the presence or quantification of bacteria before and after the second surgical preparation solution. SSI was used as the end point, as it is a more clinically relevant finding than detection of bacteria in the surgical site. In addition, this study may have been strengthened by a cost analysis, as the use of a second surgical preparation solution slightly increases costs, but the implementation of infection control interventions may increase health benefits while reducing the economic burden [28]. This study was also limited in that a single surgical site preparation (iodine povacrylex and isopropyl alcohol) was used in the intervention group, whereas other studies have demonstrated that other surgical preparation solutions may be effective at reducing bacteria at the site of surgery [11-13]. Finally, this study was only conducted in an elective, primary TJA orthopedic patient population, and further studies are needed to determine whether this approach is applicable to other types of surgical procedures.

Despite these limitations, the beneficial effect of applying a second surgical site preparation solution can be primarily attributed to a reduction in the number of organisms that gain access to the surgical site during draping. Because the flora on a patient's skin can be a source of infection, the secondary application of skin antisepsis in the intervention group removed potential bacteria gathered on the skin after draping and significantly reduced the rate of superficial SSIs. In addition, the use of the iodine povacrylex and isopropyl alcohol preparation solution reduced blistering in the intervention group, which may have preserved the integrity of the skin and resulted in a lower SSI rate.

Based on the findings of this study, we recommend that a second surgical preparation solution be applied to the skin after draping and before making a surgical incision in TJA to reduce the risk of SSI.

Table 4
Surgical Site Infections (SSIs) and Blistering in THA and TKA Patients Who Did and Did Not Receive the Application of an Additional Surgical Skin Preparation Solution After Standard Draping.

Events	THA				TKA			
	Control (n = 149)	Intervention (n = 144)	RR (95% CI)	*P* Value	Control (n = 145)	Intervention (n = 139)	RR (95% CI)	*P* Value
Superficial SSI	9 (6.0%)	2 (1.4%)	0.26 (0.06-1.07)	.06	10 (6.9%)	3 (2.2%)	0.33 (0.10-1.14)	.09
Deep/organ-space SSIs	2 (1.3%)	1 (0.7%)	0.52 (0.05-5.81)	1.00	0 (0.0%)	1 (0.7%)	3.16 (0.12-78.42)	.49
Blistering	3 (2.0%)	1 (0.7%)	0.44 (0.06-3.00)	.62	16 (11.0%)	6 (6.5%)	0.57 (0.25-1.32)	.21

THA, total hip arthroplasty; TKA, total knee arthroplasty; RR, risk ratio.

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