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Original research

Evaluation of Incise Drape Lift Using 2% Chlorhexidine Gluconate/70% Isopropyl Alcohol Preoperative Skin Preparations in a Human Volunteer Knee Model

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ABSTRACT

Background: Before surgery, skin is prepped with antiseptics to reduce risk of surgical site infections. An incise drape can be used as an additional modality to immobilize any remaining bacteria. Good adhesion of this drape is critical for infection prevention.

Methods: This is a randomized controlled study using a human volunteer knee model (n = 30) to evaluate the adhesion performance of an incise drape comparing 2 skin preparations. A new investigational 2% chlorhexidine gluconate/70% isopropyl alcohol skin prep (prep A) was compared with an existing skin prep containing the same active agents (prep B). Two samples of an iodine-impregnated incise drape were placed on each knee after prepping. Knees were flexed in dry conditions, under a saline-soaked gauze, and after saline lavage. The frequency of drape lift was recorded after each challenge.

Results: After dry flex, 4 of 60 samples (6.7%) had lifted on prep A and 0 on prep B ($P = .125$). After wet flex, 20 of 60 samples (33%) had lifted on prep A, whereas 42 of 60 samples (70%) had lifted on prep B ($P < .0001$). After lavage, 23 of 60 samples (38%) had lifted on prep A, whereas 48 of 60 samples (80%) had lifted on prep B ($P < .0001$). Both preps were well tolerated with minimal erythema and no edema, rash, dryness, or denudation observed. No adverse events were reported.

Conclusions: Prep A resulted in reduced frequency of incise drape lift from skin under wet conditions in this model compared with prep B.

Introduction

Before surgery, the skin is routinely treated with a topical preoperative skin preparation containing antimicrobial agents to reduce the bacterial colony counts of the normal skin flora and therefore help lower the risk of surgical site infection (SSI). In some surgeries, an antimicrobial incise drape can be used as an additional modality. If a surgical incise drape is used, it is standard practice in the United States to use it in combination with a skin prep. The adhesion of the incise drape near the incision edge is an important performance attribute for surgeons, and it is impacted by the skin prep used [1]. Any drape lift at the edge of the incision could free potential bacteria remaining on the skin and allow it to enter the wound; it has been shown that antimicrobial incise drape lift can occur during surgery and may be associated with an increased risk of surgical infection [2]. It is therefore important to identify the optimal combination of skin prep and incise drape that demonstrates the best adhesion to skin with acceptable safety.

This study used a human volunteer knee model to compare differences in incise drape lift on skin prepped with either a new investigational 2% chlorhexidine gluconate (CHG)/70% isopropyl alcohol (IPA) preoperative skin preparation (prep A) or a commercially available skin prep containing 2% CHG/70% IPA (prep B). The investigational skin prep is different from other

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CHG-containing preparations because it is formulated to reduce incise drape lift from the incisional edge during the normal rigors of surgery (incisional manipulation and fluid exposure). The model allowed for the assessment of the incise drape performance under challenging conditions such as irrigation and movement of the draped area. We evaluated the incise drape performance by measuring the frequency of incise drape lift under dry and wet conditions.

Material and methods

This was a randomized controlled study in 30 healthy human volunteers using a human volunteer knee model to evaluate the performance of an incise drape with 2 different skin preparations (60 knees were included). The protocol was approved by the institutional review board, and informed consent was obtained. The materials tested were a new investigational skin prep (CHG/IPA skin prep; tinted formulation; active ingredients 2% w/v CHG and 70% v/v IPA; additional ingredients include acetyl tri-n-butyl citrate and trisodium hydroxyethyl ethylenediamine triacetic acid) and a commercially available skin prep serving as a comparator (ChloraPrep Hi-Lite Orange; Care Fusion/Becton Dickinson, San Diego, CA), which also contains 2% w/v CHG and 70% v/v IPA. For each skin prep, a 26-mL applicator was used. The incise drape used was 3M Ioban 2 Antimicrobial Incise Drape (3M, St. Paul, MN). The persons applying the preps and drape samples, and assessing skin irritation, were trained professionals.

When necessary, hair was clipped from the test site using a surgical clipper. Both skin preparations were applied, 1 prep only on each knee (following a pre-established randomization scheme) of 30 healthy volunteers, by the same trained professional (registered nurse trained in operating room procedures and proficient in prepping patients for surgery). For prep A, the product was applied using repeated back-and-forth overlapping strokes for 30 seconds to cover the test area and allowed to dry for a minimum of 3 minutes. Prep B (the comparator) was applied according to the manufacturer's product label (same method as prep A). After drying of the skin prep, 2 incise drape samples (3 in X 10 in each) were applied to the left and right sides of the midline of each prepped knee (in a 10- to 20-degree flexed position) covering an area measuring 3 inches above and below the knee cap, leaving a 0.25- to 0.5-inch gap between the samples (1 inch = 2.54 cm). This is illustrated in Figure 1. Both drape samples on each knee were placed over the same skin prep; the gap allowed to simulate an incision for the lavage challenge, and the 2 samples allowed to pair the data for the medial and lateral aspects of the knee.

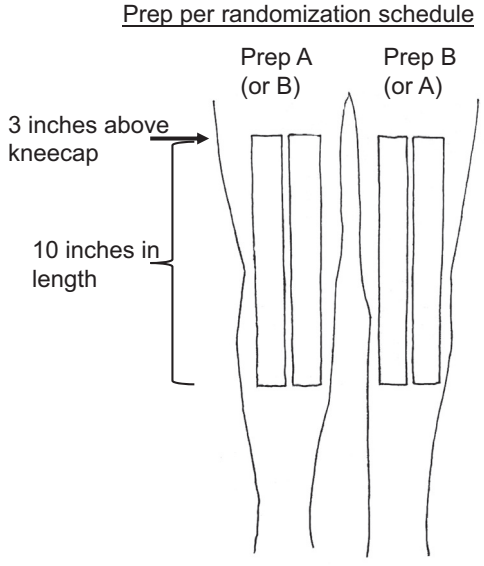

Figure 1. Description of knee model for drape lift assessment.

To simulate flexion and stresses experienced by the drape during surgery, knees were flexed in dry conditions ("dry flex"), then under a saline-soaked gauze ("wet flex"), followed by saline lavage ("lavage"). For the dry flex challenge, subjects flexed both knees fully 10 times, after which they placed their legs in an extended position. Drape lift was recorded (yes or no). For the wet flex challenge, a saline-soaked (0.9% sodium chloride; Baxter, Deerfield, IL) saturated gauze (McKesson, Richmond, VA) was applied to cover the midline between the 2 drape samples and a portion of both drape sample areas on each knee for 5 minutes with the subjects' legs in extended position. After 5 minutes, subjects flexed both knees fully 10 times with the help of the study staff to keep the wet gauze in place, and the samples were evaluated again for drape lift. For the lavage challenge, a low-pulse intermittent lavage mode (PulsaVac Plus; Zimmer Biomet, Warsaw, IN) was used to apply 200-300 mL of saline solution on the midline between the 2 drapes with the subjects' legs in an extended position. The challenges were done sequentially without replacing the samples if they had started showing signs of lift. This allowed us to test all the conditions on the same subjects to eliminate the variability between subjects and to start with the dry conditions to avoid having to thoroughly dry the skin after exposure to fluid. A final assessment of drape lift was completed. Drape samples that were still attached were manually removed using the low and slow method starting from the thigh and peeling toward the ankle. The ease of drape removal was assessed on a scale of 0 to 5 (drape comes off without help, mild force, medium force, moderate force, hard to remove, requires significant force to remove). Immediately after removal, the skin irritation (erythema, edema, rash, and dryness) was evaluated using a Modified Draize scoring system with a scale of 0 to 3 (no reaction, mild and/or transient, moderate, severe). Skin denudation (epidermal loss) was also graded from 0 to 3 (none, mild, moderate, severe). Any score of 3 for skin irritation parameters or denudation would qualify as an adverse event. Each subject's exposure to study treatments was approximately 30 minutes. Any remaining prep or residual adhesive was removed from the subjects' skin using 70% IPA on a disposable paper towel or wipe.

The statistician analyzing the data was blinded to the study products. All other study staff and study volunteers could not be blinded to the test products due to obvious differences in applicators and in the colors of the preps. The frequency of drape lift observed between the 2 skin preparations was compared in each condition (starting with lavage, where most lift occurred, then wet, and finally dry).

Statistical analysis

A statistical plan was designed prior to beginning the study. The primary endpoint of this study was the difference in frequency of drape lift after lavage (the strongest challenge) on the investigational skin prep vs the comparator. There were 2 secondary endpoints (first secondary outcome and second secondary outcome). The first secondary outcome was the frequency of drape lift after wet flex, the intermediate challenge, between test products (tested after the frequency of lift after lavage was found to be statistically significant). The second secondary outcome was the frequency of drape lift after dry flex, the mildest challenge, between test

products (tested after the frequency of lift after wet flex was found to be statistically significant). Additional observations included the ease of drape removal, skin irritation, denudation, and the occurrence of adverse events (AEs).

Summary tables were produced for all variables (lift frequency, erythema, edema, rash, and dryness) if there were observations. Frequency of drapes lifting after lavage was analyzed using McNemar's test, pairing the data by subject for the drapes that are on the lateral part of the knee and also pairing the data by subject for the drapes that are on the medial part of the knee. The level of significance used was 0.05. The frequency of drape lift after wet flex and the frequency of drape lift after dry flex were analyzed the same way. Differences between test products for the ordinal responses (erythema, edema, rash, and dryness) were calculated by subtracting the value on the investigational prep knee from the value on the control product knee. Two differences per subject were obtained (one medial, one lateral). Signed rank tests were used to test the null hypothesis (difference is 0). The level of significance used was 0.05. All statistical analyses were performed using SAS software (SAS, Cary, NC), Version 9.3.

Results

After dry flex, 4 of 60 samples (6.7%) had lifted in the prep A group and 0 in the prep B group ($P = .125$). After wet flex, 20 of 60 samples (33%) had lifted on prep A, whereas 42 of 60 samples (70%) had lifted on prep B ($P < .0001$). After lavage, 23 of 60 samples (38%) had lifted on prep A, whereas 48 of 60 samples (80%) had lifted on prep B ($P < .0001$). These data are displayed in Figure 2 (overall number of samples lifted).

Paired lift data analysis (pairing samples lateral to lateral and medial to medial across legs to leverage the fact that each subject served as their own control) under each condition is presented in Figure 3.

When the drapes were removed at the end of the study, the perceived removal force (Table 1) was higher when removing drapes from prep A than when removing them from prep B ($P < .0001$).

Both preps were well tolerated with minimal erythema and no edema, rash, dryness, or denudation observed. No AEs were reported during this study.

Discussion

This study used a human volunteer knee model with challenge conditions of irrigation and movement to allow for the assessment of the incise drape performance. The primary objective of this study was to evaluate the effect of a new investigational skin prep (prep A) on drape lift compared with a commercially available skin prep (prep B) under dry and wet conditions and after lavage. Safety was also evaluated based on the incidence of AEs reported during the study and the assessment of skin irritation and denudation. After dry flex, there was no significant difference in the frequency of incise drape lift on both skin preps tested. After wet flex and lavage, incise drapes lifted more often on prep B than on prep A ($P < .0001$). Both skin preps were well tolerated by the subjects with minimal erythema and no edema, rash, dryness, or denudation observed. No AEs were recorded during this study. The frequency of lift data were supported by the additional observation of higher perceived removal force needed when drapes were removed from prep A than from prep B.

Adhesive incise drapes were introduced in the 1960s [3] with the intent of preventing the contamination of the incised tissues with bacteria from the surrounding skin and therefore help reduce the wound infection rate [4,5]. The use of adhesive drapes is considered an option to immobilize the resident bacterial skin flora that persists after the application of antimicrobial skin preparations: Theoretically, the drape prevents lateral migration and proliferation of bacteria [6]. When the drape contains an antimicrobial agent, a reduction in bacterial wound colonization has been demonstrated [7-10]. These properties offer the potential to reduce the rate of SSIs [11]. However, the benefits of incise drapes have been debated, with conflicting results published on their efficacy [7,10,12-15], as well as conflicting recommendations regarding their use [5,16-18]. A Cochrane review on this topic concluded that standard plastic adhesive drapes led to more SSIs than no drape and that iodine-impregnated adhesive drapes had no effect on the SSI rate [19]. In addition, a recent article highlighting key updates and new recommendations for the prevention of SSI states that the use of plastic adhesive drapes (with or without antimicrobial properties) for antisepsis has been determined to be an unnecessary strategy (category II, weak recommendation) [17]. However, another recent study demonstrated than an iodophor-impregnated

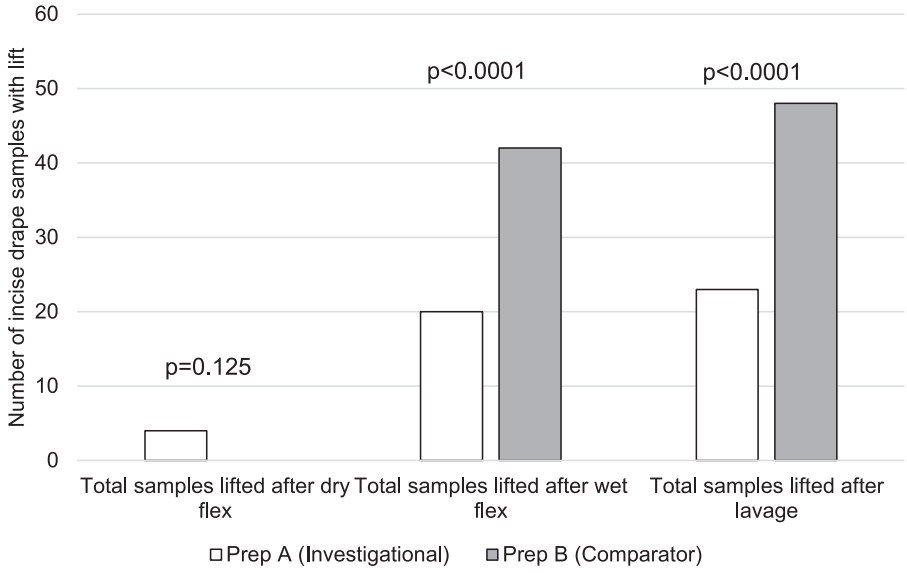

Figure 2. Cumulative frequency of drape lift after each challenge, for each skin preparation.

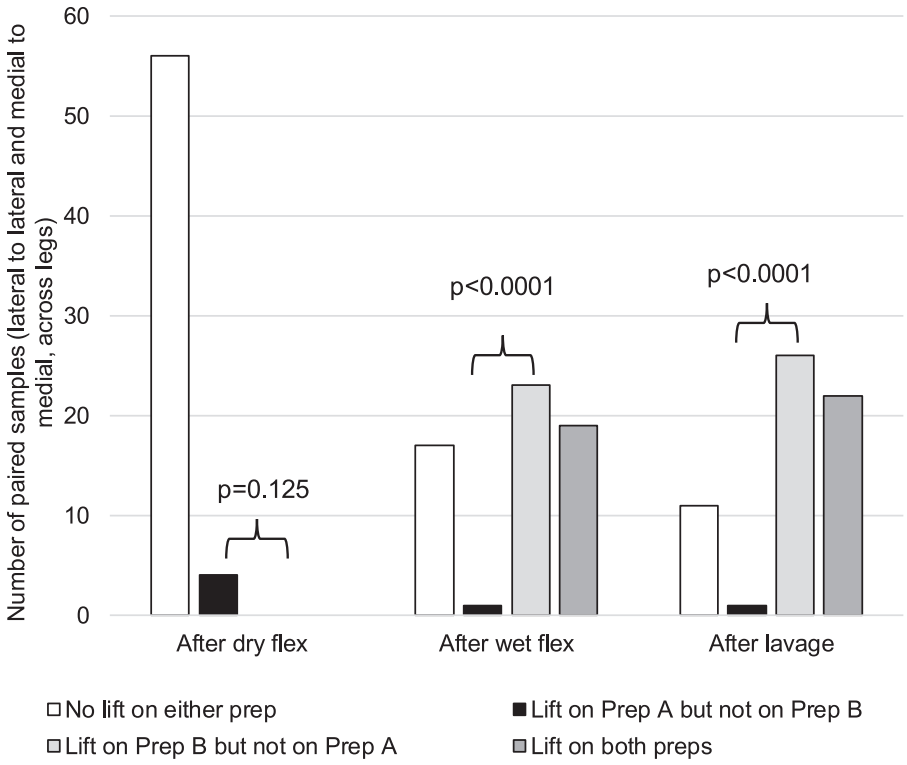

Figure 3. Paired samples comparison after each challenge (lateral to lateral and medial to medial across legs to leverage the fact that each subject served as their own control).

adhesive drape significantly reduced bacterial colonization of the incision in 101 patients undergoing open joint preservation procedures of the hip (6 incisions with drapes, or 12%, vs 14 incisions without drapes, or 27.5%, were positive for bacteria) [9]. An international consensus document on preventing orthopedic infections reports that there is evidence for antimicrobial-impregnated incise drapes resulting in a reduction in bacterial colonization of the surgical site (level of evidence: limited) [5]. A significant association has been demonstrated between intraoperative bacterial surgical wound contamination and the risk of postoperative SSI [20,21]. Importantly, some studies have highlighted the importance of good incise drape adhesion for their antimicrobial barrier effectiveness, [2,11] and others have emphasized the fact that the type of skin prep used affects the adhesion performance of the incise drape [1,22,23]. Therefore, the effectiveness of incise drapes depends on proper adhesion, which can be promoted by the skin prep used in combination with the drape. The main antiseptic agents used for skin preoperative disinfection are alcohol-based solutions, povidone iodine, and CHG. The solutions compared in this study both contain CHG in alcohol; a review of CHG chemistry, antimicrobial properties, clinical applications, and safety was recently published [24]. One hypothesis proposed to explain how incise drape lift might increase the risk of skin contamination is that lift could possibly cause skin exfoliation and expose bacteria that were in deeper layers of the skin (which may not be sufficient to lead to a SSI) [25]. In that study, the authors address the case scenario where the surgeon chooses to remove the incise drape prior to wound closure. They found only 4 of 49 swabs that were contaminated (not statistically significant), the contamination level was less than 5 cfu per plate (not significant), and none of these patients developed clinical infection up to 8 weeks postoperatively. These authors suggest repeating skin prep at the end when the drapes are removed, especially if removing the drape before wound closure. We would like to point out that is different from accidental lift, which could possibly be more consequential since surgery is still going on and lavage steps may wash the now exposed bacteria into the wound. Given that drape lift is associated with a six-fold increase in infection rate, [2] adhesion is a critical feature that is important for patient safety.

It is known that surgical preps containing chlorhexidine and/or other antimicrobials can undermine the adhesion of medical tapes, dressings, and surgical drapes, particularly under wet skin conditions. Chlorhexidine salts in particular exacerbate this problem because they are hydrophilic and remain on the surface of the skin after topical application [26]. Under wet conditions, such as in surgery when large amounts of body fluids or saline are present, the chlorhexidine salts can partially dissolve and cause the loss of adhesion of the surgical drapes and dressings. This drape lift can interrupt the sterile field, which increases the probability of a SSI. The use of a hydrophobic emollient ester in the investigational skin prep successfully mitigates this issue. The hydrophobic nature of the dried composition on skin also reduces the “wash off” effect of

Table 1
Number of drape samples with each perceived removal force.

	Drape sample comes off without help	Drape sample removal requires mild force	Drape sample removal requires medium force
Prep A	0	22	38
Prep B	3	39	18

Note: None of the drape samples required any of the 3 highest force scores for removal per our predefined scale of 0 to 5 (drape comes off without help, mild force, medium force, moderate force, hard to remove, requires significant force to remove).

the active cationic agent by hydrophilic or aqueous solutions employed in the health-care setting such as sterile saline rinses. This most likely explains the observed reduction in drape lift in our experiment.

Study limitations

Our study used a model (no incision) and only tested one type of incise drape. If lift originated along the outer edge of the drape, it was not recorded unless there was channeling from the "incision" edge. Samples were smaller than what would be representative of drapes used during an actual surgery. In actual surgical conditions, the drape would wrap around the leg and be adhered to itself. The forces applied to the tissues and the drape due to manipulation and retraction of tissues were not simulated in this model and would affect real-life results. This model also does not account for the presence of subcutaneous fat at the skin edges and its effect on the adhesive barrier between the skin prep and the incise drape, since there was no incision. More research is needed to verify how the results apply to real surgical conditions. However, to our knowledge, this is the first proposed model in human volunteers using knee flexion and wet conditions to create challenges while testing incise drape adhesion, and the products compared were subjected to the same conditions.

Conclusions

Prep A (investigational 2% CHG/70% IPA preoperative skin preparation) resulted in reduced drape lift of the iodine-impregnated surgical incise drape from skin under wet conditions in this model (measured by decreased frequency of drape lift under wet conditions and during lavage).

Acknowledgment

The human volunteers participating in the study were employees of 3M not involved with the product development project. All volunteers signed a patient informed consent. The institutional review board (IRB) was the 3M IRB, which is FDA-registered and includes 3 external members (2 scientists and 1 ethicist) in addition to the 3M members. The authors thank Kim Prinsen, RN (3M employee), for her expertise in applying the skin preps, the drape samples, and performing assessments, and Dr Matthew Cooper, MD (3M employee), for overseeing the study.

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Conflicts of interest

All the authors are employees of 3M. All authors own 3M stock and 2 of the 4 authors receive 3M stock options.

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