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Effectiveness of Antimicrobial Incise Drapes versus Cyanoacrylate Barrier Preparations for Surgical Sites

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Abstract Surgical wound infections are one of the leading causes of morbidity and mortality in surgical patients. We compared the effectiveness of antimicrobial incise drapes versus cyanoacrylate microbial sealant adhesive barrier in preventing skin flora contamination of surgical wounds in an animal model. Staphylococcus aureus in suspension was placed on fresh ovine skin across 60 circular marks of defined area: 20 circles were designated as controls, 20 were covered with antimicrobial incise drapes, and 20 were covered with cyanoacrylate. Incisions were made through the circles; swab cultures were taken, serially diluted after agitation, and cultured on blood agar plates. The number of colony forming units (CFUs) was then counted and compared between the samples from the two drapes. While there were no differences between antimicrobial incise-draped areas (108.3 ± 90 CFUs) and undraped controls (82.7 ± 93.3 CFUs), the cyanoacrylate-treated group demonstrated lower wound bed contamination (0.3 ± 0.6 CFUs) when compared to controls.

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Each author certifies that approval from his or her Institutional Animal Care and Use Committee was obtained and that all investigations were conducted in conformity with ethical principles of research.

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Introduction

Due to the morbidity, mortality, and cost associated with surgical wound infections, efforts at controlling perioperative infections including surgical preparations continue to evolve to reduce infection rates. Barrier techniques, such as placement of an adhesive iodine barrier on the skin prior to the incision, sequester the skin flora so as to not contaminate the surgical wound. The orthopaedic literature pertaining to iodophor-impregnated drapes suggests a reduction in wound contamination but without a concurrent decrease in wound infection [11].

A new adhesive barrier, cyanoacrylate microbial sealant (IntegueSeal®, Kimberly-Clark, Dallas, TX), used to immobilize the skin flora after skin preparation, obtained FDA approval in 2006 [12]. Cyanoacrylate is not purportedly antimicrobial. On the other hand, the antimicrobial incise drape apparently seals off bacteria through a barrier film technique [12].

Our goal was to determine if any differences exist between cyanoacrylate and antimicrobial incise drapes in preventing skin flora contamination of surgical wounds by evaluating skin surface contamination. The null hypothesis was that quantitative analysis of skin-edge bacteria colony counts would be similar between unprepped skin (control), skin covered with Ioban™ (3 M, St. Paul, MN), and skin treated with IntegueSeal®.

Materials and Methods

We obtained two freshly euthanized sheep sacrificed for fetal cerebral blood flow studies. Our experiment commenced within minutes of euthanasia. The experiment was carried out in an operating room environment, with sterile

technique where appropriate. We obtained cultures from three groups: (1) IntegSeal® microbial sealant on 20 samples, (2) Ioban™ on another 20, and (3) 20 controls with no adhesive barrier. After an initial pilot of 10 samples in each group, we determined the necessary sample size to produce a power of 0.80. Assuming a standard deviation of 80 CFUs to detect a difference of means of 75 CFUs at $p = 0.05$, 20 samples would be required to achieve 0.80 power. This study was repeated on a second animal. Overall, 20 samples from each group were obtained, for a total of 60 samples. Prior to beginning the study, we obtained approval from the Institutional Animal Care and Use Committee.

A combination of commercial shaver and razor was used to remove the wool from the side of the sheep flank, from the shoulder girdle to the hip girdle not including the axillae, until a smooth consistency was obtained. Using a fine-tip permanent marking pen and a circular stencil, we drew 30 circles (diameter, 11.3 mm; area, 1 cm^2) on the skin of each of the two animals (60 circles). Then, the skin was scrubbed with sterile 4x4 gauze pads saturated with 70% isopropyl alcohol for sixty seconds and allowed to dry. A suspension of Staphylococcus aureus (strain ATCC 12600) was cultured in 15 mL of nutrient broth to produce a suspension at a concentration of 10^8 colony forming units/mL. The concentration was standardized using absorptiometry via a spectrophotometer. The suspension was agitated. An aliquot of 15 mL was applied to the center of each circle using a sterile micropipette. The bacterial suspension was evenly distributed on the skin surface within the marked 1 cm^2 area using the pipette tip. A new tip was used for each circle. The suspension was allowed to dry for 5 minutes. IntegSeal® microbial sealant was then applied on 10 of the samples, Ioban™ on another 10, and on another 10 without an adhesive barrier. There were some instances of minimal drape lift at the edges, but this was not quantified.

Using a size 10 scalpel, an 11.3-mm incision along the diameter of the sample was made with a depth down through the dermal layer into subcutaneous fat within 1 minute of the test barriers being applied to the demarcated circles. A fresh, sterile blade was used for each incision. The wound was gapped open after incision and a sterile culture tip was used to swab inside the wound at the dermal/epidermal junction along the entire 11.3-mm incision. Care was taken not to contact the tip on the epidermal surface. The applicator tip was then cut using sterile scissors and dropped into 10 mL sterile saline, sonicated for 30 seconds. After the swabs were taken, the samples were taken to the laboratory for centrifugation. There was an approximately 30 minute delay until centrifugation in the lab could occur. A sample of the saline was taken after centrifugation and spread evenly on blood agar plates after 10^{-2} dilution. The plates were then incubated for 24 hours. The number of colonies per agar plate was counted.

The entire procedure was repeated on a second sheep to achieve an adequate sample size, which resulted in $n = 20$ for each of the three test groups.

Normality of the CFU data sets could not be assumed, and nonparametric analyses were chosen. Because two animals were used, between-sheep differences in CFUs by test groups were first assessed using the Mann–Whitney U. Then, pairwise comparisons for differences in CFUs were performed between both antimicrobial incise drape and cyanoacrylate groups against the control group.

Results

For the three groups (control, antimicrobial incise drape, and cyanoacrylate), the CFU data was similar in the two animals (control $p = 0.481$, antimicrobial incise drape $p = 0.353$, cyanoacrylate $p = 0.436$). The CFU data sets for the two animals were then merged to yield $n = 20$ for each group.

We found similar ($p = 0.149$) numbers of CFUs in the Ioban™ and control groups but lower ($p < 0.0001$) numbers of CFUs in the IntegSeal® than in the control group. Samples from the control group yielded a median of 24.5 CFUs (range, 0–212 CFUs). Cultures obtained from areas covered with Ioban™ produced a median of 85.5 CFUs (range, 6–250 CFUs). When IntegSeal® was used, samples produced a median of 0 CFUs (range, 0–2 CFUs).

Discussion

Wound contamination from skin flora may be reduced by barrier techniques. While the adhesive iodine impregnated film barrier has been studied, a newly introduced cyanoacrylate-based preparation has been purported to form a barrier film to seal off bacteria. Our goal was to determine if any differences exist between IntegSeal® and Ioban™ in preventing skin flora contamination of surgical wounds by evaluating the effectiveness of colony count reduction.

We note several limitations. First, we chose an ovine model since there are other studies using sheep as a skin model in surgical infection and soft tissue infection [1, 10]. Second, we chose alcohol as a skin decontaminant. A 1-minute alcohol cleansing provides greater bacterial kill than a 5-minute iodophor scrub [5]. Third, we chose to not prep the skin after application of the bacteria to maintain adequate bacterial counts. The main purpose of this study was to assess colony count reducing properties of the drapes rather than assessing effectiveness of a surgical prep sterilization solution. Therefore, we chose to apply the surgical

drapes without using a prep solution to maintain the highest colony counts possible to see if the drape preparations themselves have colony count reducing capability. Another limitation is that this is an animal model with prepared animal skin. The extrapolation to a human model requires clinical studies. Furthermore, there is a question of drape lift. One study demonstrates the addition of DuraPrep (iodine povacrylex, 3 M) improves drape adhesion [6]. Another study also reported drape adhesion is improved with using DuraPrep [7]. As mentioned earlier, we specifically did not use a surgical site skin preparation solution in order to maximize bacterial colony presence at the wound edge. Another limitation is that swabs were used to obtain cultures. We piloted the bacteria concentration to achieve the most optimal plated growth pattern to standardize initial concentration, culture acquisition, and dilution. Finally, the extrapolation of wound contamination to surgical site infection is remote at best. Ritter and Campbell reported a low infection rate regardless of preparation and that iodine spray and iodophor-incorporated adhesive drape had similar infection rates [11]. Another study reported no difference in postoperative wound infection rates when comparing randomized cohorts of drape and no-drape groups in 120 patients with acute hip fractures [2]. Finally, a third study also revealed that there is no difference in actual wound infection between iodophor-impregnated drape and in wounds in which drapes were not used [3]. This suggests that, even though basic science studies reveal decreased contamination when assessing colony counts, this may not translate into actual infection. In order to determine actual clinical efficacy in reducing infection, rather than wound contamination, the authors suggest prospective randomized clinical trials using various skin preparation solutions as well as drape methods, ie, Ioban™ versus InteguSeal® drape. However, due to the already low number of infections, very large numbers would be needed to show meaningful differences. No native bacteria were recovered. This may be due to several reasons. The skin was first sanitized by alcohol. Then, the amount of staphylococcus aureus applied was so overwhelming that normal flora is most likely masked.

Our findings suggest that the use of iodophor-impregnated plastic drapes did not reduce colony counts in and of itself. Several studies suggest iodophor-impregnated plastic drapes can reduce bacterial count [4]. In a prospective study comparing 122 patients undergoing hip surgery in which Ioban™ was applied to the operation site 24 hours before surgery, bacterial sampling of the wound at the end of the procedure showed wound contamination was reduced from 15% to 1.6% by this method. The authors concluded Ioban™ drape is likely to prove a valuable tool in the fight to prevent infection. In another study comparing various antiseptic preparations of the skin surface, Ioban™ reduced the recolonization of skin after surgical prep [8]. However, there are concerns regarding the efficacy of iodophor-impregnated plastic drapes. In their study comparing bacterial colony counts on skin with Ioban™ alone versus Betadine® preps with and without incise drapes, Lewis et al suggests that "although the use of an iodine-containing incise drape alone is attractive, its bactericidal action is inferior to conventional preparations" [9]. Our study, specifically looking at the skin edge to determine whether the incised drape or other drape methods actually reduce colony counts, reveal that the iodophor-impregnated incise drape makes no difference at the skin margin itself.

One prospective, randomized, multicenter trial performed on 177 patients undergoing open inguinal hernia repair revealed that cyanoacrylate application decreased the skin contamination rate from 47% to 31% when compared with conventional preparations [12]; the drawback is that there is no comparison with a surgical incise barrier drape. Our study data suggest using IntegeSeal® cyanoacrylate microbial sealant reduces bacterial count at the skin edge itself where surgery is performed. Our study supports that wound contamination is reduced using a cyanoacrylate-type of preparation to produce a film-type barrier.

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