

Comparison of Chlorhexidine –Alcohol and Povidone Iodine Skin Preparation Skin Preparation Solutions in Orthopaedic and Trauma Surgery at An African Tertiary Hospital

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Background: The aim of this study was to compare the efficacy of Povidone-Iodine (PI) and Chlorhexidine-Alcohol (CHG-A) skin preparation solutions in orthopaedic and trauma surgery.

Methods This prospective randomised study described the bacterial skin flora and compared the bacterial clearance rates by PI and CHG-A in patients undergoing clean orthopaedic surgery at an African tertiary hospital.

Results: There were 50 patients in each group. A baseline positive culture rate of 76.8% was found. Coagulase-negative staphylococcus was the commonest aerobe (42.9%) while Propionibacterium species was the commonest anaerobe (17.3%). The aerobic positive culture rate reduced from 60% to 22% after PI preparation and from 49% to 6.2% after CHG-A preparation ($p=0.026$). The anaerobic culture rate reduced from 54% to 44% after PI preparation and from 53.1% to 43.8% after CHG-A preparation ($p=0.435$). The mean log pre-preparation and post-preparation aerobe counts were 7.85/cm² and 7.50/cm² respectively in the PI group and 7.62/cm² and 7.65/cm² respectively in the CHG-A group ($p=0.715$). The mean log pre-preparation and post-preparation anaerobe counts were 8.06/cm² and 7.96/cm² respectively in the PI group and 7.86/cm² and 7.84/cm² respectively in the CHG-A group ($p=0.335$).

Conclusion: This study did not demonstrate an overall superiority of chlorhexidine-alcohol over povidone-iodine skin preparation solution or vice versa.

Keywords: Chlorhexidine-Alcohol, Povidone-Iodine, Skin Antiseptics, Orthopaedics, Trauma

Introduction

Infections following orthopaedic procedures can be frustrating to the surgeon and devastating to the patient, with both long term and expensive consequences¹⁻³. In developed countries, surgical site infection (SSI) rates in orthopaedics is reducing but so also is the number of procedures performed with values ranging between 1.6% and 2.1%^{3,4}. In Nigeria, the reported rates of SSI in orthopaedics ranged between 4.6% and 9.9%⁵⁻⁷. Several factors may contribute to the risk of developing postoperative SSI. These include smoking, obesity, diabetes, long preoperative stays, corticosteroids use, HIV infections, alcohol-abuse, malnutrition, prolonged operative time and blood loss⁷. Bacterial contamination at surgery has been identified as a contributor to surgical site infection and the patient's skin is a major source of these wound contaminants⁸⁻¹⁰.

Thus, one major potential risk factor for SSI is the amount of bacterial flora present at the operative site at the time of skin incision. Many strategies have been employed in minimising this particular risk, including the use of perioperative antibiotics, antibiotic impregnated incise drapes and preoperative skin preparation¹¹. Skin preparation with an effective antimicrobial solution prior to surgery is essential to reduce contamination of the surgical wound and ultimately surgical site infection. Various skin antiseptics have been studied, especially chlorhexidine alcohol and povidone iodine, but the conclusions have been controversial¹²⁻¹⁷.

The aims of this study were to identify the common bacterial flora on the skin of orthopaedic patients undergoing clean surgery and to evaluate the efficacy of chlorhexidine-alcohol and povidone-iodine in the eradication of bacterial pathogens from the surgical site following skin preparation.

Materials and Methods

This prospective randomised controlled study was carried out at the orthopaedics and trauma department of an African teaching hospital. The participants were recruited from all patients aged 10 and above scheduled for surgery who had surgical wound categorised as clean between May 2011 and April 2012. Ethical review committee approval was obtained and written informed consent obtained from all patients or their guardians. Patients were excluded if they had wounds at the site or vicinity of the planned surgery, sepsis near the site or anywhere. A proforma was completed by each patient or guardian to identify any confounding variables such as diabetes mellitus, HIV infection or chronic corticosteroid use. All patients who had implant surgery had perioperative antibiotics and a non-antibiotic impregnated drape was used for all.

Sample size requirements were based on the findings of two prospective studies evaluating the rate of positive cultures from the ankle and foot¹³ and the shoulder¹⁴. On the basis of the assumption that a 20% difference in positive culture rate would be clinically relevant, the calculated number of patients required to achieve 80% power at alpha 0.05 was 41 per group. Each patient was randomised to one of two arms in a 1:1 ratio. Arm A was prepared with 2% Chlorhexidine in 70% alcohol solution (CHG-A) while arm B was prepared using 10% Povidone Iodine solution (PI). The agent to be used for each particular patient was determined just immediately before the commencement of skin preparation by opening a sealed randomly assigned envelope.

No specific home or ward cleansing protocol was followed and patients adhered to their usual bathing routine. The operative area was then prepared with the identified solution and allowed to dry for 3 minutes to reduce fire risk and mopping-up of solutions that could continue microbial kill during transport. Aerobic and anaerobic swabs were obtained before skin preparation (pre-preparation specimen), 3 minutes after skin preparation (post-preparation specimen) and at the peri-incisional area just after skin closure (post-closure specimen). The aerobic samples were collected into Stuarts transport medium and immediately taken to the laboratory where it was plated into blood, chocolate and McConkey agar. The culture plates were then incubated aerobically at 37° C and examined every 24 hours for two days. The anaerobic cultures were inoculated into Robertson cooked-meat media at the theatre and taken immediately to the microbiology laboratory for processing. All samples for anaerobes were cultured on Anaerobic, Chocolate and MacConkey agar and incubated in Anaerobic gas packs and examined daily for 6 days.

The bacterial growth was identified using macroscopic and microscopic methods, biochemical methods and standard atlas. The total number of colonies were enumerated by macroscopic count and the two predominant organism recorded in the order of their densities and rendered as bacteria/cm² in accordance with standard laboratory identification methods^{18,19}.

The primary outcome measures were the skin microbial load in number of bacteria/cm² and the proportion of positive cultures after the use of each type of surgical skin preparation solution. Any adverse reactions were noted as well. Postoperatively the patients were followed up for a minimum of 1 year or till death.

Descriptive statistics were calculated for all variables of interest. Continuous measures were summarised with the use of means and standard deviations, whereas categorical data were summarised with the use of counts and percentages. A two-tailed Student T-test, Mann-Whitney U test, Chi squared test and Fisher's exact tests were used to compare variables as appropriate.

Statistical significance was considered at a level of $p \leq 0.05$. Because the actual colonial counts were highly skewed, logarithm transformation was carried out for normalization.

Results

A total of 100 patients were recruited. The mean age of the study patients was 40.88 years (range, 10-80 years); there were 53 females (53%) and 47 males (47%). In 3 patients the planned procedure was not carried out in order to give room for emergencies but pre-preparation and post-preparation specimens were collected in two of these patients.

Most of the surgery was in the hip and thigh region (52%), while 16% were in the forearm and hand; 15% were each in the shoulder and arm and in the ankle and foot regions; 3% and 1% were in the leg and spine respectively. The types of surgery included open reduction and internal fixations or intramedullary nailing in 55 patients (55%), Arthroscopy or Hemiarthroplasty in 17 patients (17%), soft tissue release or biopsies in 11 patients (11%), osteotomies/curettage/bone biopsies in 11 patients (11%), percutaneous wires/pin fixations in 2 patients and a laminotomy in 1 patient. The mean duration of skin preparation was 182 seconds (range, 13-660 seconds), mean duration of surgery was 125 minutes (range, 16-320 minutes) and mean duration of preoperative admission was 4 days (range, 0-35 days). In the PI group 3 patients had diabetes mellitus, none was on corticosteroids while in the CHG-A group 3 patients had diabetes mellitus while 2 were on corticosteroids. There was no significant baseline difference between the two groups.

Skin flora

Overall, a positive bacterial growth was obtained in 76 patients (76.8%) prior to skin preparation. Thirty-two patients (32.6%) had combined aerobic and anaerobic organisms before skin preparation. Pre-preparation, aerobic culture was positive in 54 patients (54.5%) while anaerobic organisms were grown in 53 (53.1%) subjects. Double aerobic isolates were obtained in 6 patients while 2 patients had double anaerobic isolates. There was no significant difference in pre-preparation culture results for the PI and CHG groups (80% versus 73.5%, chi-square analysis, $p = 0.48$).

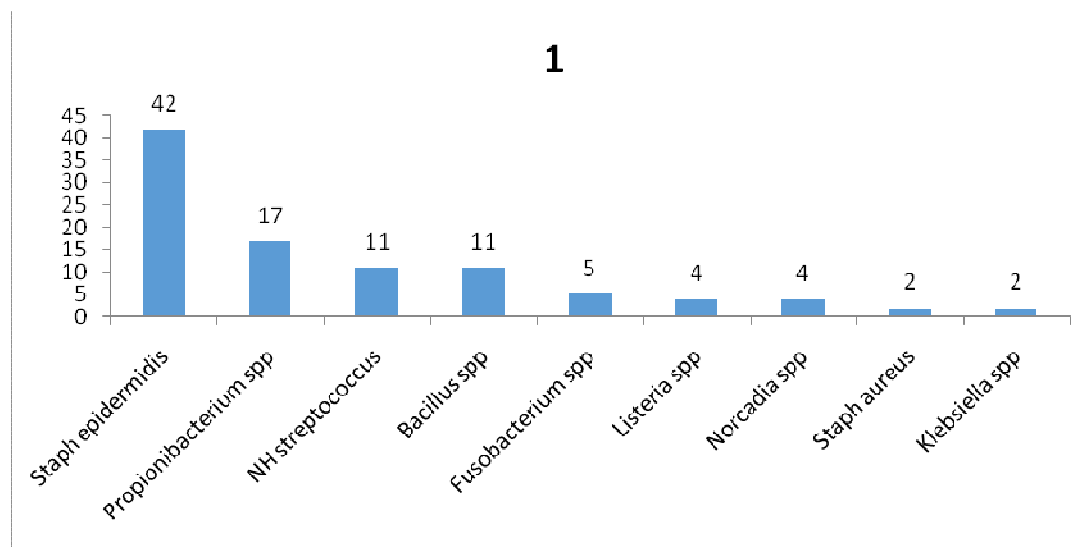


Fig. 1 A bar graph illustrating the number of positive bacterial isolates on the skin of the patients before skin preparation. Staph= Staphylococcus

The most common organisms isolated overall were Staphylococcus epidermidis (coagulase-negative Staphylococcus, 42 isolates), followed by Propionibacterium spp (17 isolates), Non-haemolytic streptococcus (11 isolates) and Bacillus spp (11 isolates). Their prevalence and that of the other major organism are as shown in Figure 1. The most common organisms isolated after skin preparation were Propionibacterium spp followed by Staphylococcus epidermidis.

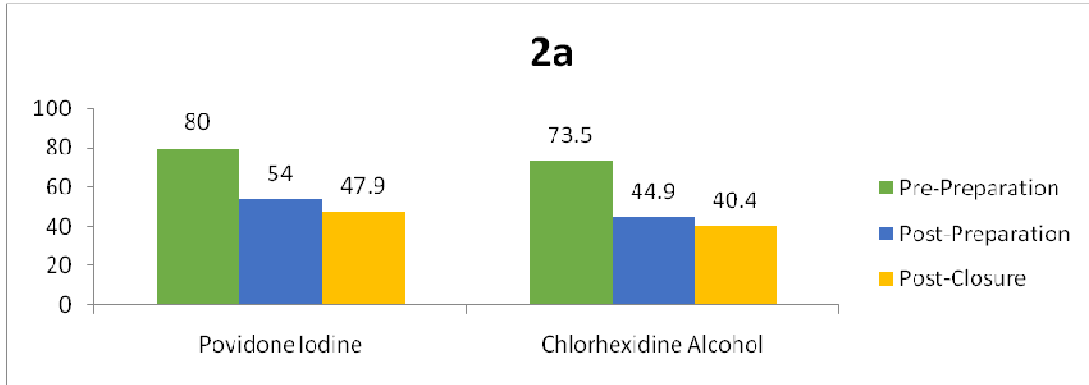


Figure 2a. Overall positive culture rates.

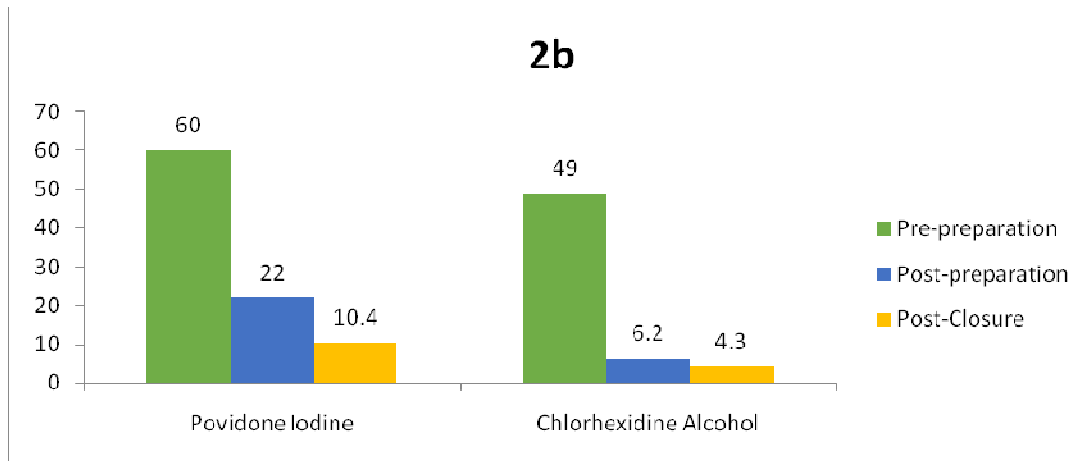


Figure 2b. Aerobic culture rates

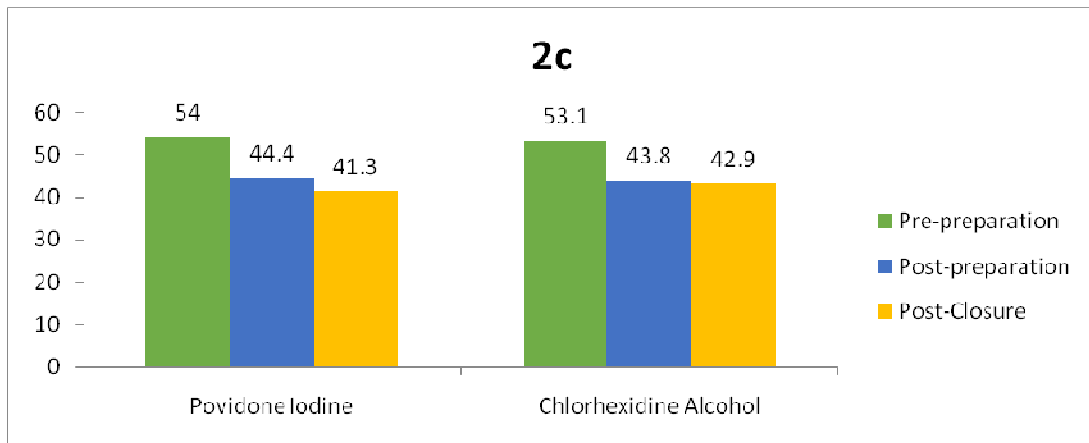


Figure 2c. Anaerobic culture rates.

Reduction in positive cultures

There was no significant difference in the overall positive culture rates following skin preparation, dropping from 80% to 54% in the PI group and from 73.5% to 44.9% in the CHG-A group ($p=0.365$). There was also no significant difference in the overall post-closure culture rate for the two groups ($p=0.462$, Fig 2A). For aerobes, there was a significant difference between the groups in their post-preparation culture rates, reducing from 60% to 22% in the PI group compared to from 49% to 6.2% in CHG-A group ($p=0.026$). Their post-closure positive culture rates were not significantly different ($p=0.435$, Fig 2B). There was also no significant difference in the anaerobic post-preparation culture positive rates ($p=0.946$) and post-closure culture rates ($p=0.883$) for the two groups (Fig 2C).

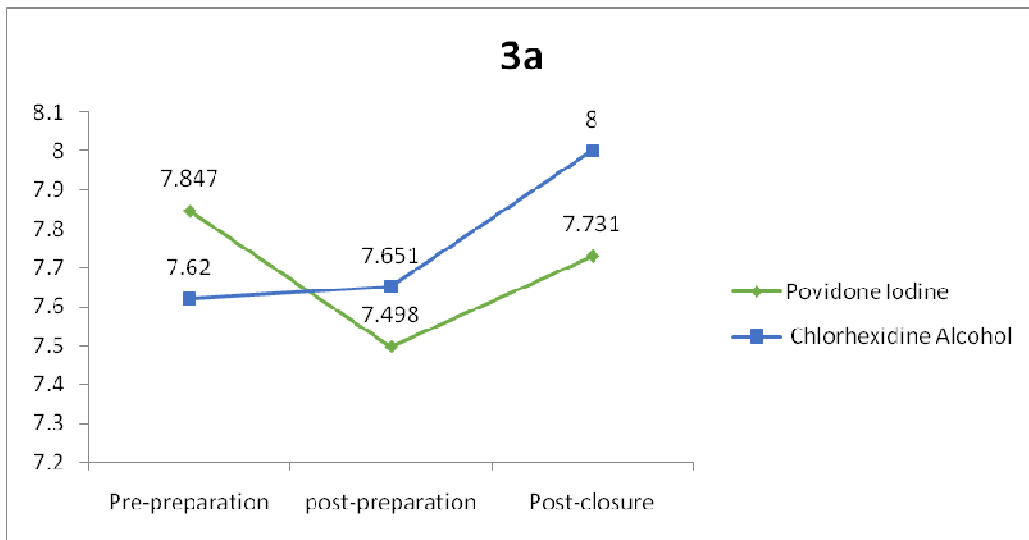


Figure 3a. Aerobes Log organism counts

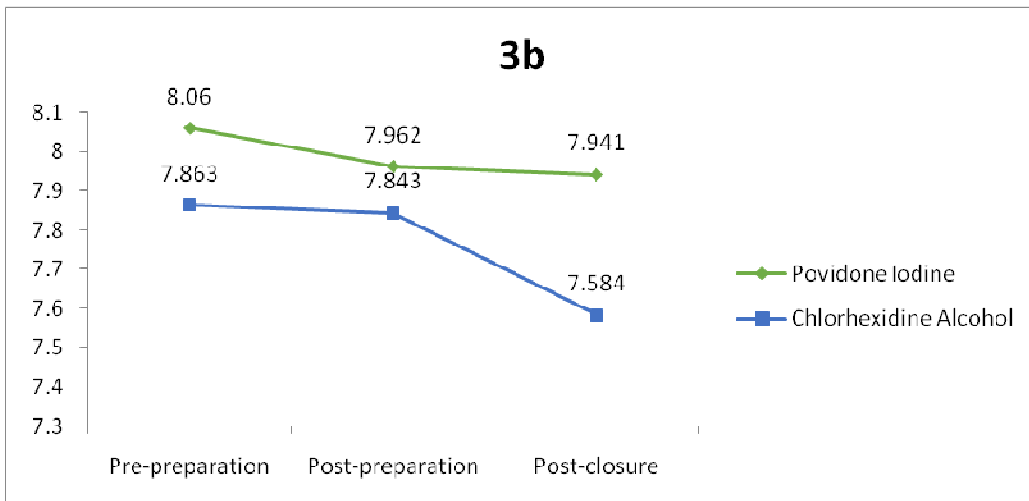


Figure 3b. Anaerobes Log organism counts

Reduction in bacterial counts

There was no difference in the pre-preparation aerobic counts, with the mean log aerobic bacterial count 7.847/cm² for the PI group and 7.620/cm² for the CHG-A group (p=0.109). The mean log anaerobic pre-preparation count was 8.06/cm² for the PI group and 7.863/cm² for the CHG-A group (p=0.58). For the aerobes, the mean post-preparation count dropped to 7.498/cm² for the PI group and increased to 7.651/cm² for the CHG-A group (Fig 3). The mean post-preparation anaerobic count reduced to 7.962/cm² for the PI group and to 7.843/cm² for the CHG-A group (Fig 3A). There was no significant difference in the post-preparation aerobic counts (p=0.715) and the anaerobic post-preparation counts (p=0.335) for the two groups. Compared to the post-preparation counts, there was an increase in the aerobic post-closure count to 7.731/cm² for the PI group and to 8.00/cm² for the CHG-A group, while there was a drop in the anaerobic count to 7.941/cm² for the PI group and to 7.584/cm² for the CHG-A group (Fig 3B). However, there was no significant difference between PI and CHG-A groups in the aerobic post-closure counts (p=0.520) while there was a significant difference in the anaerobic post-closure count (p=0.025).

Secondary outcomes

There were no recorded adverse effects in either group. The overall infection rate was 3.2%, with two infections in the PI group (one superficial and one deep incisional; no organisms grown) and one infection in the CHG group (organ space, Staphylococcus aureus and Escherichia coli) as at one year follow up.

Discussion

Post-operative orthopaedic infections are frustrating to treat and has both financial and long term consequences¹. Though the rates of orthopaedic SSI are dropping in developed countries, the number of procedures being performed is rising with concomitant increase in the number of patients with surgical site infections^{3,4}. The rates of SSI in orthopaedic practice in less developed countries are still on the high side though wide variation exists⁵⁻⁷. There are many factors associated with postoperative surgical site infections^{4,7}. Many strategies are being employed to reduce SSI rate in orthopaedics, including the use of effective skin preparation solutions^{11,20}. Many studies have evaluated the efficacy of various preoperative skin preparation solutions but their conclusions have been controversial¹²⁻¹⁷.

The current study found no overall difference in the efficacy of Povidone Iodine and Chlorhexidine Alcohol in clearing the bacterial flora of the area of operation in orthopaedic patients. Both were able to reduce the positive culture rates for all organisms overall with no significant difference between the two after skin preparation: a reduction of 26% by PI and 28.6% by CHG-A (p=0.365). Also, there was no significant difference in the mean post-preparation aerobic counts (p=0.715) and anaerobic counts (p=0.335). The apparent increase in the mean post-preparation aerobic count for CHG-A was due to the fact that only three patients with high initial bacterial counts still had culturable aerobes on their skin after preparation in the CHG-A group as compared to 11 patients for PI group. This finding correlates with the report of Savage et al¹⁵ in lumbar spine surgery in which they found no difference between the efficacy of Chloraprep and Dura-prep in eliminating skin microbes; a drop from 84% to 0% for Chloraprep and from 80% to 6% for Dura-prep (p= 0.24). Also, two studies using infection rates as a comparator found conflicting results: Darouiche et al¹⁶ found Chloraprep to be better than Betadine in preventing SSI in General surgery cases (9.5% versus 16.1%; p=0.004), while Swenson et al¹⁷ found Dura-prep and Betadine-Isopropyl alcohol to be better than Chloraprep in General surgery with the lowest infection rate in the Iodine group (3.9% and 6.4% versus 7.1%).

In analysing the differential effects of PI and CHG-A on aerobes and anaerobes, an interesting pattern emerges. CHG-A was found to significantly reduce the post-preparation aerobic culture positive rate compared to PI ($p=0.026$). Also, CHG-A was able to persistently reduce anaerobic count during the period of surgery with a significantly lower post-closure anaerobic counts ($p=0.025$). This better efficacy of CHG-A in clearing aerobic organisms have been documented in several studies. Bibbo et al¹² in Foot and Ankle surgery compared CHG scrub and isopropyl alcohol (IPA) paint to PI scrub and paint and found a culture positive rate of 79% in the PI group compared to 38% in the CHG-A group. Ostrander et al¹³ also in the foot and Ankle found no difference in infection rates in all three groups compared but found Chloraprep to have significantly less bacterial colony counts after skin preparation than Dura-prep and Technicare. A similar finding was reported by Saltzman et al¹⁴ in shoulder surgery in which Chloraprep was significantly better at reducing the overall bacterial positive rates as well as the CNS positive rates compared to PI and Duraprep. The overall positive culture rates were 31% in the Betadine group, 19% in the Duraprep group and 7% in the Chloraprep group. Similar to the results of the current study, Saltzman et al¹⁴ did not find any difference in the efficacy of the two agents on *Propionibacterium acnes*, an anaerobe.

This study also found out that in general, the bacterial flora on the skin of general orthopaedic patients is similar to that published for specialty orthopaedic surgery. The Coagulase negative *Staphylococcus* (*Staphylococcus epidermidis*) was the commonest bacterial found in this study followed by the anaerobe *Propionibacterium* spp a finding consistent with the studies of Savage et al¹⁵, Saltzman et al¹⁴ and Ostrander et al¹³.

There are some limitations to this study. First, the current study was not powered to detect differences in surgical site infections between the two groups. Second, the results might have been different if we had compared an alcoholic preparation of PI against CHG-Alcohol. Also, no neutralizing agents were used after collecting the samples to block further microbial kill during transport and this could have influenced the results.

Conclusion

Despite these limitations, this study found that both PI and CHG-A are effective at reducing bacterial colonisation of the skin of orthopaedic patients after skin preparation. However, CHG-A is better able to eradicate aerobes from the skin of orthopaedic patients and it seems to demonstrate a more persistent action on anaerobes even to the post-closure period and suppress the generally observed increase in skin organism counts that occur during surgery.

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Conflicts of interest The authors declare that there are no conflicts of interest pertaining to this article.

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