A Comparative Study on The Decontamination Efficacy of High-Level Chemical Disinfectants Against a Water Only Treatment

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A COMPARATIVE STUDY ON THE DECONTAMINATION EFFICACY OF HIGH-LEVEL CHEMICAL DISINFECTANTS AGAINST A WATER ONLY TREATMENT

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14. ABSTRACT-

Infections associated with combat-related injuries occur in approximately 25% of those arriving to the three largest U.S. military treatment facilities (MTF) with an estimated 60% deemed preventable. A critical constraint of mobile surgical teams is the inability to bring surgical instrument sterilizers. Operational challenges experienced in austere environments at times require that surgical instruments be reused to save the lives of combat wounded during mass casualty events. In such situations, it is imperative that Ground Surgical Teams (GSTs) have at their disposal a high-level disinfectant product and an effective protocol for using it. The purpose of this study was to evaluate the ability of commercially available high-level disinfectants already in use by GSTs to reduce or eliminate bacterial load from contaminated surgical instruments. The findings indicate that mechanical debridement in potable water followed by soaking in any of the three disinfectants tested achieved a significant reduction in recovered bacteria from instruments compared to rinsing in potable or sterile water only. Decontamination was durable for up to 28 days post-treatment. Of the three disinfectants tested, Cidex OPA appeared to be the most robust in terms of decontamination (no contaminated instruments detected, 0%), followed by CaviCide (15% of instruments produced at least some bacterial growth), and Neutral Disinfectant Cleaner (NDC) (40% of instruments produced some growth). This study supports the conclusion that commercially available disinfectants already in use in the field are capable of effectively disinfecting soiled surgical instruments resulting in minimal to no recoverable bacterial load.

15. SUBJECT TERMS- ground surgical teams, surgical site infections, combat trauma, disinfection, infection control, instrument sterilization

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TABLE OF CONTENTS

1.0 EXECUTIVE SUMMARY

Infections associated with combat-related injuries occur in approximately 25% of those patients arriving to the three largest U.S. military treatment facilities (MTF). An estimated 60% of these infections are deemed preventable. One critical constraint for mobile surgical teams is the inability to bring surgical instrument sterilizers. The best approach to combat this prevalent problem is to institute effective decontamination practices for surgical instruments. Operational challenges experienced in austere environments, at times, require that surgical instruments be reused to save the lives of combat wounded during mass casualty events. In such situations, it is imperative that Ground Surgical Teams (GSTs) have at their disposal a high-level disinfectant product and an effective protocol for using it. The current products of choice for the United States Air Force (USAF) and Army (USA) surgical teams are CaviCide (Metrex), Cidex OPA (Johnson & Johnson), and Neutral Disinfectant Cleaner (Ecolab). Envirocleanse A (Envirocleanse, LLC) has shown efficacy in reducing bioburden when used to treat large volumes of stagnant water; therefore, it was chosen as an addition to the Initial Treatment groups. However, the use of these products is based primarily on anecdotal information. This study was designed to evaluate the efficacy of these disinfectant products in a scientific manner using a testing design that mimics battlefield injuries typically encountered by forward military surgical teams. The goal of the study was to develop simple and effective decontamination practices for surgical instruments that could easily be put into practice where rapid reuse of surgical instruments may be required.

Four commercially available, high-level disinfectants were tested in this study for their ability to disinfect reusable stainless steel surgical instruments using a swine model to simulate a penetrating abdominal injury requiring surgical intervention. The disinfection process consisted of two treatment phases. The Initial Treatment phase included a "no treatment" (soiled instruments) group and mechanical cleaning and debriding of the instruments groups submerged in either sterile water, potable water, potable water with Envirocleanse A (ECA), or ECA alone. The Terminal Treatment phase consisted of the "no treatment" group, "sterile water" and "potable water" instrument groups alone, and the "submerged for cleaned and debrided instrument" groups into three high-level disinfectant solutions consisting of CaviCide, Cidex OPA, and Neutral Disinfectant Cleaner (NDC). Instruments that did not undergo debridement or treatment with any disinfectant served as positive controls for bacterial growth, and sterile instruments not exposed to the swine abdominal cavity, or any treatment served as the negative controls. Tables 1 and 2 show the experimental groups and process flow chart, respectively.

After opening the abdominal cavities of humanely euthanized adult Landrace-Yorkshire swine (70-90 kg), hollow organs and large vessels in the abdominal cavity were lacerated to simulate injury requiring surgical intervention. Sterilized surgical instruments from all treatment groups (not including the negative control group) were immersed in the abdominal cavity for 10 minutes to maximize exposure of instruments to fluids, tissues, and other biohazards in the internal milieu.

After removal from the swine abdominal cavity, the soiled instruments were held for one hour at room temperature (RT) to allow adherence of the bioburden. As commonly done in the far forward environment, the instruments were mechanically cleaned and debrided by hand in one of three solutions: sterile water, potable water, potable water + ECA or ECA alone, to remove any tissue fragments or solid material (initial decontamination) or offered no initial treatment at all. After the Initial Treatment phase, the instruments underwent a terminal decontamination treatment by soaking in either CaviCide for 3 and 10 min, Cidex OPA for 10 and 12 min, NDC for 10 min or no terminal

treatment at all. After the indicated manipulations were complete, the instruments were dried and placed in sterile bags and stored at 2 Hr., 24 Hr., 7 Day, and 28 Day storage time points at RT. After the indicated storage times, the corresponding bags were filled with 50 ml of sterile saline and vortexed to recover viable bacteria from the instruments. Fifty (50) µL of the wash fluid from each instrument was plated on agar plates for 24 hours at 37°C. After 24 hours, colonies on each plate were counted and the number of colony-forming units (CFU) per sample were calculated. The results indicate that all three primary disinfectants tested, CaviCide, Cidex OPA, and NDC, are capable of significantly reducing the amount of viable bacteria recoverable from stainless steel surgical instruments after a relatively short exposure time of 12, 10 or 3 minutes. Furthermore, the resulting disinfection is durable at normal RT for up to 28 days post treatment. Of the three disinfectants, Cidex OPA proved to be the most efficacious, followed by CaviCide, and NDC. Treatment with ECA as a stand-alone disinfectant during the initial phase or as a pretreatment for one of the other disinfectants did not result in a consistent reduction in bacterial burden across several experiments. Therefore, ECA is not recommended for further consideration.

This study supports the conclusion that commercially available disinfectants already in use in the field are capable of effectively disinfecting soiled surgical instruments resulting in minimal (≤ 12%) bacterial load. Based on these results, we recommend Cidex OPA as the high-level disinfectant of choice to accompany far forward GSTs, as Cidex OPA produced no bacterial growth in any samples across multiple experiments.

2.0 INTRODUCTION

Prevalence of Surgical Site Infections (SSIs)

According to the Centers for Disease Control and Prevention (CDC), surgical site infections (SSI) represent a significant proportion of health care-acquired infections, patient morbidity and mortality, and heightened health care costs[1]. The Military Health Systems – Implementation Guide for Surgical Site Infection reports that SSIs represented 20% of all health care-associated infections reported to the National Nosocomial Infections Surveillance System (NNISS) in 2002[2]. SSIs result in more than 8,000 deaths a year and occur in up to 25% of patients following major surgical procedures[3]. Moreover, infections associated with combat-related injuries occur in approximately 25% of those patients arriving to the three largest U.S. military treatment facilities (MTF), and may be as high as 50% in patients admitted to the ICU[4]. On average, SSIs extend hospital stays by 9.7 days, while increasing cost by $20,842 per admission, and yet are preventable in an estimated 40 to 60% of cases[1,3,5]. Despite implementation of guidelines for SSI prevention, these infections remain a problem faced by the military medical community. For those infections treated in austere and far forward environments the approach to reduce SSIs is to institute effective decontamination practices for surgical instruments.

SSIs in Austere Operational Settings

To ensure the earliest opportunity for surgical intervention, DoD austere trauma teams are often deployed far forward in the operational theater. A critical constraint of mobile surgical teams is the inability to bring surgical instrument sterilizers. Operational challenges experienced in austere environments at times require that surgical instruments be reused after some level of disinfection to save the lives of combat wounded during mass casualty events. In such situations,

it is imperative that Ground Surgical Teams (GSTs) have at their disposal a high-level disinfectant product and protocol that has been scientifically proven to work. It is also crucial that the decontamination treatment is low-cost, safe, effective, and easy-to-use when traditional sterilization equipment is unavailable.

Decontamination of Reusable Surgical Instruments in the Field

Currently, evaluations of chemical disinfectant products performed by microbiology testing laboratories follow the Association of Official Analytical Chemists (AOAC) Use-Dilution Method[7]. However, the results from these standardized tests do not necessarily translate into real world application[7,8]. Furthermore, the AOAC method is not consistently reproduced across multiple laboratories[7]. Thus, one should not necessarily base the choice of a chemical disinfectant on this standard testing method alone. This study addressed this issue by testing the efficacy of three (3) specific high-level disinfectants plus the addition of ECA, using a design that simulates the real-world scenarios in which far forward military surgical teams operate.

Evaluation of Selected Disinfectants

The current products provided for the USAF and USA surgical teams are CaviCide (Metrex), Cidex OPA (Johnson & Johnson), and NDC (Ecolab). Envirocleanse A (Envirocleanse, LLC) has shown efficacy in reducing bioburden when used to treat large volumes of stagnant water, therefore it was chosen as an addition to the Initial Treatment groups. The use of these products is based mainly on anecdotal information. Numerous past studies have evaluated methods of decontaminating commonly reused, semi-critical items[9,10]. However, these studies did not examine decontamination methods on critical items outside the typical hospital setting. In one study similar to this study, Knox et al. investigated simple rapid methods of sterilizing surgical instruments that could be applicable in austere conditions[11]. They decontaminated sets of 13 different surgical instruments using a combination of chlorhexidine scrubbing and UVC exposure. Each group contained a total of 120 instruments contaminated by dipping in a solution of four different strains of bacteria. Chlorhexidine scrubbing alone or in combination with UVC irradiation resulted in a >99% reduction in bacteria recovery from treated instruments[11]. Chlorhexidine scrubbing alone resulted in 20/120 instruments with residual contamination, while the additional exposure to UVC light reduced that number to 0 -1/120 (<1%).[11]

The goal of this study was to evaluate the ability of three (3) commercially available disinfectants already in use by GSTs to reduce or eliminate bacterial load from intentionally contaminated surgical instruments. An advantage this study has compared to that of Knox et al.[11] (above) is that damaged internal organs of a euthanized swine were used to contaminate the instruments in order to mimic the type of wounds that might be observed in a combat casualty situation. The results of the study provided important information regarding decontamination of surgical instruments for reuse in austere settings when traditional sterilization equipment is unavailable.

3.0 METHODS, ASSUMPTIONS AND PROCEDURES

The purpose of this study was to test the efficacy of commercially available high-level disinfectants in a simulated environment which models the real-world use of these products in

austere conditions. Surgical instruments were contaminated in a manner comparable to conditions found in Role-2 battlefield surgical environments. The instruments were treated with a selection of high-level chemical disinfectants combinations with sterile water, potable water and potable water plus ECA (Table 1) to assess their respective efficacies in eliminating or reducing bacterial bioburden.

Experimental Design and Methods

Humanely euthanized adult Landrace-Yorkshire swine (70-90 kg) were obtained from the Center for Investigation and Research Support (CIRS) at Lackland AFB, with Institutional Animal Care and Use Committee approval[12]. After opening the abdominal cavity, hollow organs and large vessels were lacerated to simulate a penetrating abdominal injury, requiring surgical intervention. Sterilized surgical instruments (5.50-inch straight jaw, box lock Kelly Artery Forceps) were introduced into the abdominal cavity and remained immersed for 10 minutes. The instruments were then transferred to sterile plastic containers and held for 1 hour at room temperature to allow adherence of biological material to the instruments. Table 1 lists the different experimental groups, and Table 2 illustrates the experimental design and timeline for each step.

After the one-hour incubation, the contaminated instruments were distributed to specified sets of two-stage disinfection protocols. The initial stage involved removal of all visual bioburden with a soft bristle brush while submerged in one of three different water-based baths: sterile water, potable water, and potable water with ECA (1:1 dilution). Once visible bioburden had been removed, instruments were treated in the terminal stage by submerging in one of three disinfectants for a time specified by the manufacturer: CaviCide, 3 and 10 minutes; Cidex OPA, 10 and 12 minutes; and NDC, 10 minutes. Positive contamination control instruments were instruments that were immersed in the swine abdominal cavity, but not debrided, washed, or treated in any way. The positive control instruments were removed from the swine abdominal cavity, patted dry, and placed directly into sterile bags. The sterile negative control instruments were autoclaved and aseptically placed directly into sterile bags.

To determine whether disinfection was maintained over time, the instruments were tested for residual viable bacteria post disinfection at 2 Hr., 24 Hr., 7 Day, and 28 Day storage time points. Following treatment with the terminal disinfectants, instruments were dried with sterile towels, placed into sterile wire-closure bags, and sealed until processed for bacterial recovery. At the designated storage time points, 50 mL of 0.9% sterile saline was added to the individual sample storage bags and the bags were vortexed for 2 minutes to release any residual organisms from the surface of the instruments. Each sample was then serially diluted with 0.9% sterile saline; and 50µL of each diluted sample was aseptically spread onto two separate 2% sheep blood agar plates. The plates were incubated under aerobic or anaerobic conditions. An anaerobic environment was achieved by placing agar plates into an air-tight container with activated desiccant sachets. All plates were incubated for 24 hours at 37°C, and the number of colonies on each plate was manually counted. The number of colony forming units (CFUs) per sample was calculated by multiplying the number of colonies from plates with between 30 – 300 colonies by the dilution factor for that plate.

Table 1. Experimental Disinfection Groups

Experiments 1 − 4

INITIAL TREATMENT	TERMINAL TREATMENT
None (Soiled)*	None
Sterile Water	None
Potable Water	None
Potable Water	CaviCide (3 min)
Potable Water + ECA	CaviCide (3 min)
Potable Water	Cidex OPA (12 min)
Potable Water + ECA	Cidex OPA (12 min)
Potable Water	NDC (10 min)
Potable Water + ECA	NDC (10 min)
None (Sterile)[#]	None

Experiment 5

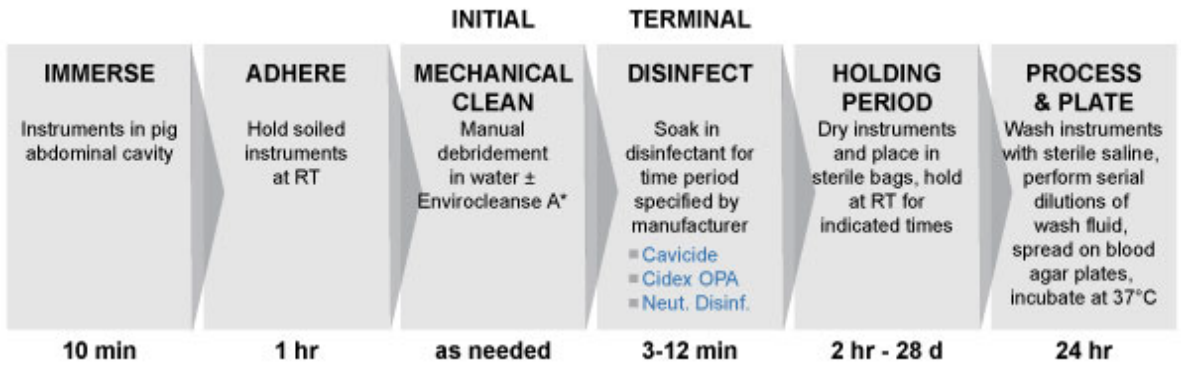
INITIAL TREATMENT	TERMINAL TREATMENT
None (Soiled)*	None
Potable Water	None
ECA (5 min)	None
ECA (10 min)	None
Potable Water	CaviCide (10 min)
Potable Water	Cidex OPA (10 min)
Potable Water	NDC (10 min)
Potable Water + ECA	CaviCide (10 min)
Potable Water + ECA	Cidex OPA (10 min)
Potable Water + ECA	NDC (10 min)
None (Sterile)[#]	None

All groups were debrided during the Initial treatment EXCEPT those in the Positive and Negative control groups.

*Positive Bacteria Growth Control: Instrument soiled in abdominal cavity−no debridement−no initial treatment−no terminal treatment.

[#]Negative Bacteria Growth Control: Sterile instrument−no debridement−no initial treatment−no terminal treatment.

Table 2. Experiment Flow Chart and Timetable



All groups were debrided during the Initial treatment EXCEPT those in the Positive and Negative control groups.

Positive Bacteria Growth Control: Instrument soiled in abdominal cavity − no debridement − no initial treatment − no terminal treatment.

Negative Bacteria Growth Control: Sterile instrument − no debridement − no initial treatment − no terminal treatment.

*Where indicated sterile water or ECA alone was used in the initial treatment

4.0 MAJOR EVENTS/MILESTONES/SUCCESS

In preparation for the execution of this project,

- Kick Off Meeting – **November 2018**
- IRB/IACUC Approval – **December 2018**
- All experimental procedures completed: **December 2019**
- Data Analysis: **December 2019**
- Poster presentation: **MHSRS, August 2019, Kissimmee, FL**
- Manuscript submitted to: **Military Medicine, January 2020**
- Dissemination of Results – pending

5.0 RISK ASSESSMENT

5.1 Risk Analysis:

Low Risk to Completion. Evaluation of the high-level disinfectants using the swine cadaver model was completed on time and within budget.

5.2 Technical Challenges

No significant technical challenges were encountered.

6.0 TRANSITION PLAN

6.1 Military Relevance

Infections associated with combat-related injuries occur in approximately 25% of those arriving to the three largest U.S. military treatment facilities (MTF) with a reported rate as high as 50%. High-level disinfectant product and/or methodology that is low cost, safe, effective, and easy-to-use when traditional sterilization equipment is not available.

Due to operational restrictions and challenges in austere environments, it is critical to determine the most effective decontamination approach to efficiently utilize limited resources. Due to the limited accessibility of sterilized surgical instruments, the available materials must be reused to treat multiple combat patients during mass casualty events. This limitation drives the need for an adequate decontamination product and/or methodology that is inexpensive, rapid, effective, and easy to use.

This study provides improved knowledge and guidance for the development of more effective operational decontamination practices to mitigate high risk infectious agents seen in combat trauma treatment areas.

Lessons learned from this study will improve infection control in austere settings and allow for the development of Clinical Practice Guidelines (CPGs) that offer instruction on how to properly disinfect/decontaminate surgical instruments in forward field positions when conventional sterilization methods are not available.

Knowledge and Capability Gaps Addressed by this Study:

2017 AFMS ICL 20, ACC: Prevent Wound Infection, Expeditionary Medicine Research Development Gaps: Prevent Wound Infection (2), Sterilization Methods That Don't Require Steam For Austere Field Environment (16), DHA Quadruple Aim: Better Care, Knowledge Readiness Level: 3.

6.2 Transition Strategy

This study provides the only direct comparison of efficacy of currently used field disinfectants for rapid reprocessing of critical surgical instruments and demonstrated that these disinfectants are capable of rapidly producing clinically effective decontamination of the instruments in an austere setting. Effective and sustained disinfection of experimental instruments was observed with all three terminal disinfectants tested. Cidex OPA provided the greatest evidence of elimination of microbial contamination followed by CaviCide, and NDC.

This study further provides improved knowledge and guidance for the development of more effective operational decontamination practices to mitigate high risk infectious agents seen in combat trauma treatment areas. Future experiments should include other types of instruments and medical devices such as endotracheal tubes and determine the minimum exposure time required to achieve optimum disinfection. It would also be valuable to determine if these disinfectants are effective against bacterial spores and fungal pathogens. Finally, concentration and packaging options could be explored to reduce weight and volume for forward GSTs.

Additional avenues of investigation could include evaluation of portable sterilizers such as the Eniware nitric oxide (NO) sterilizer and the Ross M1 ozone (O_3) sterilizer from SteriO3, and

dispersal of selected disinfectants using misting devices such as the eMist Backpack Electrostatic Sprayer.

7.0 RESULTS

The efficacy of each of the treatment protocols for aerobic and anaerobic bacteria are displayed qualitatively in the form of a heat map in Figure 1. The absence or presence of CFUs for each instrument tested is represented by a white cell (negative) if 0 CFUs, gray (marginal) if 1-29 CFUs, and black (positive) if ≥30 CFUs was present on any of the aerobic or anaerobic titration plates for that treatment. It is widely accepted that plates with <30 colonies produce unreliable results with regard to titers. However, for the purpose of rigorous qualitative evaluation we scored any plate with even a single colony as positive according to the rules above.

Bacteria were introduced to the instruments via incubation inside the abdominal cavity of a swine cadaver as it contains a mixture of aerobic and anaerobic flora. To determine if each disinfectant was active against both types of bacteria, we cultured under both aerobic and anaerobic conditions. Each disinfectant appeared to be equally effective against both aerobes and anaerobes as indicated by the observation that in nearly all cases the level of growth of aerobes and anaerobes was similar for each individual instrument tested.

For the first four experiments, all terminal disinfectants were used in accordance with manufacturer specifications. (Table 1, Figure 1A). Cidex OPA (undiluted, 12 min exposure) demonstrated the most consistent bactericidal activity with 100% of treated instruments showing no CFUs across all storage time points. CaviCide (undiluted, 3 min exposure) was the next most effective with only 7.5% of the instruments testing positive and an additional 7.5% showing growth below the positive threshold (<30CFU). NDC (1:250, 10 min exposure) was able to eliminate growth in the majority of samples but had a higher failure rate with 27.5% of instruments producing ≥30 colonies, and 12.5% producing marginal CFU growth (1-29 CFU). The addition of ECA (1:1, 10 min exposure) during the initial stage of decontamination did not appear to affect the results for Cidex OPA or NDC but may have produced slightly better results in the CaviCide portion of the study. In the vast majority of cases, washing in either sterile or potable water alone also resulted in significant bacterial growth.

In a separate experiment, we standardized all disinfectant contact times to 8 minutes for each and adjusted disinfectant exposure volumes to the amount of bioburden (number of contaminated instruments) for each stage of cleaning. Additionally, we tested the effect of ECA alone without a terminal stage disinfectant (Table 1, Figure 1B). Despite a small sample size, some notable trends were evident. Cidex OPA maintained 100% bactericidal effectiveness even with a 4-minute shorter contact time in this group; while CaviCide, with a longer exposure time, had only 1 of 18 plates with marginal growth. Longer exposure to NDC decreased its failure rate of positive CFU plates to 11%, with 28% showing only marginal growth.

The impact of ECA on bacterial growth was evaluated in three circumstances without subsequent treatment by a terminal stage disinfectant: a 1:1 dilution in potable water, undiluted for 5 minutes, and undiluted for 10 minutes. While both the 1:1 dilution and 5-minute exposure time resulted in 45% of instruments producing positive plates, instruments exposed to 10 minutes of undiluted ECA had only an 11% positive CFU rate and a 22% marginal result. As in the previous

set of experiments (Figure 1A), washing in sterile water or potable water with no disinfectant treatment resulted in significant bacterial growth when compared to the experimental positive control.

Figure 2 shows a scatter plot of the calculated numbers of CFUs seen at the 2-hour, 24 hours, and 7 day storage time points. Of interest is the low numbers of CFUs for the treated instruments after 24 hours compared to the 7 days. As discussed previously, Cidex OPA treatment resulted in no bacterial recovery in any samples (0 colonies cannot be plotted on a log scale). The scatter plot emphasizes the multi-log reduction in CFUs detected from utilization of terminal disinfectants.

Figure 1A. Heat Map of Bacterial Growth Following Disinfection

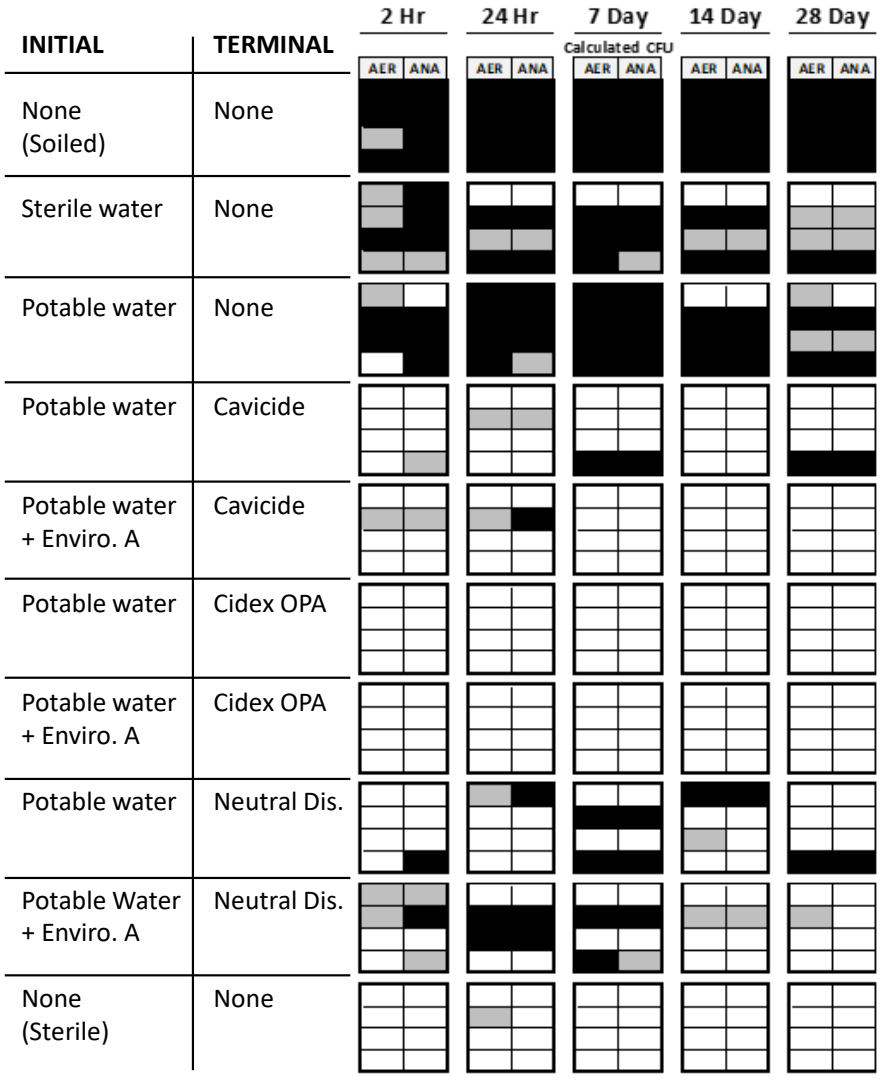


Figure 1B. Heat Map of Bacterial Growth Following Disinfection

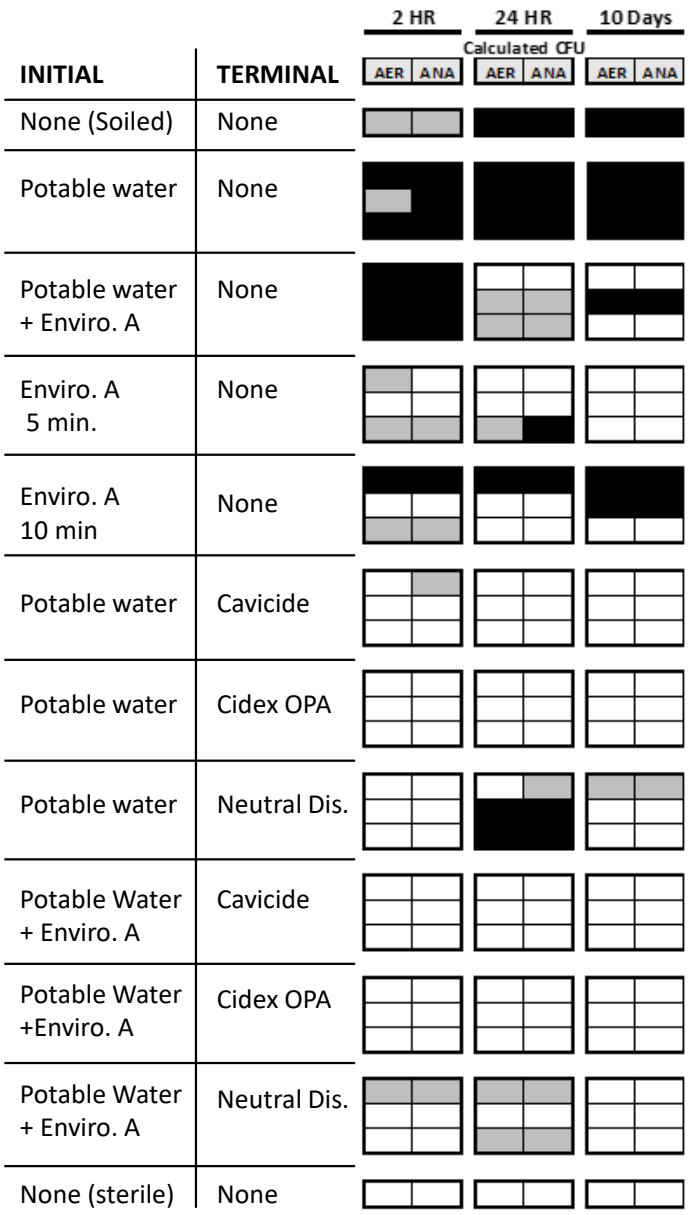


Figure 1. Heat Map of Bacterial Growth Following Disinfection

Figure 1. Surgical instruments were treated as indicated in a two stage process. During the initial stage instruments were cleaned by manual debridement. During the terminal stage the instruments were soaked in one of three disinfectants and then held at RT for the indicated times before rinsing and plating. In Figure 1A the results of four independent experiments are combined. Data in Figure 1B are from one experiment. Colony Forming Unit data are presented in a heat map format. Each cell represents one plate (aerobic or anaerobic) for one instrument at one time point (holding time post-disinfection). Rows represent one treatment; pairs of columns represent one instrument at a specified time point for the indicated treatment. AER: aerobic culture, ANA: anaerobic culture.

No growth observed. At least one plate had 1 – 29 colonies. At least one plate had ≥ 30 colonies.

Figure 2. Calculated CFU Counts

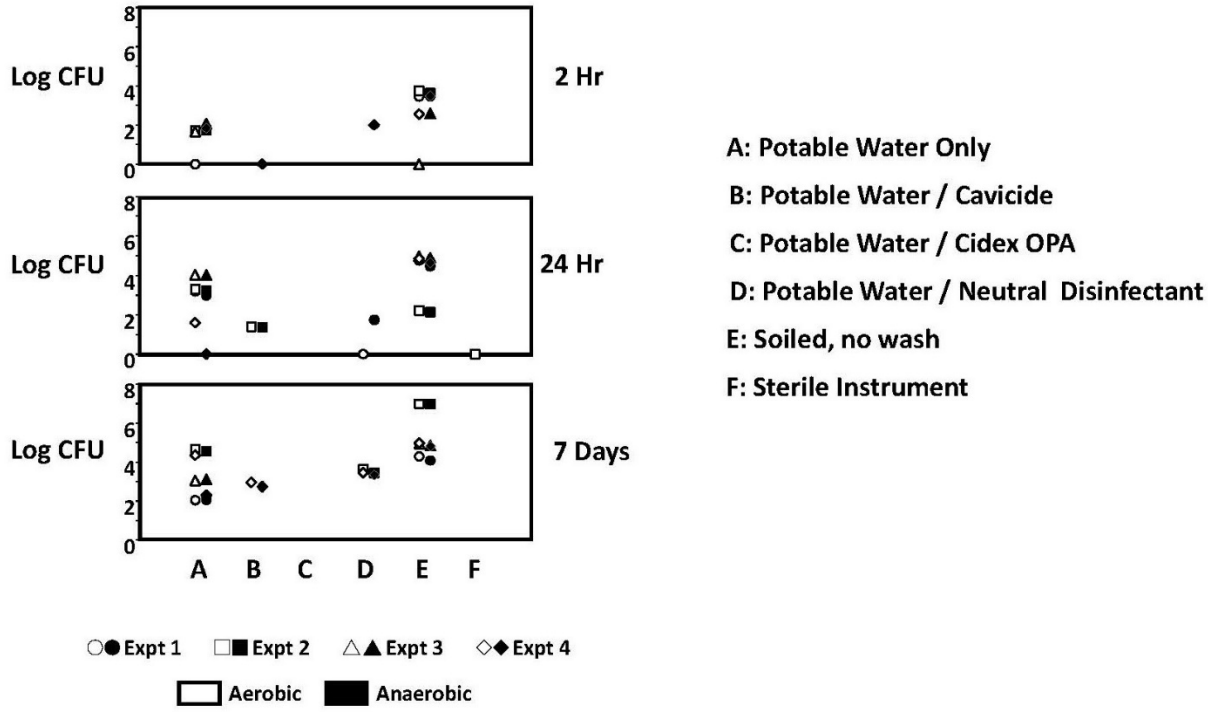


Figure 2. Surgical instruments were treated as indicated in a two stage process. During the initial stage instruments were cleaned by manual debridement. During the terminal stage (indicated by →) the instruments were soaked in one of three disinfectants and then held at RT for the indicated times before rinsing and plating. Data are from the four experiments described in Figure 1A. CFU counts were calculated only from titration plates with 30 – 300 colonies multiplied by the dilution factor. Separate experiments are represented by different shapes. Open shapes: aerobic cultures; closed shapes: anaerobic cultures. A. 2 hr holding time post-disinfection. B. 24 hr holding time. C. 7 days holding time.

8.0 DISCUSSION/CONCLUSION

DISCUSSION

Commercially available disinfectants were evaluated for efficacy in austere environments by establishing a porcine model of catastrophic internal trauma and grading criteria. It was determined that a decontamination process that routinely produces no growth at any given storage time point would be considered effective to warrant use in an austere environment. For study purposes, a decontamination process resulting in over 90% negative bacteria growth on aerobic/anaerobic plates was considered highly effective and yielding over 70% considered effective. The products' sporicidal effectiveness was not evaluated in this study. However, in this experimental design it would be unlikely for bacterial spores to contribute to the results.

Cidex OPA delivered highly consistent and significant results producing 100% bacteria-free instruments at all storage time points tested. CaviCide was deemed highly effective with 92.5%

of cultured instruments found to have no bacterial contamination. NDC's 72.5% success rate illustrated the product's disinfection capability but was the least reliable of the terminal products, especially at the later storage time points of 7, 14 and 28 days. In general, 24-hour results showed better outcomes than 7 days, suggesting that when instruments need to be cleaned and reused immediately, all terminal disinfectants should provide an acceptable level of effectiveness for austere application. Only Cidex OPA should be used if instruments are going to be stored for longer times between uses. While the addition of ECA does appear to marginally reduce bacterial load in comparison to instrument debridement in potable water alone, it had minimal impact when instruments were subsequently treated by the other three disinfectants. Since the chemistry of ECA is similar to that of bleach, caution should be advised since corrosive materials are caustic to skin and metals. Thus, ECA is less desirable than the other disinfectants for use in the field.

The commercial products were employed per manufacturer's instructions for both concentration and contact times. As demonstrated in the final experiment, altering the exposure time and/or compound volume from the manufacturer's suggested guidelines may result in improved outcomes. Furthermore, since contaminated instruments were serially cleaned in the same container initially. It is possible that instruments cleaned later in the process were disadvantaged due to increasing bioburden in the terminal stage of decontamination. The addition of an intermediate rinse may negate the increased bioburden and produce more consistent results.

The active disinfecting ingredients for each product, ECA – hypochlorous acid; NDC - didecyl dimethyl ammonium chloride (germicidal); CaviCide - isopropanol (intermediate disinfectant); and Cidex OPA - ortho-phthalaldehyde (high-level disinfectant/sterilant), could contribute to the unique levels of effectiveness.

Upon reaction with water, ECA produces "free" chlorine which is extremely reactive to many components of bacterial cell walls. While the addition ECA does appear to marginally reduce bacterial load in comparison to instrument debridement in potable water alone, it had minimal impact when instruments were subsequently treated by the terminal disinfectants.

NDC currently is provided in packets of highly concentrated disinfectant which are diluted to create a 1:250 working solution with potable water. Thus, approximately 100 instrument disinfecting procedures can be performed with NDC as with the same amount of Cidex OPA or CaviCide.

CaviCide, an alcohol-based product, proved very effective at eliminating bacterial contaminates in this study, resulting in only occasional positive cultures. Since alcohols are most effective at concentrations of 60-80%, the possibility of further dilution is minimal, since it would lower the alcohol concentration below its effective range[13].

Cidex OPA (ortho-phthalaldehyde) is commonly used in hospital settings to provide sterilization-level decontamination on instruments that are fragile or sensitive to normal heat or steam sterilization procedures. Cidex OPA is effective in a concentration range of 0.1% to 1%. This study found Cidex OPA to provide the most consistent bactericidal results at all storage time points and, therefore, to be the best choice as a deployable decontamination agent for surgical instruments. Cidex OPA has the advantage of being able to be reused over several days.

While we tested the pre-diluted, ready-to-use product as supplied by the manufacturer, the potential for a concentrated version of Cidex OPA that can be diluted at the point of use could reduce the weight burden for far forward surgical teams.

Proper perioperative decontamination of surgical instruments is a vital strategy in infection control due to the increased probability of preventing transmission of pathogenic organisms from a contaminated instrument to a patient. Therefore, effective and prompt surface decontamination of reprocessed surgical instruments and short turn over times are paramount to mitigate infection[14].

CONCLUSION

This study provides the only direct comparison of the efficacy of currently used disinfectants for rapid reprocessing of austere surgical team's critical instruments. Effective and sustained disinfection of experimental instruments was observed with all three terminal disinfectants tested. However, Cidex OPA provided the greatest evidence of elimination of microbial contamination compared to CaviCide, NDC and ECA.

Differences in bactericidal effects of the terminal disinfectants might be a function of the active ingredients, volume, concentration and time of exposure. CaviCide and Cidex OPA were utilized undiluted, whereas NDC was diluted 250-fold with potable water, all per manufacturer's specifications. Since weight and volume are critical attributes for any item carried by austere surgical teams, obtaining these products at a higher concentration would be advantageous. Thus, options for concentrated formulas of Cidex OPA and CaviCide should be explored.

Various soak times of 3, 10, and 12 minutes for CaviCide, NDC, and Cidex OPA respectively further add to the complexity of evaluating products. This variable was addressed in the final experiment, when contact times was standardized to 8 minutes for all three disinfectants. Even with a 4-minute shortened contact time, Cidex OPA was still capable of 100% bacterial elimination. This leads to potential investigations to determine if reagents can be concentrated, or the exposure time adjusted further to render a more easily transported product that can be effectively deployed in the field.

This study demonstrates that all currently used disinfectants are capable of rapidly producing instruments with reduced to no detectable bacterial contaminates when standard sterilization is unavailable. As multiple factors impact disinfectant choice in the unique austere surgery team environment further evaluation is prudent to establish a preferred standard product, packaging, and cleaning protocol. Austere surgical environments encountered by deployed military medical teams demand effective and efficient disinfection alternatives that can reduce bacterial infections related to life-saving procedures, especially during multi-casualty events. Although the methods being utilized were not tested on spores, they do provide a fast and efficient means to greatly reduce the microbiological burden compared to surgical instruments that are cleaned in potable or sterile water only. The results of this study provide convincing data that clinically effective disinfections can be achieved in the field setting; and also provides guidance for a number of follow-up evaluations which can serve to better delineate more effective and logistically accommodating products and packaging in the future.

9.0 DELIVERABLES

9.1 Publications:

Hune SR, DiGeorge-Foushee AM, Ervin MC, Anderson SJ, Ervin MD, Mallory AM. 2020. An Analysis of the Effectiveness of High Level Disinfection for Surgical Instruments Used by DoD Austere Surgical Teams. Military Medicine, In Press.

9.2 Presentations:

Ervin MD, Hune SR, DiGeorge-Foushee AM, Ervin MC, Mallory AM. 2019. An Analysis of the Effectiveness of High-Level Disinfection for Surgical Instruments Used by DoD Austere Surgical Teams. Poster Presentation, Military Health System Research Symposium (MHSRS), Kissimmee, FL.

10.0 COST

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FIGURES AND TABLES:

12.0 LIST OF SYMBOLS, ABBREVIATIONS AND ACRONYMS

AER	Aerobic
ANA	Anaerobic
AOAC	Association of Official Analytical Chemists
CDC	Centers for Disease Control and Prevention
CFU	Colony Forming Units
ECA	EnviroCleanse A
GST	Ground Surgical Teams
MTF	Military Treatment Facility
NDC	Neutral Disinfectant Cleaner
NNISS	National Nosocomial Infections Surveillance System
NO	Nitric Oxide
O_3	Ozone
OPA	Ortho Phthalaldehyde
RT	Room Temperature
SSI	Surgical Site Infections
UVC	Short Wave, Germicidal Ultraviolet Light