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Field Testing of a Commercially Available Pressure Cooker for Sterilizing Medical and Dental Instruments in an Austere Environment

MAJ Hong, Seung H.

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INTRODUCTION

During the military's Dental Civic Action Plan (DENTCAP) or civilian dental humanitarian missions in austere locations, one of the leading challenges is proper sterilization of medical and dental instruments. The military-standard sterilization equipment may be difficult or impossible to transport in harsh conditions. Electricity may be unavailable or available only intermittently. Instruments not intended for reuse may need to be reused. Sterilization equipment that is easy to transport, rugged, and effective when used with simple heat sources, such as a portable propane burner or a wood fire, can support the mission when standard equipment will not. This study demonstrates the effectiveness of an ordinary, non-electric pressure cooker, heated and pressurized over a simple heat source, for sterilization of dental instruments in austere locations.

Statement of the Problem

In austere locations, a lack of public infrastructure, a hostile environment, and an unstable society are not uncommon; these conditions create strains for logistic maneuvers to deliver and resupply through scheduled air or ground convoys. On civilian dental humanitarian missions in such locations, the sterilization of medical and dental instruments is often essential yet problematic.

The process of cleaning, sterilizing, and repacking instruments for the next patient is called reprocessing, defined as a validated process to render a medical device, which has been previously used or contaminated, fit for subsequent single use. It involves physical cleaning, to remove contamination, followed by the elimination of microorganisms through disinfection or sterilization.[1] Not only is sterilization the professional standard but, more importantly, it eliminates or reduces the risk of postoperative infections following medical or dental treatment.[2]

Several methods are used to carry out sterilization for the reprocessing of instruments; these include dry heat, steam, and chemical-liquid liquid methods. Dry heat takes 60 minutes to kill one million spores of *Geobacillus stearothermophilus* at 320F° (160C°), while steam sterilization at the same temperature takes less than a minute.[3] Chemical sterilization, or high-level disinfection (HLD), does not kill spores of *G. stearothermophilus*, and it requires a proper disposal system for the toxic chemical solution. The improper disposal of hazardous waste solutions creates an environmental hazard that may outweigh the benefits of the chemical-liquid sterilization method.[4]

In modern hospitals and clinics worldwide, an autoclave machine is the primary method for reprocessing instruments. However, while several manufacturers have developed autoclaves small enough to be portable, portable autoclaves weigh in the range of 50 to 200 lbs., require a constant and stable electricity supply, and can be bulky. Thus, not all medical and dental missions can take an autoclave machine with them. In a conventional Army unit, each Brigade has a Brigade Support Battalion (BSB) and, under the BSB, a Logistic Company and Medical Company organic to the BSB. These two companies are responsible for allocating, transporting, and providing medical treatment facilities in the vicinity of maneuvering and supporting units under each brigade during military operations.[5] The author was a brigade dentist in a conventional Army unit between 2013 and 2016, and witnessed the collective sophistication required for logistical maneuvering to transport medical assets, including an autoclave. The autoclave weighed over 120lbs. with its case and accessories, and always required a generator to ensure it could reprocess instruments continuously. In addition, on a weekly basis, the supply team had to plot a route for the resupply of disposable medical assets, including distilled water for the autoclave. The efficient logistics systems provided during large-scale operations have meant little demand for an alternative to sterilizing instruments with an autoclave.

In contrast, small-scale operations associated with DENTCAP and Medical Civic Action Plan (MEDCAP) take place in austere locations. A constant electricity supply to run an autoclave may not be available, nor may a logistic route for the transport and resupply of medical assets. Additionally, these resources may not always be available because, during military operations, infrastructure can be damaged due to enemy engagement, logistic routes for transport can be restricted due to an enemy presence in the vicinity, and logistic maneuvers may no longer be carried out due to the loss of air superiority in a multi-domain operation. Because of the complexity of military operations, the consideration of alternative methods to sterilize dental instruments may be of worth.

Significance

If, as an alternative and temporary method, commercially available pressure cookers can sterilize dental and medical instruments, remote missions will benefit greatly. Effective sterilization with simple pressure cookers could eliminate challenges at an austere location or typical Forwarding Operation Base (FOB). Among the challenges potentially erased are transporting an autoclave, supplying additional resources for weekly maintenance of an autoclave, and providing constant electrical power for running an autoclave in an austere location.[6]

A commercially available pressure cooker, such as the Presto® 4-quart stainless steel pressure cooker, is portable and lightweight, and costs as little as $40 compared with a $2,000 autoclave. A pressure cooker can also be used as a storage container for dental instruments. Furthermore, it does not rely on electricity, an infrastructure requirement for autoclave use. A pressure cooker can be heated using various heat sources, such as a portable butane gas burner, a kerosene heater, or a fire in a pit. Research has shown that sterility can be achieved using a pressure cooker by meeting the following criteria: the internal temperature must reach 250°F at 15 psi for 20 minutes.[7]

A pressure cooker is small and lightweight enough to enable a medical soldier or medical/dental provider to transport it and provide a sustainable reprocessing capability in a situation where transporting and utilizing an autoclave are not possible. Based on the author's previous dental missions with U.S. Special Forces, most medical and dental missions consist of a one- or two-person team to transport all equipment and materials, and set up a mobile clinic at the austere site. Therefore, sterilization equipment must be packed and stored in a relatively small size and be transportable by the providers. A current Army-authorized portable sterilizer, the Tuttnauer® 2540, weighs 85 lbs. (and costs $7,800) and is not feasible to carry in a portable dental set due to its size and weight.[8]

In a recent review of the literature, Swenson et al. were found to have investigated four commercially available pressure cookers as means for achieving sterility without relying on expensive and cumbersome methods in a laboratory setting.[9] All four pressure cookers inhibited bacterial and fungal growth after heating at 121C° for 15 minutes, and the researchers successfully sterilized stainless steel dissection scissors after 30 minutes in one of the pressure cookers.[10] The study also pointed out that, because the cost of pressure cookers is low and they are small and lightweight, they are less of a burden for under-funded laboratories or persons in the developing world who lack funding and procurement resources.[11,12]

For sterilization or reprocessing, the study recognized the pressure cooker as an alternative method for heat sterilization as long as it could achieve 250°F (121°C) at 15 lbs. (1.03421 bar) for 30 minutes. The research by Swenson et al. was intended to accomplish the premarket validation of an off-label pressure cooker as an FDA-cleared sterilizer.[13] In contrast, the present study is intended to test the off-label pressure cooker to ascertain if it can achieve sterility for the reprocessing of dental instruments in austere locations where using a 510K sealed medical sterilizer is not feasible due to logistic challenges, time constraints, or a lack of electrical power.[14]

To the author's knowledge, no standard operating procedure exists—in writing, in an Army or Department of Defense (DOD) publication—for reprocessing medical or dental instruments under conditions such as a lack of electrical power, time constraints, or a logistic backlog.

PURPOSE

The purpose of this study is to evaluate the sterility of dental and medical instruments processed in a commercially available pressure cooker in outdoor conditions that mimic an austere operational location, in order to validate the use of commercially available pressure cookers as a sustainable, alternate method to using an autoclave.

HYPOTHESIS

The commercially available pressure cooker Presto® 4-quart stainless steel is capable of achieving sterility in austere conditions, defined as lacking electricity and an autoclave.

MATERIALS AND METHODS

Overview

This study was designed to utilize a pressure cooker—the Presto® 4-quart stainless steel pressure cooker—outdoors at 250°F at 16 psi for 20 minutes to achieve sterility. To validate sterility, a steam chemical integrator (3M Comply™ SteriGage™ 1243A) and a biological indicator (3M Attest™ Rapid Readout 1292) were utilized. Steam chemical integrators are chemical indicators (CI) that consist of a paper wick and a steam- and temperature-sensitive chemical pellet contained in a paper/film/foil laminate. The Comply SteriGage (1243A) chemical integrator's instructions state that 121°C/250°F is the critical minimum temperature threshold, i.e., the chemical pellet responds at the critical temperature 121°C/250°F and no lower, Thus, the Comply SteriGage can detect whether the contents of the packet did not reach the critical temperature for proper sterilization.[15]

The 3M Attest Rapid Readout (1292) is a dual-readout biological indicator. It detects the presence of *G. stearothermophilus* by detecting the activity of alpha-glucosidase, an enzyme present in the organism. The presence of this enzyme is detected by an auto-reader that recognizes the fluorescence produced by the enzymatic breakdown of a non-fluorescent substrate. A fluorescence change indicates a failure of the steam sterilization process.[16]

For a heat source, this research used a 10-lb. propane tank and burner as a reliable heat source for the pressure cooker. Electricity was not used to heat instruments in the pressure cooker in order to mimic the austere location where electricity and generators are scarce resources compared to propane or other combustible gases or liquids, which are relatively abundant in the developing world. This study limited the heat source to a propane tank because the intent was to test one variable, the outdoor environment that mimics an austere location versus the indoor, fully electrified environment, and not to test different types of non-electric heat sources.

Detailed Methodology

1. A test packet (3.5" x 5.25" Henry Schein sealed sterilization pouch) containing the following items was prepared:
    - 3M Attest Rapid Readout (1292) biological indicator
    - 3M Comply SteriGage (1243A) steam chemical integrator strip

2. A Presto® 4-quart stainless steel pressure cooker was filled with 12 ounces of tap water.
3. A metal grate was placed in the bottom of the cooker.
4. The researcher verified that the metal grate was not submerged in the water.
5. A surgical towel was placed on the metal grate to prevent the heated metal from melting the test packet.
6. The test packet was placed on top of the surgical towel.
7. The pressure cooker was placed on the propane burner, and the gas turned on and ignited.
8. A total of 140 trials was run, with each trial using one test packet.
9. The pressure and temperature established by the manufacturer for the stock weight is 15 psi and 250°F.[17] In each trial, the pressure cooker was subjected to heat until the researcher could detect audible sounds and visually confirm the rattling movement of the excess pressure relief valve (EPRV) on top of the lid. The sounds and the rattling of the EPRV indicate internal pressure is at 15 psi and temperature is at 250°F; at that pressure and temperature, the pressure cooker requires 20 minutes to achieve sterility.[18]
10. After each trial, the pressure cooker was allowed to cool for at least 5 minutes before the next trial was started.
11. At the end of each trial, the readings for the Attest Rapid Readout pouch indicators and Comply SteriGage strips were recorded. The Attest vials were incubated in a 3M Attest 290 auto-reader with a control vial for at least three hours, following US Army protocol and the manufacturer's recommendation.[19]
12. The recording procedure was as follows:
    a. On each trial Attest vial, the date of testing, sequence number assigned to the vial, and LOT number were recorded.

b. The temperature, humidity, and wind were recorded when the propane burner was ignited.
c. A blinded observer recorded the results of each incubation, either a positive or negative value.

DATA ANALYSIS

Statistical analysis can be used quantitatively to determine the following variables:

- Percentage of sterility after heating for 20 minutes at 250°F and 15 psi
- The atmospheric temperature range during the trials
- The atmospheric wind or wind gusts range during the trials

Methods of Data Analysis

Measures of central tendency are presented as means with associated standard deviations. Multiple regression analyses were used to test if the ambient temperature and wind speed affected either the pressure cooker's time to achieve required psi or the achieved depth on the sterility indicator strip. All analyses were conducted using SPSS version 25 (IBM, Chicago, IL).

Results

Of the 144 samples tested, five failed to achieve sterility within the 20-minute heating time due to high winds blowing out the fire. Because the heat source was removed from these samples during testing, they were excluded from further analysis. Among the remaining 139 samples, 100% achieved sterility following the 20-minute heating time and all achieved the required pressure within the first 9 minutes.

The mean wind speed during testing was 12 mph (SD = 5) and the mean temperature was 72F (SD = 7). The average depth of the indicator strips was 6 mm (SD = 3). Regression analysis showed no relationship between strip depth and ambient temperature, P=0.53. However, wind speed was found to be positively associated with indicator strip depth, P=0.01 (see Figure 1). The overall model fit was r2 = 0.05, indicating a rather weak effect of wind speed on strip depth.

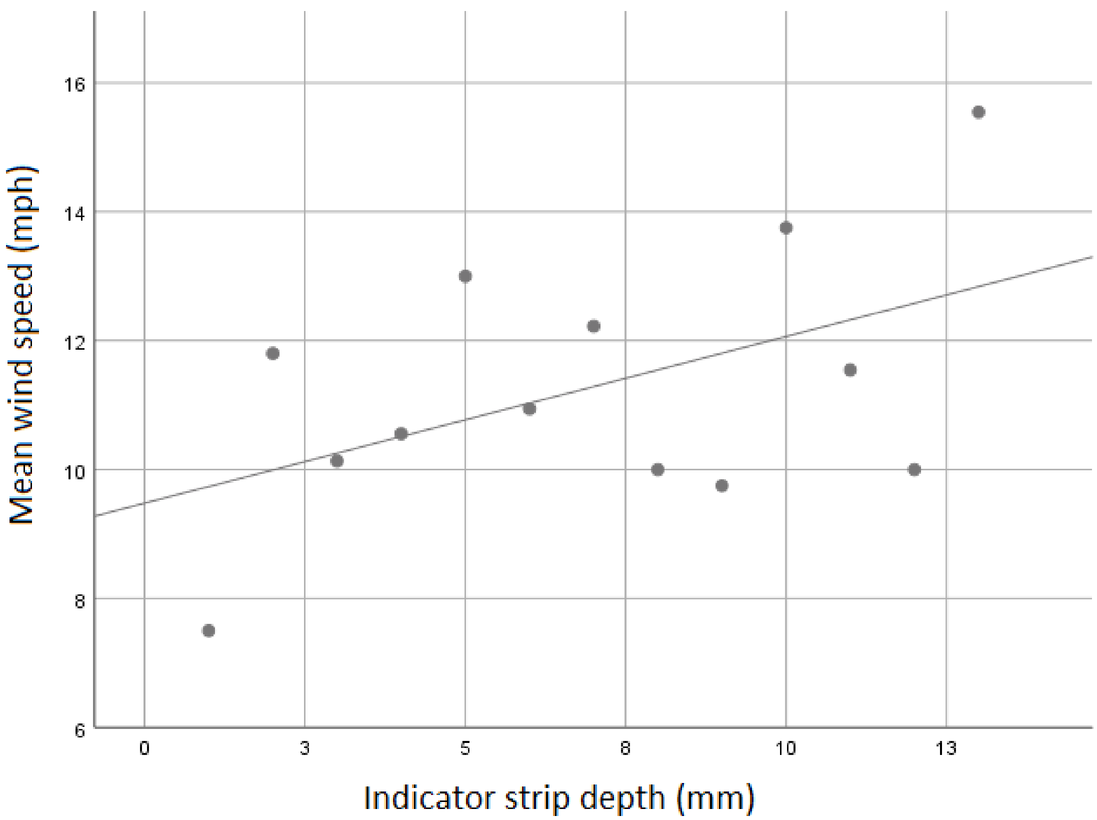

Figure 1.Mean Indicator Strip Depth by Wind Speed

DISCUSSION

Out of 140 trials, five samples failed to achieve desired sterility because fire from the propane burner was blown out multiple times due to high wind gusts. The gusting wind changed speed rapidly; consequently, the author could not measure wind speed at a precise moment, but average wind gusts over 30 mph were consistently strong enough to frequently extinguish the fire from the propane burner. In results, Comply SteriGage strips from those five samples indicated that conditions for sterilization failed; Attest Rapid Readout markers also indicated failure. These failures indicate that careful monitoring of the fire source during heating of the pressure cooker is paramount in an austere location or outdoor setting. Also, the fire source in this study was a particular propane burner; if the operator intends to use other types of fire sources—such as kerosene burner, wood fire, small individual fire burner—these will mostly likely respond to wind differently. Some will withstand stronger winds than other types of fire sources. The keys to success in using a commercially available pressure cooker as an alternate means of sterilization are the following:

- Careful monitoring of the audible, weighted pressure valve on the pressure cooker must be maintained for 20 minutes in order to achieve desired sterility.
- Careful monitoring of the fire source is needed to ensure that it maintains constant fire and heat to the pressure cooker.
- The fire source should be placed in a location that has at least the outside wall of a building or other structure blocking wind gusts. Even adjacent cooking vessels could moderate the wind. The author recommends against placement of the fire source in a completely open place.
- Due to durability limitations on these commercially available pressure cookers, the author recommends annual replacement of the pressure cooker or at least of the sealer on the pressure cooker's lid to ensure proper pressure (15 PSI) throughout use. This recommendation is made on the assumption that dental or medical missions occur once a year and are no more than 2 to 3 weeks in length.

Further studies can be conducted with a variety of variables:

- Similar trials can be conducted with a random selection of commercially available pressure cookers to ascertain if these pressure cookers achieve the desired sterility as compared to the one in this study.
- Similar trials can be conducted with a random selection of operators, preferably Medics 68W or 18D, to see if they can follow procedures to achieve sterility. The current study testing the use of a pressure cooker for sterilization was designed to benefit both medical and dental professionals. Nonetheless, a study focusing on Medics can determine their ability to perform sterilization in the field with a pressure cooker and non-electric heat source, enabling them to extend their care missions in austere locations in the face of a lack of logistic resources or infrastructure, and/or the limitations of missions in which a one- or two-person team carries all professional equipment and supplies.

BENEFIT FOR THE DOD

This research is focused on dental officers and non-dental providers, like Special Operation Medics (91W1) and Special Forces Medical Sergeants (18D), who are or will be providing dental care such as extractions. On the operational medical side, most medical instruments, including chest tubes, IO and IV central lines, and tracheostomy tubes, are supplied in disposable single-use packaging; hence the author has not seen many multiple-use instruments in military missions taking place in austere locations. However, on the operational dental side, most procedures involve the extraction of teeth, and these extraction procedures are mostly carried out with dental elevators and forceps that are made of stainless steel. The author has not seen or heard of disposable single-use dental instruments designed for extraction procedures. Thus, the sterilization of these instruments is necessary to enable dental extraction operations for multiple patients.

If a reliable alternative to an autoclave, like a portable sterilizer, can be identified, dental care providers in an austere location where an autoclave is not an option will embrace the alternative. If they have an alternative way to sterilize dental instruments using a commercial pressure cooker, then dental outreach programs such as DENTCAP can be sustained with effective reprocessing of dental instruments. Furthermore, DENTCAP has been proven to be an effective way to build rapport with local populations, and a reliable means to expand DENTCAP will enhance operations.

Lastly, the United States Military Armed Forces face a contest with the revisionist powers of China and Russia in multi-domain operations. In recent decades, US superiority in operating domains has been challenged by these revisionists.[20] For example, in the past, the US military relied heavily on air medevac for patient transport and air supply drops to resupply ongoing operations; all these types of maneuvering were feasible due to uncontested air superiority. However, in future conflict and warfare, the US military must anticipate a reliance on ground forces that need to be sustained for longer periods without air support due to a lack of air superiority. Required logistics may be delayed or even halted for an extended time. Thus, it is desirable to invest in and develop alternate ways to sustain medical and dental operations for an extended period with limited or delayed logistics. Commercially available pressure cookers may be feasible as an alternative or even superior way to reprocess durable medical and dental instruments in an austere location.

CONCLUSION

This study proves the feasibility of using a commercially available pressure cooker to achieve the desired sterility of dental instruments, but this alternative is not meant to replace the current primary method of sterilizing. Rather, this alternate method may be useful for situations when resources are limited or completely unattainable due to the operational situation. In particular, Medic and SF Medical sergeants, who may perform dental procedures, require sterilization to extend their care. Having not only a primary method of sterilization but also a secondary or alternative method of sterilization in a battle plan will minimize shortfalls and keep valuable medical and dental missions functioning at full capacity.

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ENDNOTES

[1] US Food and Drug Administration. *Reprocessing medical devices in health care settings: Validation methods and labeling*. FDA Guidance for Industry and Food and Drug Administration Staff; March 17, 2015 (Appendix E updated June 9, 2017). https://www.fda.gov/ regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling.

[2] Risk DL. Infection control in austere practice settings. *Journal of Multidisciplinary Care: Decisions in Dentistry* 2017, Aug. https://decisionsindentistry.com/article/infection-control-austere-practice-settings/. Accessed Feb 10, 2020

[3] Perkins JJ. *Principles and methods of sterilization in health sciences*. 2nd ed. Springfield, IL: Charles C. Thomas Pub. Ltd.; 1976.

[4] Hamann C, Palenik C. Mission trips: First do no harm. *Dental.com* 2012. Proctor & Gamble. https:\\www.dentalcare.com/en-us/professional-education/ce-course/cd397. Accessed Feb 10, 2020

[5] US Department of the Army. *The U.S. Army in Multi-Domain Operations 2028*. TRADOC Pamphlet 525-3-1, 2018. https://www.ncoworldwide.army.mil/Portals/76/courses/mlc/ref/Multi-Domain-Operations-2028

[6] Doona CJ, Feeherry FT, Kustin K, Olinger GG, Setlow P, Malkin AJ, Leighton T. Fighting Ebola with novel spore decontamination technologies for the military. *Front. Microbiol.* 2018;6:article 663. doi: 10.3389/fmicb.2015.00663

[7] Swenson VA, Stacy AD, Gaylor MO, Ushijima B, Philmus B, Cozy LM, Videau NM, Videau, P. Assessment and verification of commercially available pressure cookers for laboratory sterilization. *PLOS One* 2018;13(12):e0208769. doi: 10.1371/journal.pone.0208769

[8] Cook RK, M. J. Use of a pressure cooker to achieve sterilization for an expeditionary environment. *Journal of Special Operations Medicine.* Breakaway Media, LLC 2021;5(5). Retrieved from https://www.jsomonline.org/jsomstorefront/index.php?rt=product/product&path=7&product_id=2759

[9] Swenson, et al. *Op. cit.*

[10] *Ibid.*

[11] *Ibid.*

[12] US FDA. *Reprocessing. Op. cit.*

[13] 3M Comply™ SteriGage™ Steam Chemical Integrator (1243) Technical Information. 3M; 2008. https://multimedia.3m.com/mws/media/356429O/technical-info-3m-comply-sterigage-steam-chemical-integrator.pdf. Accessed Feb 10, 2020.

[14] 3M Attest™ Rapid Readout Biological Indicator (1292) Technical Information. 3M; 2016. https://multimedia.3m.com/mws/media/497747O/attest-rrbi-for-steam-1292-package-insert-english.pdf. Accessed Feb 10, 2020.

[15] 3M Comply™ SteriGage™. *Op. cit.*

[16] 3M Attest™ Rapid Readout. *Op. cit.*

[17] Presto Pressure Cookers Instructions & Recipes. National Presto Industries, Inc.; 2009. https://www.gopresto.com/uploads/01362_72856A[5].pdf Accessed Nov 09, 2019

[18] DENCOM Pam 40-5-1, Appendix J, Instrument Processing and Sterilization. June 2015.

[19] *Ibid.*

[20] US Department of Defense. *Summary of the 2018 national defense strategy of the United States of America: Sharpening the military's competitive edge.* 2018. https://dod.defense.gov/Portals/1/Documents/pubs/2018-National-Defense-Strategy-Summary-1.pdf