


Identification and Analysis of Bacterial Contamination of Ultrasound Transducers and Multiuse Ultrasound Transmission Gel Bottle Tips Before and After the Aseptic Cleansing Technique

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Abbreviations

CR, clinically relevant;; NCR, non-clinically relevant

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Objectives—To provide a descriptive analysis for species identification of culture and Gram stain results from ultrasound transducers and multiuse ultrasound transmission gel bottle tips in active clinical use and to compare bacterial cultures from ultrasound transducers before and after aseptic cleansing.

Methods—A prospective blinded descriptive analytic study of 18 distinct clinical care sites within a single primary clinical institution was conducted. Before and after a disinfectant towel cleanse, transducers were pressed against tryptic soy agar contact plates. Plates were deidentified and submitted for blind incubation, Gram staining, and species identification with microsequencing. Results were classified as clinically relevant (CR) or non-clinically relevant. In total, 188 samples were analyzed: 80 from ultrasound transducers before and cleansing, 13 from multiuse gel bottle tips before and after cleansing, and 2 precleansing samples from the data collector's pen and badge.

Results—Fifty-nine precleansing samples (73.8%) grew cultures with CR bacteria, and 21 samples (26.3%) did not. *Staphylococcus simulans* represented 31.0% of all positive culture samples. Thirteen postcleansing samples (16.3%) grew cultures with CR bacteria, equating to a 78.0% reduction of CR bacterial growth (likelihood ratio, 57.10; $P < .001$).

Conclusions—Ultrasound transducers have a notable CR bacterial burden and may serve as potential infective vectors. Aseptic cleansing effectively eliminates most of the bacterial load from ultrasound transducers, but some bacteria persist, presenting a risk of nosocomial infection with ultrasound-guided interventions. These findings support American Institute of Ultrasound in Medicine 2018 guidelines intended to ensure an appropriate level of transducer preparation based on the examination type while emphasizing rational infection control measures to minimize the risk of potential patient harm.

Key Words—aseptic cleansing; bacteria; bacterial contamination; gel bottle tips; transducers; ultrasound

Ultrasound use in clinical medicine has become increasingly common and is now considered the standard of care for many diagnostic and therapeutic interventions.¹ However,

although the popularity of ultrasound-guided procedures continues to rise, the methods used for cleaning remain variable among medical practitioners.² The Centers for Disease Control and Prevention published updated guidelines in 2019 for disinfection and sterilization in health care facilities, which highlight the importance of using safe practices for maintaining transvaginal and surgical-use ultrasound transducers.³ These recommendations build on the original guidelines created by Earlie H. Spaulding,⁴ who detailed a key classification scheme for disinfection and sterilization. However, despite available international guidelines for ultrasound cleaning,^{5,6} it has been reported that 87% of academic medical centers do not have a mandated protocol or standard contact time for transducer disinfection.⁷ By definition, there are 2 types of disinfection: high level and low level. Historically, high-level disinfection refers to the removal of all microorganisms except for bacterial spores, unless used under specialized conditions. This typically is done with a chemical sterilant or germicides and physical sterilization. In contrast, low-level disinfection destroys most bacteria, some viruses, and some fungi, through the use of soap, water, or quaternary ammonia sprays or wipes.⁸

At present, the aseptic technique is widely used for many ultrasound-guided procedures, in which the ultrasound transducer is cleansed with antimicrobial wipes rather than using a sterile ultrasound transducer cover.⁹ It is known that ultrasound transducers commonly have a bacterial burden after contacting a patient's skin.^{10–12} Visual inspection alone cannot exclude contamination, as one study found that only 51% of blood-contaminated ultrasound units were visibly stained.¹³ A second study demonstrated that, of clinical ultrasound equipment that practitioners deemed ready for patient use, 26% had bacterial contamination.¹⁴ Several major ultrasound-associated bacterial infections resulting in patient harm have been reported in the literature.^{15–21} Review of these case series reveals that endocavity ultrasound interventions are the most common causes of major ultrasound-associated bacterial infections. The other notable etiology of iatrogenic infection in ultrasound-guided procedures is the use of contaminated ultrasound transmission gel from multiuse bottles. A recent case-control study evaluated 40 patients who developed post-procedure soft tissue or bloodstream

infections during a 3-year period and found a positive association with contaminated ultrasound gel. After replacement of the contaminated gel, there were no new cases detected during 18 months of follow-up.²² In another review of all cases of septic arthritis in Iceland over a 12-year period, the iatrogenic etiology of septic arthritis tripled, with the leading causes being arthrocentesis and joint injections.²³ In this study specifically, we delineated whether bacteria was clinically relevant (CR) or non-clinically relevant (NCR) based on a careful review of the literature and documented cases or case series detailing human harm.

Sterile ultrasound transducer covers and sterile ultrasound gel are widely available; however, sterile procedures present the potential for disadvantages such as increased cost as well as the possibility of diminished image quality.^{9,24} Although some advocate for a complete sterile technique with every interventional ultrasound procedure,²⁵ others have proposed that nonsterile gel has no relevant bacterial burden.²⁶ Adding to the uncertainty of bacterial seeding from ultrasound-guided interventions is the inadequacy of surgical preparation solutions to remove the bacterial burden.²⁷ Previous articles have evaluated bacterial growth on ultrasound devices; however, it remains unclear whether a full sterile technique should be recommended for all ultrasound-guided procedures, particularly in musculoskeletal settings (Table 1).

To further understanding of the appropriate protocol for ultrasound-guided procedures, this study aimed to provide a descriptive analysis of culture and Gram stain results from ultrasound transducers and multiuse ultrasound transmission gel bottle tips in active clinical use and to compare bacterial cultures from ultrasound transducers before and after aseptic cleaning.

Materials and Methods

The study was reviewed, approved, and funded by the University of Utah Medical Group Quality Assurance Committee. Informed consent was not necessary for this study, as no patients were involved. Ultrasound transducers and multiuse gel bottle tips from active clinical use were evaluated in 18 distinct clinical care sites. The transducers and multiuse gel bottle tips were pressed against tryptic soy agar contact plates (Carolina Biological Supply Company, Burlington,

Table 1. Literature Comparison for Ultrasound Cleansing

Study	Departments	Machines	Transducers	Bottles	Cultures	Precleanse Growth Rate, %	Postcleanse Growth Rate, %
This study	18	41	80	26	192	73.8	16.3
Whiteley, 2018	5	NR	NR	NR	750	26	6%
Westerway, 2017	2	NR	60	7	171	38.3	3.3
Lawrence, et al. ³⁹	9	43	82	NR	320	5.60	NR
Chu, et al. ⁴⁰	1	31	31	0	31	22.60	NR
Ejtehadi, 2014	1	1	3	NR	50	98	21
Sherman, 2015	1	NR	NR	26	26	35	4
Casalegno, et al. ⁴¹	1	NR	NR	NR	417	28	18
Provenzano, et al. ⁴²	0	0	0	212	212	7	NR
Fraze, et al. ⁴³	1	NR	6	NR	164	67	0
Sanz, 2011	3	NR	11	0	110	1	NR
Karadeniz, 2001	1	NR	1	0	43	0.79	NR

NR indicates not reported.

NC). These plates were then deidentified and submitted to Nelson Laboratories (Salt Lake City, UT) for blinded incubation, Gram staining, and species identification with microsequencing. All transducers were then cleansed with manufacturer-recommended disinfectant-impregnated disposable towels containing dimethyl benzyl ammonium chloride (Professional Disposables International, Inc, Orangeburg, NY). The cleansed transducers were then pressed to a second agar media plate. All agar media plates were cultured for 5 days. Nelson Laboratories technicians, who were blinded to the agar plate source, analyzed all agar media plates. Any formed bacterial colonies then underwent DNA microsequencing for organism identification.

Prior studies demonstrated that approximately 60% of ultrasound transducers have bacterial isolates after coming in contact with patients,¹² and 4% of transducers have bacterial isolates after antimicrobial cleansing.¹¹ Using free software from DSS Research (Fort Worth, TX) for power calculation, assuming an α error level of 5%, 1 tailed, which corresponds to a 95% confidence interval, a sample size of 50 ultrasound transducers yields statistical power of 100% to detect the true impact of aseptic cleaning. Data were evaluated with Stata data analysis and statistical software (StataCorp, College Station, TX) at the University of California, Davis. The Fisher exact test was used to analyze the positive culture rates before and after disinfectant wipe cleaning. A simple prevalence of positive cultures was relayed with respect to multiuse ultrasound transmission gel bottle tips, with a breakdown by organism.

Results

A total of 192 samples were obtained across 18 distinct clinical care locations. One hundred sixty of these samples were obtained directly from ultrasound transducers, which included 80 precleansing and 80 postcleansing samples. Twenty-six of these samples were from multiuse ultrasound transmission gel tips, which included 13 precleansing and 13 postcleansing samples. Two samples were from the data collector's pen and badge; both were precleansing samples. The 4 remaining collected samples did not have a label to accurately identify the source from which they were obtained; thus, these samples were excluded from the study.

Table 2 outlines the sites where samples were obtained. The largest number of samples was collected in radiology.²⁸ Within each clinical setting, samples were obtained from varying transducer types and gel tip bottles. Our research team sampled all unoccupied transducers that were available during the data acquisition phase, which were approximately 50% of the machines and transducers. Table 3 illustrates the transducer type distribution from which the samples were gathered. Initial samples from the ultrasound transducers were categorized into CR microorganisms, NCR microorganisms, or no microorganisms. A positive sample was classified as one containing cultures with either CR growth, NCR growth, or both CR and NCR growth. In total, there were 14 different microorganisms identified in this study, 7 of which

Table 2. Number of Samples by Location (N = 186)

Sample Location	n (%)
Radiology department (4)	31 (16.7)
Main operating room (1)	18 (9.7)
Huntsman operating room (3)	14 (7.5)
Trauma bay (7)	14 (7.5)
Emergency department, main (6)	13 (7.0)
Orthopedic center (15)	12 (6.5)
Burn intensive care unit (14)	9 (4.8)
South Jordan emergency department (17)	9 (4.8)
Postanesthesia care unit orthopedic center (16)	8 (4.3)
Medical intensive care unit (13)	8 (4.3)
Echocardiogram laboratory (5)	8 (4.3)
Neonatal intensive care unit (12)	7 (3.8)
Cardiovascular intensive care unit (11)	7 (3.8)
South Jordan sports clinic (18)	7 (3.8)
Preoperative clinic (2)	6 (3.2)
Surgical intensive care unit (10)	6 (3.2)
Labor and delivery (8)	6 (3.2)
Obstetrical Emergency Medicine (9)	3 (1.6)
Additional samples	
Identification badge	1
Marking pen	1
Unlabeled	4

Table 3. Number of Samples by Surface Type (N = 186)

Sample Type	n (%)
Phased transducer (2)	72 (38.7)
Linear transducer (1)	48 (24.7)
Curved transducer (3)	32 (17.2)
Hockey stick transducer (5)	8 (4.3)
Gel bottle tip (6)	26 (14.0)

were classified as CR and the other 7 as NCR. The delineation between CR and NCR microorganisms was based on a careful literature review pertaining to the potential for human harm of each respective organism.

Of the total precleansing samples obtained from ultrasound transducers in this study, there were 59 samples (73.8%) that grew cultures with CR bacteria and 21 samples (26.3%) that did not. In comparison, after cleaning the transducers, only 13 samples (16.3%) of the postcleansing cultures contained CR bacteria. This reduction from 59 to 13 positive samples equated to a 78% reduction of CR bacterial growth on samples (likelihood ratio, 57.10; $P < .001$), a statistically significant relationship

Table 4. Frequency on Ultrasound Transducers and Bottle Tips

CR		NCR	
Microorganism	n (%)	Microorganism	n (%)
<i>Staphylococcus simulans</i>	54 (31.0)	<i>Bacillus pumilus/sefensis</i>	6 (3.4)
<i>Micrococcus luteus</i>	44 (25.3)	<i>Exiguobacterium artemiae</i>	3 (1.7)
<i>Paenibacillus provencensis</i>	24 (13.8)	<i>Brevundimonas species</i>	2 (1.1)
<i>Brevibacterium pityocampae</i>	19 (10.9)	<i>Bacillus altitudinis</i>	2 (1.1)
<i>Bacillus simplex</i>	8 (4.6)	<i>Microbacterium saccharophilum</i>	1 (0.6)
<i>Bacillus thuringiensis</i>	6 (3.4)	<i>Alternaria alternata</i>	1 (0.6)
<i>Staphylococcus warnei</i>	3 (1.7)	<i>Pseudomonas mucidolens/sacch</i>	1 (0.6)

Number indicates a positive culture (N = 174).

between aseptic cleaning and reduction in CR bacteria. A postcleansing sample was not obtained from 1 ultrasound transducer; the precleansing results were imputed forward.

The most frequently cultured microorganism was *Staphylococcus simulans*, representing 31.0% of all positive culture samples (Table 4). In total, the CR microorganisms collectively occurred at a much higher frequency than the NCR microorganisms, by an approximate ratio of 10:1. After aseptic cleansing, growth of 4 of the 7 CR microorganisms (*S simulans*, *Micrococcus luteus*, *Paenibacillus provencensis*, and *Brevibacterium pityocampae*) was significantly reduced (Table 5). Of the NCR microorganisms, only 2 of the 7 were found to have statistically significant reduction growth.

Discussion

We performed a descriptive analysis of culture and Gram stain results from ultrasound transducers and multiuse ultrasound transmission gel bottle tips in active clinical use throughout a single health care system. To our knowledge, our study examined the largest number of health care settings of any study to date. All ultrasound transducer surfaces tested in our study were considered ready for patient use. Precleansing samples grew CR microorganisms at a high rate

Table 5. Frequency of All Precleanse and Postcleanse Microorganisms on Ultrasound Transducers

CR Microorganism	Precleanse	Postcleanse	P
<i>Staphylococcus simulans</i>	42	5	<.001
<i>Micrococcus luteus</i>	38	4	<.001
<i>Paenibacillus provencensis</i>	16	6	.020
<i>Brevibacterium pityocampae</i>	18	0	<.001
<i>Bacillus thuringiensis</i>	5	1	.083
<i>Bacillus simplex</i>	5	1	.083
<i>Staphylococcus warner</i>	2	0	.094
NCR Microorganism			
<i>Bacillus pumilus/sefensis</i>	6	0	.003
<i>Exiguobacterium artemiae</i>	3	0	.040
<i>Brevundimonas species</i>	2	0	.094
<i>Bacillus altitudinis</i>	2	0	.094
<i>Microbacterium saccharophilum</i>	1	0	.238
<i>Alternaria alternata</i>	1	0	.238
<i>Pseudomonas mucidolens/sacch</i>	1	0	.238

Number indicates a sample with at least 1 microorganism culture growth.

(73.8%), which supports conclusions drawn from prior literature that cleanliness standards based on visual inspection are insufficient, and there remains a need for further education and implementation of cleaning guidelines.

We observed that aseptic cleaning with disinfectant-impregnated disposable towels containing dimethyl benzyl ammonium chloride significantly reduced the prevalence of CR microorganisms, from 73.8% to 16.3%. These findings indicate that an aseptic technique reduces, but does not eliminate, ultrasound transducer bacterial burden. Three of the 7 CR and 5 of the 7 NCR microorganisms did not reduce in growth after aseptic cleansing. Although other rationale may be posited for this finding, we would anticipate significant reductions in growth with larger sample sizes.

Of the remaining bacterial contaminants after cleansing, *S simulans* was the most prevalent. *Staphylococcus simulans* historically was a zoonotic infection, but over the past 2 decades, human infections with *S simulans* have been reported in patients who have had

repeated contact with animals, with most presenting as cardiac or osteoarticular infections.^{28–30} There has also been a demonstrated rise in the prevalence of *S simulans* nosocomial infections, and those who are hospitalized or immune compromised are at the greatest risk.³¹ The hospital from which our samples were collected does not contain a particularly high farming demographic. However, the hospital is a major tertiary referral center serving as the definitive care for a 5-state region, serving a large population with advanced disease.

Ultrasound use in clinical practice has become progressively more common in the United States, a trend likely to continue as portable ultrasound machines become more accessible³² and residency and fellowship programs implement ultrasound curricula.³³ As stated by the American Institute of Ultrasound in Medicine, “Infection control is an integral part of the safe and effective use of ultrasound in medicine.”³⁴ However, despite increased ultrasound use,³⁵ institutions have adopted widely varied approaches to ultrasound cleaning. Some hospitals have yet to implement any cleaning protocol for ultrasound procedures.³⁶ The American Institute of Ultrasound in Medicine recently introduced new guidelines intended to ensure appropriate level or transducer preparation based on the examination type. A review of the current literature and data from our study support these guidelines.

Given microbial persistence after low-level disinfection, aseptic techniques alone before percutaneous procedures are likely inadequate. Although high-level disinfection remains the reference standard, this cleaning process presents potential risks to ultrasound transducers that may shorten their lifespan through crystal damage.³⁷ Consequently, we recommend low-level disinfection in conjunction with the use of single-use, sterile ultrasound transducer covers and sterile ultrasound gel for all interventional ultrasound-guided applications. Specifically, the procedures that we refer to include major and minor joint percutaneous injections as well as soft tissue musculoskeletal percutaneous injections. However, it may still be reasonable to consider high-level disinfection for specific high-risk patient populations, such as those who are severely immune compromised with neutropenia.

Strengths of the study included the prospective blinded study design and high volume of samples collected across a wide array of clinical environments.

To our knowledge, this was the first study to assess ultrasound machines among multiple departments within a health care system. Despite careful efforts with the large number of samples, there were unfortunately 4 postcleansing samples lost during transit. However, the precleansing results were imputed forward, thus decreasing the chance of a type I error.

There were limitations to this study. For instance, although a large number of cultures were collected from ultrasound transducers, no samples from additional surfaces of the ultrasound machine were obtained. Recent literature has suggested that potential vectors for infection are complex and multidirectional: ultrasound transducer handles, cords, and keyboards can all be substantial sources of infection and should be cleaned routinely.³⁸ Unfortunately, these surfaces are sometimes difficult to clean because of their physical design; some electrical equipment, such as keyboards, may be damaged by fluid disinfectants. Additional studies may be warranted to assess these factors. Another limitation was that gel tips were cultured at room temperature: recent literature demonstrated that warmed ultrasound gel can promote colonization and bacterial growth.³⁴ Consequently, our study may have falsely underrepresented bacterial growth compared to a clinical practice that routinely heats ultrasound gel for patient comfort.

In conclusion, we demonstrated a significant CR bacterial burden from ultrasound transducers in clinical use, which may serve as potential infectious vectors. An aseptic cleansing protocol reduces but does not eradicate the bacterial load from ultrasound transducers; this may present a risk of nosocomial infections with ultrasound-guided interventions. Our data support the use of single-use, sterile ultrasound transducer covers and sterile ultrasound gel for percutaneous, ultrasound-guided procedures. High-level disinfection between patients may be beneficial in surgical and endocavity applications and in some high-risk patient groups. Overall, our findings support American Institute of Ultrasound in Medicine 2018 guidelines intended to ensure an appropriate level of transducer preparation based on the examination type. We strongly agree with rational infection control measures to minimize the risk of potential patient harm.

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