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Major Article

# Is retained bone debris in cannulated orthopedic instruments sterile after autoclaving?

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***Aims:*** Cannulated surgical instruments may retain biologic debris after routine cleaning and sterilization. Residual debris after cleaning is assumed to be sterile; however, there is no experimental basis for this assumption. The purpose of this study was to determine the sterility of retained biodebris found within cannulated surgical instruments after autoclave sterilization.

***Materials and Methods:*** Fifteen cannulated drill bits were used to drill pig scapulae to create a plug of bone that was exposed to a mixture of *Bacillus cereus*, *Pseudomonas aeruginosa*, and methicillin-resistant *Staphylococcus aureus* for 60, 120, or 180 minutes prior to sterilization. The drill bits were autoclave sterilized using standard settings. The "sterilized" bone cores were then incubated in solution and streak-plated on blood agar.

***Results:*** All 3 positive controls were positive for the experimental bacteria. Two negative controls were positive for contaminant bacteria. A *B. cereus* strain was recovered from 1 of the experimental group drill bits in the 180-minute group. Pulsed-field gel electrophoresis confirmed that the recovered *B. cereus* strain was identical to the experimental inoculate.

***Conclusion:*** Retained biodebris in cannulated drills may not be sterile after standard autoclave sterilization. In addition, delay of surgical instrument reprocessing may increase the risk of resistant contamination.



Many surgeons have faced the disquieting situation of discovering retained biodebris in a cannulated drill or reamer during a procedure. Although caution is always advisable, and the instrument is removed, uncertainty exists regarding the potential effect of the finding. One may suppose that the retained debris is sterile after autoclaving, but there is no literature to support this assumption or provide guidance for the practicing surgeon. It is unknown if the specimen should be considered sterile, if the patient should be empirically treated with antibiotics, if cultures of the retained debris should be performed, or, when an infection results, if the debris was potentially responsible.

Healthcare-associated infections are a major strain on the healthcare system and lead to direct and indirect annual costs of $96-$147 billion in the United States.[1] Improvements in instrument sterilization is one area that can be targeted to reduce this burden. Cannulated surgical instrument reprocessing is one particularly challenging area, as these instruments have been reported to harbor biodebris even after manufacturer-suggested cleaning and sterilization.[2] In the past 2 decdes, 3 studies of outbreaks after arthroscopic surgery have been conducted.[3-5] The initial report from 1999, involving a cluster of 3 cases of septic arthritis of the knee after arthroscopic meniscal repair, concluded that retained "dried organic matter" within the lumina of the arthroscopic inflow/outflow cannulas was the source of infection.[4] In a second report, after an outbreak of multiple surgical site infections of the knee after anterior cruciate ligament reconstruction during a 14-week period, it was surmised that residual bioburden in the cannulated portion of a tibial fixation hex screwdriver was the source of contamination that led to the infection.[5] A third report, in which 7 deep surgical site infections due to *Pseudomonas aeruginosa* occurred after shoulder and knee arthroscopies, postulated that "bacterial contamination of surgical instruments likely survived the sterilization process

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because of residual tissue within the lumens of arthroscopic equipment."[3] Because of this, the U.S. Food and Drug Administration (FDA) released a safety alert in 2009 urging reprocessing facilities to consider scope-assisted inspection of cannulated instruments after reprocessing.[6] In each of these reports, the retained material thought to be responsible for the clinically relevant infection was a thin layer of dried matter on arthroscopic equipment and not a thick plug of biodebris that may be encountered with improperly cleaned cannulated instruments. To date, there are no published reports of infection after orthopedic surgery when residual bone and other macroscopic biodebris are discovered in cannulated instruments after sterilization procedures. In addition, the literature is lacking on whether standard sterilization protocols are effective in completely sterilizing cannulated instruments with retained bony debris within the lumens. Given the uncertainties surrounding retained bony biodebris, we sought to determine through in vitro experiments whether a retained core of bone could harbor viable bacteria and render autoclave sterilization ineffective.

## MATERIALS AND METHODS

### *Study design*

After receiving institutional review board approval, we sought to replicate a typical surgical scenario whereby a drill is used to create a hole in cortical and cancellous bone and then is set aside for variable time periods without being properly cleaned and sterilized. We used the largest cannulated drill bit commonly employed at our institution: an 8.0-mm drill bit with a 3.2-mm cannula used for percutaneous screw fixation of sacral and femoral neck fractures (Stryker, Kalamazoo, Michigan). Given that surgery times can vary widely, we chose the experimental "wait times" prior to sterilization of 60, 120, and 180 minutes.

Fifteen cannulated drill bits were used to drill clean pig scapulae obtained from a grocery store and meant for human consumption to create 5-8-mm-long cylindrical plugs of bone that were left in the cannulas of the drill bits. Twelve drill bits were exposed to a mixed bacterial inoculum for 60, 120, or 180 minutes before further processing (3 drill bits for each time period). These experimental conditions created the largest possible volume of biodebris burden left untreated for the longest period of time. Three of the 12 bits, designated as positive controls, were not sterilized. The remaining 3 drill bits, designated as negative controls, received only sterile water. Thus, we had 5 separate groups with 3 drill bits in each group (Fig 1). The drill bits were autoclave sterilized and then examined for bacterial growth. The details of these steps can be found in the sections below.

### *Bacterial strains*

The following reference type strains were obtained from the American Type Culture Collection (ATCC): *Bacillus cereus* (ATCC #10876), *P. aeruginosa* (ATCC #27853), and methicillin-resistant *Staphylococcus aureus* (MRSA) (ATCC #43300) *P. aeruginosa* and MRSA were included because they represent clinically relevant gram-negative and gram-positive nosocomial pathogens, respectively. *B. cereus* was selected because it is a hardy, spore-forming bacterium that has been implicated as a pathogen in surgical site infection and represents a worst-case scenario due to difficulties in sterilizing bacterial spores.[7,8]

### *Bacterial inoculum preparation*

Lyophilized bacterial strains were hydrated and prepared as instructed by ATCC, then stored frozen at –80°C until needed. Prior to performing the experimental procedures, each bacterial strain was inoculated onto trypticase soy agar with 5% sheep blood (TSA) and incubated overnight at 37°C. Bacterial growth was removed from the plates, and serial 1:10 dilutions were prepared in saline, which were then spread-plated onto TSA using a calibrated loop and incubated again overnight to determine the numbers of colony forming units (CFU)/mL present. Each saline dilution of the original inoculum was tested with a nephelometer to determine its turbidity reading. Turbidity readings were then compared to the actual CFU/

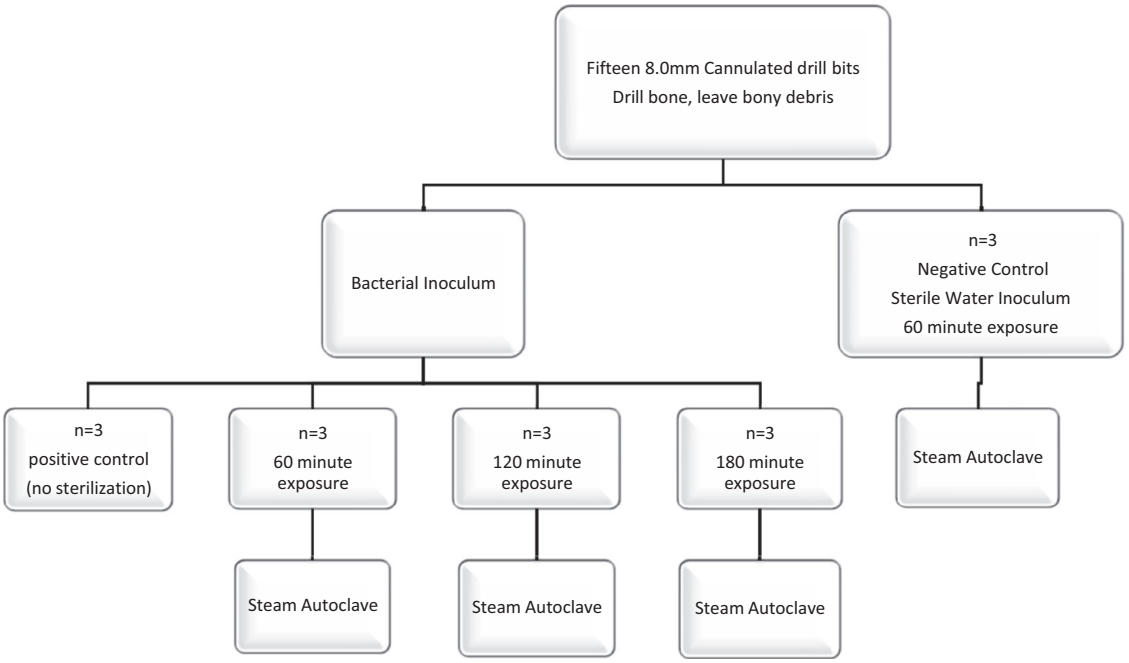


**Fig 1.** Experimental Protocol.