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Risk of Contamination in Assembled vs Disassembled Instruments in Hip Arthroplasty Surgery

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ABSTRACT

Background: Periprosthetic joint infection (PJI) is one of the most common causes of revision total hip arthroplasty (THA) and associated with higher costs, prolonged pain, and worse clinical outcomes. Many factors have been linked to increased infection rates, one being the operative equipment and instrumentation used during the surgical procedure. With few arthroplasty instruments designed for complete disassembly and increasingly complex instrument designs, this study seeks to understand the effect that instrument disassembly plays on infection using disassembled and assembled standard femoral broach handles (BHs).
Methods: Two BHs, not designed for disassembly, were modified and then contaminated in the disassembled state with *Geobacillus stearothermophilus* vegetative-form bacteria and spores. Using both flash and standard sterilization cycles, the BHs were steam sterilized in the disassembled or assembled state and then analyzed for remaining bacteria and spores.
Results: At all target locations after either a flash sterilization cycle or a standard sterilization cycle, complete eradication of both the vegetative-form and spore-form of *G stearothermophilus* was achieved.
Conclusion: This study demonstrates that adequate decontamination of the tested BHs can be achieved after steam sterilization in either the disassembled or assembled state, without an increased risk of infection transmission.

The estimated rate of periprosthetic joint infection (PJI) after total hip arthroplasty (THA) is 0.88%-3.0% [1-3]. Postoperative infection is one of the most common causes of revision THA, which costs 3.6 times more than primary THA or approximately $100,000 per patient [4-7]. Increased infection rates have been linked to patient characteristics, length of surgical procedure, length of hospital stay, and factors related to the operative environment [8-10]. These include the number of personnel in the operating room and contamination of equipment or instrumentation [11-18].

Reusable surgical instruments that are not properly cleaned, disinfected, and sterilized according to manufacturer and regulatory guidelines can become a potential source of contamination [19-21]. Manufactures must provide detailed guidelines for reusable surgical instruments regarding decontamination, including cleaning and disinfection, and sterilization steps for each instrument, but these can vary significantly depending on variations in device construction, materials, and design [19]. Instruments made of multiple components or devices can complicate these processes, but mandates exist for instruments to be disassembled to allow uninterrupted contact to the sterilization methods used [19-21]. Also, devices with complex design features, such as sharp angles, occluded dead ends, complex jaw assemblies, articulations, furrows, and irregular surfaces, can affect the sterilization process by making them more likely to trap bioburden, a population of viable microorganisms, and debris including blood and bone [20-26].

With the increasing complexity of instrument design, and few arthroplasty instruments designed to be completely disassembled,

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this study seeks to evaluate the current sterilization practices by comparing the contamination level between disassembled and assembled standard femoral broach handles (BHs).

Materials and Methods

This study was approved by our institutional biosafety committee for research. Two standard femoral BHs (Smith & Nephew, Memphis, TN), not originally designed for disassembly, were modified to allow for component disassembly (Fig. 1). Two pins holding the instrument's internal components together were removed and replaced by threaded stainless steel screws and nuts (Fig. 1). Before the instrument being modified, the areas surrounding the internal components were not directly exposed to steam during the sterilization procedure.

Five test sites were studied on each BH, with one site serving as a control (Fig. 2). These sites were selected because they were considered the most difficult locations to clean and had the highest potential to retain organic matter. In the first experiment, the BHs were contaminated at these 5 sites with a vegetative-form bacterium, *Geobacillus stearothermophilus* (ATCC 12980; Manassas, VA). In the second experiment, the BHs were contaminated with *G stearothermophilus* spores resistant to steam sterilization (NAMSA SUS-06, derived from ATCC 7953; Northwood, OH) in the same 5 locations. *G stearothermophilus* was chosen for this experiment because it is a spore-forming bacterium that is resistant to steam sterilization, and it is commonly used as a biological indicator to evaluate the efficacy of sterile processing and infection control [27].

In the first experiment, a tryptic soy broth (TSB) suspension containing vegetative-form bacteria (4.0×10^6 *G stearothermophilus* organisms per milliliter) was inoculated onto the BHs using sterile cotton-tipped swabs. In the second experiment, 100 μL of a water-and-ethanol suspension of spores (2.4×10^7 *G stearothermophilus* spores per milliliter) was inoculated onto the BHs using a pipette. To quantify the *G stearothermophilus* vegetative-form bacterial suspensions, dilutions in TSB were performed up to 1:10,000 and inoculated onto trypticase soy agar plates. These plates were then incubated for 48 hours at 55°C, the temperature at which *G stearothermophilus* undergoes optimal growth.

After inoculation of the instruments, one BH was reassembled before sterilization, whereas the other one was kept in the disassembled state. The BHs were then placed into sterilization pouches and sterilized using a prevacuum steam sterilizer; no further cleaning was conducted besides the sterilization process. Three trials of the experiment were performed using a flash sterilization cycle at 132°C for 4 minutes with a 1-minute dry time, and 3 trials of the experiment were performed using a standard sterilization cycle at 132°C for 4 minutes with a 20-minute dry time. These sterilization times complied with the sterilization practices used by our institution and also met the minimum sterilization cycle times recommended by the Association for the Advancement of Medical Instrumentation (AAMI) and Association of Perioperative Registered Nurses (AORN) [21,25,28].

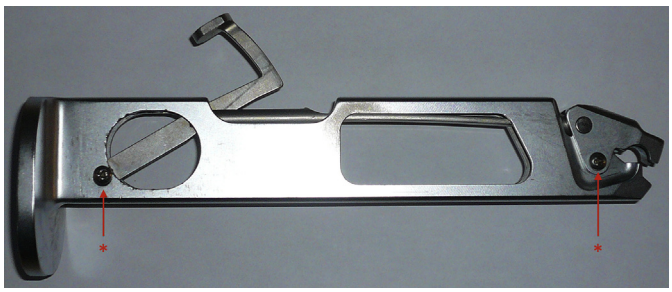

Fig. 1. Standard femoral broach handle in assembled state. Note the screws (asterisk), which replaced the original pins so that the instrument could be disassembled.

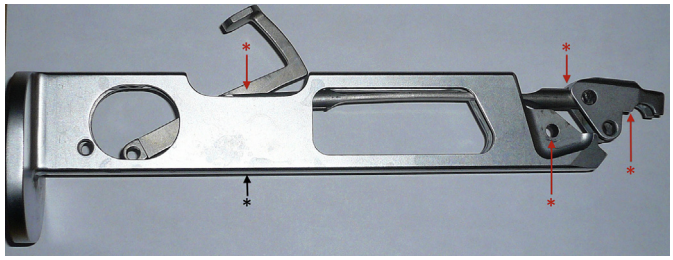

Fig. 2. Standard femoral broach handle in a disassembled state with the 5 tested locations labeled (red asterisk = test sites; black asterisk = control).

After the sterilization process was complete, all BHs were disassembled and the test sites were cultured using a sterile cotton-tipped swab moistened with sterile TSB. The contaminated swabs were then placed into 2 mL of TSB and incubated for 7 days in a shaking water bath at 55°C. Growth was then checked by subculture on trypticase soy agar plates.

A total of 6 control trials were also performed during which the BHs were inoculated in the disassembled state but not sterilized. The BHs were inoculated with either vegetative-form bacteria (3 trials) or bacterial spores (3 trials) and placed into sterilization pouches in the disassembled state for the duration of a typical sterilization cycle. The test sites on each instrument were then cultured using the same methodology as described previously (Fig. 3).

Results

The control trials, during which disassembled BHs were contaminated without sterilization, yielded positive culture results in all 5 locations on the BHs with both *G stearothermophilus* bacteria and spores. Because 3 control trials were performed with vegetative-form bacteria and 3 trials were performed with bacterial spores, this resulted in 15 potential contamination sites per arm of the study. Bacteria were detected at each of the test sites, therefore resulting in a total of 15 of 15 positive cultures for both the vegetative-form and spore-form of the bacteria (Table 1).

For the trials that underwent steam sterilization, complete eradication of both the vegetative-form and spore-form of *G stearothermophilus* was achieved at all target locations after both the flash sterilization cycle (4 minutes at 132°C followed by 1-minute dry time) and the standard sterilization cycle (4 minutes at 132°C followed by 20-minute dry time). This resulted in a total of 0 of 15 positive cultures in both the BHs in the assembled and disassembled states (Table 1). Both the flash and standard sterilization cycles were equally efficacious in sterilizing the studied instruments in both the assembled and disassembled states after contamination with vegetative-form bacteria or bacterial spores.

Discussion

PJI leads to decreased clinical outcomes and increased economic impact for both patients and society; it is imperative to decrease infection rates and minimize potential sources of contamination. One possible source of contamination is the surgical instrumentation. This study is the first to evaluate if an instrument designed for hip arthroplasty has different contamination rates after steam sterilization in either the disassembled or assembled state. This