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Sterility of the Personal Protection System in Total Joint Arthroplasty

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Abstract

Background Bacteria shed by operating room personnel is a source of wound contamination and postoperative infections. The personal protection system (PPS) was designed to decrease airborne bacteria and intraoperative contamination in total joint arthroplasty.

Questions/purposes We determined the microbial contamination rate of the PPS and incidence of contamination with key pathogens, Staphylococcus aureus and coagulase-negative staphylococci.

Patients and Methods We prospectively evaluated PPS contamination in 61 primary THAs and 41 TKAs. The PPS were assumed to be sterile before opening the packs. The initial culture was taken immediately after the hood was placed over the helmet. Four cultures were collected at the conclusion of the procedure. Plates were examined and colonies were classified according to Gram stain results and biochemical tests. S. aureus was classified as methicillin-resistant or -susceptible.

Results At time zero, 22 of 102 cultures isolated an organism, accounting for a contamination rate of 22%. The bacterial contamination rate of the PPS at the conclusion of the procedure was 47% (48 of 102). The relative percentage of the various organisms found was coagulase-negative staphylococci 50%, Micrococcus sp. 20%, methicillin-susceptible S. aureus 11%, and methicillin-resistant S. aureus (MRSA) 1%.

Conclusions The external surface of the PPS cannot be assumed to be sterile after its removal from the original packaging. Of all the PPS studied, the potential pathogens coagulase-negative staphylococcus, S. aureus, and MRSA were found in 43%. This study supports the need to change gloves if the PPS is touched or adjusted during the procedure.

One of the authors (JP) is a consultant for Stryker Orthopaedics (Mahwah, NJ) and has intellectual properties on SmarTech (Philadelphia, PA).

Each author certifies that his or her institution has approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

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Introduction

Bacteria shed by operating room personnel is a potential source of wound contamination and postoperative infections [1, 7, 13, 19]. The human exhaust system first introduced by Sir Charnley in the 1960s was designed to decrease airborne bacterial colony-forming units (CFUs) and intraoperative contamination in total joint arthroplasties (TJAs). Multiple approaches such as the use of prophylactic antibiotics, laminar air flow, and meticulous sterile technique, including handwashing, antimicrobial skin preparation, sterilized drapes and instruments, and decreased traffic flow, have reduced the incidence of prosthetic joint infections (PJIs) to currently reported rates of 0.3% to 1.3% for THA and 1.0% to 2.0% for TKA [6]. However, postoperative infections are a devastating complication and a challenge to control. Therefore, continued quality improvements to further reduce the incidence of infections remains a goal. At the forefront of TJA is the elimination of iatrogenic intraoperative causes. The easiest high-impact interventions mentioned previously have

already been studied and implemented. To further reduce PJI, studies must search for residual sources of microbial contamination.

The original Charnley personal protection system (PPS) has undergone technical advances over the years to reduce airborne bacterial counts as well as make it portable, comfortable, and easy to adorn. The PPS is applied to the surgeon in a sterile fashion by the surgical technician and is believed to be an extension of the sterile field. It is common practice for surgeons to adjust their helmets, fan strength, and to clean their face shield throughout the duration of the procedure. Many TJAs in the United States are performed using the PPS because it is believed to be a valuable component in decreasing PJI, although we found no data confirming this belief.

We therefore determined the microbial contamination rate of the PPS and incidence of contamination with key pathogens, Staphylococcus aureus and coagulase-negative staphylococci.

Patients and Methods

During a 20-week period, 102 primary THAs (n = 61) and TKAs (n = 41) were evaluated for PPS hood contamination. All surgeries were performed in HEPA-filtered vertical laminar flow, nonultraviolent light operating rooms by five experienced high-volume total joint surgeons. The surgeon, first assistant, and the scrub technician all wore T5 Personal Protection Systems™ (Stryker Corporation, Kalamazoo, MI). All hoods were assumed to be initially sterile before use as per the manufacturer's literature. Immediately after the hoods were placed over the helmets, a culture was taken from the bottom of the posterior neck drape (P1) of the first assistant in the procedure, either a fellow or a resident. This location was selected to prevent any possible bacterial contamination to the PPS within the surgical field. P1 is adequate to establish an initial time zero microbial load, because the PPS hood is a single sterilized piece exposed to the same chance of contamination as other parts of the suit at that initial stage of the process. Four specimens were collected at the conclusion of surgery from the center of the shield (P2), bottom face bar (P3), neck of the hood (P4), and over the fan controls (P5). The duration of all TJAs was less than 80 minutes with a mean of 56 minutes. We obtained approval from our Institutional Review Board before beginning this study.

Because most PJIs are the result of staphylococcal species [1, 7, 13, 19], the protocol was designed to further characterize that genus. Other types of organisms were noted and less extensively characterized. All laboratory testing was completed by experienced, registered medical microbiology technologists. We used BBL™ Trypticase™ Soy Agar containing lecithin and polysorbate 80 RODAC™ (Replicate Organism Detection and Counting) touch plates (BD Corporation, Franklin Lakes, NJ) to aseptically collect samples. These plates, approximately 2 inches in diameter, sampled approximately 3 square inches of surface. Efforts to minimize contamination by the person obtaining the cultures were made. Aseptic handling of the plates was used. The RODAC™ plates were quickly opened, used, and reclosed. Plate surfaces were not touched except to the sampled surface. The collector wore a paper cap to cover the hair and mask covering the nose and mouth. Although the hands never touched the plate surface, bulk pack nitrile gloves of the type used in the clinical microbiology laboratory were worn during the collection to minimize possible skin shedding of microbes from the hand getting onto the culture media. The collector did not wear a sterile gown so his skin flora could have become airborne, but the plates were only briefly open to air.

Cultures were incubated at 36°C for 24 to 48 hours in 5% CO_2. Plates were examined, colonies were quantified, and all different colony types were subcultured to blood agar plates and incubated for 24 hours at 36°C. Isolated pure colonies were initially characterized according to the Gram stain results. The goal was not to exhaustively identify each isolate to species but to place organisms into basic presumptive identification categories and further work up isolates more typical of Staphylococcus. We did not perform susceptibility testing, except for Staphylococcus aureus. S. aureus was classified as methicillin-resistant or -susceptible.

All Gram-positive cocci were tested for the presence of catalase. Catalase-positive, Gram-positive cocci in clusters, with typical Staphylococcus-like colonies, were checked for coagulase production to identify S. aureus. Beta hemolysis and typical morphology were also noted. S. aureus isolates were tested for methicillin resistance using the cefoxitin disk method (M100-S19 Performance Standards for Antimicrobial Susceptibility Testing, Clinical and Laboratory Standards Institute, Wayne, PA). Coagulase-negative Staphylococci were reported as such.

Small Gram-positive cocci, which had a negative catalase test and with characteristic streptococcal Gram stain and colony morphology, were considered to be Streptococci. Nonhemolytic Streptococci were noted. Gram-positive cocci, not in chains that were catalase-positive and coagulase-negative, were checked for some or all of the following characteristics: oxidase positivity, tetrads on Gram stain, and/or a distinct pigment such as a pink or yellow color. Those organisms were considered to be nonstaphylococcus species resembling members of the family Micrococcaceae, which was further confirmed with a positive oxidase test.

Large, aerobic, Gram-positive rods, often with spores, with colonies typical of Bacillus species were considered to be presumptive Bacillus species. Small Gram-positive nonspore-forming rods with typical coryneform shapes and small typical coryneform colonies were considered to be coryneform species. Gram-negative rods were only characterized as to major grouping using oxidase testing, isolation to MacConkey agar, and colony morphology. Fungal colonies were microscopically examined for the presence of hyphae or yeast cells. For individual colonies, additional agar media and testing were occasionally used as needed to confirm the proper presumptive identifications listed previously.

Results

At time zero, immediately after the hood was placed over the helmet, 22 of 102 (P1) cultures isolated an organism, accounting for a contamination rate of 22%. The bacterial contamination rate of the PPS at the conclusion of the procedure was 47% (48 of 102). Specifically, P2, P3, P4, and P5 positive rates of 24 of 102 (24%), 13 of 102 (13%), 23 of 102 (23%), and 22 of 102 (22%) were found, respectively. The total bacterial contamination rate from all areas of the PPS was 49% (50 of 102). Procedure-specific rates were 29 of 61 THAs (48%) and 21 of 41 TKAs (51%). Thirty-two percent (33 of 102) of PPSs had more than one positive plate and some were positive for more than one organism. Eleven different types of microbes were detected, including coagulase-negative Staphylococci (50%), Micrococcus sp. (20%), methicillin-susceptible S. aureus (11%), Bacillus sp. (6%) Neisseria sp. (4%), black mould (1%), Coryneform bacteria (2%), Gemella, Streptococci (2%), methicillin-resistant S. aureus (1%), Escherichia coli (1%), and Gram-negative rod, not Enterobacteriaceae (1%).

Discussion

PJIs are the most frequently reported cause for TKA revisions and the third most for THA revisions in the United States [3]. According to 1997 to 2006 Medicare outcome data, TKA and THA infection rates 2 years postoperatively were 1.55% and 1.63%, respectively [11, 15]. Despite low reported incidence, further reduction in PJI should be an ongoing effort as a result of associated costs and serious patient impact. Because many consider the PPS an important component in ultraclean operating rooms, further reduction of its bioburden is a useful next step. We therefore determined the microbial contamination rate of the PPS and incidence of contamination with key pathogens, Staphylococcus aureus and coagulase-negative staphylococci.

Our study does have some important potential limitations. First, it is not known if our findings have any clinical importance. The microbial colony counts on the RODAC^{TM} plates ranged from one to slightly over 100 colonies per plate. Further studies are needed to determine whether these microbes could be a source of PJI. However, it is difficult to statistically determine if the bacterial load on the PPS directly leads to PJI given the many confounding variables and large numbers needed to power a study to directly test and isolate a specific component. Additional conclusions could be drawn from a subsequent followup study of our cohort to determine if any PJI matched the same bacterial isolate from the RODAC^{TM} plate. Second, we surprisingly found greater than 20% positive P1 plates, indicating that contamination starts while gowning for surgery. It is unclear if the hood is immediately contaminated as it is removed from its sterile packaging or as it is draped the over the PPS helmet. In addition, the hood could have simply been contaminated by CFUs in the circulating air, because it is often put on outside the laminar flow. Third, the plates could have been contaminated during the collection period. Fourth, it is possible for crosscontamination from other areas of the sterile field such as the gown, gloves, or the instruments themselves, all of which were not tested but were considered to be sterile when opened. Lastly, we did not control for room traffic, which could have influenced our results. However, room traffic is routinely kept to essential personnel only.

No uniform opinion exists with regard to the use of PPS and the incidence of PJI because its effects are difficult to quantify [2, 5, 9, 10, 17, 20–22]. As a result of the low incidence of PJI and simultaneous evolution of multiple confounding factors aimed at reducing intraoperative infection such as improved air turnover, standardization of perioperative antibiotics, and behavioral changes, a study with the power to statistically determine the efficacy of the PPS is unlikely [6]. Regardless, the literature is compelling and the current Centers for Disease Control and Prevention (CDC) recommends considering performing TJA in ultraclean air and PPS to decrease surgical site infections, Category II (suggested for implementation and supported by suggestive clinical or epidemiologic studies or theoretical rationale) [14]. Therefore, given the CDC recommendations and widespread use of the PPS, we decided to prospectively evaluate its sterility and potential source of iatrogenic PJI.

Throughout the duration of TJA, it is commonplace for operative personnel to adjust their helmet or clean their face shield. These routine contacts are potential sources of

wound contamination and subsequent PJI if the PPS is deemed to be unsterile. One study suggests operative personnel were the source of contamination in 98% of cases with 30% reaching the wound through the air and 70% directly from hands or instruments [23]. In our study, all areas of the hood, except the face bar, were contaminated in over 20% of the samples collected, resulting in numerous opportunities to directly introduce pathogens into the operative field.

The dose of contaminating micro-organisms required to produce infection is lower when foreign material such as an implant is present. Ten CFU or less is estimated to be a relatively safe bacterial content per cubic meter of air in the operating room where TJAs are performed [4, 8, 12]. Stryker™ literature indicates a 99.4% average effective bacterial filtration efficiency with a single challenge [16]. Therefore, if one challenges the PPS with 10^3 to 10^5 organisms, the estimated breakthrough could be on the order of six to 600. This would be multiplied by each subsequent challenge such as a cough or sneeze and each additional person wearing the PPS. In addition, other sources such as nonsterile personnel and the patient's own bacteria becoming disassociated and relocated could add to the bioburden of the PPS exterior, resulting in increased bacterial loads.

Of the 102 PPSs tested, 53 had a staphylococcus species, including one MRSA strain. Staphylococci are assumed to be from human sources. The origin could be endogenous flora from the patient's skin or mucous membranes that became disassociated and settled on the PPS, but more likely from operative personnel given the perioperative skin cleansing and occlusive drapes [18]. Numerous studies have documented that Gram-positive organisms are the most common bacteria to cause PJI with S. aureus and Staphylococcus epidermidis causing the majority of infections [1, 7, 13, 19]. Other sources of contamination could be inanimate objects and air flow. These would likely contribute far fewer numbers but might be the source for the occasional mold or environmental species. Micrococcaceae organisms, not frequently associated with orthopaedic prosthetic infections, were isolated from 22% of the plates. The source of these are unknown but are often considered to be environmental contaminants and of little clinical importance.

Using RODAC™ plates, our observations suggest microbial contamination of the PPS occurred frequently. Although the PPS does provide a two-way safety barrier that protects operative personnel from potentially contaminated tissue, fluid, and blood splashes, this study confirms that it does not remain externally sterile in approximately half of the cases. This supports our recommendations to avoid touching the PPS and the need to change gloves if hand contact with the PPS occurs.

References

1. Ayers DC, Dennis DA, Johanson NA, Pellegrini.VD Jr. Common complications of total knee arthroplasty. *J Bone Joint Surg Am.* 1997;79:278–311.
2. Bohn WW, McKinsey DS, Dykstra M, Koppe S. The effect of a portable HEPA-filtered body exhaust system on airborne microbial contamination in a conventional operating room. *Infect Control Hosp Epidemiol.* 1996;17:419–422.
3. Bozic KJ, Kurtz S, Lau E, Ong K, Chiu V, Vail TP, Rubash HE, Berry DJ. The epidemiology of bearing surface usage in total hip arthroplasty in the United States. *J Bone Joint Surg Am.* 2009;91:1614–1620.
4. Charnley J, Eftekhar N. Postoperative infection in total prosthetic replacement arthroplasty of the hip-joint. With special reference to the bacterial content of the air of the operating room. *Br J Surg.* 1969;56:641–649.
5. Der TJ, Ong SM, Taub NA, Taylor GJ. Body-exhaust suit versus occlusive clothing. A randomised, prospective trial using air and wound bacterial counts. *J Bone Joint Surg Br.* 2003;85:490–494.
6. Evans RP. Laminar air flow in the operating room. How effective is it in reducing infection? Anonymous. 2011. 4-19-2010. http://www2.aaos.org/aaos/archives/bulletin/jun06/fline7.asp.
7. Fulkerson E, Valle CJ, Wise B, Walsh M, Preston C, Di Cesare PE. Antibiotic susceptibility of bacteria infecting total joint arthroplasty sites. *J Bone Joint Surg Am.* 2006;88:1231–1237.
8. Gosden PE, Macgowan AP, Bannister GC. Importance of air quality and related factors in the prevention of infection in orthopaedic implant surgery. *J Hosp Infect.* 1998;39:173–180.
9. Howard JL, Hanssen AD. Principles of a clean operating room environment. *J Arthroplasty.* 2007;22(Suppl 3):6–11.
10. Howorth FH. Prevention of airborne infection during surgery. *Lancet.* 1985;1:386–388.
11. Kurtz SM, Ong KL, Lau E, Bozic KJ, Berry D, Parvizi J. Prosthetic joint infection risk after TKA in the Medicare population. *Clin Orthop Relat Res.* 2010;468:52–56.
12. Lidwell OM, Lowbury EJ, Whyte W, Blowers R, Stanley SJ, Lowe D. Effect of ultraclean air in operating rooms on deep sepsis in the joint after total hip or knee replacement: a randomised study. *Br Med J (Clin Res Ed).* 1982;285:10–14.
13. Mahomed NN, Barrett JA, Katz JN, Phillips CB, Losina E, Lew RA, Guadagnoli E, Harris WH, Poss R, Baron JA. Rates and outcomes of primary and revision total hip replacement in the United States Medicare population. *J Bone Joint Surg Am.* 2003;85:27–32.
14. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for Prevention of Surgical Site Infection, 1999. Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee. *Am J Infect Control.* 1999;27:97–132.
15. Ong KL, Kurtz SM, Lau E, Bozic KJ, Berry DJ, Parvizi J. Prosthetic joint infection risk after total hip arthroplasty in the Medicare population. *J Arthroplasty.* 2009;24(Suppl):105–109.
16. Parker R. Summary Report Stryker™ Surgical Helmet System Filtration Testing. Anonymous. 5-14-2003. Stryker™ Instruments. http://sars.medtau.org/strykerreport.doc.
17. Pasquarella C, Pitzurra O, Herren T, Poletti L, Savino A. Lack of influence of body exhaust gowns on aerobic bacterial surface counts in a mixed-ventilation operating theatre. A study of 62 hip arthroplasties. *J Hosp Infect.* 2003;54:2–9.
18. Pasquarella C, Sansebastiano GE, Ferretti S, Saccani E, Fanti M, Moscato U, Giannetti G, Fornia S, Cortellini P, Vitali P, Signorelli C. A mobile laminar airflow unit to reduce air bacterial contamination at surgical area in a conventionally ventilated operating theatre. *J Hosp Infect.* 2007;66:313–319.

19. Rao N, Cannella B, Crossett LS, Yates AJ Jr, McGough R III. A preoperative decolonization protocol for Staphylococcus aureus prevents orthopaedic infections. *Clin Orthop Relat Res.* 2008; 466:1343–1348.
20. Ritter MA, Eitzen HE, Hart JB, French ML. The surgeon's garb. *Clin Orthop Relat Res.* 1980;153:204–209.
21. Sanzen L, Carlsson AS, Walder M. Air contamination during total hip arthroplasty in an ultraclean air enclosure using different types of staff clothing. *J Arthroplasty.* 1990;5:127–130.
22. Shaw JA, Bordner MA, Hamory BH. Efficacy of the Steri-Shield filtered exhaust helmet in limiting bacterial counts in the operating room during total joint arthroplasty. *J Arthroplasty.* 1996;11:469–473.
23. Whyte W, Hodgson R, Tinkler J. The importance of airborne bacterial contamination of wounds. *J Hosp Infect.* 1982;3:123–135.