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Sterility of Miniature C-arm Fluoroscopy in Hand and Upper Extremity Surgery

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Abstract

Previous studies have demonstrated that sterile equipment is frequently contaminated intraoperatively, yet the incidence of miniature c-arm (MCA) contamination in hand and upper extremity surgery is unclear. To examine this incidence, a prospective study of MCA sterility in hand and upper extremity cases was performed in a hospital main operating room (MOR) (n = 13) or an ambulatory surgery center operating room (AOR) (n = 16) at a single tertiary care center. Case length, MCA usage parameters, and sterility of the MCA through the case were examined. We found that MOR surgical times trended toward significance (p = 0.055) and that MOR MCAs had significantly more contamination prior to draping than AOR MCAs ($p < 0.001$). In MORs and AORs, 46.2 and 37.5% of MCAs respectively were contaminated intraoperatively. In MORs and AORs, 85.7 and 80% of noncontaminated cases, respectively, used the above hand-table technique, while 50 and 83.3% of contaminated MOR and AOR cases, respectively, used a below hand-table technique. Similar CPT codes were noted in both settings. Thus, a high-rate of MCA intraoperative contamination occurs in both settings. MCA placement below the hand-table may impact intraoperative contamination, even to distant MCA areas. Regular sterilization of equipment and awareness of these possible risk factors could lower bacterial burden.

Keywords
- Miniature C-arm
- infection
- contamination
- surgical contamination
- hand
- surgery

Introduction

Postoperative infections after hand surgery have been reported to occur in 1.1 to 3.2% of patients and subsequently lead to significant morbidity and cost.[1-5] Several factors have been associated with a higher incidence of postoperative infections, including increased operating room time, increased invasiveness, increased operating room personnel, patient comorbidities, and injury characteristics.[6-10] In addition, equipment thought to be sterile such as an intraoperative fluoroscopy device or microscope has been shown to be significantly contaminated and may contribute to increased infection risk.[6,7,10-17] Due to the rising emphasis placed on quality of care, improving patient safety, and reducing costs, avoiding surgical site infections has become a

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priority for surgeons and clinical leaders. Thus, identification of surgical site contamination risk factors can allow for application of more effective avoidance strategies.[10]

Miniature C-arm (MCA) fluoroscopy is commonly used during hand and upper extremity surgery. If contaminated, there would be potential for direct inoculation of the wound because, in hand and upper extremity cases, it is most often a surgeon-directed device. Prior studies investigating the sterility of large fluoroscopy or microscopes during orthopedic surgeries and have shown that a sterilely draped large C-arm can be contaminated up to 56% of the time, and the sterile portion of the microscope can have contamination rates as high as 44%.[6,7] To our knowledge, no study to date has evaluated sterility of the MCA when performing hand and upper extremity surgery. Furthermore, prior research on surgical site infections have mainly been confined to the inpatient setting, despite the majority of hand and upper extremity surgery being performed on an outpatient basis. As nearly two-thirds of surgeries in the United States are performed on an outpatient basis, assessment of the differences in MCA sterility between hospital main operating rooms (MOR) and ambulatory surgery center operating rooms (AOR) is warranted and deserves evaluation.[18]

It is our hypothesis that there will be no difference in MCA contamination rates between MORs and AORs; however, we anticipate that under hand-table MCA technique will have increased contamination rates in both surgical settings.

Materials and Methods

To evaluate the sterility of the MCA at our institution in two operating room settings and two MCA positions, a prospective study of 29 consecutive hand and upper extremity cases was performed after institutional review board approval (IRB) #161591. Cases selected were those in which the MCA is traditionally utilized, that is, involving the elbow, forearm, or hand. Cases in which patients were considered infected or contaminated prior to surgical intervention, as well as those where the MCA is not utilized, were excluded.

Surgeries were performed in a university hospital main operating room (MOR) setting or an outpatient ambulatory operating room (AOR) setting by one of three hand and upper extremity surgeons. Operating rooms were negative pressure, temperature, and humidity controlled and approximately equal in size. Every procedure involved at least a primary surgeon, assistant, scrub tech, and scrub nurse present in the operating room. Each of the three surgeons had his preferred method of MCA use, which he used exclusively without deviation in all cases assessed. During surgeries, the MCA was used either in a horizontal position above the hand-table (►**Fig. 1A**) or in a vertical position with the image intensifier below the hand-table (►**Fig. 1B**). Throughout surgery, the MCA approached and was removed from the operative field as needed at the direct control of the primary surgeon or assistant, using the sterilely draped portions of the MCA.

For each of the 29 cases, 18 sterile culture swabs (BBL CultureSwab) were used to assess sterility of the MCA at various portions of the surgery and specific areas of the MCA (►**Supplementary Figure S1**, available in the online version). Prior to draping, two swabs of the MCA X-ray tube, image intensifier, and middle portion connecting these parts were acquired to assess baseline contamination rates (n = 13 cases in MOR, n = 11 cases in AOR). MCA was then draped by the scrub tech, using aseptic technique, after draping the surgical field, but before the start of surgery. Following draping, two swabs of the primary surgeons' hands following sterile gowning/gloving, two swabs of the X-ray tube, two swabs of the image intensifier, and two swabs of the middle connecting portion were collected, totaling eight swabs (►**Fig. 2**). Throughout the case, standard aseptic techniques were used by the surgical team. Four percent chlorhexidine gluconate solution was used for surgical site sterilization prior to draping in all cases. After completion of the case, two culture swabs were again taken of the still gloved primary surgeon's hands and still draped X-ray tube, image intensifier, and middle portion of the MCA. The surgeon did not change gloves throughout the case and the MCA drape was not changed. Gloves and MCA drapes were visually inspected for perforations at the end of the case by the surgical team, but none were found in our cohort.

Each culture swab was then streaked on a quadrant of 5% sheep blood agar within 24 hours of the completion of the

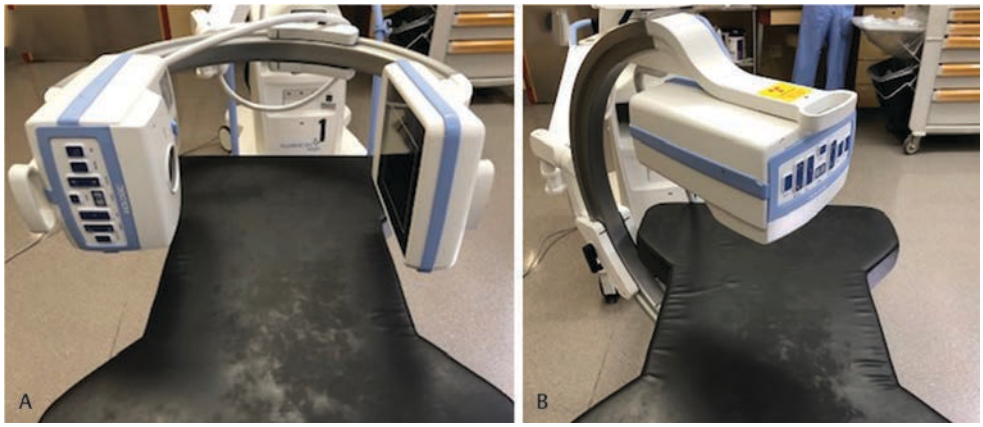

Fig. 1 (**A**) MCA being used in above hand-table technique with primary surgeon, assistant, and scrub technician. (**B**) MCA being used in below hand-table technique with primary surgeon, assistant, and scrub technician. MCA, miniature c-arm.

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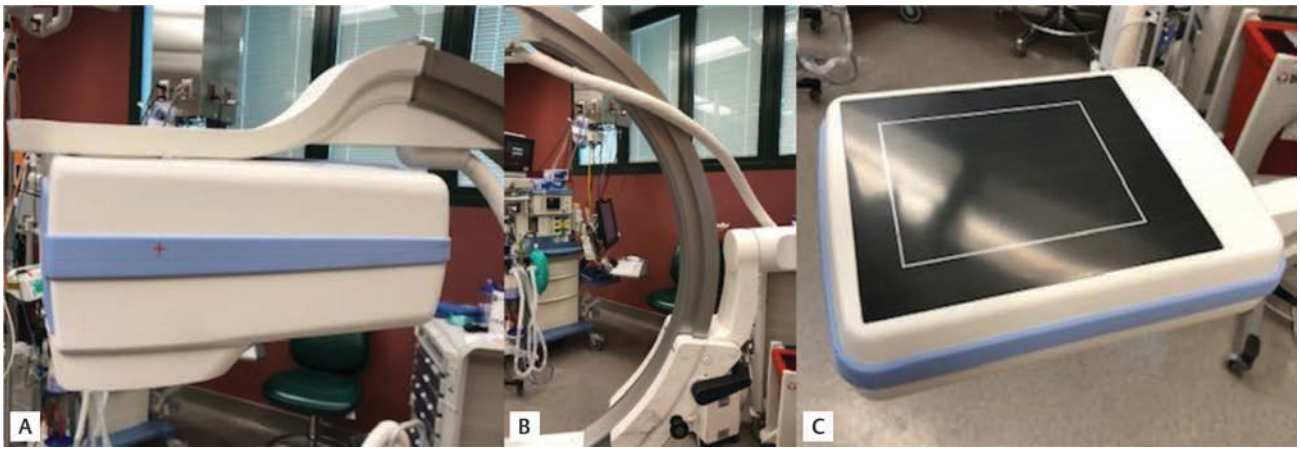

Fig. 2 (**A**) X-ray tube (top) portion of the MCA. (**B**) Middle portion of the MCA. (**C**) Image intensifier (bottom) portion of the MCA. MCA, miniature c-arm.

surgery and incubated in an aerobic environment at 35°C for 72 hours to evaluate contamination per standard protocol. Five percent sheep blood agar is a nonselective culture media that is useful for culturing different types of bacteria, including Gram-positive and Gram-negative species. The number of colony-forming units (CFUs) was counted for each quadrant and added together for each region (two swabs per region) of the MCA and surgeon's hands assessed. To determine the overall contamination of the MCA per case, each of the three regions of the MCA and the surgeon's hands were totaled together. Positive contamination was defined as two or more total CFUs among all locations assessed. Speciation of bacteria was not performed in this study. CPT code (n = 29 cases), case length in minutes (n = 29 cases), method of MCA use (above or below hand-table) (n = 29 cases), number of times the MCA approached the field (n = 24 cases; MOR–13, AOR–11), and total time of MCA usage in seconds (n = 21 cases; MOR-11, AOR-10) were recorded for cases conducted in either the MOR or AOR. Demographic information, patient comorbidities, and if future infection occurred was not recorded, as this study was conducted in a deidentified fashion. Given that study data was collected in a deidentified manner, missing information not collected during the case could not be collected retrospectively. One case was excluded during posthoc data analysis for possible swab labeling error.

Due to comparisons not passing the D'Agostino–Pearson normality test, the Mann–Whitney U test was used for a nonparametric analysis on data collected. Fisher exact test was additionally used due to the small sample size. Statistical significance was set at $p \leq 0.05$. Power analysis was not performed, and number of cases was determined using similar prior studies of this nature.

Results

The purpose of this study was to assess the sterility of the MCA before and after hand and upper extremity cases in either a predominantly inpatient hospital MOR or an outpatient AOR. Secondarily, we also assessed the sterility of the MCA in each operating room, and in association with the placement of the MCA relative to the hand-table. Primary outcomes include baseline MCA contamination prior to draping, MCA contamination after draping prior to the start of surgery and at case completion, and contamination of the surgeon's hands prior to surgery and at case completion. Case distribution among the three hand and upper extremity surgeons was eleven, eleven, and seven.

Sterility of the MCA was assessed in 13 MOR and 16 AOR cases. Of cases conducted in the MOR, nine cases used an above hand-table method and four used a below hand-table technique. Of cases conducted in the AOR, nine cases used an above hand-table method and seven used a below hand-table technique. Assessment of procedural CPT codes indicated both unique and overlapping procedures performed between cases at the MOR and AOR (►**Supplementary Table S1**, available in the online version). In assessing number of times the MCA approached the field and MCA usage time in seconds, no significant differences were observed between cases assessed in the MOR or AOR; however, case length in minutes trended toward being significantly longer in MOR cases (p = 0.055) (mean MOR: 142.4 minutes, mean AOR: 95.1 minutes) (►**Fig. 3**).

In assessing baseline contamination of the undraped MCAs, we observed a significantly greater number of CFUs collected from MOR MCAs (mean :40.2 CFUs, range: 1–200 CFUs) compared with those collected from AOR MCAs (mean: 1.4 CFUs, range: 0–10 CFUs) ($p < 0.001$) (►**Fig. 4**).

Following draping prior to surgery in the MOR, we observed no contamination of the MCA. After the completion of the case, 46.2% of the cases assessed from the MOR tested positive for contaminate (n = 6) (►**Fig. 5A**). Of the six contaminated cases, equal proportions of the cases were conducted using above the hand-table or below the hand-table techniques. Of the noncontaminated cases, 85.7% (n = 6) of the cases were conducted using above the hand-table techniques, while only 14.3% (n = 1) of the cases were conducted using below the hand-table techniques (►**Fig. 5B**). No MOR cases had contamination of surgeon hands prior to surgery

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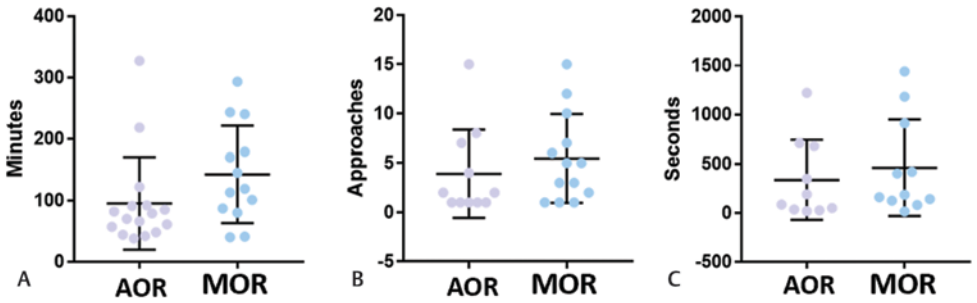

Fig. 3 (**A**) Comparison of surgery length, median case length–MOR (n = 13): 142.4 minutes (range: 40–293 minutes); AOR (n = 16): 95. 1 minutes (range: 38–327 minutes); p = 0.055, ns. (**B**) Number of times MCA approached the surgical field, MOR (n = 13): median = 5 approaches (range: 1–13 approaches); AOR (n = 11): median = 2 approaches (range: 1–15 approaches); p = 0.273, ns, (**C**) and time of MCA use, median usage time (seconds)–MOR (n = 11): 187 seconds (range: 16–1441 seconds); AOR 285 (n = 10): 139 seconds (range: 19–1221 seconds); p = 0.468, ns. AOR, ambulatory operating room; MCA, miniature c-arm; MOR, main operating room.

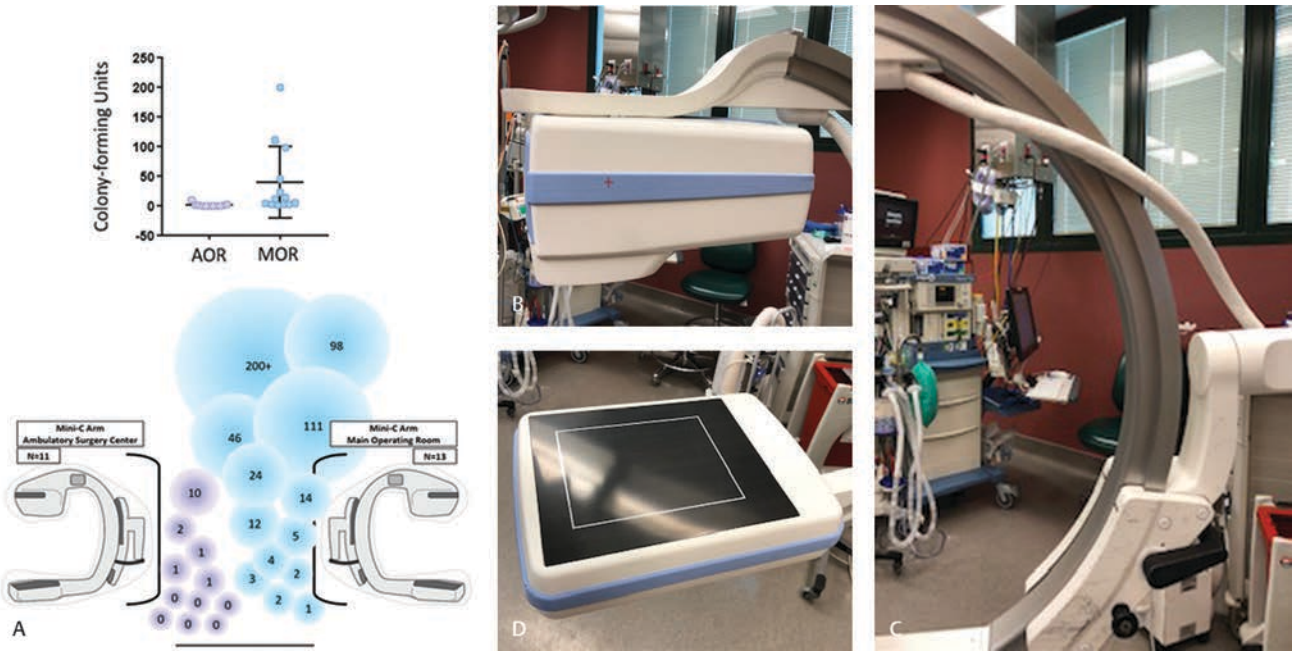

Fig. 4 (**A-D**) Comparison of CFUs collected prior to draping of MCAs in MOR and AOR settings. AOR, ambulatory operating room; CFU, colony-forming unit; MCA, miniature c-arm; MOR, main operating room.

start. After surgery completion, one case had contamination with two CFUs. This case used a below hand-table MCA technique.

No contamination of AOR MCAs occurred after draping but prior to surgery start. At case completion, 37.5% of the cases assessed in the AOR tested positive for contamination (n = 6) (►**Fig. 6A**). Of the six contaminated cases, 16.7% (n = 1) of the cases were conducted using an above hand-table technique, while 83.3% (n = 5) of cases were conducted using a below hand-table technique. Of the noncontaminated cases, 80.0% (n = 8) were conducted using an above hand-table technique, while only 20.0% (n = 2) were conducted using a below hand-table technique (►**Fig. 6B**). We observed 1 of 16 AOR cases that had minimal yet detectable (2 CFUs) contamination of the surgeon's hands prior to surgery start. However, zero contaminations of surgeon's hands were found at the completion of all cases, indicating a possible cross-contamination in this singular case or a decreased sensitivity in the ability of culture swabs to detect contamination.

Further analysis of the location of contamination on the MCA and number of CFUs collected following cases in the MOR and AOR were assessed and dichotomized based on MCA placement relative to the hand-table (►**Fig. 7**). In cases conducted in the MOR, using an above hand-table technique, we observed CFUs at all MCA positions assessed as well as on the surgeons' hand upon completion of the case. In cases conducted using a below hand-table technique, we saw greater average number of CFUs that were detectable on the middle and the image intensifier (bottom) of the MCA, yet no CFUs were observed on the X-ray tube (top) of the MCA. Yet, comparable CFUs were collected from the surgeons' hands at the completion of the case (►**Fig. 7A**).

In cases conducted in the AOR using above the hand-table techniques, we observed minimal CFUs collected from the

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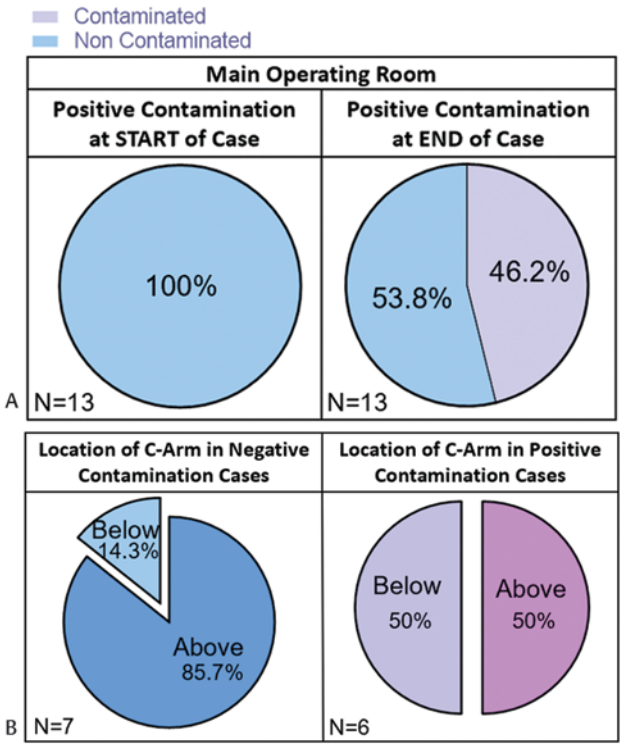

Fig. 5 Incidence of MCA contamination in MOR cases (n = 13). (**A**) Percentage of cases where contamination was identified at either the start of the case after draping or at the end of the case. (**B**) Analysis of MCA location in negative or positive contamination cases. Contamination defined as > 2 CFUs across all locations assessed. CFU, colony-forming unit; MCA, miniature c-arm; MOR, main operating room.

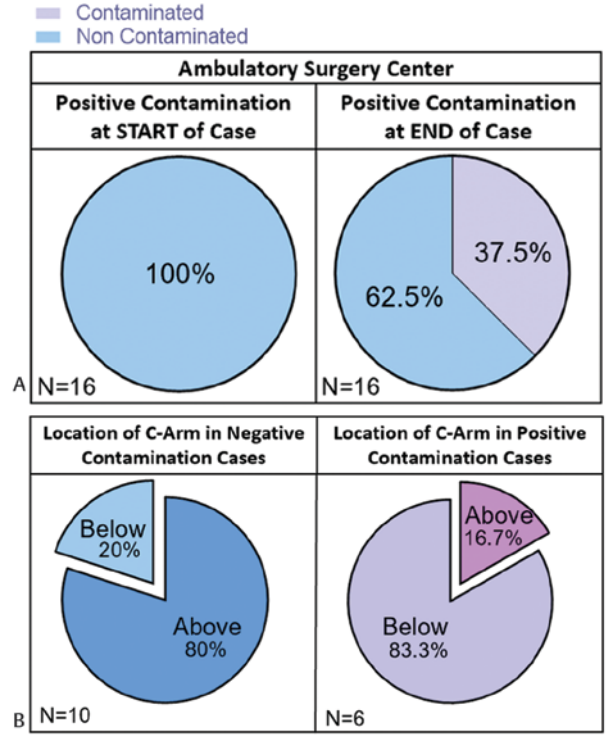

Fig. 6 Incidence of MCA contamination in AOR cases (n = 16). (**A**) Percentage of cases where contamination was identified at either the start of the case after draping or at the end of the case. (**B**) Analysis of MCA location in negative or positive contamination cases. Contamination defined as > 2 CFUs across all locations assessed. AOR, ambulatory operating room; CFU, colony-forming unit; MCA, miniature c-arm.

X-ray tube (top) and middle section of the MCA (►**Fig. 7B**). Alternatively, in cases where the MCA was employed using a below hand-table technique, we collected an overall greater number of CFUs, with contamination being found at all MCA positions assessed (►**Fig. 7B**). No contamination was detected on the surgeons' hands following the completion of the case, independent of the MCA placement relative to the hand-table.

Discussion

MCAs are a vital tool in hand and upper extremity surgery, allowing for assessment of alignment, fracture reduction, and implant placement. However, we found a high-rate of MCA intraoperative contamination, as demonstrated previously.[6,7,10-17]

MCAs assessed in the MOR prior to draping had significantly greater baseline contamination, with as high as 20 times greater CFU counts than the highest AOR CFU counts. In a previous study, we showed that 100% of nonsterile items brought into the operating room grew varying degrees of bacteria.[19] Given that these nonsterile items or equipment brought into the operating room can increase bacterial loads and increase infection risk, we advocate for the regular cleaning of MCAs in both surgical settings to decrease the overall bacterial burden exposed to the surgical site.

No significant difference in contamination rates was detected between surgical settings (p = 0.72); however, the number of CFUs collected upon case completion in the MOR tended to be greater than those in the AOR. We also observed more widespread contamination of MOR MCAs, independent of the placement relative to the hand-table. These higher CFU counts may be a result of higher baseline MOR contamination or the trend toward longer case time in the MOR (p = 0.055). Greater surgical times are a known risk factor for contamination and infection[6,7,10-12] It has been shown that a majority of MCA contamination occurs within 20 minutes of surgery start, and 80% of MCAs are contaminated 80 minutes into surgery.[12] The MCAs in our study were draped prior to surgery start, increasing their time for contamination risk. Perhaps draping the MCA at the time of need in the surgical field could decrease contamination rates and be examined in future studies. Another possible explanation is increased operating room traffic, which is typically higher in hospital MORs compared with AORs; however, this variable was not assessed during this study.[3-5]

As much as 85.7% and 80% of noncontaminated cases used an above hand-table method in the MOR and AOR, respectively. In the AOR, 83.3% of contaminated cases used a below hand-table technique, while 50% of contaminated cases in the MOR used the below the hand-table technique. While the total number of contaminated MOR cases was equal between both MCA techniques, ¾ of the cases where the MCA was used below the hand-table were positively contaminated. This small sample size does not permit us the ability to fully examine if the location of the MCA impacts contamination rates. However, due to the majority of noncontaminated cases using

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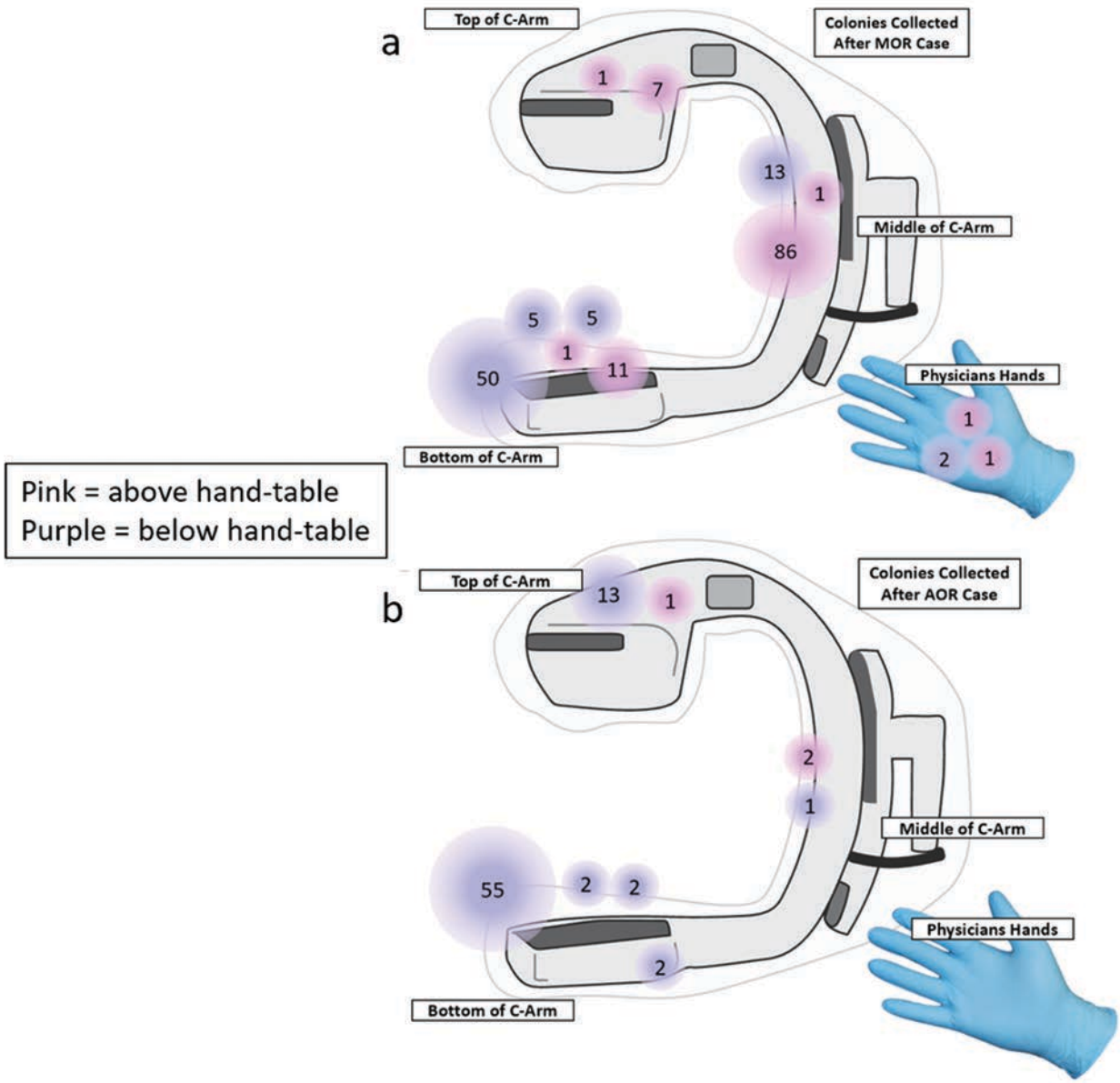

Fig. 7 Comparison of contamination after the completion of a case between MOR (n = 6) (**A**) and AOR (n = 6) (**B**). Pink indicates cases where above hand-table technique was used; purple indicates cases where below hand-table technique was used. Number indicates CFUs found at each location assessed upon case completion. Only cases with positive contamination are plotted. AOR, ambulatory operating room; CFU, colony-forming unit; MOR, main operating room.

an above hand-table technique in both settings, the majority of contaminated AOR cases using an under hand-table method, and a greater proportion of total under hand-table cases being contaminated in the MOR, it appears that using the MCA in a below hand-table manner may increase contamination rates, even to MCA areas not directly under the hand-table.

Limitations for this study include the small case number assessed and the fact that all cases were conducted at a single institution. Another drawback of our study is that an a priori or posthoc power analysis was not performed, possibly leading to type 1 or 2 error. Given that patient identifiers were not collected as part of this study, instances where data on MCA usage was not recorded were unable to be added retrospectively and therefore were not included for analysis. Additionally, patient follow-up and rates of infections were not assessed. Interestingly, not all below hand-table MCA swabs were positive for contamination despite being outside the sterile field. A low-sensitivity for culture swabs to detect contamination could explain this; however, in the future, it may be helpful to perform control swabs to determine the minimum swab area for a positive culture. Broad regions of the MCA were swabbed during this study, thus precluding more specific analysis of MCA locations prone to contamination. Further, low-sensitivity of culture swabs to detect contamination or differing swabbing techniques could explain opposing contamination rates. As the goal of this work was to assess bacterial growth, 5% sheep blood agar plates were selected as a growth medium to support both routine and

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fastidious bacterial growth. Specific bacterial isolates were not characterized as part of this study. Future studies could evaluate specific bacterial species' colonization rates in different surgical settings. It should be acknowledged that findings could be a result of specific surgeon technique and not MCA placement, due to each surgeon using their same preferred technique each case. Finally, although similar procedures were seen in each operative setting, varying complexity and use of various other equipment was not accounted for and may have introduced bias to our findings.

MOR MCAs may possess greater baseline bacterial load than AOR MCAs prior to draping, and regular sterilization of this equipment could decrease bacterial burden exposed to surgical sites. High intraoperative contamination rates were found in both surgical settings, with MOR MCAs having a higher contamination rate. Possibly longer trending surgical lengths, greater baseline MCA contamination, and an under hand-table MCA technique may increase intraoperative contamination risk. Patient safety and outcomes might be improved by minimizing these factors.

Authors' Contributions

J.P.H.: Wrote the manuscript with support from S.N.M.L., D.H.L., and J.G.S. Contributed to interpretation of results and data presentation. S.N.M.L.: Assisted with project design and preparation of IRB materials, performed data analysis, assisted in manuscript preparation, and headed up data analysis and figure preparation. A.M.: Contributed to sample collection and data analysis. B.H.Y.G.: Contributed to sample collection and data analysis. D.R.W.: Conducted surgical cases and assessed and contributed to sample collection and data analysis. M.J.D.: Conducted surgical cases and assessed and contributed to sample collection and data analysis; assisted with project design and preparation of IRB materials. S.S.G.: Devised the project and main conceptual ideas presented within; assisted with project design and preparation of IRB materials, and aided in interoperating the results. J.G.S.: Devised the project and main conceptual ideas presented within; provided funding for experimental examinations, aided in interpreting results, and offered critical revisions of the manuscript. D.H.L.: Assisted in manuscript presentation, aided in interpreting results, offered critical revisions, and supervised collection of data.

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Conflict of Interest

J.G.S. reports that he is a member of the education advisory board at OrthoPediatrics; is a member of the POSNA board; receives research funding from Orthopediatrics; receives research support in the form of materials from IONIS pharmaceuticals; receives research support from PXE international.

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