

# STERILITY OF SURGICAL SITE MARKING

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**Background:** Over the past decade, wrong-site surgery has been a popular topic of discussion, not only in medical and legal journals but also in the mainstream press. Marking of the surgical site according to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Universal Protocol was implemented at our institution to help reduce the number of wrong-site operations. In this study, we determined whether marking of the site affected the sterility of the surgical field.

**Methods:** The study included twenty volunteers. The right forearm was used as the experimental (marked) arm and the left forearm, as the control arm. The experimental forearms were marked with a surgical marker as described by the protocol. Both upper extremities were then sterilized from the antecubital fossa to the phalanges with a 7.5% povidone-iodine scrub followed by the application of a 10% povidone-iodine paint. Swabs were used to obtain samples from the experimental and control arms as well as from the marker and were sent for microbiological culture and analysis.

**Results:** No growth was seen in the cultures of the swabs used on the experimental or control arms or on the marking pens.

**Conclusions:** Preoperative marking of surgical sites in accordance with the JCAHO Universal Protocol did not affect the sterility of the surgical field, a finding that provides support for the safety of surgical site marking.

Over the past decade, wrong-site surgery has been a popular topic of discussion in medical and legal journals as well as in the mainstream press. The issue has become prominent in the current literature because of profound patient, social, professional, and medicolegal consequences. Although controversial<sup>1,2</sup>, a report by the Institute of Medicine estimated that 44,000 to 98,000 Americans die each year from preventable medical errors rather than from the admitting diagnosis<sup>3</sup>. The estimated annual cost to United States taxpayers is approximately \$9 billion<sup>3</sup>. In 1994, the Canadian Orthopaedic Association instituted an educational program intended to prevent wrong-site surgery by recommending that the incision site be marked with an indelible marker. As a result, the number of cases of wrong-site surgery declined from thirteen in 1994 to five in 2000<sup>4</sup>. A 2001 poll of 167 randomly selected Canadian orthopaedists showed that 52% of them always marked their surgical site, despite the lack of a mandatory universal protocol for identification of the surgical site prior to operations<sup>4</sup>.

In an effort to address the issue of surgical site marking, the American Academy of Orthopaedic Surgeons (AAOS) instituted a voluntary "Sign Your Site" campaign<sup>5</sup> in 1997. The

Joint Commission on Accreditation of Healthcare Organizations (JCAHO) established a Universal Protocol in 1998 to prevent wrong-site surgery and its consequent complications<sup>6</sup>. The Universal Protocol includes the patient's verbal verification of the surgical site, active discussion of the procedure with the patient, marking of the surgical site by the physician or another specified health-care proxy using permanent marker that can withstand the local sterilization procedure, use of a verification checklist or pertinent documents and images, and oral verification of the site by the surgical team in the operating room during a "time out."<sup>7</sup> This protocol has introduced new variables, particularly the application of a potentially nonsterile chemical marking substance, to the operative field.

The aim of this study was to determine whether the sterility of the surgical field was affected by the use of a permanent-ink marker for identification of the intended surgical site. Our hypothesis was that there would be no difference between the results of standard bacterial cultures of specimens taken from the marked and analogous unmarked areas.

## Materials and Methods

After we obtained approval for the study from our institutional review board, twenty randomly selected volunteers were recruited from our locale to participate in this study. After they had provided written informed consent, one site (the anterior antebraclial skin) on the right upper ex-



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tremity, which was chosen as the experimental arm, was marked according to the JCAHO recommendation<sup>8</sup> with a 2 × 5-cm YES with use of a standard surgical site marker (Kendall-LTP, Chicopee, Massachusetts). The same marker was used on all of the subjects and was not considered sterile prior to the study. Both forearms were then prepared in the standard preoperative fashion with a 7.5% povidone-iodine scrub followed by a 10% povidone-iodine paint and allowed to dry in room air for ten minutes. This process created sterile areas from the elbow to the distal phalanges that were identical to those prepared for the operating theater.

### *Sterility Assessment*

The prepared, marked areas and the contralateral, unmarked areas were then sampled with use of standard Kendall sterile bacterial swabs (Becton Dickinson Laboratories, Franklin Lakes, New Jersey), and the swabs were placed into 16 × 125-mm sterile culture test tubes in a standardized sterile fashion. The samples were obtained from areas of skin directly over the markings which, having been placed by an indelible marker, were minimally altered by the sterilization process. Samples were also taken from analogous sites (as could best be identified) on the contralateral forearm. In addition, a direct sample was taken from the permanent marker in a sterile fashion. The specimens were then sent to the hospital microbiology laboratory for routine culture.

The swabs were placed on chocolate, blood, and MacConkey aerobic agar plates and were observed for seventy-two hours. A culture was deemed to be positive when any bacterial growth was noted on the agar plate. Routine bacteriological investigation at our institution includes a gram stain and cultures for gram-negative rods and gram-positive organisms, with a specific focus on Staphylococcus, Streptococcus, and Enterococcus species. This regimen allows reporting of up to three gram-positive species. Agar dishes containing more than three gram-positive species are reported to be "mixed." We did not test for anaerobes in this series. If colonies formed, the species were identified, the colony size was estimated, and antibiotic sensitivities were determined.

### *Statistical Analysis*

The proportions of positive cultures were compared between the experimental and control groups. Our study had an 80% power to detect a difference of ≥5% in the infection rates between the two groups. With a 95% confidence interval set, the likelihood of bacterial colonization could be as high as 8.8%. Our study protocol indicated that if positive cultures were identified, an independent t test would be used to compare colony sizes between the two groups. Statistical tests were to be two-tailed and conducted with use of JMP Statistical Discovery Software (version 5.1.1; SAS Institute, Cary, North Carolina) and a Type-I error rate of 0.05 (p).

### **Results**

The results of twenty cultures of the swabs used on each of the experimental and control arms as well as on the per-

manent marker were available. Thus, there was a total of forty-one culture results. After three days of culture, as dictated by the hospital protocol, there was no growth in any culture of specimens obtained from the control or experimental arms or from the marking pen. Because all cultures were negative, no more statistical analyses were conducted.

### **Discussion**

Monitoring of sentinel events by JCAHO revealed that 278 incidents of wrong-site surgery were reported from January 1995 through September 2003<sup>9</sup>. Thirty-five percent of those incidents involved orthopaedics<sup>9</sup>. In another review, JCAHO identified 126 cases of wrong-site, wrong-person, or wrong-procedure surgery as of December 2001, and 41% of the cases were related to orthopaedics<sup>10</sup>. As of January 2004, wrong-site surgery was the third highest sentinel event, accounting for more than 12% of all sentinel events reviewed by the Joint Commission since 1995<sup>9</sup>. JCAHO continues to receive five to eight reports of wrong-site surgery per month<sup>7</sup>.

Several other authors have addressed this problem. In a poll of 1560 active members of the American Society for Surgery of the Hand, Meinberg and Stern found that 16% had prepared to operate on the wrong site but had corrected the error prior to incision and 21% had performed wrong-site surgery at least once<sup>11</sup>. The overall incidence of wrong-site surgery was one per every 27,686 procedures performed<sup>11</sup>.

Wong estimated that at least one in five orthopaedists will have an occurrence of wrong-site surgery in his or her career<sup>9</sup>. Watson et al. reviewed claims against an orthopaedic training program and found that operations at the wrong anatomic site, improper use of equipment, and missed or delayed diagnosis were all reasons for a favorable decision regarding the claim for the plaintiff<sup>12</sup>. DiGiovanni et al. implicated non-compliance of the patient as a factor in wrong-site surgery, finding that only 59% of patients complied with instructions to mark NO on the uninvolved extremity<sup>13</sup>. The Physician Insurers Association of America reported 213 paid claims, with an average indemnity payment of \$54,800, for suits involving wrong-site surgery between 1985 and 1997<sup>8</sup>.

It is hoped that the marking of surgical sites, which is currently done with ink in a nonsterile fashion, will not affect the sterility of the surgical field. The present study showed the prevalence of laboratory-detected microbacterial growth to be 0% in cultures of specimens obtained from prepared marked and unmarked surgical sites.

Some potential limitations of our study include the observation of the laboratory cultures for only seventy-two hours. If some slow-growing flora were present, they may not have been detected in the allotted time frame. However, that is unlikely as most bacteria colonizing the skin grow rather quickly. It is also possible that the media used were inappropriate for the growth of colonies of certain bacteria. Although this remains a concern, most epidermal flora routinely thrive in the agar solutions that we used. In a series of eight infections that developed following office-based face-lifts and augmentation mammoplasties, the causative organism was

found to be an acid-fast bacillus, *Mycobacterium chelonae*, that had been delivered through contaminated gentian-violet ink used to mark the skin prior to incision<sup>14</sup>. Ultimately, only rarer species, such as *Mycobacterium chelonae*, require special culture dishes or more time to be identified. However, special circumstances would be required for those bacteria to become a surgical wound issue. This, combined with the rigorous sterile preparation of the extremities, makes it highly unlikely that these more obscure pathogens would be of common clinical importance.

As more institutions implement the JCAHO Universal Protocol<sup>6</sup>, it is hoped that the incidence of wrong-site surgery will be significantly reduced. Cooperation among physicians, operating room staff, and pre-operating room staff will greatly facilitate the implementation and efficiency of procedures for marking surgical sites. Recently, there have been clarifications of some of the points of the Universal Protocol; these include: (1) the surgical site is to be marked by the surgeon or a "credentialed provider" (which includes residents or fellows or licensed physician assistants); (2) the actual surgical site should be marked (reproducibly); (3) an X should not be used (as it may be imprinted on other sites in a mirror fashion); (4) patient cooperation should be garnered (this does not preclude use of mild sedatives) and, when appropriate, may include the family; and (5) an indelible marker must be used<sup>9</sup>.

Only time will tell if the JCAHO's current recommendations will have a noteworthy impact on the incidence of

wrong-site surgery. It is believed that institutions that have implemented the process of repeated confirmation, involving not only hospital staff but also the patients, may already have diminished the rate of wrong-site surgery. Our results should encourage physicians to be less concerned regarding the deleterious side effects of signing sites and more proficient in confirming them preoperatively, for both the patient's benefit and their own. ■

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