

## Surgical Site Markers: Putting Your Mark on Patient Safety

### ABSTRACT

*During the PA-PSRS preventing wrong-site surgery initiative, several inquiries were received regarding the performance and sterility of surgical site marking pens. The majority of surgical site marking pens contain gentian violet ink, which has antifungal properties. Other types of marking pens used by some hospital staff to mark surgical sites are permanent ink markers and, infrequently, ballpoint pens. The surgical site mark should not be easily removed with skin preparation but should not be so permanent as to last weeks or months after the surgical procedure. Three studies describing the performance of pens or markers used to mark surgical sites were reviewed. None was conclusive in determining the best performance of marks on skin when used with skin prep solutions. Also reviewed were three studies that described the sterility of single-use surgical site marking pens and two studies that looked at cross-contamination from surgical site marking pens used on multiple patients. Based on the results of each sterility study, no infection or contamination was observed from single-use pens; however, the potential exists for cross-contamination from pens used on multiple patients. The results of the reviewed studies are not definitive as to the type of surgical site marking pen or the type of skin prep solution to use to obtain the optimal mark at the surgical site. Healthcare facilities may wish to conduct their own studies of surgical site markers and/or skin prep solutions to determine performance between markers and skin prep solutions. (Pa Patient Saf Advis 2008 Dec;5[4]:130-5.)*

### Introduction

As part of its accreditation program, the Joint Commission established the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery.<sup>TM</sup> Included in the protocol is marking the surgical site for procedures involving incisions, percutaneous punctures or insertions with respect to laterality (e.g., right/left distinction), levels (e.g., spine), or multiple structures (e.g., fingers, toes).

During the PA-PSRS preventing wrong-site surgery initiative, several healthcare facilities inquired about the performance and sterility of surgical site marking pens. Facilities were looking for information regarding the permanence of the mark when the skin has been prepared with a prep solution (e.g., Betadine®, alcohol) and infection issues with the use of the pens. A literature search found several studies evaluating the performance and sterility of surgical site marking pens. The information discussed below does not provide definitive conclusions but may provide

healthcare facilities with some insight in evaluating surgical site marking pens.

### Marking Ink Composition

Gentian violet ink is water-based and is the predominant ink used in surgical site marking pens. Gentian violet has antifungal properties and has been used as a topical treatment for some types of fungus infections such as oral thrush,<sup>1</sup> a type of yeast infection.

Skin marking pens are classified by the U.S. Food and Drug Administration (FDA) as Class 1 medical devices.<sup>2</sup> According to FDA, Class 1 devices present minimal potential for harm.<sup>2</sup> As Class 1 medical devices, the markers are exempt from FDA premarket clearance (i.e., FDA clearance is not required before marketing the device). However, manufacturers of Class 1 devices are required to register with FDA.

There have been anecdotal reports, including one study described below, of some surgical facilities using permanent ink markers (e.g., Sharpie®)<sup>6</sup> or ballpoint pens for marking surgical sites. Many of these permanent ink markers comply with the nontoxicity American Society for Testing and Materials D4236 standard for art materials; however, they are not necessarily cleared by FDA for direct skin use, nor have they been cleared or registered with FDA for use as surgical site marking pens.

The Association for periOperative Nurses (AORN) recommends using only nontoxic skin markers registered with FDA to mark the surgical site.<sup>3</sup> AORN also recommends checking the marker label because some manufacturers sell markers for use on skin (i.e., surgical site markers) and markers for utility use (e.g., labeling medications).<sup>3</sup>

### Surgical Site Marker Performance

One of the main issues associated with use of skin markers is the permanence of the mark (i.e., whether the mark will be visible after skin preparation to identify the appropriate surgical site). Ideally, the mark should not be easily removed when prepping the skin with a prep solution so that the mark is not visible before the time-out and the first incision. But, the mark should not be so permanent as to last weeks or months after the surgical procedure and may be an inconvenience or cause for embarrassment to the patient (e.g., facial markings on a patient undergoing plastic surgery).

Few published studies evaluate the performance of surgical skin marking inks or pens. One study (Mears et al.) compared the effects of two skin prep solutions (chlorhexidine and iodine povacrylex combined with isopropyl alcohol) on skin markings.<sup>4</sup> Mears et al. examined the effects of skin prep solutions

on a permanent ink marker (e.g., Sharpie), not on skin markers specifically marketed for surgical site marking.

In the Mears et al. study, three skin flaps were harvested from the thighs of male cadavers. Twenty random three-letter combination marks were made on the skin flaps using the permanent ink marker. The marks were allowed to dry for approximately 15 seconds before applying the prep solutions; half the skin flaps were prepped with chlorhexidine, and half were prepped with iodine povacrylex and isopropyl alcohol. The chlorhexidine was applied using forward and backward strokes lasting 30 seconds, while the iodine povacrylex and isopropyl alcohol were applied in a single layer without scrubbing. The solutions were allowed to dry for approximately three minutes. Photographs of the marks were taken before and after the prep solutions were applied to the skins. The photographs were shown to 10 surgeons, separately, and each surgeon was asked to write down the letters in each photograph.<sup>4</sup>

The results of the study demonstrated that the chlorhexidine solution was 21.8 times more likely to erase the mark than the iodine povacrylex and isopropyl alcohol solution.<sup>6</sup>

Another study (Stromberg) compared 13 commercially available surgical site marking pens.<sup>5</sup> All the pens contained gentian violet ink with varying tip widths. Stromberg evaluated the ability to make an easily discernable mark, assessed the performance of marking clarity after a one-year storage interval of the pens, and evaluated the effects that degreasing the skin had on the marking performance of the pens.

Four areas of the skin of a volunteer subject were used to assess the performance of the marking pens. One area of skin was not prepped, one area was prepped with povidone-iodine solution, one area was prepped with 3% hexachlorophene, and one area was prepped with 4% chlorhexidine gluconate. All areas were prepped in accordance with the instructions from each prep solution's respective supplier. After prepping the areas, marks were made on the volunteer's skin. Note that marking the surgical site is typically performed before applying the skin prep solution; however, for this study, the mark was made after the prep solution was applied to the skin, which the author does not explain. After storing the pens for one year, the testing was repeated. To determine the effects of degreasing, the skin was degreased with alcohol or acetone, marks were made on the skin, and then the skin was prepped similarly to the methods described above.

Stromberg observed that for the unprepped and prepped areas over the one-year period, the majority of pens performed uniformly well while a few pens performed poorly. One brand of pen did not produce a discernable mark during any of the testing. Stromberg also noted that a skin prep solution containing soap (3% hexachlorophene containing a synthetic

detergent) left a residue, which made marking more difficult.<sup>5</sup> The length and clarity of the markings were not attributed to the ink used (all the pens used gentian violet ink), but differences in the marker tips affected the amount and ease of ink application.<sup>5</sup> However, the performance level for the specific tip types was not described in the study. Testing also demonstrated that degreasing the skin before applying the marks did not appreciably reduce the visibility of the marks on the skin.<sup>5</sup>

A third study (Tatla et al.) evaluated six marking pens from various suppliers to determine their relative performance and their ability to withstand surgical skin prep solutions.<sup>6</sup> The specific ink used with each pen was not described, however. Testing was performed using chlorhexidine gluconate and povidone iodine skin prep solutions.

The forearm of a volunteer was used to assess the performance of the pens. Each marked area of the volunteer's forearm skin was cleaned with the prep solutions for a period of 60 seconds. The results demonstrated that the majority of the pens performed poorly when used with chlorhexidine gluconate and moderately well to well when used with povidone iodine.<sup>6</sup>

### Sterility of Surgical Site Markers

Another concern of some surgical facilities has been the potential contamination of the surgical site from surgical marking pens. A search of the literature regarding the sterility of surgical marking pens revealed some anecdotal reports of infections attributed to marking pens used on only one patient (single-use) and reports of pens used on more than one patient (multiuse). The literature search revealed the following studies that assessed the sterility of surgical and nonsurgical marking pens on skin:

Cullan et al. evaluated the sterility of surgical marking pens on the skin of surgical wounds.<sup>7</sup> Thirty patients having upper extremity surgery were included in the study. Half of the intended incision length for each surgical site was marked, with a nonsterile surgical marking pen, based on the Joint Commission guidelines for surgical site marking. Each upper extremity was prepped with iodine povacrylex and isopropyl alcohol using a "standard" surgical method.<sup>7</sup> A single incision was made starting in the unmarked area through to the marked area of each extremity. Separate cultures were taken from the unmarked and marked areas. Sixty cultures were taken in all. After 72 hours, the cultures were analyzed; the analysis revealed no positive results.

Tenenhaus et al. examined the sterility of surgical marking pens (used and new markers) and nonsurgical, permanent marking pens (e.g., Sharpie). Cultures were taken of all markers and were reviewed every 48 hours for a one-week period.<sup>8</sup> All cultures were negative for bacterial growth. The authors theorized that bacterial growth did not occur because the pens

specifically marketed for surgical site marking are typically sterilized by the manufacturer and shipped in sterile packages. Additionally, the authors believed that the pens containing gentian violet ink most likely demonstrated no bacterial growth because gentian violet ink is recognized as an antiseptic agent, whereas the permanent marking pens most likely demonstrated no bacterial growth due to the pens' high alcohol content.<sup>8</sup>

Cronen et al. evaluated the sterility of a surgical marking pen used on 20 volunteers. The upper extremities of each volunteer were chosen as the marked sites; one arm of each volunteer was used as the marked site, and the other arm of each volunteer was used as the unmarked (control) site. The authors used a typical surgical site marker for the experiment. The same marker was used for all volunteers. Each arm was prepped in a "standard" preoperative method of a 7.5% povidone-iodine scrub followed by 10% povidone-iodine paint. Cultures were taken of the unmarked and marked sites of each volunteer. A total of 41 cultures were collected, and after three days, no bacterial growth was observed in any of the cultures.<sup>9</sup>

**Cross-Contamination of Surgical Site Markers**

A more important sterility issue for healthcare facilities may be cross-contamination between patients from use of surgical marking pens on more than one patient. Two studies looked at the potential for cross-contamination in this manner.

One study (Ballal et al.) examined the potential for cross-contamination from two types of marking pens, not specifically marketed as surgical site markers, with each type containing different alcohol

concentrations. The authors wanted to determine the risks of cross-infection of the two markers over different time intervals.<sup>10</sup>

The study included 24 dry white-board markers with 75.5% alcohol concentration and 24 permanent markers with 60% alcohol concentration. Twenty-four patients, undergoing various elective surgeries, were divided into two groups. Included in the 24 patients were 4 patients with methicillin-resistant *Staphylococcus aureus* (MRSA)-positive ulcers. Each patient was marked with a dry white-board marker and a permanent marker. After marking the patients, the tips were then used to inoculate blood agar plates at different time intervals. Inoculation for the pen tips used on the first group (group A) occurred at 0 and 3 minutes, and the pens used on the second group (group B) occurred at 0 and 10 minutes. As a control, 24 new dry white-board and 24 new permanent markers were used to inoculate blood agar plates without any contact with the patients. The markers used as the control did not show any bacterial growth.

The authors observed that immediately following inoculation (0 minutes) 96% of the dry white-board markers showed positive growth for microorganisms while 29% of the permanent markers showed positive growth. Upon examination at 3 minutes and 10 minutes, all dry white-board markers remained positive for microorganisms, while microorganism growth decreased to 17% and 0%, respectively, for the permanent markers. The MRSA-positive sites stayed positive for MRSA for the dry white-board and permanent marker pens up to 3 minutes and stayed positive at a 10-minute interval for the dry white-board pens.

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**Table 1. Included Performance Studies and Key Results**

STUDY	YEAR PUBLISHED	SURGICAL MARKING PEN	NONSURGICAL MARKING PEN	PREP SOLUTION	RESULT
Stromberg	1987	✓		Povidone-iodine Hexachlorophene Chlorhexidine gluconate	Majority of pens performed similarly well. A few pens performed poorly. Hexachlorophene-containing synthetic detergent left residue, which made marking more difficult.
Tatla et al.	2001	✓		Povidone-iodine Chlorhexidine gluconate	Majority of pens performed moderately well with povidone-iodine. Majority of pens performed poorly when used with chlorhexidine gluconate.
Mears et al.	2008		✓ (permanent ink marker [e.g., Sharpie®])	Iodine povacrylex and isopropyl alcohol Chlorhexidine	Chlorhexidine was 21.8 times more likely to erase the mark than iodine povacrylex and isopropyl alcohol.

**Sources:** Stromberg BV. The surgical marking pen: a comparative study. *Plast Reconstr Surg* 1987 Jul;80(1):104-7; Tatla T, Tehrani HY, Shibu M. Preoperative surgical skin marking in plastic surgery. *Br J Plast Surg* 2001 Sep;54(6):556-7; Mears SC, Dinah AF, Knight TA, et al. Visibility of surgical site marking after preoperative skin preparation. *Eplasty* [online]. 2008 Jul 16 [cited 2008 Sep 3]. Available from Internet: [http://www.eplasty.com/index.php?option=com\\_content&task=view&id=218&Itemid=36](http://www.eplasty.com/index.php?option=com_content&task=view&id=218&Itemid=36).

**Table 2. Included Sterility Studies and Key Results**

STUDY	YEAR	SURGICAL MARKING PEN	NON-SURGICAL MARKING PEN	METHOD	RESULT
<b>Contamination</b>					
Cullan et al.	2007	✓		Observed potential contamination of surgical marking pens on surgical wounds of 30 patients undergoing upper extremity surgery.	The outcome of 60 cultures was negative for bacterial growth 72 hours after inoculation on blood agar plates.
Tenenhaus et al.	2006	✓	✓	Observed potential contamination of surgical and nonsurgical marking pens taken from preoperative holding areas and operating rooms from three medical facilities.	All cultures were negative for bacterial growth after observations every 48 hours for a 1 week period.
Cronen et al.	2005	✓		Observed potential contamination of surgical marking pen on 20 volunteers.	All cultures were negative for bacterial growth 72 hours after inoculation on chocolate, blood, and MacConkey agar plates.
<b>Cross-Contamination</b>					
Ballal et al.	2007		✓	Observed potential for cross-contamination of nonsurgical marking pens on 24 patients, including 4 patients with methicillin-resistant <i>Staphylococcus aureus</i> - (MRSA-) positive ulcers, undergoing various elective surgeries.	<p>Cultures were positive for bacterial growth:</p> <ul style="list-style-type: none"> <li>■ 0 minutes following inoculation                             <ul style="list-style-type: none"> <li>—96% of dry white-board markers</li> <li>—29% of permanent markers</li> </ul> </li> <li>■ 3 minutes following inoculation                             <ul style="list-style-type: none"> <li>—100% dry white-board markers</li> <li>—17% permanent markers</li> </ul> </li> <li>■ 10 minutes following inoculation                             <ul style="list-style-type: none"> <li>—100% dry white-board markers</li> <li>—0% permanent markers</li> </ul> </li> </ul> <p>MRSA:</p> <ul style="list-style-type: none"> <li>■ 0 minutes following inoculation                             <ul style="list-style-type: none"> <li>—100% dry white-board markers</li> <li>—100% permanent markers</li> </ul> </li> <li>■ 3 minute following inoculation                             <ul style="list-style-type: none"> <li>—8% dry white-board markers</li> <li>—8% permanent markers</li> </ul> </li> <li>■ 10 minutes following inoculation                             <ul style="list-style-type: none"> <li>—8% dry white-board markers</li> <li>—0% permanent markers</li> </ul> </li> </ul>
Wilson et al.	2006	✓	✓	Observed potential for cross-contamination of MRSA between patients. A line from each surgical and nonsurgical pen was drawn onto bacteriologic plates containing MRSA. Each pen was then used to draw an arrow onto blood agar plates at various intervals after inoculation.	MRSA did not survive after 3 weeks from inoculation on the surgical marking pens nor did it survive after 15 minutes from inoculation of the nonsurgical marking pens

**Sources:** Cullan D, Wongworawat M. Sterility of the surgical site marking between the ink and the epidermis. *J Am Coll Surg* 2007 Aug;205(2):319-21; Tenenhaus M, Bhavsar D. Do marking inks pose an infection risk? A surgeon's perspective. *Surg Inf* 2006 Oct 1;7(5):481-3; Cronen G, Ringus V, Sigle G, et al. Sterility of surgical site marking. *J Bone Joint Surg Am* 2005 Oct;87-A(10):2193-5; Ballal MS, Shah N, Ballal M, et al. The risk of cross-infection when marking surgical patients prior to surgery—review of two types of marking pens. *Ann R Coll Surg* 2007 Apr;89(3):226-8; Wilson J, Tate D. Can pre-operative skin marking transfer methicillin-resistant *Staphylococcus aureus* between patients? A laboratory experiment. *J Bone Joint Surg Br* 2006 Apr;88(4):541-2.

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The authors noted that even though the dry white-board pens contained a higher concentration of alcohol than the permanent marking pens, they posed a greater risk of cross-contamination from one person to another when used within 10 minutes between patients than the permanent marking pens.<sup>10</sup>

Another study (Wilson et al.) evaluated the potential for marking pens to transmit MRSA between patients. The study included 31 marking pens specifically marketed for surgical site marking and 30 permanent marking pens not marketed for surgical site marking. A single line was drawn using each pen onto bacteriologic plates containing MRSA as a standardized contamination inoculum for each pen. Each pen was then used to draw an arrow onto blood agar plates at intervals of 0, 5, 15, and 60 minutes; 24 and 48 hours; and 1, 2, and 3 weeks after inoculation.<sup>11</sup>

Results showed that MRSA did not survive on the permanent marking pens after 15 minutes from inoculation; however, the MRSA survived up to 3 weeks on the surgical marking pens. The authors theorized that MRSA did not survive on the permanent marking pens because the ink contained isopropyl alcohol and ethanol but was able to survive on the surgical marking pens because the ink contained water as the main solvent.<sup>11</sup>

## Conclusions

Healthcare facilities use a variety of marker types to mark surgical sites. Based on the results of our literature review, pens specifically marketed for marking surgical sites appear to be more prevalent, but some surgical facilities have used standard permanent markers (e.g., Sharpie), or even ballpoint pens,<sup>3</sup> to mark sites. Our search identified no head-to-head clinical studies comparing the safety of different markers. Since gentian violet ink must undergo the FDA clearance process, facilities may be more compelled to use surgical marking pens containing gentian violet ink than standard permanent markers, which are not cleared by FDA.

The performance studies described above are inconclusive in determining the optimal permanence of marks when using skin prep solutions. The studies are not directly comparable because they did not use the same types of ink or the same skin prep solutions, although there was some overlap. Additionally, based on Stromberg's observations in the first study about performance described in Table 1, differences in permanence may be due more to the type of pen tip (e.g., narrow, wide) than to the ink, since all the pens used in that study contained gentian violet ink. Although not stated in the study, an assumption could be made that a wider tip pen would make a more permanent mark on the skin.

Based on the sterility studies described in Table 2, contamination or infection does not appear to be an

issue for single-use pens; however, cross-contamination may be problematic when the same pen is used on more than one patient, at the very least during short intervals between patients. The results of the cross-contamination studies described above suggest that facilities may want to consider using surgical marking pens for single-use only.

The studies above do not provide definitive conclusions as to the type of surgical marking pen or the type of skin prep solution to use to obtain the optimal mark at the surgical site. However, two studies described above (Mears et al., Tatla et al.) demonstrated that surgical site markings may degrade more easily with chlorhexidine solution than with povidone iodine or iodine povacrylex and isopropyl alcohol solution. To help assess which surgical skin marker and skin prep solution to use, some facilities have sought advice from surgical skin marker and/or skin prep solution manufacturers that may have unpublished performance data.

## Editor's Note

*As of press time, the editorial staff were made aware of another study (Burton et al.) that evaluated cross-contamination between patients from using the same surgical marking or nonsurgical marking pen on more than one patient. The study was presented at the October 2008 Interscience Conference on Antimicrobial Agents and Chemotherapy/Infectious Diseases Society of America annual meeting, held jointly by the American Society of Microbiology and the Infectious Diseases Society of America. The study has not been published; however, it has been described in mainstream medical news sources such as medpagetoday.com (<http://www.medpagetoday.com/MeetingCoverage/ICAAC-IDS/11440>). Burton et al. evaluated the potential for cross-contamination of strains of MRSA, Escherichia coli, vancomycin-resistant Enterococcus faecalis, and Pseudomonas aeruginosa from the tips of surgical marking pens containing gentian violet-based ink and nonsurgical permanent marking pens (e.g., Sharpie) containing alcohol-based ink. The Burton et al. study was excluded from the discussion above because the study details have not yet been published. Once the study is published, the topic may be addressed further.*

## Notes

1. Mayo Clinic. Gentian violet (topical route) [online]. 2008 Jan 1 [cited 2008 Aug 28]. Available from Internet: <http://mayoclinic.com/health/drug-information/dr600723>.
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