Effect of the Surgi-Sign® Marking System on Effectiveness of Surgical Site Prepping of Human Skin with 7.5% Povidone-Iodine USP Scrub or 10% Povidone Iodine USP Solution

Wade T. Goolishian, M.D., Tracy P. Thorpe, Ph.D. Director of Research, OR-6 LLC

Abstract

The incidence of wrong site/side surgeries performed in the U.S. each year is estimated to be between 1 in 17,000 and 1 in 117,000 cases. Despite multiple attempts by national medical organizations and the federal government to prevent this error, the problem continues to persist. This study addresses the concern that the Surgi-Sign Marking System®, a novel method for preventing wrong site/side errors might impair the effectiveness of standard antimicrobial surgical site prepping with povidone iodine scrub or solution and therefore increase the risk of surgical site infections. **Conclusion.** The Surgi-Sign Marking System®did not impair the effectiveness of 7.5% Povidone-Iodine USP Scrub Solution or 10% Povidone-Iodine solution in reducing bacterial growth from sampled human skin.

Introduction

Production pressures to maximize efficiency in the peri-operative period without a corresponding change in process have created safety issues in the operating room. One of these issues is operating on the wrong side, at the wrong site, on the wrong patient, or performing the wrong procedure (WSP). Due to a lack of accurate reporting, an exact incidence of the problem is difficult to obtain but the incidence of WSPs is estimated to be 1 in 17,000 surgeries to 1 in 117,000 surgeries annually.[1] WSPs occur most commonly in surgeries where there is laterality such as orthopedics, ophthalmology, urology, and neurosurgery.[2] It is also not isolated to the operating room as WSPs have been commonly reported wherever invasive procedures are performed such as interventional radiology.[3]

Currently, most surgeons mark their patients using a surgical marker in the preoperative

[1] PA-PSRS Patient Safety Advisory – Vol. 4, No. 2 (June 2007)

[2] Seiden, S., Barach, P., Arch Surg; 141:932 (2006)

[3] Mills, Neily J. et.al., Arch Surg; 144 (11) 1028-34 (2009)

Address correspondence to Dr. Goolishian, Department of Anesthesiology, Cape Cod Hospital, Hyannis, Massachusetts, 02601.

holding area as part of the Joint Commission's Universal Protocol® for all surgical patients.[4] However variability in site marking including type of mark and location are a major contributing factor to causing this error. In addition, limited patient participation, a lack of confirmation by other team members, and verification procedures based on memory instead of markings are also why this error persists.

The Surgi-Sign Marking System® was developed by OR-6, LLC. to address the key issues of marking and location standardization. The Surgi-Sign (Figure 1) is a temporary tattoo that has the proposed surgery printed on the front surface together with a space for the patient's initials and a space for the surgeon's initials. After the pre-operative nurse completes the initial patient admission, including a verbal confirmation of the correct procedure, site and side with the patient and the chart, the Surgi-Sign is applied to the patient's skin at or near the identified surgical site prior to surgery. The Surgi-Sign is easily removed in the operating room by lightly scrubbing with surgical prepping solutions leaving the surgeon's initials completely intact on the patient's skin. Since the Surgi-Sign tattoo is unsterile and covers the skin prior to surgical skin disinfection, there was a concern for an increased risk of bacterial contamination at the surgical site with the application and removal of the tattoo. We conducted a study using healthy volunteers comparing bacterial growth after a standard surgical site prep with either 7.5% Povidone-Iodine USP Scrub Solution or 10% Povidone-Iodine solution to bacterial growth after the application of the Surgi-Sign Marking System® followed by prepping with 7.5% Povidone-Iodine USP Scrub Solution or 10% Povidone-Iodine solution.

Figure 1. The Surgi-Sign® Temporary Surgical Tattoo

Study Design

Three healthy volunteer subjects (one male, two female) were selected for this study.

[4] Joint Commission, Hospital Accreditation Program-National Patient Safety Goals: UP 01.01.02 (2008)

The anterior thigh 3-4 cm above the knee or the mid volar forearm was chosen as the experimental site. All subjects were instructed not to shower or use any anti-bacterial soaps for at least 24 hours prior to each sampling.

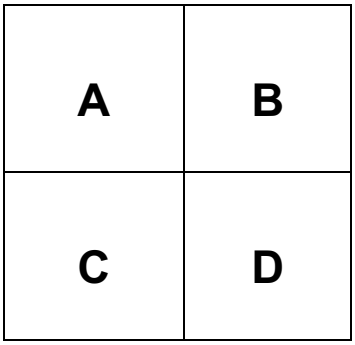
Experimental Method: The experimental site was divided into quadrants (Figure 2) using an indelible surgical skin marker (Medline standard marking pen, Medline Industries, Inc.). Samples were taken first from either quadrant A or B (**Skin**). A Surgi-Sign tattoo was then applied to the subject in both quadrants C and D according to the manufacturer's directions using non-sterile towel moistened with tap water for 30 seconds. After allowing the tattoos to air dry for 2 minutes, quadrants A and C were then vigorously scrubbed simultaneously using a sterile Foerster sponge forceps and gauze sponge soaked in 7.5% Povidone-Iodine USP Scrub Solution **(**Novaplus, Triad Group, Inc.) for 2 minutes in an up and down motion, carefully avoiding quadrants B and D (**Scrub).** After this, the amount of Surgi-Sign tattoo remaining was recorded. A second sterile Foerster sponge forceps and gauze sponge soaked in 10% Povidone-Iodine solution (Applicare, Inc.) was then used to coat the surface in all four quadrants (A-D) together using light pressure in an expanding circular motion from the center of the four quadrants. (**Paint**) The amount of Surgi-Sign tattoo remaining was again recorded. The coated skin was allowed to air dry for 30 seconds and samples were then taken from each of the four quadrants. A set of five plates (one for bare skin and one for each treated quadrant) was obtained for each data set. At total of fifteen data sets were obtained.

Sampling procedure and specimen handling: A sterile cotton tipped applicator (Puritan Medical Products, LLC) moistened with sterile 0.9% normal saline (Hospira, Inc.) was used to rub the skin of the subject in a circular 2 cm^2 area with moderate pressure for 2 minutes. The cotton tip was then immediately rolled across the surface of a 100 x 15mm Luria Agar petri dish (Carolina Biological Supply Company #216610) in three consecutive passes. A second moistened sterile cotton tipped applicator was then used to streak the remaining surface of the plates.

The petri dishes were incubated in a sealed, aerobic, non-humidified chamber at 37.4 (C) for 48 hours. Bacterial colonies were counted manually using a clear Plexiglas colony counter (Redco Science, Inc.) and a hand tally register. All bacterial colonies were counted and the results recorded as colony-forming units (CFU) per plate.

Statistical analysis: A total of 15 data sets were analyzed using Chi-square and a paired 2-tail Student's T test.

Figure 2. Quadrant layout



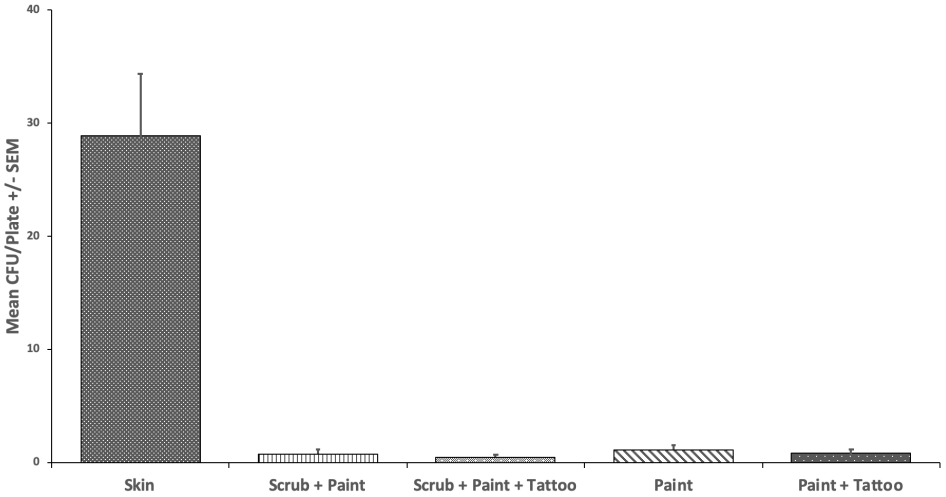
Results

There was bacteriological growth from 100% of samples taken from untreated skin and 30-60% bacteriological growth of at least one CFU from samples taken from skin treated either with 7.5% Povidone-Iodine USP Scrub Solution and/or 10% Povidone-Iodine Solution (Table 1). Staphylococcal species were the predominant bacteria cultured after 48 hours. In those areas treated with 7.5% Povidone-Iodine USP Scrub Solution, 100% of the Surgi-Sign tattoo was removed. In those areas treated only with 10% Povidone-Iodine solution, at least 80% of the tattoo remained after treatment. There was a statistically significant difference in the amount of bacterial growth from samples taken from untreated skin versus samples taken from skin with the Surgi-Sign tattoo, (p=.001). In addition, there was no difference in bacterial growth between samples taken from skin with the Surgi-Sign tattoo treated with either 7.5% Povidone-Iodine USP Scrub Solution or 10% Povidone-Iodine solution and identically treated samples taken from skin without the Surgi-Sign tattoo. (Figure 4).

Table 1.

	Skin	Scrub + Paint	Scrub + Paint +Tattoo	Paint	Paint + Tattoo
N	15	15	15	15	15
# plates with growth (%)	15(100)	5(33)	9(60)	5(33)	7(47)
P value	.001	--	0.58	--	0.39
mean CFU/plate	28.87	0.73	0.47	1.13	0.80
standard deviation	21.20	1.58	0.74	1.41	1.15
standard error	5.48	.41	0.19	0.36	0.30
% of tattoo present	-	-	0	-	80-100

Figure 4. Bacteriologic Growth after 48 hours



Discussion

Wrong site/side errors are associated with extremely negative publicity and a loss of public confidence in a particular healthcare system. It costs US hospitals approximately $800M each year in penalties, malpractice payments, and cost for additional care. Although various authors have speculated on the reasons why these errors occur, the most common themes are poor surgical marking and a reliance on memory of the "correct site" by the surgeon in the operating room. Healthcare prociders face increasing production pressures, as the number of procedures both inside and outside the operating room grow. The desired goal of increased "efficiency" has only exacerbated the risk of wrong site/side errors and further increased the demand for a solution.

The Surgi-Sign Marking System® was developed to address the limitations of current site marking protocols while still incorporating the successful elements of previous solutions in site identification. The Surgi-Sign Marking System® eliminates wrong-site/side errors by achieving all the key elements of the Universal Protocol. Specifically, the Surgi-Sign eliminates marking variability with fill-in boxes that place the operator's initials and operative date directly at the proposed operative site. A checkmark boxes for the patient, confirms the correct operative site has been identified. The standardized site marking and confirmations creates a universal expectation of how the site will be identified and also creates a shared responsibility with active roles for the surgeon and the patient. The Surgi-Sign® tattoo is made of a specially formulated hypoallergenic co-polymer acrylic similar to currently used surgical skin adhesives used to close wounds. However, the special formulation of the Surgi-Sign® allows the tattoo to be removed from the skin in seconds with just water or prepping solution, but all of the previously made pen marks including the patient and team confirmations remain visible on the skin in the operative site to identify the correct operative site.

Surgical site infections are also a major concern for surgeons. The process of creating a sterile environment at the operative site is critical. Some healthcare providers have expressed concern that any additional elements in the operative site including stickers, temporary tattoos, or even pen marks will lead to an increased risk of surgical site infections. Because the Surgi-Sign® tattoo is placed in the operative site and remains on the patient's skin until removed in the operating room, it could pose a potential risk. This study addresses whether that the Surgi-Sign Marking System®, a novel method of preventing wrong-site/side surgery might impair the effectiveness of standard antimicrobial surgical site prepping with 7.5% Povidone-Iodine USP Scrub Solution or 10% Povidone-Iodine solution and therefore increase the risk of surgical site infections. The results from this small study of healthy adults demonstrates that the application of the Surgi-Sign® tattoo did not impair the effectiveness of 7.5% Povidone-Iodine USP Scrub Solution or 10% Povidone-Iodine solution in reducing bacterial growth from sampled human skin. A limitation of our study was that we did not study every surface area of the body or other surgical prepping products. We believe however the results would be the same for typical skin flora regardless of the location or skin preparation. **Conclusion.** The Surgi-Sign Marking System® did not impair the effectiveness of 7.5% Povidone-Iodine USP Scrub Solution or 10% Povidone-Iodine solution in reducing bacterial growth from sampled human skin.

References

1. PA-PSRS Patient Safety Advisory—Vol.4, No.2 (June 2007)

2. Seiden, Samuel C. and Paul Barach, Arch Surg; 141:932 (2006)

3. Mills, Neily J. et.al., Arch Surg; 144(11) 1028-34 (2009)

4. Joint Commission, Hospital Accreditation Program—National Patient Safety Goals: UP 01.01.01 – UP 01.03.01 (2008)

Disclaimer

This study was sponsored by OR-6, LLC. Dr. Goolishian is the inventor of the Surgi-Sign Marking System®. Dr. Goolishian and Dr. Thorpe have a financial interest in OR-6, LLC, which manufactures the Surgi-Sign Marking System®.