Effect of the Surgi-Sign® Marking System on Effectiveness of Surgical Site Prepping of Human Skin with 2% Chlorhexidene w/v 70% Isopropyl Alcohol (ChloraPrep®)

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ABSTRACT

Wrong-site/side surgical errors continue to happen with alarming frequency throughout the world. Adoption of any new solution to prevent this error is predicated on not only preventing this error but also on not causing other problems such as surgical site infections. This study addresses the concern that the Surgi-Sign® Marking System, a novel method of preventing wrong-site/side errors might impair the effectiveness of standard antimicrobial surgical site prepping with chlorhexidene and therefore increase the risk of surgical site infections.

Conclusion. The application of the Surgi-Sign® tattoo and its subsequent removal did not impair the effectiveness of chlorhexidene in reducing bacterial growth from sampled human skin.

INTRODUCTION

Wrong-site/side surgical errors, operating on the wrong side or site of the body, happens with an alarming frequency throughout the world. In the United States alone the incidence is between 1:17,000 to 1:112,000 cases each year.[1] This means on average over 5 wrong-site/side errors occur in the US each day. Since the beginning of the Patient Safety Movement in the 1990's, great attention has been focused on eliminating this specific error. Multiple organizations including the federal government, regulating bodies like the Joint Commission, national medical organizations, and even medical device companies have attempted to end wrong-site/side surgical errors in a variety of ways. None of these attempts have succeeded and wrong-site surgical errors remain one of the top three most commonly reported medical errors each year. A common factor identified in many cases of wrong-site/side surgery is poor site marking.[2] A new device, the Surgi-Sign® Marking System, utilizing a specially-formulated temporary tattoo (Figure 1), was developed by OR-6, LLC to address the key issues of surgical site identification errors including the marking location, standardization of surgical marking, and confirmation of the correct operative site and side.

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

[2] Joint Commission Center for Transforming Healthcare, Wrong-site Surgery Project, Press release (June 2011)

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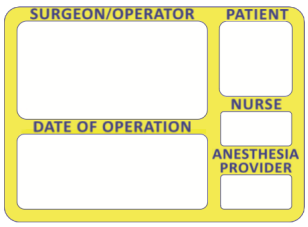
Figure 1.



The Surgi-Sign® tattoo is placed on the patient's skin during the preoperative phase of the surgical admission. The surgeon, patient, nurse, and anesthesiologist fill in the appropriate boxes in the tattoo design with a standard surgical pen marker to confirm that the correct surgical site is identified. The Surgi-Sign® tattoo is then wiped completely away from the patient's skin immediately prior to surgical prepping, using either a non-sterile moistened gauze or the surgical prepping solution applicator. The marks made with the pen, however, remain on the patient's skin for continued confirmation of the correct surgical site. Another key component of surgical safety is the avoidance of surgical site infections. Mitigation of infection risk is highly dependent on the effectiveness of surgical site prepping with antimicrobial solutions such as chlorhexidene to reduce pathogenic flora on the skin's surface prior to the procedure. Since the Surgi-Sign® tattoo is not sterile and is placed on the skin prior to surgical prepping, this study was done to evaluate whether application of the Surgi-Sign® tattoo or its method of removal impaired the effectiveness of standard surgical site prepping with chlorhexidene.

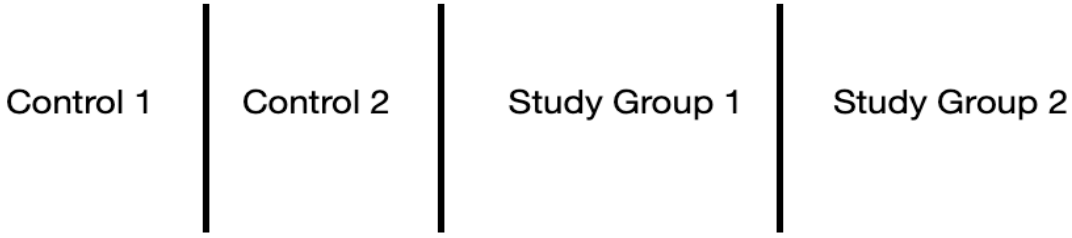
HYPOTHESIS

The application and removal of the Surgi-Sign® tattoo would not alter the effectiveness of surgical site prepping as demonstrated by no significant bacterial growth.

STUDY DESIGN

Two healthy volunteers, 1 male, 1 female were recruited for this study. All subjects were instructed not to shower or use any anti-bacterial soaps for at least 24 hours prior to each sampling. Bilateral areas on the volunteer's body (shoulder, breast, hip, thigh, and knee) were divided into four areas using a single use Mini Reg/Fine Tip XL Prep Resistant Ink Marker (Viscot Medical, LLC) (Figure 2.)

Figure 2.



Sampling procedure and specimen handling. Each data set consisted of four samples from each anatomic area. A sterile cotton tipped applicator (Puritan Medical Products, LLC) pre-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 plate. First a sample was taken from untreated skin (Control 1). Two Surgi-Sign® tattoos (OR-6, LLC) were then applied to the areas designated Study Group 1 and 2, respectively, according to the manufacturer's instructions. The empty boxes in the tattoo design were then written in with a Mini Reg/Fine Tip XL Prep Resistant Ink Marker (Viscot Medical, LLC). Chlorhexidene was then applied to the area designated Control 2 using a ChloraPrep® with Tint 2% w/v CHG and 70% v/v isopropyl alcohol patient preoperative skin preparation 26 ml applicator (Becton Dickinson) according to the manufacturer's instructions, being careful not to touch either area designated as Study Group 1 or 2. A sample was then taken from the area designated Control 2. The tattoo was then removed completely from the skin in Study Group 1 with a non-sterile gauze (McKesson Medical-Surgical) moistened with tap water using a gentle up and down rubbing motion for 10 seconds. The skin in Study Group 1 was then treated with chlorhexidene identical to the area designated as Control 2 using a new prep stick. Again, care was taken not to touch the area designated Study Group 2. A sample was then taken from the area designated as Study Group 1. The skin and tattoo in the area designated as Study Group 2 were treated with chlorhexidene with a third ChloraPrep® stick using a gentle up and down rubbing motion until the tattoo was removed completely, approximately 30-60 seconds. A sample was then taken from the area designated as Study Group 2.

All sample 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 plexiglass colony counter (Redco Science, Inc.) and a hand tally register. All visible bacterial colonies were counted and the results recorded as colony-forming units (CFU) per plate.

STATISTICAL ANALYSIS

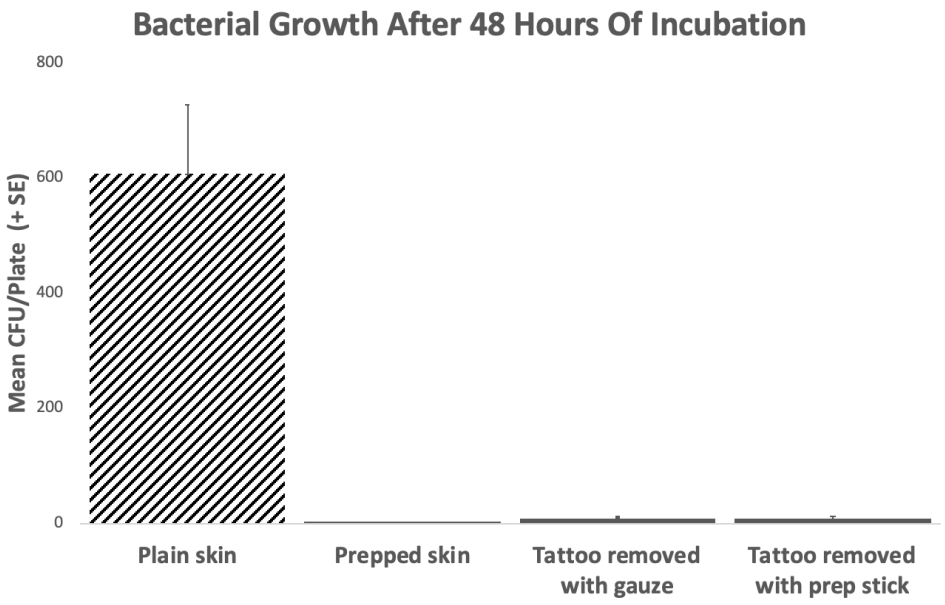
A total of 20 data sets were analyzed using a paired 2-tail Student's T-test.

RESULTS

Staphylococcal and Streptococcal species were the predominant bacteriological species identified in all plates after 48 hours of incubation. (Table 1)

Table 1.

	Plain Skin (Control 1)	Prepped Skin (Control 2)	Tattoo removed with gauze (Study Group 1)	Tattoo removed with prep stick (Study Group 2)
N	20	20	20	20
Mean CFU/Plate	608	1	9	7
Standard deviation	525	1	20	22
Standard Error	118	0.3	4	5



There was significantly greater bacterial growth from sampled Plain Skin (Control 1) versus Prepped Skin (Control 2), p value =.001, Tattoo removed with gauze (Study Group 1), p value =.001, and Tattoo removed with prep stick (Study Group 2), p value = .001. There was no significant difference in bacterial growth between Prepped Skin (Control 2) and Tattoo removed with gauze (Study Group 1), p value =.07, or Tattoo removed with prep stick (Study Group 2), p value =.2. There was no significant difference in bacterial growth between Tattoo removed with gauze (Study Group 1) and Tattoo removed with prep stick (Study Group 2), p value =.79.

DISCUSSION

There are an estimated 2036 wrong-site surgeries performed in the US each year.[3] It has remained one of the three most common medical errors reported to the Joint Commission for over three decades. It costs US hospitals approximately $800M each year in penalties, malpractice payments, and costs for additional care. Because of this hospitals and medical providers have been desperate for a solution to

[3] Mehtsun et.al. *Surgical Never Events in the United States,* Surgery 2013 Apr;153(4):465-72.

end this error. Previous suggestions have focused primarily on the person performing the procedure and site marking. In 1997, the American Academy of Orthopaedic Surgeons encouraged its members to "Sign your site" as a way of reducing wrong-site errors.[4] The continued report of wrong-site surgeries prompted the Joint Commission to develop the Universal Protocol® in 2005, expanding the focus to include the patient and also other providers in the process.[5] Key elements of the of the Universal Protocol® included marking the site with standardized marks, involving the patient in the marking process, and confirmation by the surgical team that the correct site was visibly marked and identified before incision. Variable success in achieving the elements of the Universal Protocol, especially visible surgical markings and patient involvement continued and wrong-site/side surgical errors have persisted. Several medical companies have also attempted to end wrong-site errors by developing different marking devices. The TAT Marker (Viscot Medical) and the Sandel® Correct Site Sticker (Ansell Sandel) are examples of skin stickers intended to identify the correct site. These devices have failed because of the same inability to ensure visible site marking, support for active patient involvement, and promoting surgical team confirmation. Providers continue to face increasing production pressures as the number of surgical procedures increases. The goal of higher "efficiency" has only exacerbated the risk of wrong-site/side surgical errors and further increased the demand for a successful solution to this problem.

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. Checkmark boxes for the patient, nurse, and anesthesiologist actively involve the patient and the entire surgical team to confirm 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 entire team 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

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[4] Canale, S. Terry, 1997 AAOS Sign Your Site Task Force

[5] Joint Commission, Hospital Accreditation Program-National Patient Safety Goals: UP 01.01.01 - 01.03.01, 2008.

preventing wrong-site/side surgery might impair the effectiveness of standard antimicrobial surgical site prepping with chlorhexidine 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, marking with standard surgical marking pen, and the subsequent removal of just the tattoo with either a moistened gauze or the application of chlorhexidine did not impair the effectiveness of chlorhexidine in reducing bacterial growth from sampled human skin.

CONCLUSION

The application and removal of the Surgi-Sign® Marking System did not impair the effectiveness of chlorhexidine as an antimicrobial skin prepping solution on human skin.

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DISCLAIMER

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