A Novel Method for Preventing Wrong-Site Procedure Errors

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Abstract

Wrong site errors have been one of the top three errors reported by hospitals for the past two decades. The Joint Commission proposed the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ in 2004, however key elements are often ignored and the error continues. We studied whether using a novel new marking system based on a rapidly dissolving temporary tattoo could improve performance of key elements of the Universal Protocol including standardized site marking, active involvement of the patient in operative site verification, and using the site markings during the Time-Out verification. Forty patients undergoing elective, unilateral or site-specific surgeries from multiple subspecialties were divided using the new marking system versus the surgeon's typical method for marking the surgical site. 100% of surgical cases marked using the new marking system were marked with the surgeons' initials, at the operative site, and verified by the patient marking themselves. This was significantly different from cases using the typical method of marking. In addition, 100% of Time-Outs performed on cases marked using the new marking system used the site markings to verify the correct operative site was identified. This was also significantly different from cases using the typical method of marking. This study demonstrates that using a novel new marking system based on a rapidly dissolving temporary tattoo greatly improves performance of key elements of the Universal Protocol including performance of the Time Out procedure.

Introduction

Wrong-site procedure errors broadly defined as performing a procedure at the wrong site, on the wrong side, or on the wrong patient have been a worldwide problem for decades. They have remained one of the three most common sentinel events reported to the Joint Commission since reporting began in 1995. Multiple reasons have been proposed for why these errors continue to occur but two of the most common factors are inconsistent operative site markings and a lack of confirmation by the patient and the care team that the correct site has been identified.[1] In 2004, the Joint Commission proposed the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™. Key elements of the Universal Protocol include:[2]

- A facility-consistent unambiguous marking, preferably initials, at or near the intended procedure site;
- Site marking before the procedure and with the patient involved, awake, and aware if possible;
- Final confirmation of the correct procedure site during the Time-Out by verification of the site marked

Despite strong advocacy for the Universal Protocol as a national patient safety goal, the key elements are often ignored and wrong-site errors continue to occur.[3] To address this, a study was done of a novel, new site marking system, the Surgi-Sign®, that uses a specially formulated dissolving tattoo to place the operator's initials together with confirming checkmarks from the patient and team on the patient's skin directly at the operative site that remain visible after surgical skin prepping. **(Figure 1).**

Figure 1.

Before Prep **After Prep**

Our hypothesis was that Using the Surgi-Sign Marking System would improve performance of key elements of the Universal Protocol including standardized site marking, active involvement of the patient in operative site verification, and using the site markings during the Time-Out verification. Providers would perceive the unique mechanism for achieving improved performance as helpful in eliminating wrong-site errors.

Methods

Part 1. Tattoo vs. No Tattoo. With IRB approval, 40 elective unilateral or site-specific surgeries were serially selected from the daily operating room schedule at a 283-bed community hospital. **(Figure 2)**. The cases were divided into two groups: **tattoo study group** and **no-tattoo control group**. Four surgeons (Vascular, General, Orthopedics, and Podiatry) and six circulating nurse volunteers comprised the tattoo group (n=20). Four surgeons (Orthopedic, General, Vascular, and Neurosurgery) and five circulating nurses comprised the no-tattoo group (n=20). The tattoo group was given a single practice session to verify they were using the Surgi- Sign according to the manufacturer's instructions for use. Circulating nurses were instructed to remove the tattoo by gently rubbing it off the patient's skin during their normal skin prepping routine using either Betadine®, Chlorhexidine™, or Duraprep™ solutions according to individual surgeon preference. The surgeons were responsible for instructing the patient in how to mark the proposed operative site. The unit secretary placed Surgi-Sign marking kits at each patient's bedside in the preoperative holding unit.

Study variables. A single observer who was not involved in either the site marking or the Time-Out process recorded the following:

- How the patient verified the proposed operative site (marking, verbally, none)
- How the proposed operative site was marked by the surgeon (initials, symbols, none)
- If the marks were less than or greater than 12 inches from the proposed operative site
- How the correct operative site was confirmed during the Time-Out procedure (by markings, with the chart only, or by memory)

All subjects were unaware of the specific variables being recorded.

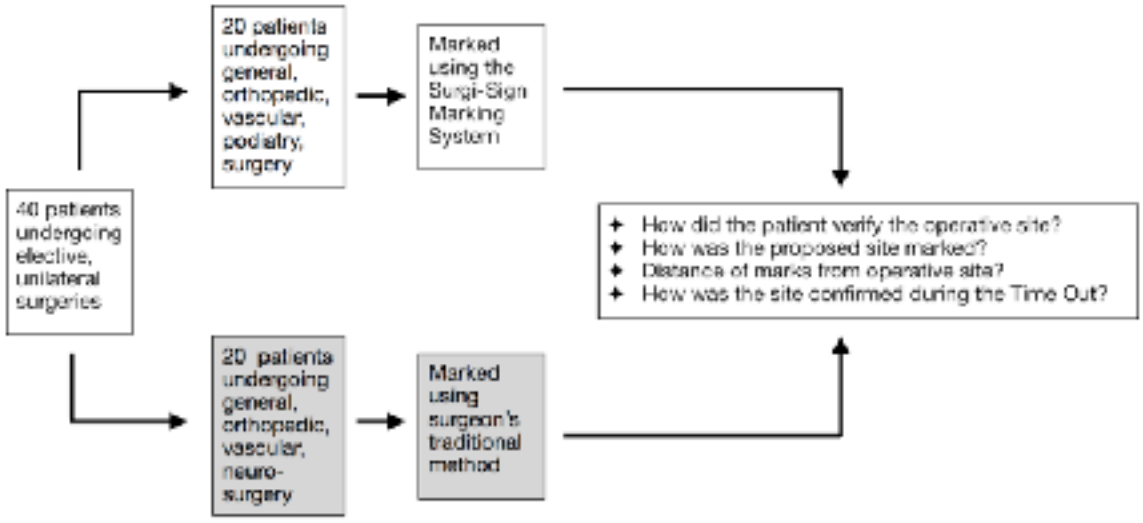


Figure 2. Study design for Surgi-Sign Marking System (Part 1)

Part 2. Provider Experience. The Surgi-Sign Marking System was then used in a second study (Part 2) by eight volunteer surgeons (1 Vascular, 2 General, 4 Orthopedic, 1 Podiatry) as part of their site verification process of 15 elective surgical cases. Surgeons and circulating nurses were given a single practice session for using the tattoo and the surgeon's were asked to also instruct the patient in site marking. The surgeons were then asked by questionnaire a) how easy the marking system was to use and b) if using it would help prevent a wrong-site error. The nurses were similarly asked a) how many minutes after starting to prep the skin did the tattoo come off, b) did checking the boxes help confirm the correct site, and c) if using the marking system would help prevent a wrong-site error.

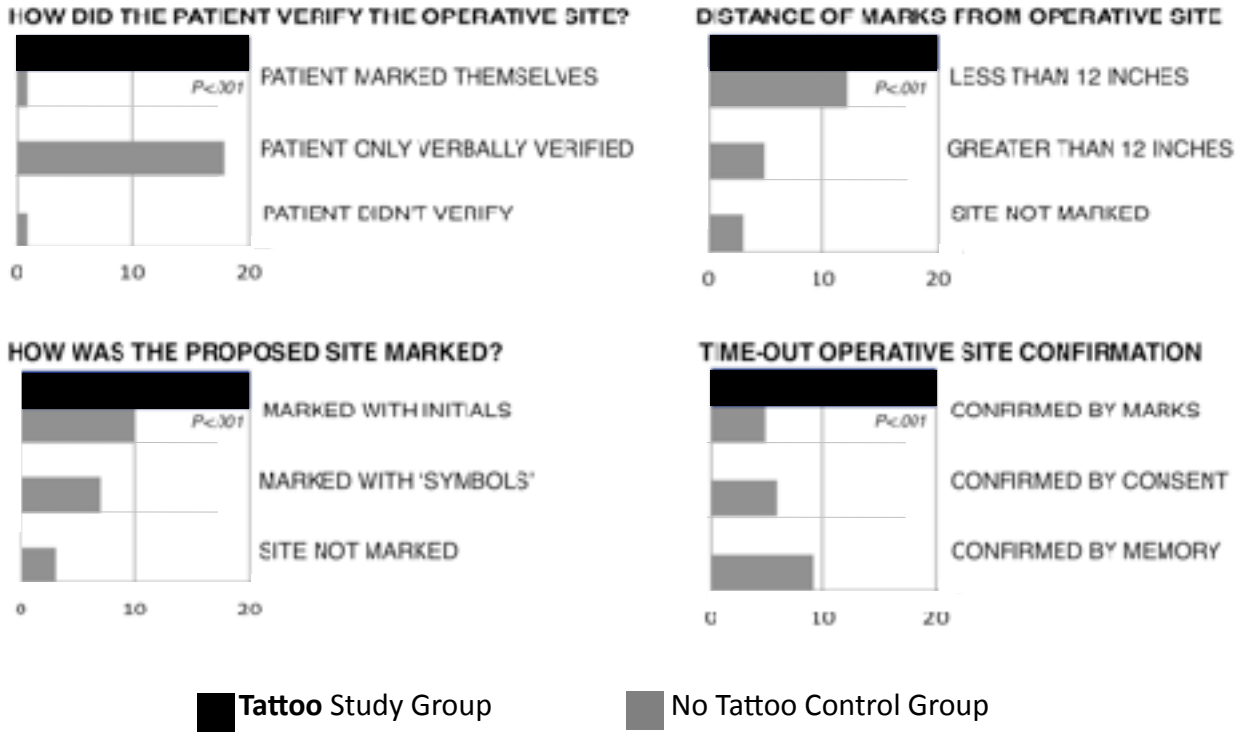
Statistical Analysis

The data was analyzed using a 2x3 Fischer 2-tailed test.

Results

In part 1 of the study, the Tattoo Study group was significantly different from the control group in all four variables**. (Figure 3).**

Figure 3. Tattoo vs. No Tattoo



In part 2 of the study, the surgeons completed 7 questionnaires and the nurses completed 13 questionnaires. 6/7 surgeons said the Surgi-Sign was very easy to use and 7/7 surgeons said using the marking system would help prevent a wrong-site error. 1/10 nurses noted the tattoo came off in less than 1 minute, 6/10 nurses noted the tattoo came off in 1-2 minutes, 3/10 nurses noted that it took 2-5 minutes. 10/13 nurses said the checkboxes helped confirm the correct site was marked and 3/13 said the checkboxes possibly helped. 9/13 nurses said using the marking system would help prevent a wrong-site error and 4/13 nurses said it would possibly prevent a wrong-site error.

Discussion

Everyday hospitals, providers, and patients worry about wrong-site procedure errors. Despite this it continues to occur an estimated 40 times/week in the US and results in permanent injury or death in 42% and 3% of cases respectively.[4] Attempts at specific tools and strategies for preventing wrong-site errors have been divided into macro level interventions such as accreditation standards and provider level interventions such as surgical checklists and

protocols.[5] The translation of macro interventions into globally adopted provider actions has proved especially challenging. Mark Chassin, President of the Joint Commission has pointed out it “involves changing the culture of hospitals and getting doctors to follow standardized procedures and work in teams.” Similarly, Peter Pronovost of Johns Hopkins University has pointed out that provider level interventions have also been hampered by issues such as checklist fatigue and “ritualized compliance”.[6] Health care systems now look to other fields with successful safety programs such as aviation to find more readily adopted tools and strategies. A good example is the adaptation of the aviation “2-challenge rule” to medical care, requiring confirmation of a medical treatment plan from a second provider before proceeding.[7,8,9]

I believe adapting these successful methods in a hybrid approach of both macro and a provider level intervention offers the best approach to preventing wrong-site errors. The Surgi-Sign® Marking System is a hybrid solution, incorporating both macro level elements such as the Universal Protocol together with provider level interventions such as the “2-challenge rule” for confirmation. In addition, simple tools like the Surgi-Sign that strongly support individual actions to prevent this error while minimizing disruption of workflows are more likely to be successfully used by healthcare providers.

Conclusion

The Surgi-Sign® Marking System, based on a dissolving temporary tattoo, greatly improves the performance of key elements of the Universal Protocol including performance of the Time Out procedure. The Surgi-Sign creates a mechanism for actively confirming the correct operative site with minimal disruption of workflow that the majority of providers believe would help prevent a wrong-site error.

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Disclaimer

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