Novel Skin Prep Technique Reduces OR Preparation Times in a Randomized Trial for Podiatric and Orthopedic Procedures

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ABSTRACT

The primary objectives of any high-volume surgery department should be patient safety, block time utilization and operating room efficiency. Reducing preparation time in the OR prior to actual surgery can improve operating room efficiency and utilization, but only if patient safety can be maintained. With this goal, this study evaluated a novel skin preparation technique using a device named ULTRAPREP™, a sterile, medical-grade plastic bag that is applied to the upper or lower extremity in the pre-operative holding area which allows for skin disinfection outside the OR (referred to as "disinfection bag"). The study compared preparation times required in the OR and antiseptic efficiency (through Colony Forming Units (CFU) counts) for traditional methods versus using the disinfection bag on a total of 115 patients undergoing podiatric or orthopedic surgeries (upper and lower extremities) in one hospital. The disinfection bag reduced skin preparation time in the OR from 16.8±3.5min to 10.9±2.7min, which was a 35.2% reduction, and was statistically significant ($p<0.01$). Skin antisepsis met safety standards of <15 CFUs for all cases regardless of preparation type at 48h and 72h. There was no statistical difference in CFU levels between the traditional and disinfection bag methods at 48h or 72h ($p>0.11$). Therefore, ULTRAPREP™ has shown the ability to decrease operating room time while keeping surgical site infection rates to a minimum. Minimizing activities in the OR optimizes use of this costly resource and brings overall savings to the surgery department.

INTRODUCTION

Advances in surgical technology and equipment have enabled surgeons to perform procedures faster and with greater precision while achieving successful surgical outcomes. Among other factors, this has led to a steady increase in the volume of surgeries performed. However, with the increased requirements of electronic medical records, the peri-operative setting has become more burdensome for operating room (OR) personnel. This increased burden along with the increased cost of healthcare has driven the need to reduce unnecessary or non-value-added activities in the OR.

OR time is both a major cost-driver and a tremendous source of revenue for hospitals;[1] it has been estimated that each minute in the OR costs from $22 to $133.[2] Inefficiency in OR utilization is negatively related to patient care and patient satisfaction, and is also one of the leading causes of surgeon dissatisfaction.[3-5] Improving OR time utilization may help reduce wait lists for elective surgeries.[3]

Researchers have examined the root causes of delays as well as process improvements that can help reduce turnaround times[1,5,6] and intraoperative time.[7] Surgical preparation time should last 10 minutes to 13 minutes [8] (SD = 8) regardless of the surgical category, since the time required is largely influenced by nursing competency and attitude, rather than case complexity.[9] Delays in surgical preparation have been attributed to equipment-related issues/delays, contamination of surgical instruments or delays in having these available, and insufficient communication and collaboration among the OR team and nursing staff.[8]

Another major driver of the current study is the desire to minimize the risk of surgical site infections (SSIs). Orthopedic surgeries are associated with higher infection rates due to the morphology of the foot, its environment and the types of skin flora.[10] Chang et al.[11] used a bag design and antisepsis agents on 51 patients and found that their method was safe and effective. The present study builds on this existing work to examine the time required and the efficacy of a disinfection bag product for use in orthopedic surgeries.

One area for improving efficiency in the OR is patient preparation. Pre-operative skin preparation impacts the surgical site infection rate, and thus morbidity, mortality, length of stay in the hospital, health care costs and readmission rates. ULTRAPREP™ (Prep Tech, LLC; Lake Charles, LA) is a novel sterile, medical-grade plastic bag (referred to as a "disinfection bag") that is applied to an upper or lower extremity in the pre-operative holding area and allows a nurse to complete disinfection prior to entering the OR (Fig. 1). This prospective, randomized study was performed to determine the clinical and time-saving benefits of using this device for upper and lower extremity orthopedic procedures in a single hospital outpatient surgical setting with respect to two aims.

Aim 1: Determine if using the disinfection bag for preoperative skin antisepsis while the patient is in the day surgery room results in reduced OR time compared to the conventional patient flow process.

Aim 2: Determine if the antiseptic efficacy of the disinfection bag meets or exceeds the immediate efficacy of conventional skin preparation techniques.

METHODS

This study used scheduled surgical patients who were prepped for surgery in one of two ways; the conventional method (or standard of care) or using a disinfection bag plus a disinfectant solution that has already been demonstrated to be effective for killing skin bacteria. In conventional patient flow, patient preoperative skin antisepsis is performed in the OR after anesthesia has been induced and the patient is positioned, but prior to surgery. Relocation of skin antisepsis to the day surgery room and the use of a disinfection bag is expected to reduce OR time. Closed containment of the antiseptic solution for skin antisepsis in the skin pre-op phase, as provided by the disinfection bag, is expected to provide a more uniform distribution of the antiseptic agent and exposure for a longer duration than conventional methods. Use of the disinfection bag is hypothesized to be equal to or better than the conventional approach in terms of the level of disinfection achieved and minimizing time in the OR.

Experimental Design

The study used a between-subjects, two-arm parallel, randomized block design to determine the impact of using the disinfection bag for skin disinfection on surgical times and efficacy compared to the current standard of care for disinfection. Consenting patients were randomized into two study arms: a control (conventional skin preparation technique) and a treatment (disinfection bag) group.

Conventional Prep/Control: The patient is prepped using ChloraPrep™ (2% chlorhexidine and 70% isopropyl alcohol). Up to 125 cc of antiseptic solution is "painted" onto the patient's skin using a sponge-on-a-stick. The entire preparation is performed in the OR and should take approximately 3-5 minutes, plus an additional 3 minutes IPA evaporation time with the extremity held in the air by a nurse.

ULTRAPREP™/Treatment: The disinfection bag enclosure contains the same solutions at the same concentrations as in the conventional study arm (i.e., 125 cc of 70% isopropyl alcohol and 2% chlorhexidine). The disinfection bag is placed on the patient's lower extremity or upper extremity while in the preoperative holding area. The disinfectant solution is poured into the disinfection bag with a scrubbing time of 3 min. Since the disinfection bag covers the extremity, an antiseptic environment is maintained outside of the OR. Once the patient is transferred to the OR, the liquid is drained out of the disinfection bag, and the bag is removed. The patient is draped after the solution on the patient's extremity has evaporated (no less than 3 min).

Randomization

The study used a randomized design in which patients were assigned to one of the study arms using nurses as a stratum. The study design was single-blinded, with patients blinded and randomly assigned to one of two study arms. The participating podiatrists and orthopedic surgeon were not completely blinded due to participant recruitment, but they were partially blinded by only entering the OR after patient preparation was complete. Laboratory assistants/technicians were partially blinded by having no study arm details on the laboratory specimen labels. The randomization process was stratified by a surgical nurse to neutralize the potential influence of nurse competency on the preoperative patient antisepsis time. Each participating nurse cared for an approximately equal number of patients from each study arm.

Randomization took place at the

Table I
Dependent Measures

Study Aim	Variable	Definition
#1 (Time)	Elapsed prep time in Day Surgery Room	Minutes – time elapsed between when the patient is admitted to the day room to when the patient is ready to be transferred to the OR
#1	Elapsed time for Skin Disinfection in the Day Surgery Room (Study arm #2 only)	Minutes – time from when the disinfection bag is placed on an extremity to when scrubbing is complete
#1	Elapsed time for Prep in OR	Minutes—time from when the patient is ready for prep to when the extremity is ready for draping
#1	Surgery time	Minutes –time from the incision start time to the end of the surgical procedure
#1, #2	Surgical wound classification (Class I – IV)	Categorical data
#1, #2	Patient characteristics	Race (White/ African American/ Other); Gender (Male or Female); Patient Age (Years)
#1, 2	Primary Circulating Nurse experience	Number of Years of Relevant Experience in Whole Numbers Novice < 3 y experience Moderate 3 ≤ 7 y Experienced: >7 y
#2	Colony forming units at 48 and 72 hours	Colony forming units of bacteria per plate

patient level, which should have minimized possible patient-specific confounding variables such as the personal hygiene of the patient, location and type of surgery, and the size of the patient preparation area.

Dependent Measures

The primary endpoint for Aim 1 was the reduction in OR time (in minutes) required for preoperative patient disinfection, i.e., from the time when the patient was ready for prep to the time when the patient was ready for draping. Most of the measures described in Table I are part of the patient's medical record (or chart). The primary outcome for efficacy (Aim 2) was the number of colony forming units (CFU) per plate. For both study arms, the initial swab to determine the baseline bacterial load was taken in the day surgery room before any disinfection was started. A second culture (test specimen), which is the focus of this study, was taken after disinfection, immediately prior to application of the sterile drape (in the OR).

Participants

Patients associated with the clinical members of the research team (two podiatrists and one orthopedic surgeon) could participate in the study. Inclusion criteria included elective, weekday, prescheduled, podiatry and similar orthopedic cases scheduled at Lake Charles

Figure 1. ULTRAPREP™ Device. (Prep Tech, LLC; Lake Charles, LA)

Memorial Hospital (LCMH) that were classified as "clean" (Class 1) as defined by the American College of Surgeons.[12] All cases were reasonably similar in terms of the area of surgery (e.g. feet, bunions, toes, hands) and had a similar skin surface area with the same level of nurse staffing/support. Exclusion criteria included weekend or emergency surgeries, pregnancy, and open wounds that would be classified as "contaminated" or "dirty" by the surgeon.

Patients completed the informed consent process while with their physician prior to the day of surgery. All IRB approvals and documentation were managed by a third party (Clinical Trials of SWLA, LLC), and approval was obtained for the study through Quorum Review IRB.

Sample Size

The sample size calculation was based on the following assumptions: a mean prep time of 13 min (SD = 8 min) for the control group, and a mean OR time of 6 min (SD = 5 min) for the experimental group. With 80% power, the minimum sample size per study arm was 36 patients. After adjusting for possible missing data and a Bonferroni correction for multiple comparisons, we determined that a reasonable total sample size was N =114 (or 57 participants per study arm) for study Aim 1 related to timeliness. Few analogous measures were available for estimating the sample size for the efficacy measure (Aim 2); however, a pilot study that demonstrated equal efficacy as the disinfection bag found a relatively high percentage of unusable specimens. For this reason, a sample of 30 per study arm or N = 60 was considered to be reasonable. Following these recommendations, 57 patients were enrolled in the first arm, and 58 were enrolled in the second arm, for a total of 115 participants.

Setting

The study was performed at Lake Charles Memorial Hospital (LCMH), a community hospital with 352 licensed acute care beds and 16 operating rooms. Each OR has one Registered Nurse (RN) and one surgical prep technician. For the day surgical area, pre-op nurses prepare patients and one RN manages the entire surgical preparation.

Patient flow for same-day surgical patients follows these steps: pre-assessment, meeting with the anesthetist, and transfer to the OR. Once in the OR, patients are transferred to the OR table, anesthetized, and positioned on the OR table. After the skin is disinfected by nurses and is allowed to dry for 3 minutes, the patient's extremity is draped and ready for surgery.

Procedures

Prior to data collection, the clinical research coordinator (CRC) provided hands-on training for the nurses to teach them how to use the disinfection device, how to obtain cultures from the patient's foot or hand, and how to fill out the data-collection form. As patients were enrolled, the CRC randomly assigned patients to one of the study arms. The following steps describe the procedure for data collection on the day of surgery.

1. Nurses who were scheduled to work in select ORs with a designated physician were informed by the CRC the arm to which each patient was assigned.
2. The CRC completed data-collection worksheets as information became available.
3. The nurse or CRC noted the total time (in minutes) that the patient spent in the day surgery room and how much of that elapsed time was prep time.
4. While the patient was in the day surgery room, the designated prep nurse took the first culture or swab of the patient's nailbed on the great digit (great toe) and the spaces between the toes or the thumb and the space between the fingers, before any preoperative disinfection began. The nurse placed the specimen in a pre-labeled laboratory vial (with no PHI), and the vials were stored in a safe place near the day surgery rooms.
5. Once the patient was transferred to the OR, the nurse or CRC recorded the time-related variables when anesthesia was induced and the time for surgical disinfection (control arm) and when patient prep was complete and the patient was ready for draping.
6. Just before the patient's extremity was draped, the OR nurse took the next culture/specimen (post-patient antisepsis) for the efficacy study. At this time, the CRC took both lab specimens to the hospital's laboratory for processing and culture.
7. The surgery time began at incision, and this, along with the time to completion, was recorded on the data-collection worksheet.

For the laboratory specimens, each sample followed a consistent protocol, plated consistently and left to culture for a maximum of 72 hours; each plate was examined and CFUs per plate were counted. Laboratory results were recorded on the hospital patient chart and shared with the CRC for input into data-collection endeavors.

Statistical analysis

The appropriate analysis for a randomized design is an Intention to Treat analysis (ITT), which includes all randomized participants. Descriptive analyses included mean times for parts of the patient flow process, standard deviations, and cross tabulations (or 2x2 tables). The statistical analysis included checking for a normal distribution and the homogeneity of variance, followed by analysis of variance (ANOVA) to determine any significant differences ($\alpha = 0.05$) in the dependent measures due to the study arm or anatomical location using JMP 17.0 Pro. Both time and efficacy variables violated the ANOVA assumption of normal distributions, so data were log-transformed prior to analysis. Effect sizes were calculated by eta-squared calculations.

RESULTS

A total of 115 patients participated in the study: 57 underwent conventional preparation techniques and 58 were treated with a disinfection bag. All nurses had a minimum of five years of experience. Descriptive statistics for the time variables and efficacy variables are provided in Tables II and III. Overall, the disinfection bag group showed a 35.2% reduction in skin preparation time (from 16.8±3.5 min to 10.9±2.7 min; p=0.01). ANOVA revealed a significant main effect for treatment ($F=113$, $p<0.01$, ES= 0.51) and anatomical location ($F=6.32$, $p=0.01$, ES=0.05), but not a significant interaction effect between treatment and

Table II
Mean (Standard Deviation) of Time Variables (minutes)

	Conventional		Disinfection Bag	
	Lower Extremity (n=17)	Upper Extremity (n=40)	Lower Extremity (n=22)	Upper Extremity (n=35)
Room to Drape	18.0 (3.9)	16.3 (3.2)	11.7 (3.2)	10.3 (2.2)
Surgery Time	44.7 (28)	29.0 (17)	50.7 (22)	32.6 (13)
Time Bag On	-	-	30.0 (11)	34.4 (22)

Table III
Mean (Standard Deviation) of Efficacy Variables

	Conventional		Disinfection Bag	
	Lower Extremity (n=16)	Upper Extremity (n=40)	Lower Extremity (n=22)	Upper Extremity (n=36)
CFU avg, 48h	0.146 (0.298)	0.217 (0.620)	1.02 (2.37)	0.388 (0.930)
CFU avg, 72h	0.255 (0.534)	0.258 (0.660)	1.62 (3.38)	0.500 (0.991)
(Note: all samples passed the safety range of having CFU <=15)				

anatomical location ($F=0.04$, $p=0.84$, $ES<0.01$). Regardless of the treatment, the prep time for the lower extremity took on average 57 seconds longer to complete (6.5% increase in prep time).

All samples taken for bacterial counts passed the safety range of CFU $\leq$ 15 regardless of the study arm. The maximum CFU at 48h was 3.33 for conventional and 9.67 for the disinfection bag. The maximum CFU at 72h was 3.33 for conventional preparation and 11.0 for the disinfection bag. ANOVA did not reveal a significant main effect on average CFU at 48 hours for treatment ($F=2.06$, $p=0.16$, $ES=0.069$) or anatomical location ($F=0.0024$, $p=0.96$, $ES=0.0001$), or a significant interaction effect between treatment and location ($F=0.97$, $p=0.33$, $ES=0.033$). Likewise, ANOVA did not reveal a significant main effect on average CFU at 72 hours for treatment ($F=2.74$, $p=0.11$, $ES=0.070$) or anatomical location ($F=0.62$, $p=0.44$, $ES=0.016$), or a significant interaction effect between treatment and location ($F=0.94$, $p=0.34$, $ES=0.024$).

DISCUSSION

This study investigated the benefits of using a new medical device (ULTRA-PREP™, Prep Tech, LLC; Lake Charles, LA), for surgical skin preparation. The device allows for skin disinfection outside the OR in the pre-operative holding area, which in theory may reduce the use of costly OR resources, assuming that the device is at least as effective as conventional skin preparation techniques. The study followed 115 patients, divided into conventional and disinfection bag groups, through lower and upper extremity podiatric and orthopedic same-day surgeries to record preparation time and the efficacy of skin preparation (measured in terms of bacterial CFUs at 48 and 72 hours post-disinfection). Overall, the preparation time in the OR decreased by approximately 6 min (35%) while efficacy was statistically equivalent for both types of skin preparation.

Prepping patients outside the OR has several advantages. First, reducing prep time in the OR may reduce the costs of using already strained OR resources by shifting some work to the pre-operative holding area. Second, it reduces the time the patient spends under anesthesia, which could lead to improved outcomes.[13] Finally, using the bag over the extremity allows for the disinfectant to remain on the skin for longer, which can ultimately prevent infections. Recent reviews and studies recommend chlorhexidine and alcohol solutions for foot and ankle surgery which was used in both groups in the current surgeries.[14,15]

Use of a disinfection bag carries some potential drawbacks that will need to be addressed in future studies. Future studies may take a more comprehensive approach to tracking time and resources used from the time the patient arrives for surgery to the end of the preparation period (ready for first incision). Transferring preparation time outside the OR may not save much overall surgical costs depending on how a hospital bills. Theoretically, the resources required in the pre-operative holding area are less expensive than those in the actual OR, but capturing those savings and translating them to patient or hospital savings may be difficult. Furthermore, simply moving work to a different location may not decrease the overall time for the patient.

On the other hand, there is a potential for increased revenue or cost savings by prepping the patient outside the OR. The current study found a reduction in OR time of 6 min, which in high-volume surgical centers over the course of a day, may allow for an extra case to be performed, since many procedures on the foot or hand are of shorter duration. Alternatively, the time savings may allow the surgical team to finish earlier and avoid overtime costs. Interestingly, the current study did show slightly longer surgery times for the disinfection bag group (by approximately 6 min for the upper extremity and 3 min for the lower extremity). However, these differences were not statistically significant ($p=0.158$ and $p=0.228$, respectively).

The study also has a few weaknesses that can be addressed. The surgeries were limited to those on the hands and feet, and to three surgeons at one hospital, thus constraining the patient flow steps to one example. The impact of using a disinfection bag may differ depending on the surgical location, the physical layout of the environment, and the flow of patients through various care providers. There were three outliers in the disinfection bag group with higher levels of CFUs, though none exceeded the acceptable upper limits. However, this may indicate a need to examine the methods more closely. Both groups used the same disinfectant solution, but preparation with the disinfection bag may benefit from more vigorous scrubbing, as recommended in other studies.[14] Since the current study, an improved version of the disinfection bag, with an abrasive surface on the bag, has been developed, which may improve disinfection even further.

Future studies can continue to evaluate the disinfection bag approach for preparation for surgery on the extremities in terms of overall costs and time savings. The ULTRAPREP™ device is approved for use by the FDA in the US, so hospitals can choose to use the device in perioperative areas if deemed acceptable. The scale of time-savings found in this study indicates that the greatest advantages may be observed for surgical centers with high volumes of short-duration cases. In this scenario, extra cases may be scheduled without incurring overtime from the surgical team, thus increasing access for patients and efficiency and revenue for the organization.

This initial evaluation of the ULTRAPREP™ device shows that the OR preparation time for podiatry and orthopedic cases of the hands and feet can be reduced by 35% while maintaining equivalent efficacy in terms of disinfection compared to conventional preparation methods. This device can optimize OR utilization, potentially leading to cost reductions and improved workflow. Likely, it is possible that additional time savings may be achieved as nursing staff become more familiar with the device and efficiency improves. **STI**

AUTHORS' DISCLOSURES

LI has received Research Support from PrepTech LLC. The other authors declare that there are no conflicts of interest.

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