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RESULTS: The HPPL trials contaminated the entire room with droplets that were too numerous to count. The HPPL-S trials reduced the number of droplets in quadrants outside of the "head right" quadrants, to a range of 0-12 droplets. In addition, the HPPL-S trial reduced the droplet distance to levels comparable to or below the GF and ABS droplet distance.

DISCUSSION: This is the first study to characterize splash patterns seen with different irrigation systems. The addition of an inexpensive splashguard during high-pressure irrigation drastically reduced splash displacement. Decreased splash displacement theoretically reduces OR contamination and the resultant risk of nosocomial contamination.
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### Author Comments:
In vitro characterization of lavage splash and effectiveness of lavage shield

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INTRODUCTION

The use of fluid to remove debris from surgical and/or traumatic wounds has been the standard of care for centuries. Historically, gravity-based fluid delivery systems were utilized to pour fluid from a holding vessel into an open wound to flush contamination from the operative field. Bulb syringes, pressurized by the surgeon’s hand squeeze force have also been used for this purpose. More recently the use of small electrically powered mechanical pumps have become a common place method of delivering pressurized intermittent flow of liquid in order to wash contamination and debris from wounds, so called “pulse lavage” systems.

In the 1960’s, the United States Department of Defense medical staff recognized wound contamination as a major cause of delayed healing in casualties injured during the Vietnam conflict. The clinical application of pulse lavage systems in the treatment of contaminated battle wounds was the subject of several published studies. Numerous studies have since reported on the application of pulse lavage systems in the civilian wound management setting. Both positive and negative reports on the merits of the civilian application of mechanical pulse lavage fluid for wound washing can be found in the medical literature since that time. These electric powered pumps have now been collectively referred to as High-Pressure Pulse Lavage (HPPL) systems. Many manufactures currently market HPPL devices.

Several reports have demonstrated the risk of nosocomial infection due to residual contamination on surfaces in hospitals. Known high-risk nosocomial infection pathogens including methicillin resistant Staphylococcus aurous (MRSA), vancomycin resistant Enterococcus species
(VRE), Clostridium difficile spores, Pseudomonas species, Actinobacter species and Norovirus have been shown to survive on dry surfaces for up to 5 months\textsuperscript{26,34}. Guidelines have been published on the proper cleaning of hospitals and their contents\textsuperscript{32}. In spite of these measures, nosocomial infections continue to have a major impact on morbidity, mortality and increased medical related costs\textsuperscript{23}.

To date no study has evaluated the contamination caused to the surrounding physical space, equipment/furniture and surfaces of the operating room through the use of any irrigation system. Our goal is to compare the spread of fluid from the surgical field into the surrounding room when various irrigation systems are employed. Additionally, we will demonstrate a simple method to reduce splash back and subsequent contamination through the use of an inexpensive disposable physical splash barrier.
MATERIALS AND METHODS

To characterize splash patterns of various irrigation methods we measured splash distance, volume of irrigation fluid “lost” during the procedure, and the patterns of contamination. To do so, we have chosen four common methods of intraoperative irrigation systems including: gravity flow (GF), asepto bulb syringe (ABS), high-pressure pulsatile lavage (HPPV), and high-pressure pulsatile lavage with splash shielding (HPPV-S). Six experimental iterations were preformed.

Trial #1: Gravity Flow (GF): Simulation of gravity-based irrigation for wound cleansing. A 1L stainless steel pitcher was used to pour irrigation fluid over the knee model from a distance of 15cm. Force of the irrigation was gravity based. The simulation surgeon was instructed to irrigate the knee model through a gentle wrist turning maneuver with the pitcher positioned directly above the model.

Trial #2: Asepto Bulb Syringe (ABS): A bulb syringe irrigation simulation was evaluated. The bulb syringe is generally considered a low-pressure method of cleansing a wound. This experiment used a 50ml Davol® plastic and rubber surgical bulb syringe. The simulation surgeon was instructed to irrigate the knee model with the bulb syringe from a distance of 15cm directly over the knee model.

Trial #3 and Trial #4: High-pressure pulse lavage without splash shield (HPPL): To investigate the splash generated by high-pressure irrigation systems, two different commercial systems were utilized, the Stryker® InterPulse (Stryker) and the Davol® Simpulse SOLO High Flow Tip (Davol). Irrigation of the knee model with each respective HPPL system was conducted from a
distance of 15cm above the knee model.

Trial #5 and Trial #6: High-pressure pulse lavage with splash shield (HPPL-S): A simple splash shield device was utilized with both of the HPPL systems in separate trials. A radiographic plastic cassette cover 60 cm by 120 cm was fashioned into a splash barrier by cutting away one of the sealed corners, creating an opening through which the HPPL system could then be inserted. The shield was tented about the knee model and the HPPL systems were again used to simulate irrigation 15cm above the knee model.

A Sawbone® right knee model with elastic cording as the knee joint served as the experimental model in an operational operating room (OR) of a community hospital actively engaged surgical management of patients in all surgical subspecialties. The contents of the OR were removed with the exception of the anesthesia equipment, the surgical table and the fixed overhead lighting system. The OR had been terminally cleaned per standard protocol and had been out of service for 18 hours prior to this experiment. The walls were then covered with Husky® 2 mm clear plastic sheeting from ceiling to ground, using adhesive tape at the ceiling to hold the sheeting up. The anesthesia equipment, at the head of the surgical table was draped in a similar fashion. The surgical table padding was removed and the table was then covered with Husky® 2 mm plastic sheeting that reached the floor. The OR floor was covered with standard white fabric sheeting, obtained from the facility central supply. After initial OR preparation and between each trial iteration, the area was surveyed with the UV light source and confirmed that no visible contamination was present. The floor sheeting was changed following each trial in order to ensure the area was free of residual fluorescent splatter contamination. The plastic wall coverings were wiped clean under UV inspection to ensure the walls were also free of residual fluorescent splatter contamination between each trial.
The dimensions of the room were measured as noted in Figure 1. Each experimental trial was performed in the same operating room. The surgical table used was an Amsco® 3085 SP with a length of 200cm and width of 50cm and set at a height of 81cm which was constant throughout all trial iterations. The experimental quadrants of the room divided into patient’s head left (HL), patient’s head right (HR), patient’s Foot Right (FR), and patient’s Foot Left (FL) (Figure 1). The surgeon was positioned on the table’s right side at mid table during all trials. The knee model was attached to the surgical table with the use of a clamp and flexed to 100 degrees. The knee model was positioned on to mimic the left knee of a supine patient. The two over-head surgical lights with a diameter of 58.4 cm were positioned directly over the head of the bed and at the foot of the bed, angled 45 degrees directed towards the knee model. Each light was positioned 90 cm above the table at its lowest point.

Study participants consisted of a simulation surgeon and an observation team of 6 persons. The simulation surgeon wore a standard surgical hood, Stryker® T5 “Personal Protection System” and a Kimberly Clark Standard surgical gown, latex surgical gloves and fluid impervious protective boots. Clean disposable surgical shoe covers were worn and changed by observation team upon entering/exiting OR.

To trace the irrigation fluid during all experimental models, a fluorescent chemical marker (uranine dye, yellow 73, CAS No 518-47-8, Trace-A-Leak®) was added to the irrigation and used during all iterations. 2.5 tablets of florescent dye were dissolved in 10 liters of tap water at 25C. An ultraviolet (UV) light source (a hand held lamp with 13 watt compact florescent light black light) was utilized to effectively illuminate this fluorescent liquid. A “splatter droplet” was defined as fluorescent liquid outside of the collection vessel and visible to all observers under the UV light source. The splattered liquid droplets were evaluated for number per quadrant and
maximum distance from the center of the knee model.

A plastic 6-liter basin was positioned beneath the flexed knee model as a collection vessel, to gather the fluid after the irrigation simulation had washed over the knee model. The amount of fluid experimentally irrigated during each cycle was measured by mass and converted to milliliters (mL) using the density of water (1g/ml). Each trial consisted of 3Kg of the fluorescent dye-containing fluid. An electronic scale, manufacturer OXO®, was used for mass measurement. The mass of fluid was measured prior to each irrigation trial and adjusted to exactly 3Kg. The mass of collected fluid was then measured after each trial. The net difference between pre and post trial mass was assumed to be fluid lost. Fluid not gathered in the collection vessel but pooled on the table was not measured directly. Fluid splattered into the OR was evaluated by the quadrant method previously described.
RESULTS

The data collected from each trial is supplied in Table 1. The data collected includes: initial weight of irrigation in mL, recovered weight of irrigation in mL, fluid lost in mL (difference from initial and recovered irrigation), surgeon splash pattern, number of droplets in quadrant (HR, HL, RF, LF), and furthest droplet in quadrant distance (HR, HL, RL, LF).

Fluid Lost

The gravity flow had the least amount of fluid lost at 47 mL whereas the Stryker® InterPulse without splash shield had the most fluid lost at 869 mL. In comparing the Styker without splash shield to the Davol without splash shield, an additional 366 mL of irrigation was lost (869 mL vs. 503 mL), an amount that cannot be accounted for by a change in methods and likely due to differences in engineering specifications of the HPPL. The addition of the splash shield drastically reduced fluid lost in both the Stryker with splash shield and the Davol, comparable to the ABS trial (222 ml vs. 209 ml vs. 248 ml, respectively).

Quadrant droplet numbers

The number of droplets in the quadrants varied with each trial (Table 1). With exception of the gravity flow trial, most trials had frank pooling in the HR quadrant at the feet where the surgeon stood. Frank pooling was also noted at the RF quadrant during the asepto bulb syringe trial. The HPPL without splash shield contaminated the entire room with droplets that were too numerous to count. The HPPL-S trials reduced the number of droplets in quadrants, outside of the HR quadrants, to a range of 0 to 12 droplets.

Droplet distance travelled
The furthest distance droplets travelled in the quadrant was more predictable. The gravity flow trial furthest droplet distance ranged from 138 cm in the HR quadrant to 201 cm in the LF quadrant. The asepto bulb syringe trial droplet distance ranged from 170 cm in the HR quadrant to 213 cm in both the HL and RF quadrants. The HPPL trials droplet distance ranged from 272 cm (HL) to 412 cm (RF). Droplets were recorded on the overhead light positioned above the patient's head (Stryker: 2 droplets, Davol: 20 droplets). 15 droplets were recorded on the elbow of the overhead light fixture (Stryker). On the plastic sheeting covering the anesthesia equipment, there were 5 droplets recorded at a maximum height of 179 cm during the Stryker trial and too numerous to count during the Davol trial at a maximum height of 122 cm. The HPPL-S reduced the droplet distance to levels comparable to or below the gravity flow and asepto bulb syringe droplet distance with no contamination of anesthesia equipment or overhead lights. The Stryker with splash shield droplet distance ranged from 0 cm (HL and LF) to 183 cm (RF). The Davol with splash shield droplet distance ranged from 0 cm (HR and LF) to 150 cm (RF).
Operative site lavage is an effective, regularly used intraoperative procedure with wide surgical application. Advancement in technology of lavage systems has produced more effective means of wound debridement and decontamination. It has become common practice for orthopedic surgeons to utilize these technologies in many procedures such as septic joints, abscesses, and osteomyelitis in addition to aseptic procedures such as total joint arthroplasty and open reduction internal fixation. Although the positive and deleterious effects of operative site lavage have been well characterized in the literature, there is a paucity of data investigating contamination of the intraoperative surrounding environment due to lavage back splash. Several reports have demonstrated the risk of nosocomial infection due to residual contamination on surfaces in hospitals\textsuperscript{12,14,28,29}. With risk of splash back from lavage and subsequent surrounding surface contamination, investigation of OR contamination with different lavage systems is warranted. The current investigation characterizes the splash pattern and resultant OR contamination of GF, ABS, HPPL, and HPPL-S lavage techniques. The resultant data effectively demonstrates that among all trials, HPPL trials demonstrated the highest contamination and fluid loss, whereas the addition of a splash shield to the HPPL exhibited the least amount of surrounding contamination and a drastically reduced fluid loss.

Historically, low-pressure devices including gravity based fluid delivery systems and hand pressured bulb syringes have been used to flush contamination from the operative field. More recently, utilization of small electrically powered mechanical pumps (HPPL) has become a commonplace method of delivering pressurized intermittent flow of fluid in order to wash contamination and debris from wounds. HPPL systems have been shown to have positive long-term effects on bacterial reduction and wound infection\textsuperscript{10,22}. HPPL is a more effective method of
irrigation to overcome bacterial soft tissue adherence than low-pressure systems such as gravity flow and bulb syringe methods\textsuperscript{8,30}. Although many beneficial effects of HPPL systems have been documented, there have been studies that have documented deleterious effects of these systems including significant delays of early bone healing in comparison to conventional syringe\textsuperscript{15}. In addition, Bhandari et al showed that HPPL resulted in bacterial propagation inside the intramedullary canal of a fractured tibia up to 4 cm from the fracture site\textsuperscript{6}. The purpose of this study was not to characterize effectiveness of wound decontamination with each lavage technique; but rather, to illustrate dramatically different splash patterns of lavage techniques. With the continued use and development of HPPL systems, it is important to recognize that among all techniques tested, HPPL systems resulted in the greatest amount of OR environment contamination and fluid lost. With the use of a simple splash shield, we were able to drastically reduce splash amount, splash distance, and fluid lost. Although the effectiveness of a splash shield on in vivo intraoperative splash reduction has not been studied, we speculate that this could result in a significant reduction in OR environmental contamination and subsequent nosocomial infection.

It has been widely accepted that environmental contamination plays an important role in the transmission of pathogens such as Methicillin-Resistant Staphylococcus Aureus (MRSA), vancomycin-resistant Enterococcus species (VRE) species, Clostridium difficile spores, Pseudomonas species, Actinobacter species and Norovirus in the hospital setting. These known high-risk nosocomial infection pathogens have been shown to survive on dry surfaces for as long as 5 months\textsuperscript{26,34}. With many infected operative cases per week, one can see how this may easily add up to a highly contaminated surgical suite if not appropriately addressed. Improved surface decontamination has been shown to decrease environmental contamination of MRSA and VRE\textsuperscript{17}. 
and decrease the likelihood of patients acquiring VRE\textsuperscript{25} and developing MRSA infections\textsuperscript{13}.

There continues to be a much-needed emphasis placed on primary preventative measures of infection such as hand washing, proper sterile technique, and specific airflow patterns in operating rooms. However, the current data clearly demonstrates the significance of OR contamination, particularly with use of HPPL, and therefore the inferred increased risk of contamination to health care workers and patients that are in cases "to follow". The data presented here clearly demonstrates a need for greater emphasis on preventing OR contamination via surgical site splash back with methods such as the lavage shield. Further in vivo investigations are warranted to elucidate the potential beneficial effect on reducing pathogen dissemination with the use of these techniques.

We recognize there are weaknesses of this study. We used an artificial model, the Sawbone\textregistered knee, without normal tissue wound complexities and angled surfaces. The typical soft tissue envelope acts somewhat as a barrier in itself. The amount of fluid lost was very likely more extensive than one would have seen with an actual wound. We chose the Sawbone\textregistered model to act as an approximation and to avoid contamination of an OR in-service during unscheduled time. Another weakness was the sampling size. We completed each method only once and we recognize greater precision of data and statistical power can be created across multiple trials during each testing scenario. Nevertheless, we feel the controlled environment and rigorous execution of this study effectively demonstrates a characterization of splash patterns. The results of repeated trials under these testing circumstances are still yet to be seen. Lastly, splash patterns of normal saline with fluorescence serve as simulation for what occurs within actual surgery. We recognize that blood and contaminated irrigation fluids may not travel in the same manner due to different densities and droplet heterogeneities. Further in vivo investigations are
needed to characterize these dynamic parameters.

This study illustrates splash patterns seen with both high-pressure and low-pressure irrigation systems that are utilized today. With the use of an inexpensive splash guard during high-pressure irrigation, we were able to drastically reduce splash displacement with this trial. Decreased splash displacement could theoretically reduce operating room contamination and resultant nosocomial operative site contamination and translate to lower infection rates, shorter hospital stays, and ultimately to substantial financial savings. Currently, the impact of splash shield use during operative site irrigation on infection rates is unclear. However, we hypothesize that the benefits will substantially outweigh the cost.

ACKNOWLEDGMENTS

We thank Lauren Chmiel, M.A., for her editorial assistance on this project.
TABLE 1: Raw data depicting droplet counts and distance during gravity flow, asepto bulb syringe, high-pressure pulsatile lavage (Stryker pulse lavage and Davol Simpulse), and high-pressure pulsatile lavage with splash shielding (Stryker pulse lavage and Davol Simpulse).*

During trial, the sound of splashing against the plastic sheeting could be heard in hall. 2 droplets were recorded on the backside of the overhead light positioned above the patient's head. 15 droplets were recorded on the elbow of the overhead light fixture. 1 droplet was recorded on the video recorder's device. On the plastic sheeting at the head of the surgical table, covering the anesthesia equipment, there were droplets that were too numerous to count with the highest droplet recorded at 179 cm.** During trial, 5 droplets were recorded on the plastic sheeting covering the anesthesia equipment with the highest particle at 122 cm. 3 droplets were recorded on the face of the overhead light above the patient's feet. 20 droplets were recorded on the face of the overhead light above the patient's head.

FIGURE 1: Animation depicting experimental setup.

FIGURE 2: Animation characterizing droplet pattern and maximum droplet displacement in four experimental quadrants for Gravity flow trial and Asepto Bulb Syringe trial.

FIGURE 3: Animation characterizing droplet pattern and maximum droplet displacement in four experimental quadrants for Davol® Simpulse SOLO High Flow Tip high-pressure pulse lavage with and without splash shield.
FIGURE 4: Animation characterizing droplet pattern and maximum droplet displacement in four experimental quadrants for Stryker® InterPulse high-pressure pulse lavage with and without splash shield.
REFERENCES


Circles represent droplets. Filled rectangles represent too numerous to count droplets or pooling.
FIGURE

Circles represent droplets. Filled rectangles represent too numerous to count droplets or pooling.

FIGURE 3
FIGURE 4

Circles represent droplets. Filled rectangles represent too numerous to count droplets or pooling.
### Table 1

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<th>Initial weight of irrigation (milliliters)</th>
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<td>25 droplets on anterior right</td>
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<td>Too numerous to count</td>
<td>145</td>
<td>4</td>
<td>151</td>
<td>10</td>
<td>201</td>
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<td>2778</td>
<td>222</td>
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<td>170</td>
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<td>213</td>
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<td>Too numerous to count, frank pooling</td>
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<td>Frank pooling</td>
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<td>2497</td>
<td>503</td>
<td>Too numerous droplets throughout gown, exhaust hood and face shield, gloves, pooling at bilateral feet</td>
<td>Too numerous to count, frank pooling</td>
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<td>Too numerous to count</td>
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