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Comparison of Visual vs. Microscopic Methods to Detect Blood Splatter from an Intravascular Catheter with Engineered Sharps Injury Protection (ESIP)

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Comparison of Visual vs. Microscopic Methods to Detect Blood Splatter from

an Intravascular Catheter with Engineered Sharps Injury Protection (ESIP)

by

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of the requirements for the degree of
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Abstract

Intravascular devices with engineered sharps injury protection (ESIP) are

designed to reduce sharps injuries, but have not been investigated for blood splatter

potential. In this laboratory-based experiment, which did not use human subjects, 100

intravenous catheters of the same type with a retraction mechanism, were tested for blood

splatter. Once blood was obtained from a simulated brachial vein containing mock

venous blood, the devices were placed in a testing chamber and scientific filters labeled

A, B & C were used to capture blood splatter after activation. The blood splatter was

examined visually and microscopically, and the filters were weighed pre- and post-

activation on an analytical scale. The research questions in this study were: 1) do

retractable intravenous devices produce blood splatter, and 2) does blood splatter

frequency differ between visual methods vs. microscopy?

The differences in filter mass, visual inspection, and microscopic analysis for

presence of blood on filters were the units of analysis. Descriptive statistics, paired t-tests

to determine pre and post activation filter weights and kappa statistics to assess degree of

agreement between methods were used to analyze the data. For filters B and C, the

proportions with blood detected by the naked eye were 12 and 13% respectively.

However, for filter A, both visual and microscopic methods detected blood splatter on

70% and 71% of the time respectively. In addition, a statistically significant difference was observed in the mean mass of filter A between pre- and post-activation confirmed by the naked eye (t= - 0.0013, p= 0.01400) and confirmed microscopically (t= - 0.00014, p=0.0092). Substantial agreement between methods was observed for filter A (kappa=0.78; 95% CI: 0.64-0.92), filter B (kappa= 0.73; 95% CI: 0.51-0.95) and filter C (kappa= 0.75; 95% CI: 0.55-0.96). However, in 7 instances (7%), blood was detected by microscopy but not by the naked eye on filters A (5 %), B (1%), and C (1%), respectively. Also, in 6 instances (6%), blood was detected by the naked eye but now by microscopy on filter B (3%), and filter C (3%). Consequently, there is potential for a total of 13 % blood splatter.

The findings indicate potential for bloodborne pathogen exposure with use of a specific retractable intravascular catheter. The finding that blood splatter was detected by microscopy in 7% of the instances has important occupational health implications. Healthcare workers (HCWs) may not be able to detect this blood splatter when it occurs and may not report a splash to mucous membranes or non-intact skin. This study therefore reinforces the need for HCWs to wear personal protective equipment, such as masks, face shields, goggles, when using intravascular catheters with retractable mechanisms. It is recommended that the research protocol used in this study be replicated by other investigators and tested on all brands of retractable intravascular devices.

Introduction

The quantity and wide range use of devices with engineered sharps injury protection (ESIP) by all health care workers (HCWs) makes it absolutely necessary to explore every conceivable approach of potential bloodborne pathogen exposure and transmission, including the possibility of blood to aerosolize due to activation of safety mechanism of these devices. The present study was designed to evaluate the safety of retractable intravascular devices in terms of their potential to produce blood splatter.

Risk to Health Care Workers

In the last few decades, multiple diseases due to bloodborne pathogens have emerged bearing serious effects on infected persons who come in contact with infected blood (blood of person with the disease). One group at a high risk for exposure is the health care worker (HCW). HCWs, due to the nature of their occupation, are in constant contact with patients' blood and other body fluids. Consequently, they have been identified to be at high-risk for bloodborne pathogen exposure, transmission, and infection from hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV). It is estimated that 385,000 cases of occupational exposure to bloodborne pathogens from needlestick and sharps injuries are reported annually for hospital based healthcare workers (CDC-Sharps Safety 2010, and Panlilio,

1

et. al. 2004). Furthermore, after a needlestick injury (NSI), the risk of infection ranges

from 6% to 30% for HBV, 1.0% to 10.0% for HCV with an average of 1.8% , and an

average of 0.3% per percutaneous injury for HIV (CDC-NIOSH 2000). Also, the risk for

HIV infection after an exposure to mucous membranes is estimated to be around 0.09%

(CDC-NIOSH 2000). In addition to the above mentioned viruses, more than 20 other

bloodborne pathogens can be transmitted via NSI (CDC-Sharps Safety 2010).

History of Regulations

In the era when devices were not designed with engineered sharps injury

protection (ESIPs), NSIs were a major cause of health care worker exposures to

bloodborne pathogens (CDC-NIOSH 2000). To protect HCWs from bloodborne

pathogens due to NSIs, the Centers for Disease Control and Prevention (CDC) published

a list of recommended Universal Precautions in 1987 (CDC 1987). Later on, in

November of 2000, the US congress passed the Needlestick Safety & Prevention Act

(NSPA, House of Representatives, and CDC-NIOSH 2000). This was followed by the

subsequent 2001 revision of the Occupational Safety and Health Administration's

(OSHA) Bloodborne Pathogens Standard (BPS). The OSHA BPS requires employers to

provide devices with ESIP for all HCWs, and their use has significantly reduced the risk

of NSIs (Panlilio, et. al. 2004). Prior to the implementation of the state and federal laws

for the use these safety devices, just 15% of US hospitals were practicing with this type

of the devices (Foley & Leyden 2005). Since the Needlestick Safety & Prevention Act,

commercial ESIP devices were brought to the market with the aim of reducing the risk of

NSIs to HCWs. One of these of devices is an intravenous catheter with a retractable mechanism, with one specific brand being tested in this study.

Research on Exposure to Blood Splatter

Criteria used for the evaluation of ESIP devices efficacy include minimization of both the incidence of NSIs and the exposure/transmission of bloodborne pathogens to HCWs (Foley & Leyden 2005, and Haiduven, et. al. 2009). However, even though ESIP devices may protect from needlestick injuries, they may not protect from exposure to bloodborne pathogens. The safety activation of the device may cause blood splatter, which is the microaerosolization of blood (Haiduven, et.al. 2009). Taylor (1990) indicated that mucous membranes of the face and none-intact skin are potential portals for transmission of bloodborne pathogen from miniscule amounts of infected blood. In 17 out of 20 cases the blood splatter occurred and in some cases, the amounts were invisible to the naked eye. This suggests that any amount of blood splatter can pose a potential health risk and more importantly if it occurs in aerosol form.

Review of the studies on health care workers and the use of devices with ESIP indicate that blood splatter does occur when ESIP devices are activated, and the mucus membranes and non-intact skin are potential paths of transmission. As a result, some HCWs have contracted bloodborne pathogens while using these devices.

A study of 43 HCW exposed to bloodborne pathogens conducted in Poland from 2001 to 2004 found that HCWs were exposed to HBV, HCV, and HIV. Thirty-four (34)

of these injuries were by needlestick, and four (4) cases due to splash on the skin and conjunctiva, while performing procedures. The rest of the injuries were due to other types of sharp. This study indicated that from all these cases one HCW was treated for HBV and four (4) were being observed due to HCV (Dancewicz, et.al. 2005).

A report from Australia, based on research carried out from 1998-2003 retrospectively, indicates 931 HCWs out of 2200 HCWs were exposed to blood and body fluid. The study found that sharp injuries and activation of safety intravascular devices resulted in 594 of percutaneous and 337 mucocutaneous cases of exposed HCWs to blood and body fluid splatter (Bi, et.al, 2006). Another study from Turkey indicated that HCWs exposed to blood splatter on their conjunctiva from infected patients with HCV were at risk for developing the disease (Hosoglu et.al, 2003). This study mentioned one confirmed case of infection with HCV due to blood splatter to the mucous membranes during in a hemodialysis unit. Wines et. al. (2008) also indicated that mucocutaneous and transconjunctival exposure remains as routs for the transmission of bloodborne pathogens to HCWs. The study that included 118 cases indicated that a modern forensic method was used to detect blood splash not visible by the naked eye during procedures performed by the HCWs. The study found evidence of positive blood splash in 84.2% even in video laparoscopic procedures. Furthermore, this study recommends use of personal protective equipment (PPE) by all HCWs while performing procedures in all healthcare sittings.

Based on anecdotal reports from HCWs in the field and the potential risk of blood exposure from intravascular devices with retractable mechanisms, Haiduven, et.al (2009)

designed a laboratory study to evaluate the potential of blood splatter. They conducted

pilot testing of several different devices in order to develop methods for the measurement

of blood splatter. More specifically, they studied three types of retractable intravascular

devices: two phlebotomy devices (a vacuum tube device and a winged butterfly device)

and a retractable IV catheter with a retractable mechanism. They tested one hundred of

each of the devices using an injectable extended antecubital fossa (ACF) pad attached to

a blood bag containing mock venous blood. They used filters to collect the blood splatter

when the devices were activated. They found a significant difference in the weight of the

filters before and after activation for the IV catheter and the winged butterfly set due to

blood splatter. Results for the vacuum tube device were equivocal.

A recent report from England (Ford & Phillips, 2011) found that when three

different intravascular devices with safety mechanisms were tested [two with needle

shields Eclipse (Becton Dickinson), and Quick Shield (Greiner Bio-One)] and one with a

retractable needle [Push Button (Becton Dickinson)] used for blood evacuation), the

HCWs in the study reported blood splatter. The researchers then tested simulated blood

with the same devices (twenty of each type) and placed a colored paper underneath the

device. The researchers confirmed via an ultraviolet light that there was blood splatter in

areas close to the activation of the safety system. The author confirmed that all 3 types of

devices caused blood splatter on activation. The study reported that the frequency of

blood droplets from Eclipse was eight out of 20 (40%), 2 out of 20 for Quick Shield

(10%), and for the Push Button, the frequency was 7 out of 20 (35%). These laboratory

studies confirm that there is a potential for occupational exposure to bloodborne

pathogens for the HCW associated with the activation of intravascular devices with retraction mechanisms that were originally designed to avoid needlestick injuries. These results support the need for the use of personal protective equipment to protect the mucous membranes and skin of HCWs when they are performing intravascular procedures with such devices.

Hypotheses

To build on the work of Haiduven, et.al. (2009), the present study investigated a different type of automatic retractable intravascular device (the Becton Dickinson Insyte Autoguard). An activation assembly chamber was designed for this experiment in a attempt to capture of all possible blood splatter onto several filters located in the immediate vicinity. The study tested not only the difference in filter weight before and after activation of the retraction mechanism on the device in order to confirm the previous results, but also compared the visibility of blood splatter by the naked eye vs. microscopic examination using Cohen's kappa statistics that measures the degree of agreement between categorical judgments (i.e., "yes" vs. "no").

A review of the literature yielded no results on other studies that used the microscope as an instrument to detect blood splatter from the activation of retractable safety mechanisms. Nonetheless, the microscope has been an innovative and useful tool for bloodstain pattern analysis during criminal investigation when it is necessary to use small stains that are difficult to measure. A study by Valkiūnas et al. (2008) compared parasitic prevalence information obtained by both microscopy and polymerase chain

reaction and showed that both methods yielded similar results, reinforcing the notion that microscopy is a reliable tool that is relatively inexpensive, provides valuable information, and is unlikely to result in false positives. In this study, the microscopic examination was being used to demonstrate that there is blood splatter even when the HCW cannot perceive its presence.

The research questions in this study were: 1) do retractable intravascular devices produce measurable blood splatter; and 2) does blood splatter frequency differ between visual methods vs. microscopy? The hypotheses were: 1) there will be a significant difference in the mean mass of the filters used to detect blood splatter at three different locations before and after activation of the intravascular device; and 2) the presence of blood splatter on the filters can be seen by microscopic examination even if not visible to the naked eye.

Research Methods

In this section, the following will be presented: an overview of the research methods in this study, a description of the testing materials and how they were used, an explanation of the testing protocol, a description of the data collected and the statistical analyses performed.

Methods Overview

In this experiment, which did not use human subjects, 105 intravenous catheters with a retraction mechanism were tested for blood splatter. The experiment was conducted in a controlled laboratory environment designed to simulate the environment of the health care setting. The study was performed inside two separate tissue culture hoods, which provided a controlled environment free from contamination and any sudden changes in airflow.

Injectable extended antecubital fossa (ACF) pads that simulate the human brachial vein were attached to a mock venous blood bag consistently containing 500 ml and infusion tubing. The retractable intravascular device being tested was inserted into an injection site in the ACF pad to simulate and serve the purposes of use in humans in healthcare sittings. After insertion, each retractable device was placed in a testing chamber and activated. Scientific filters were placed in the activation chamber and used

to capture blood spatter after activation. For identification purposes, the three filters were denoted as Filter A, Filter B, and Filter C based on their location and use at different points of the activation chamber. Filter A was located inside the activation chamber's cylinder, to capture splatter from around the activation mechanism, Filter B was located anterior to the device to capture splatter from the tip of the needle, and Filter C was used to wipe the device, the researcher's gloves, and the back section after device activation.

The weights of the three scientific filters used for each retractable intravascular device were measured pre- and post-activation by an analytical scale and recorded on a spreadsheet. Before recording any weights, it was ensured that the scale was zeroed with the specimen receptacle attached. All filters were visually and microscopically inspected pre-activation for the integrity of the filter and the presence of foreign materials, and post-activation for the presence of visible blood. Digital microscopic photographs were taken of any visible blood. Findings were recorded for each of the parameters as a dichotomous outcome ("Y" [Yes] was assigned to denote the detection of visible blood, and "N" [No] where blood was not detected.). The presence or absence of mock venous blood by either the naked eye or the microscopic examination of each of the filters, and the difference in filter mass before and after device activation, were the primary units of analysis for detecting blood splatter. Data were recorded on an EXCEL spreadsheet and triple data checking was performed to record each measurement.

Retractable Intravascular Device

In this study, 105 retractable intravascular devices were tested. The retractable intravascular safety device that was tested was Becton Dickinson's Insyte Autoguard, with a 2 0 gauge 1.1 X 25mm needle, and an automated mechanism that, when activated, rapidly retracts the needle into its barrel, as shown in Figure 1.

Figure 1. Retractable intravascular device (Becton Dickinson, 2011). Retrieved from http://www.vitalitymedical.com/intravenous-shielded-catheter-infusion-sets-insyte-autoguard-by-bd-becton-dickinson.html

The specific protocol developed for this study was based on the retraction mechanism, its activation, and the manufacturer's instructions for use. Activation was defined as the motion resulting in retraction of the needle itself from its own plastic cannula into the barrel of the device as seen in Figure 1 (device post activation).

Antecubital Fossa (ACF) Pad and Mock Venous Blood

Two injectable extended antecubital fossa (ACF) pads (a soft tissue pad that simulates the antecubital fossa of the human's right arm and was used for venipuncture and the introduction of cannulae; Limbs & Things, Bristol, UK) were attached to a blood bag containing mock venous blood and infusion tubing as displayed in Figure 2.

Figure 2. ACF pad in the tissue culture hood.
Note: Pad is attached to a mock venous blood bag (left upper corner) and infusion tubing.

The mock venous blood used in this experiment, was an artificial blood simulant with the same color and viscosity of human venous blood. Two intravenous catheters

were inserted into the ACF pad. One catheter was inserted into the top portion of the pad (blood entrance site) and the other catheter was inserted into the distal end of the venous system of the ACF pad (venous blood exit site). The injection pad was supplied with a continuous flow of mock venous blood from a 500 mL supply bag connected to the catheter at the proximal end via intravenous tubing with an on/off flow clamp. The supply of blood was monitored and adjusted as necessary in order to keep the volume between 400-500 mL. The catheter at the distal end was connected to an empty supply bag to maintain a continuous flow system and served as a collection system for the mock venous blood as it exited the ACF pad. The amount of mock venous blood that moved into the device on each insertion was not measured. For this experiment a total of 15 mock venous blood bottles (250 ml each) were used.

As shown in Figure 3, each ACF pad was pre-marked and numbered with 50 insertion sites (1-50 and 51-100, respectively; an additional 5 sites were tested on a third pad). A sequence pattern was established so that the insertion sites into the 3 simulated veins were not consecutively placed. Each new insertion site was not adjacent to the previous insertion site; rather the sites rotated in location, as shown in Figure 4. However, each of the ACF pads was pre-marked with the same pattern to minimize the threat of misclassification.

Figure 3. ACF pad pre-marked and numbered for each insertion site.
Note: This is a smart site infusion set from Cardinal Health, with continuous blood source and receptacle for the artificial blood.

An absorbent pad (cotton on one side and plastic on the other) was placed on the ACF pad above and below each insertion site to provide additional protection and prevent any seepage that could occur. Stomahesive tape was used to cover each insertion site after the device and the number were removed from the previous numbered insertion site of the ACF pad. The reasons for this were: 1) to prevent excess seepage from the insertion site, and 2) to avoid entering the same insertion site twice.
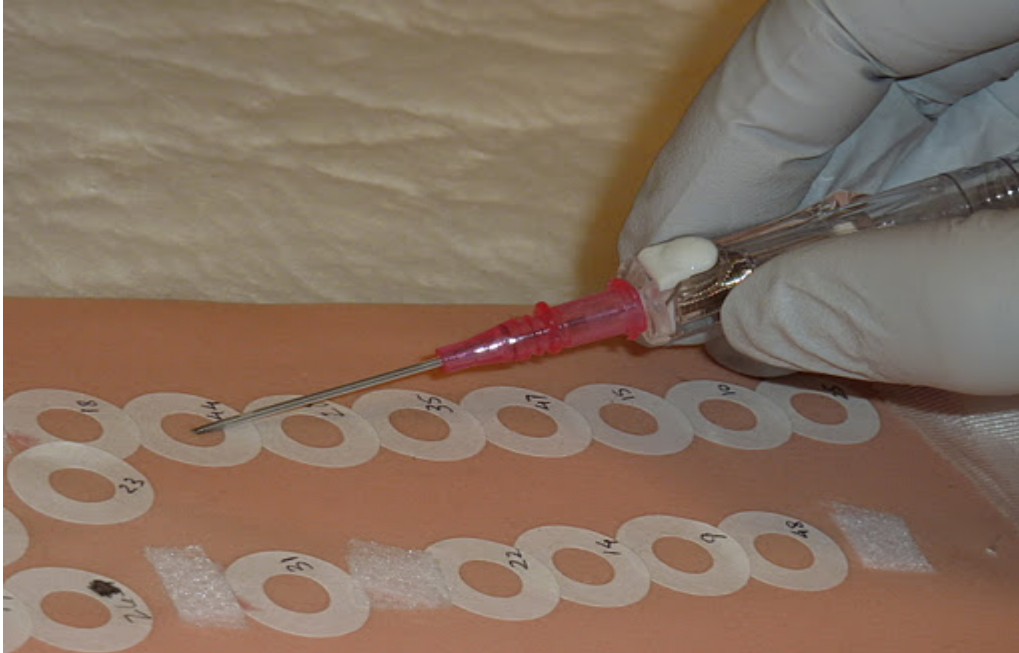
Figure 4. Close up view of the insertion sites on the ACF pad.

Activation Chamber

The terms "Activation Chamber or Assembly Chamber" were used interchangeably to represent a custom-designed apparatus to hold the retractable intravascular device for the purpose of device activation, the detection of blood splatter at the activation site and the immediate vicinity. "Activation Chamber" was used to collect any blood splatter resulting from activation of the device after the catheter was removed from the ACF pad but before the needle was retracted into its barrel, as shown in Figure 5.

Figure 5. Retractable intravascular device positioned in activation chamber

Scientific Filters

Over three hundred scientific filters composed of Kimberly Clark heavy duty coverall particulate arrester material, tested at greater than 0.3 microns, pre-labeled 1-X, were used to capture blood splatter from the retracting devices positioned at different points inside of the activating chamber. The scientific filters were designated filter A, filter B, and filter C. Filter A was positioned inside and around the activation chamber's cylinder and filter B was positioned anterior to the retractable intravascular device (see Figure 6). Filter C was used to wipe the back section of the chamber, the glove, and the outside of the intravascular device.
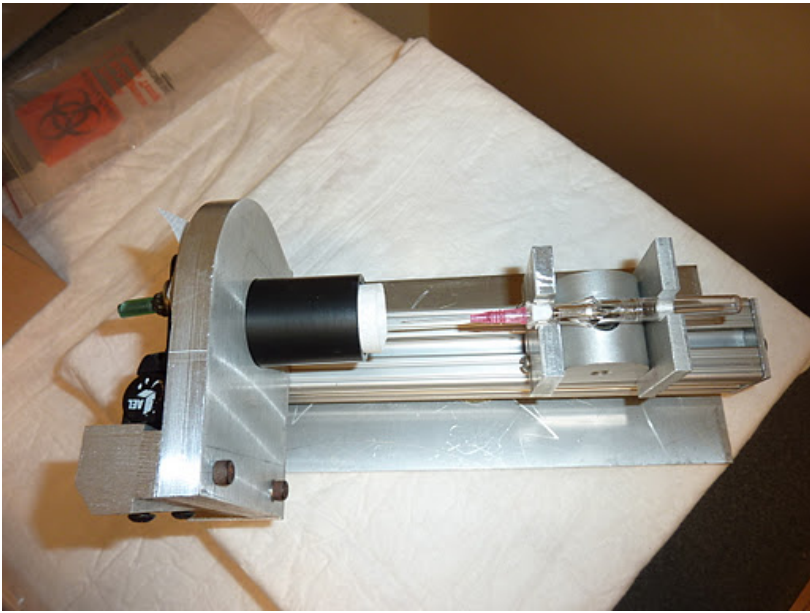
a.
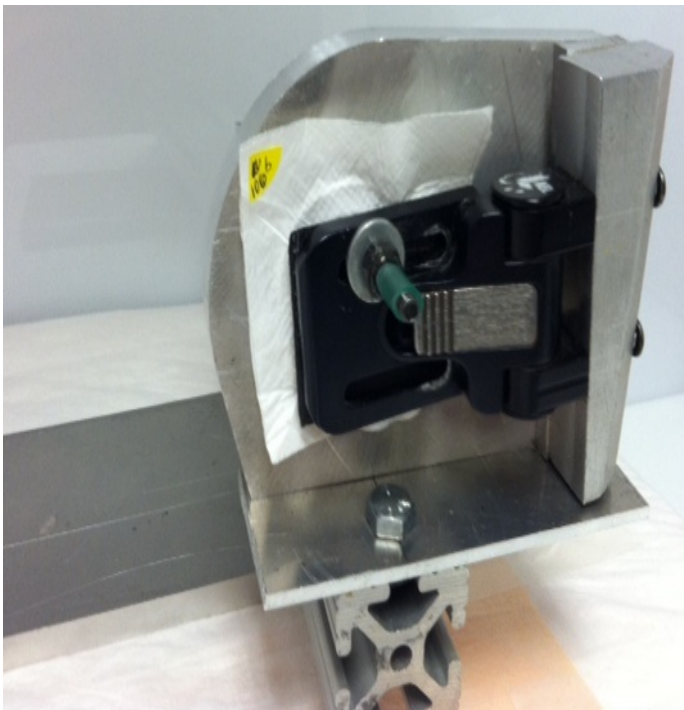
b.

Figure 6. Filters A and B in the assembly chamber.
Note: Filter A is shown in a) and filter B is shown in b).

Analytical Scale

As illustrated in Figure 7, an Ohaus Adventure Pro Analytical Scale calibrated to 1/1000g was used to weigh the filters before and after activation of each device. The experiment was conducted inside a tissue culture hood, which provided a controlled environment free from contamination and any sudden changes in airflow. A pre-validation protocol was performed to determine the reliability of the scale. The weights of the three scientific filters used for each retractable intravascular device were measured in milligrams on the analytical scale and recorded on an Excel spreadsheet.
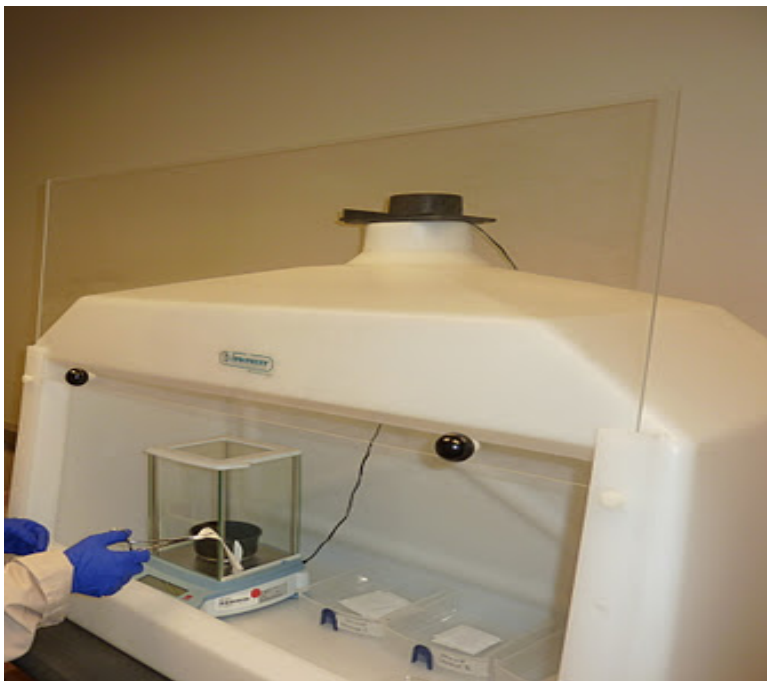

Figure 7. Ohaus adventure pro analytical scale in tissue culture hood.

Digital Microscope

      For this experiment a stereoscopic microscope with digital camera (Model DC5-420TH 10x-40x magnification, National Optical & Scientific Instruments, San Antonio, Texas; with digital camera: software Motic Image Plus Version 2.0, Richmond, British Columbia V6V 2K9 Canada) was used. The filters were divided into 9 areas that allowed the viewer to provide a more specific location when describing any material seen during the microscopic inspection of the filter as shown in Figure 8 (Areas of the Filter).

Left upper corner (LUC)	Upper border (UB)	Right upper corner (RUC)
Left border (LB)	Center (C)	Right border (RB)
Left bottom corner (LBC)	Bottom border (BB)	Right bottom corner (RBC)

Filter number identification here

Figure 8: Division and labeling of nine areas of the filter.
Note: The presence of blood was examined for each area in the microscopic review.

All the filters were perused with the low power objective (10x) using the pattern shown on Figure 9 (a diagram of how to scan the filters pre and post device activation). This allows for overlapping of the fields when looking under the microscope, reducing the chances of missing an area of the filter. Any suspicious material was further examined using the high power objective (40x), and results were recorded in a worksheet by the research team using triple data checking.
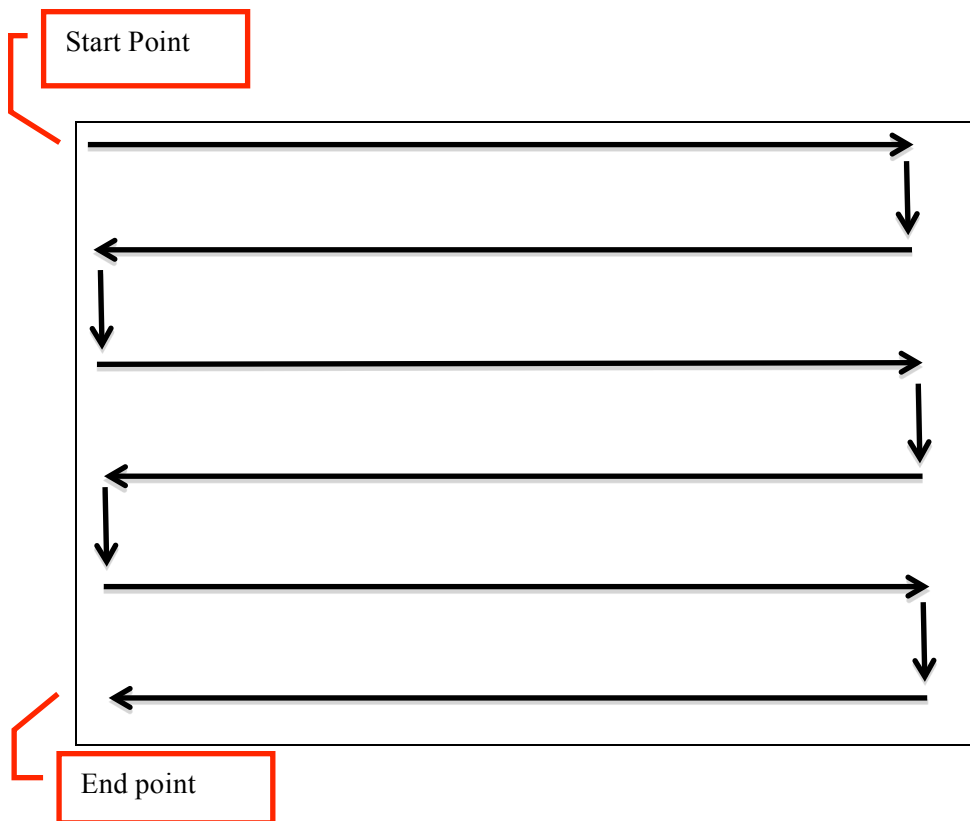
Start Point

End point

Figure 9. Diagram of filter scans pre and post device activation.

Blood splatter was photographed with the microscope's digital camera, with some examples shown in Figure 10. The digital pictures were labeled with the filter

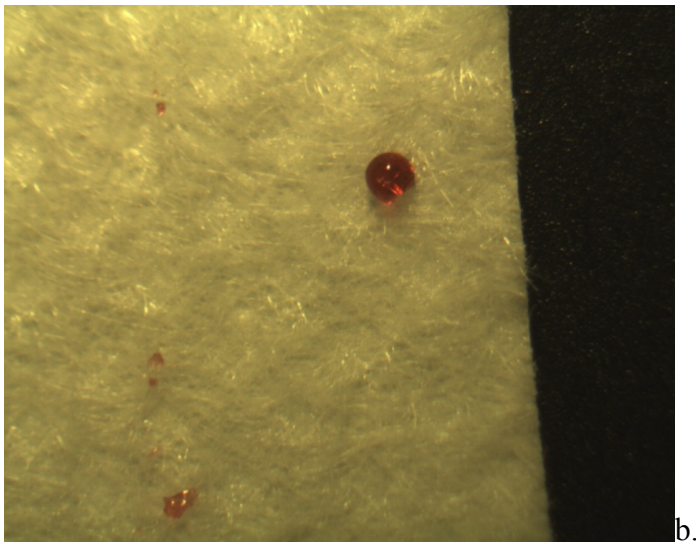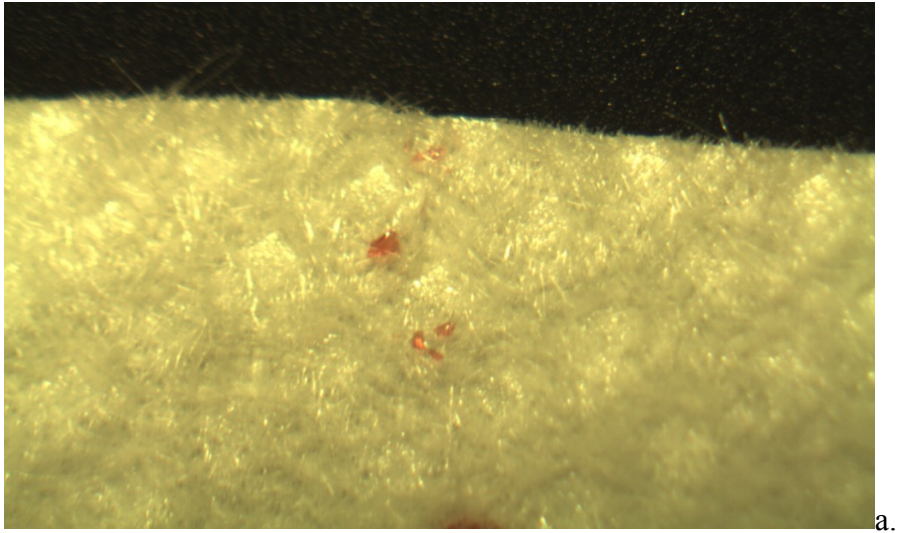identification number, and stored in a computer file that could be accessed for future

references.

a.

b.

Figure 10. Filters with blood splatter.
Note: Photos a) and b) were photographed with the microscope's digital camera.

Testing Protocol

Four researchers (R1, R2, R3, and R4) conducted the testing protocol. The researchers included an occupational health resident physician for device insertion and activation (R2), biomedical engineer assistant for analytical scale measurement and passing of filters (R1), a medical microbiology technician to examine scientific filters under the microscope (R4), and an infection prevention and occupational health expert who timed the experiment and recorded the data (R3). R1 worked primarily inside the tissue culture hood number one with the scale and the filters, while R2 worked inside tissue culture hood number two to insert and retract the device, and to activate the device in the activation chamber located next to the second tissue culture hood. R1 did all of the scale readings. R3 opened the I.V. mock blood flow system, monitored R1 & R2's activities, connected the IV needle to a luer-lock syringe, operated the timer, called the steps, recorded data, opened and closed the clamps of the IV tubing, and carried the filters to R4. R4 examined the filters under the microscope pre-activation weighing for any artifacts and then post-activation weighing for the presence or absence of blood. R1 used bent forceps to place filters on and off the scale and to hand filter "C" to R2. R1 used straight forceps to place used filters into microscopy storage bins. R4 used forceps to handle all filters.

A 111-step protocol was developed by the research team. The sections of the protocol were as follows: pre-trial activities; initial filter weights; device preparation, insertion & activation; filter visual inspection, weighing, and microscopic inspection; and post-trial activities. In order to collect data for 105 trials (5 trials were excluded but a

total of 100 were needed, thus the reason for sequencing up to 105), the steps were followed 105 times.

Before beginning of the experiment each day, each tissue culture hood surface and the activation chamber were cleaned out thoroughly. All equipment and supplies (filters, syringe materials, scale, injection pad, sharps collection receptacle, sharps container and cleaning wipes) were placed inside the work area. Once the work areas and inside the tissue culture hoods were completely stocked, the adjustable shield was moved to the lowest possible position that allowed R1 and R2 to place both of their arms into the work area and to conduct the experiment. All researchers donned lab coats and clean gloves.

Pre-Trial Activities

The analytical scale was zeroed with the attached specimen receptacle, the blood bags were checked to ensure 500 cc levels were maintained; sites of insertions were prepared and protected from potential contamination.

Initial Filter Weights

R1 removed appropriately the numbered filters from the unused filter storage bin in order (filters A, B, and C). R1 placed each filter on the scale with the numbered, non-

absorbent side down; then called out the weight as read off the scale and repeated the number for verification. In this set of steps, all the filters were handled with a forceps.

Device Preparation, Insertion and Activation

The company's instruction for the use of the device and insertion into the vein were followed by R2. After inserting one of the devices into a pre-marked site, blood return was observed, and the needle removed from the designated vein location on the ACF pad without activating the retraction mechanism. The device was then positioned in the activation chamber and the safety mechanism activated.

Filter Visual Inspection, Weighing, and Microscopic Inspection

R2 thoroughly examined the fingers, palm and back of the inner pair of the gloves on the right hand; filter A ; filter B; filter C, and the back section of the device holder for the presence or absence of visible blood and was recorded after verification by R4. The scale was zeroed each time prior to weighing each filter by R1. All the filters were thoroughly examined under the microscope and the presence and the absence of blood were recorded. Filters with the presences of blood were photographed by R3.

Post-Trial Activities

Once all of the filters were examined, each filter was placed in a designated temporary container labeled for each filter (A, B, and C). In this period the instruments used were cleaned, in preparation for the next trial.

Post-Experiment Activities

After each 10th time, the balance on the scale was checked and gloves were changed. At the end of the day, used filters were placed into storage containers labeled separately for "A", "B", & "C".

Statistical Analyses

The data set encompassed a total of 105 experimental trials on one specific design of a retractable intravascular device. Data from five trials were excluded to prevent any compromise to the validity, leaving a total of 100 trials were retained for the final analysis. The difference in mass of filters A, B, and C (the mass of the filter post-activation minus the mass of the filter pre-activation) were computed to determine whether a change in weight occurred. To determine whether or not the observed mean difference was due to blood splatter or merely due to chance, a paired sample t-test was conducted to compare the mean weight of each filter pre- and post-activation.

Furthermore, the data for detected blood on all of the filters was compared for visible blood detected by the naked eye and by the microscope. Because two different methods for detecting the presence of blood were utilized, it was necessary to measure the magnitude of agreement between the two methods of blood detection for each of the 300 filters. To determine whether the agreement can be attributed to chance findings, a kappa statistic (Landis & Koch, 1997) was calculated to compare the degree of agreement between filter examination results with the naked eye versus microscopy with respect to the presence of blood for each filter. Tests of hypothesis were two-tailed with a type I error rate fixed at 5 percent. SAS version 9.1 (SAS Institute, Cary, NC) was used to perform all analyses.

Results

The research questions in this study were: 1) do retractable intravascular devices produce measurable blood splatter; and 2) does blood splatter frequency differ between visual methods vs. microscopy? The hypotheses are: 1) there will be a significant difference in the mean mass of the filters used to detect blood splatter at three different locations before and after activation of the intravascular device; and 2) the presence of blood splatter on the filters can be observed by microscopic examination even if not visible by the naked eye.

Table 1. Frequency and percentage of filters A, B, & C with blood by visible detection and microscopic methods based on 100 trials.

	Visible Blood by Naked Eye			Visible Blood by Microscopy		
	Filter A	Filter B	Filter C	Filter A	Filter B	Filter C
Frequency	70	12	13	71	9	10
Percent (%)	70.00	12.00	13.00	71.00	9.00	10
Cumulative Freq	100	100	100	100	100	100
Cumulative Percent (%)	100	100	100	100	100	100

Table 1 shows that the proportion of filters with detectable blood examined by the naked eye were 70%, 12%, and 13% for filters "A", "B" and "C" respectively, while examination by microscopy showed that the proportion of filters with detectable blood were 71%, 9%, and 10% respectively. Compared to filter "A," a smaller proportion of filters "B" and "C" contained detectable blood. Thus, the filter with the highest proportion of detected blood using both methods of detection, as compared to the remaining filters (B and C), was filter A. Figure 1 illustrates the proportion of filters with detected blood through microscopic vs. naked eye examination, for filters A, B & C respectively.
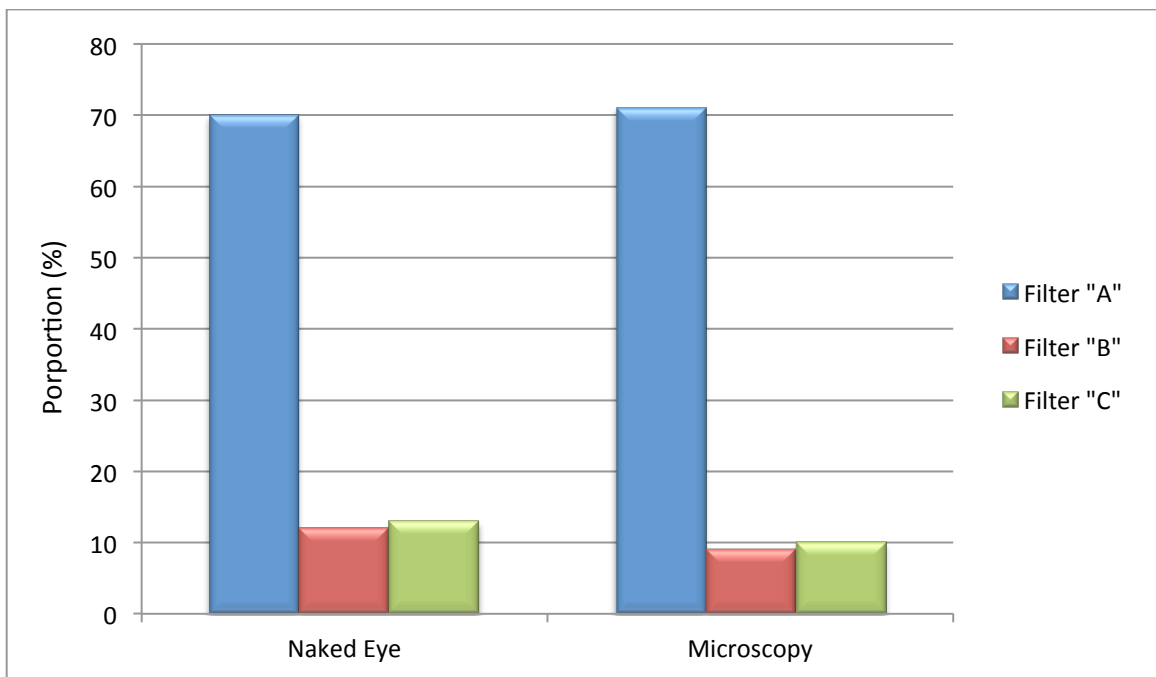

Figure 11. Proportion of filters A, B, and C with detected blood.
Note: This compares the filters with blood detected by visual vs. microscopic methods.

A paired student t-test was used to compute the mean (± standard error) mass difference for filters A, B, and C before and after activation. The analysis of the mass difference for each filter included only those observations where blood was detected on the specified filter by the naked eye or microscopically. Table 2 illustrates the mean differences for each filter type by detection method. The results indicate that there was negative mass difference for some of filters for both detection methods.

Table 2. Mean mass difference, standard deviation, and confidence intervals by filter type and detection method

	Visible Blood by Naked Eye			Visible Blood by Microscopy		
	Filter A	Filter B	Filter C	Filter A	Filter B	Filter C
N	70	12	13	71	9	10
MD	-0.00013	0.000025	0.000115	-0.00014	0.000156	0.000200
SD	0.000431	0.000569	0.000580	0.000447	0.000525	0.000643
95% CI	-0.00023 -0.00003	-0.00034 0.000387	-0.00024 0.000466	-0.00025 -0.00004	-0.00025 0.000559	-0.00026 0.000660

Note: N= number of trials with blood splatter, MD= mean mass difference, SD= standard deviation, SE= standard error, CI= confidence interval

The statistical significance [$p < .05$] of the mean mass difference is shown in Table 3. Results indicate that the difference between the mean mass of filter A pre-activation and mean mass post-activation was statistically significant for the proportion of filters with detected blood by the naked eye [t= - 0.0013, p= 0.0140] and microscopically [t=- 0.00014, p= 0.0092]. However, there was no statistically significant

difference between the mean mass of filters B and C pre- and post-activation for either

detection method.

Table 3. Mean mass differences and significance values by filter type and detection
method

	Filter A$^{\neq}$ MD [p-value]	Filter B$^{\neq}$ MD [p-value]	Filter C$^{\neq}$ MD [p-value]
Naked Eye[*]	**-0.0013** **[0.0140]**	0.00003 [0.8818]	0.0012 [0.4869]
Microscopy[*]	**-0.00014** **[0.0092]**	0.00156 [0.3997]	0.0002 [0.3509]

Note: MD = Mean mass difference
$^{\neq}$ Mean mass difference of specified filters as assessed by t-test, p<0.05
[*]Analysis of the mean mass difference for each filter was conducted including only
those observations where blood was detected on the specified filter.

The second research question was whether there was a difference in visible blood

detection by the naked eye vs. microscopic examination. Table 4 shows the percentage of

agreement between these two methods of detection. The associated frequency data for

filter A shows that in 66 out of 70 times there was agreement that visible blood was

present, and 25 out of 30 times there was agreement that visible blood was not present.

The frequency data for filters B and C shows similar agreement on the presence of visible

blood (8 out of 12 and 9 out of 13, respectively) and on the absence of visible blood (87

out of 88, and 86 out of 87, respectively).

Table 4. Percentage and frequency of agreement on presence or absence of visible blood for filters A, B & C

Filter Type	Presence [Freq]	Absence [Freq]
Filter A	94 [66/70]	83 [25/30]
Filter B	67 [8/12]	99 [87/88]
Filter C	69 [9/13]	99 [86/87]

Note: [Freq] = frequency

    To determine whether the degree of agreement on the presence or absence of visible blood between the two methods of examination was significant, a kappa test was performed. A statistically significant kappa indicates that the agreement is better than chance. Based on a commonly cited scale, where the possible values range from 0 to 1.0, 0 equals no agreement and 1.0 indicates perfect agreement. The relationship between the statistic and level of agreement is presented in Table 5.

Table 5. Interpretation of the kappa statistic

Kappa	Poor	Slight	Fair	Moderate	Substantial	Perfect
	0.0	0.20	0.40	0.60	0.80	1.0

Kappa	Agreement
< 0	Less than chance agreement
0.01-0.20	Slight agreement
0.21-0.40	Fair agreement
0.41-0.60	Moderate agreement
0.61-0.80	Substantial agreement
0.81-0.99	Almost perfect agreement

Table 6. Kappa statistic on agreement between methods of blood detection on filters A, B, & C

Filter Type	Kappa [95% CI]
Filter A	**.78 [0.65-0.92**]
Filter B	.73 [0.51-0.96]
Filter C	.75 [0.55-0.96]

The kappa results for this study are summarized in Table 6. Assessing agreement between the two detection methods for the presence of visible blood resulted in a kappa statistic of 0.78 [95% CI 0.65-0.92] for filter A, 0.73 [95% CI: 0.51-0.96] for filter B, and 0.75 [95% CI 0.55-0.96] for filter C. These results show that there is substantial agreement between detection methods regarding the presence or absence of visible blood for each of the filter types. Furthermore, the confidence intervals show that the degree of agreement was statistically significant.

Despite the overall agreement on the presence of visible blood between methods of detection, there were trials that demonstrated that the human eye is not capable of detecting all blood splatter. Table 7 provides a comparison of the trials in which there was disagreement between the methods of detection. Seven trials did not have visible blood detected by the naked eye, but showed evidence of blood splatter under the microscope. For filter A, there were five trials where blood was detected solely by the microscopic examination, while for filters B and C there was one trial each where blood

was detected by microscopic examination. Thus, these results indicate that seven percent

(7%) of the trials exhibited blood microscopically that was not visible to the naked eye.

Table 7. Comparison of trials showing the presence of visual blood via microscopic examination but not the naked eye

Trial Number	Filter A		Filter B		Filter C	
	Naked Eye	Micros copy	Naked Eye	Micros copy	Naked Eye	Micros copy
6	N	Y	N	N	N	N
7	N	N	N	Y	N	N
16	N	Y	N	N	N	N
53	N	Y	N	N	N	N
55	N	Y	N	N	N	N
72	N	Y	N	N	N	N
102	N	N	N	N	N	Y
Total 105[#]	0	5	0	1	0	1

Note: Y= presence of blood, N= no presence of blood. One hundred and five trials were completed but five were eliminated due to factors compromising the validity.

Discussion

HCWs have been identified to be at high-risk for bloodborne pathogen exposure, transmission, and infection from HBV, HCV, and HIV. The results in this study are consistent with previous research on such exposures. Several studies have evaluated intravascular devices in relation to potential blood splatter to face and mucus membranes (Ford & Phillips, 2011; Haiduven et.al, 2009). Taylor (1990) found that mucous membranes are potential routes of transmission from miniscule amounts of infected blood. In some cases, the amounts were invisible to the naked eye. This suggests that any amount of blood splatter can pose a potential health risk, especially if it were to become aerosolized. In this study, the scientific filters captured blood splatter that was not noticeable by the naked eye but was detected by microscopy in 7% of the instances. In another 6% of instances, blood visible to the eye was not evident by microscopy and may have been explained by small fibers falling off of the filter in between visual examination and microscopic examination. Therefore, a potential of 13 /100 times, blood splatter might have occurred to HCWs who may not have been aware of the exposure. HCWs may not be able to detect the blood splatter when it occurs and may not report a splash to mucous membranes or non-intact skin.

Prior research has confirmed that HCWs are the one group with the highest risk for bloodborne pathogen infection after exposure by NSIs. The risk of infection ranges from 6% to 30% for HBV, 1.0% to 10.0% for HCV (with an average of 1.8%), and an average of 0.3% per percutaneous injury for HIV (CDC-NIOSH 2000). Also, the risk for HIV infection after an exposure to mucous membranes is estimated to be around 0.09% (CDC, 2010). Because of this risk, it is necessary to reinforce the need for HCWs to wear personal protective equipment, such as masks, face shields, and goggles, when using retractable intravascular devices to prevent exposure, transmission, and infection by bloodborne pathogens. Furthermore, this study reinforces the need for redesign of the device in order to eliminate the potential for blood splatter and exposure of HCWs to bloodborne pathogens.

This study has multiple strengths. First, the presence/absence of blood splatter on the filters was confirmed by examination of all filters pre and post activation of the intravascular device by a high powered microscope (equipped with digital camera), which enhanced validity of the study. This eliminated the potential presence of confounders on each filter. Second, the entire experiment was performed under a tightly controlled environment to prevent changes in temperature and air flow. Third, once the protocol was finalized, it was adhered to strictly in each trial to ensure standardization and strengthen internal validity. Fourth, the sample size was greater than for many other studies testing blood splatter by retractable intravascular devices. Fifth, a single health care physician conducted all the intravascular device insertions in the ACF pad, therefore, eliminating variation. Sixth, the entire experiment (material and methods) process was designed to

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resemble the conditions in a health care facility. Finally, the researcher group included a multi- disciplinary team: an MD, a RN- PhD in occupational health, a biomedical engineer assistant, a medical microbiology technician, and an MD, PhD in biostatistics.

This study has a few limitations. First, and probably the most important one, is that it was not conducted on human subjects. For humans, device activation would occur while the needle is in the vein, whereas in this study, device activation occurred away from the site of insertion. The transportation of the device may have resulted in a loss of blood droplets. Second, the class of filters used for this experiment to capture blood splatter had a large amount of thin fibers on the surface of the filters. The results indicated that there was a negative mean mass difference for filter A. The negative mass difference might be attributed to several factors. One of these factors is the potential loss of thin fibers from the filters during the process of wiping, transporting, and examining the filters. Another possible factor is a loss of moisture from the filters during the time period between pre and post activation of the device. The blood on the fibers of the filters could fall off from the filter due to the thin surface fibers. For these reasons, this study has expanded the previous work of Haiduven et al. (2009), in the area of no longer using change in mean mass filter weight as a parameter. Rather, the microscope should be used to examine the filters. Finally, the protocol did not include a standardized method for describing or characterizing the patterns of blood splatter.

The results of this study provide several implications for future research. Future studies could investigate the direction, location, and distance of blood splatter. High-speed

photography might be used to represent the motion and location of blood splatter at the moment of device activation. This protocol could be replicated by other investigators and tested on all brands of retractable devices. Research on human subjects could provide information on how device activation affects blood splatter in humans, and whether personal protective equipment can eliminate exposure. Furthermore, research could be done on potential methods for redesigning ESIP devices to completely eliminate blood splatter.

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