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WHITE PAPER

COMPARISON OF BLOOD CLEARANCE AND HEMOLYTIC PERFORMANCE OF BLOOD CONTROL IV CATHETERS

Background

Vascular Access Devices (VADs) are a common and important part of daily clinical practice for the administration of parenteral fluids, nutrients, medications and blood products. These devices may need to be left in place for days or even weeks[1]. Medical devices in direct contact with blood have the potential to increase the risk of bloodstream infections, since blood provides many nutrients supporting the growth of bacteria[2, 3]. The resulting catheter-related bloodstream infections (CRSBIs) are the most life-threatening form of all hospital acquired infections (HAIs)[4]. Apart from microbial infection, common complications associated with peripheral access devices are phlebitis, thrombosis and extravasation.

The microbial infection originates from microbial transfer onto or into the devices. The main sources of microbial contaminations are:

- Bacteremia in the patient's body
- Patient's skin
- Handling of drugs and devices
- Aerosols

In addition, devices in direct contact with blood have the potential to increase the risk of occlusion by blood clots or bloodstream infections, since blood components such as plasma proteins and platelets rapidly adhere to the contact surfaces and provide nutrients supporting the growth of microorganisms and biofilm formation[2,3].

Hence, flushing vascular access devices is a key pillar of proper vascular access maintenance. The Infusion Nurses Society's Infusion Nursing Standards of Practice defines three advantages of catheter flushing[5]:

- Assessment of catheter function
- Prevention of contact of incompatible medications or fluids that could produce precipitations
- Maintaining catheter patency

Maintaining catheter patency is an important measure for all types of vascular access devices. Regardless of the frequency, type or volume, the majority of literature on maintaining patency recommends the use of correct flushing and locking techniques[6]. Flushing helps to prevent the mixing of incompatible medications or solutions and/or clear the catheter lumen of blood or fibrin buildup. Locking helps to prevent blood from backing up into the catheter lumen when the device is not in use[7].
Sterile 0.9% sodium chloride should be used to flush and lock catheter lumens that are accessed frequently[8]. Although the volume of the flush solution can vary depending on the patient, device, catheter size and nature and type of infusion/medication, a minimum is at least twice the volume of the catheter is recommended[5]. Flushing should be performed before, between and after the administration of incompatible medications and/or solutions[5].

In addition, pulsatile flushing technique was more effective in than continuous flushing in clearing or reducing endoluminal contaminations and, thereby reducing vascular access device associated complications[9, 10, 11].

Administering intravenous medication is one of the most common nursing interventions[1, 6, 7, 9]. Gravity infusion, which is still one of the most widely used methods, has undergone various modifications and improvements in terms of safety and performance over the years[1, 7, 9].

Nevertheless, two disadvantages of standard gravity infusion systems remain[2, 8]:

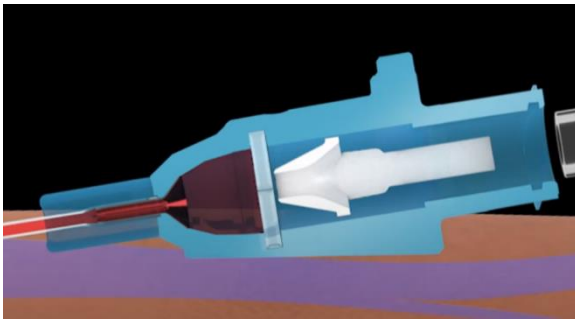
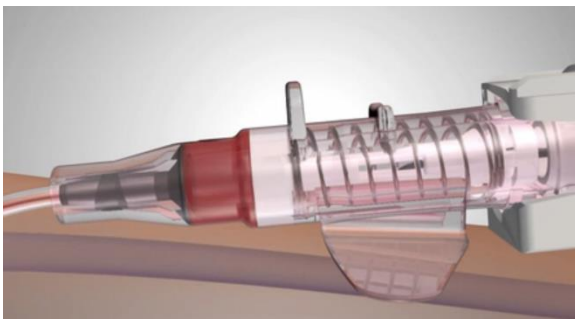
- Fluid loss during preparation or during air elimination
- Influx of air into the infusion system

Additionally, the use of infusion systems carries a general risk for nosocomial infections, among them phlebitis[3, 4, 5].

Purpose

The latest generations of peripheral IV catheters are equipped with so called multi access blood control functionality (i.e. additional components) inside the fluid path that enable closing-off the peripheral IV catheter during cannulation and after disconnection of luer devices to prevent blood exposure from the open luer. The aim of the lab test conducted by Brünke[14] was to evaluate efficacy of blood clearance through flushing and mechanical hemolysis properties of IV catheters featuring such multi access blood control functionality, i.e. Introcan Safety® 3 (B. Braun Melsungen AG, Melsungen, Germany) and Cathena™ (Becton Dickinson, Franklin Lakes, USA) (Figure 1).

Figure 1: Multi access devices Introcan Safety® 3 and Cathena™

Introcan Safety® 3	**Cathena™**
	

Source Introcan Safety® 3: https://www.youtube.com/watch?v=milFQ1Vtg3M, time : 3:32
Source BD Cathena™: https://www.youtube.com/watch?v=b28GXRVuQqA, time: 0:22

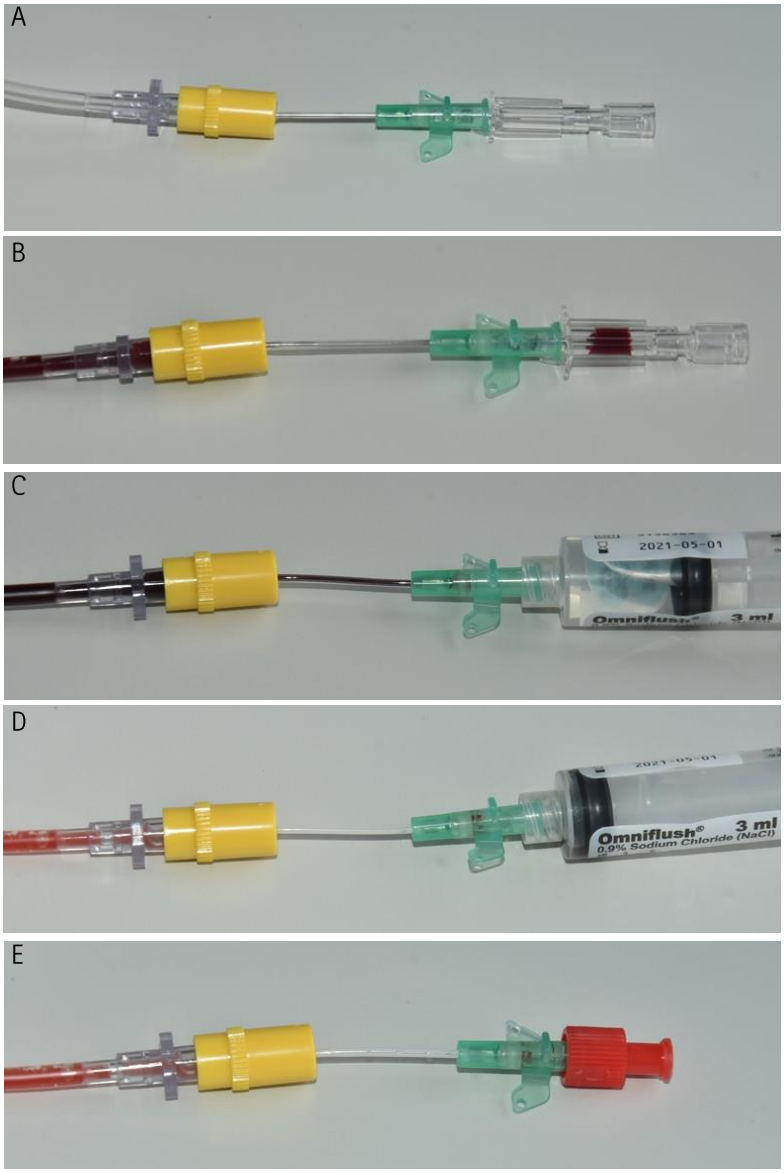
Methods

Brünke used a blood clearance test to determine the clearance of blood of medical devices by flushing procedures. Here, the blood component hemoglobin is used for the determination and quantification of residual blood.

Blood Clearance Test:
The IV catheter was placed in the In-Stopper, which was connected to an extension line type Heidelberger connect to a blood bottle containing human blood (Figure 2A). The blood bottle was elevated that the blood could flow through the extension line, the In-Stopper and the IV catheter, simulating blood pressure (30cm/wc).
When the IV catheter cannula was filled with blood the cannula was removed from the IV catheter (Figure 2B). The internal septum of the IV catheter prevented the release of blood. After needle withdrawal the IV catheter was left open for 30s to simulate utilization of blood control feature by users.
A syringe filled with 3ml of 0.9% sodium chloride solution was connected to the IV catheter (Figure 2C). The Extension Line was disconnected from the blood bottle and 3ml of the sodium chloride solution were administered

through the IV catheter using pulsatile flushing technique (Figure 2D). The syringe is removed from the IV catheter and the port was closed with a Combi Stopper (Figure 2E).
After 24h incubation at room temperature, the IV catheter was disconnected from the In-Stopper and a syringe filled with 3ml of 0.9% sodium chloride solution was connected to the IV catheter. 3ml of the sodium chloride solution were administered through the IV catheter and the flow-through solution was collected. The flushing process is repeated 2 more times.

Figure 2: Test procedure of blood clearance test with a random peripheral IV catheter



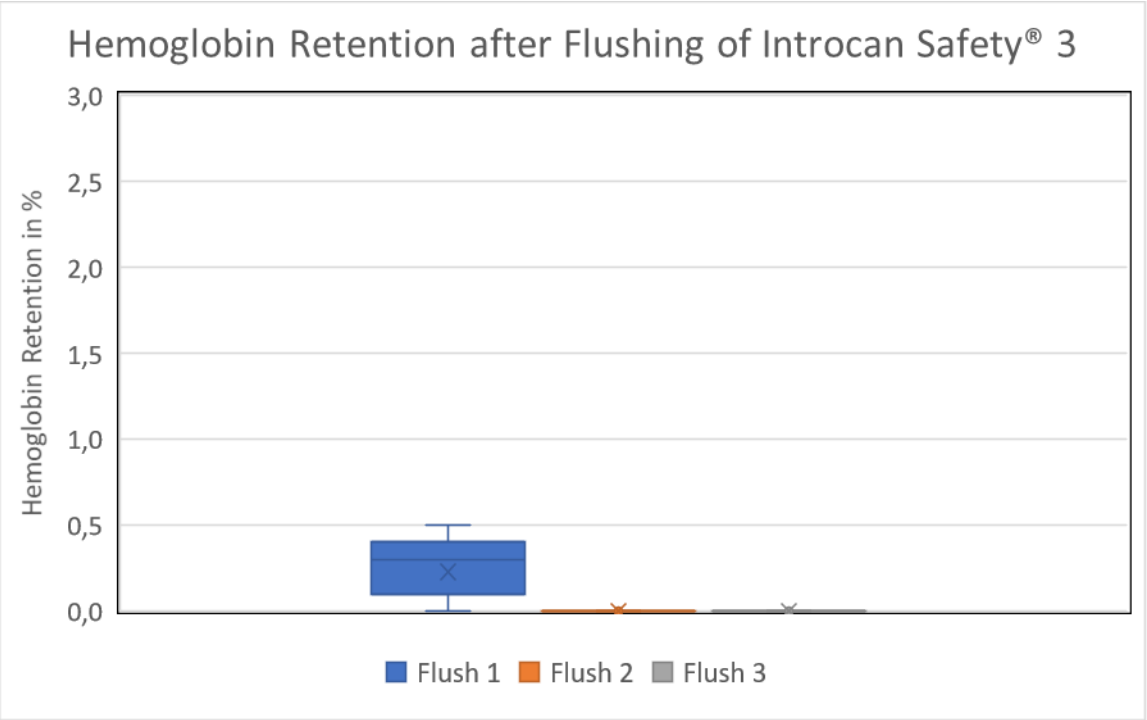
The flow-through fractions were analyzed for presence of hemoglobin by use of Drabkin's reagent and spectrophotometric analysis[12, 13]. An IV catheter filled with blood was used as a positive control.

In additionally performed mechanical hemolysis tests no significant mechanical hemolysis of human blood during aspiration, injection or aspiration by use of a Vacutainer EST tube was detected for both tested devices, Introcan Safety® 3 and Cathena™, respectively.

Results

In the study conducted by Brünke[14], no release of blood was observed for all 15 tested devices after removal of the cannula. During the blood clearance study with 3 consecutive flushing steps, Introcan Safety® 3 showed a clearance of 99.8% in average by applying the first flush. After the second and the third flush no traces of hemoglobin were detected in the flushing fractions (Figure 3). After the second and third flushing step, all 15 tested Introcan Safety® 3 devices showed total blood clearance (Figure 5).

Figure 3: Hemoglobin retention of Introcan Safety® for 3 consecutive flushes



For Cathena™, no release of blood was observed for all 15 tested devices after removal of the cannula. During the blood clearance study with 3 consecutive flushing steps, for Cathena™ 89.7% of blood was cleared in average by applying the first flush. After the second and third flush, the average clearance was 99.6% and 99.9%, respectively (Figure 4). Of the 15 tested Cathena™ devices, 4 devices showed complete blood clearance (Figure 5).

Figure 4: Hemoglobin retention of Cathena™ for 3 consecutive flushes

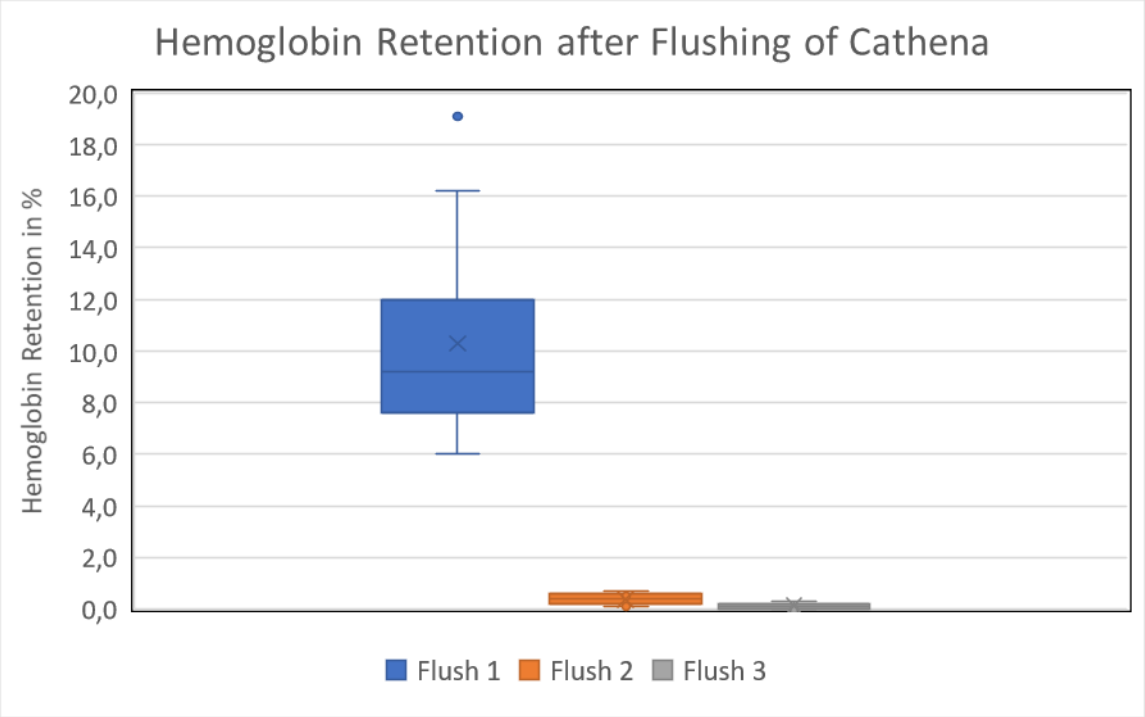


Figure 5: Blood clearance of the tested vascular access devices Introcan Safety® 3 and Cathena™.

Summary - Blood Clearance (number of cleared samples / number of tested samples)			
Device	Clearance after 1. Flush	Clearance after 2. Flush	Clearance after 3. Flush
Introcan Safety® 3	3 / 15	15 / 15	15 / 15
Cathena™	0 / 15	0 / 15	4 / 15

Conclusion

As outlined above, proper blood clearance of peripheral IV catheters through flushing is an important factor contributing to maintaining catheter patency and reducing the risk of bacterial growth after microbial contamination.

In Brünke's study[14], blood clearance of peripheral IV catheters showed significant differences between the tested products when applying flushing techniques according to common guidelines. The first applied flushing step showed a blood clearance from the VAD of 99.8% for Introcan Safety® 3 and 89.7% for Cathena™, respectively. A complete blood clearance of Introcan Safety® 3 was achieved after the second flushing step, whereas for Cathena™ 4 out of 15 devices were completely cleared after the third flush. In fact, Introcan Safety® 3 design enables a higher blood clearance resulting in a less blood residues inside the catheter hub.

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