

Comparison of Blood Reflux in a PICC Using a 10 mL BD PosiFlush™ Saline Syringe¹ Versus a Standard 12 mL Syringe^{2, 3}

Introduction

INS Standards⁴ for flushing vascular access devices (VAD) stress the importance of positive pressure flushing techniques. BD supports this practice standard. Positive pressure flushing while using a filled syringe is the most effective method of keeping a VAD patent. However, when positive pressure flushing is performed incorrectly, blood may reflux into the catheter. The term reflux refers to blood aspirated into the distal tip of a catheter after the clinician has relaxed pressure on the syringe plunger. Potential complications related to inappropriate flushing techniques include catheter occlusion by fibrin or thrombus.⁵ In an effort to minimize these serious complications associated with reflux, BD developed the new BD PosiFlush Saline Syringe specifically designed for flushing vascular access devices.

Background

Most standard syringes in the marketplace today were designed for medication delivery rather than with the goal of decreasing blood reflux in intravenous catheters. Early in the development of the BD PosiFlush Syringe, eliminating reflux was determined to be a key element in the design of the syringe. Several design features were implemented into the overall product design in the pursuit of eliminating reflux. Laboratory testing was performed to determine the amount of reflux generated in a 10 mL BD PosiFlush Saline Syringe and a standard 12 mL syringe* using a 4 French PICC.

Test Method Development

A reflux test method was developed that accurately measures the amount of solution aspirated into the catheter over time once the force on the syringe plunger is relaxed. In order to ensure that the test procedure reflects actual clinical practice, BD performed a simulated use study in which 30 nurses from a variety of clinical backgrounds were asked to flush a 4 French PICC multiple times with a variety of syringes. Variables measured included the time required to flush the catheter with 10 mL of saline, the force applied to the plunger at the completion of the flush, and the time required to clamp-off the extension set.

The data from the simulated use study was statistically analyzed to determine the minimum and maximum values for the flush speed, compressive force, and catheter clamp-off time to be used in a reflux bench top study. The clamp-off time is important because an increase in the time between releasing the force on the syringe plunger and clamping-off the catheter will increase the amount of blood that collects in the catheter. The average clamp-off time was 2.5 seconds. The test samples used in this study were the 10 mL BD PosiFlush Saline Syringes and the 12 mL standard syringe. In all four min/max combinations, the 10 mL BD PosiFlush Saline Syringe averaged zero reflux,* while the reflux in the 12 mL standard syringe was significant. The results also determined the speed and the compressive force used for the test method that generated the following reflux information.

Reflux Test Method

1. A filled syringe is placed in a computer controlled test fixture that maintains the syringe position throughout the test.
2. A 4 French PICC is connected to the syringe.
3. A controlled load is applied to the plunger of the syringe that depresses the plunger at the desired speed. The entire contents of the syringe are flushed through the catheter and captured in a container.
4. When the syringe is empty, the plunger is held with the desired force. As the force on the plunger is relaxed, the change in weight of the solution in the container is calculated.
5. This change in weight is from the solution aspirating back into the catheter as reflux occurs.
6. The measured weight is then converted into the comparable length in a 4 French PICC.

Results

Testing revealed a broad range in performance on reflux characteristics among the syringes tested. For simplicity, average test data is displayed in two figures below. Figure 1 summarizes the aggregate reflux results at different time intervals for all three lots of the two types of syringes tested. Figure 2 details the lot-to-lot variability for each of the six different manufacturing lots tested. The three lots being analyzed in Figure 2 were composed of 120 samples each.

Conclusion

The results indicate that, on average, 10 mL BD PosiFlush Saline Syringes achieve zero reflux* and significantly outperform standard 12 mL syringes in all aspects relating to reflux. First, BD PosiFlush Saline Syringes generate zero reflux* compared to more than 16 centimeters of reflux in standard 12 mL syringes. Second, BD PosiFlush Saline Syringes also exhibit less of an increase in reflux during the range of catheter extension set clamp-off times (1.5, 2.5, and 3.0 seconds). As mentioned previously, once the force on the syringe plunger has been released, blood will begin to accumulate in the PICC. The 30 clinicians in the simulated use study took an average of 2.5 seconds to clamp-off the line after completing the flush. Figure 1 lists the reflux values for both products at 1.5, 2.5, and 3.0 seconds. However, manual dexterity is not the same for all clinicians. Some clamped the line more quickly than 2.5 seconds, while others took much longer. Therefore, the data in Figure 1 is significant because it shows that the average reflux with BD PosiFlush Saline Syringes increases less over time than the standard 12 mL syringes, reducing the importance of manual dexterity on the part of the clinician.

It is clear that BD PosiFlush Saline Syringes are designed to eliminate blood reflux, thus enhancing catheter maintenance and providing significant benefits in circumstances when positive pressure flushing technique is not performed correctly.

Figure 1

Average Centimeters of Blood Reflux Seen in a 4 French PICC Over Time

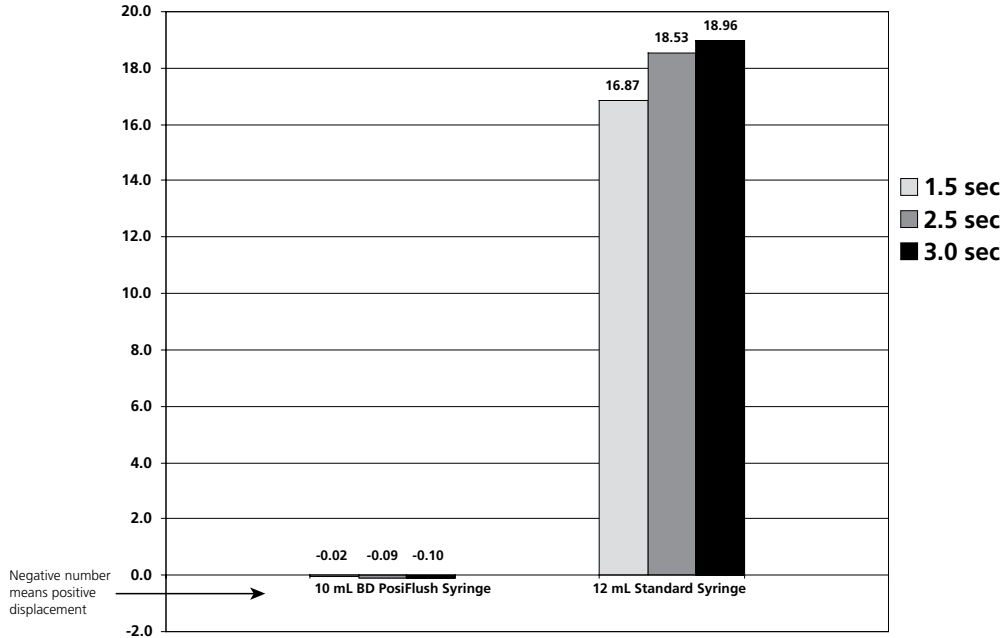
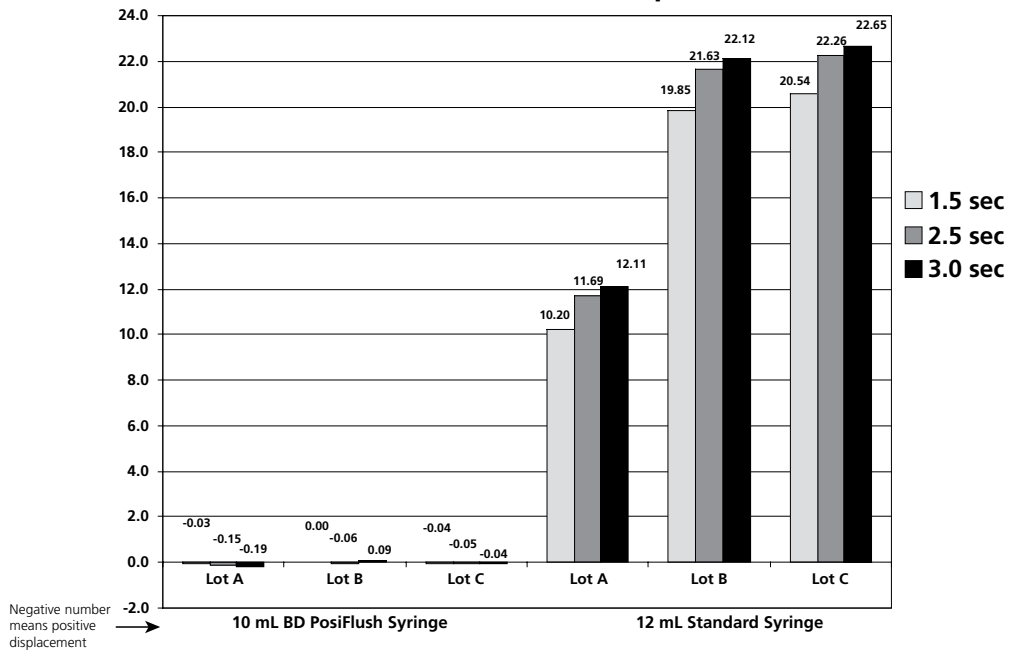


Figure 2

Average Centimeters of Blood Reflux Seen in a 4 French PICC (three different lots per manufacturer)



Footnotes:

1. The BD PosiFlush™ Syringe 10 mL Lot A lot number is 6143030, Lot B lot number is 6143032, and Lot C lot number is 6153807.
2. Standard 12 mL syringe Lot A lot number is KH02119, Lot B lot number is KH02128, and Lot C lot number is KH02138.
3. 12 mL standard syringe refers to the Sherwood 12 mL Monoject® Disposable Syringe, Reorder # 8881-112158.
4. Mayo DJ. Reflux in venous access devices a manageable problem. *Journal of Vascular Access Devices*. Winter 2001.
5. Hadaway LC. Major thrombotic and nonthrombotic complications. *Journal of Intravenous Nursing*. Vol. 29, No 1S, January/February 2006.

* Average reflux as measured in 4 Fr PICC; data on file at BD.

