The Port Clearance Test: Why It Is Important to Clinicians

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Abstract

Understanding proper chamber flushing volume for each port manufacturer and port chamber shape is of value to both clinicians and patients. Failing to follow adequate flushing volumes may lead to sludge buildup and further complications. By sampling the chamber flushing volume of ports of various shapes from different manufacturers, we were able to assess cumulative volume flushing rates using a mixture approximating the viscosity of blood. The data collected highlight the relationship between chamber shape, flushing volume, and flow rate and why it is important that manufacturers recommend adequate flushing volumes specific to each port.

Keywords: *chamber flushing volume, port clearance sludge, spherical chamber*

Introduction

During the early 1980s, when the first vascular access ports were approved for human implant, the MediPort (Norfolk Medical, Skokie, IL), Port-A-Cath (Smiths Medical, St. Paul, MN), and Infus-A-Port (Infusaid Corp, Sharon, MA) user's manuals suggested a 10-mL flush solution volume be used. If this flush volume was determined empirically by testing each port or based on previous practice with Hickman-style external lines is unknown. Similarly, according to current Infusion Nurses Society Flushing Protocols as presented in their Spotlight on Flushing and Locking, an accessed implanted port should be flushed after each use or at least 1-2 times per week with 5-10 mL 0.9% sodium chloride (saline) and locked with 3-5 mL 100 units/mL heparin.[1,2] Today's port manufacturers recommend an analogous protocol, but given the variety of ports available in today's market, is it time to question this flush recommendation and evaluate flushing requirements based on a specific testing regimen? While that flush volume has been widely accepted across the industry, based on the amount of literature pertaining to infection, withdrawal occlusions, and the incidence of sludge, it is our position that the amount of flushing solution should be questioned.[3-6]

Interestingly, while port design has changed and adapted during the past 30+ years to meet the needs of patients and health care providers alike, the flushing volume has not. The lack of literature pertaining to port clearance testing suggests that it is poorly understood and rarely discussed and presented by manufacturers. The chamber flushing volume (CFV) specific to each port manufacturer is a very important figure to know and to understand. If port manufacturers are not recommending adequate flushing volumes, this may lead to sludge buildup and further complications.[2,7]

In October 1990, the US Food and Drug Administration (FDA) Center for Devices and Radiological Health, Office of Device Evaluation, Division of Gastroenterology/Urology and General Use Devices published the document "Guidance on 510(k) Submissions for Implanted Infusion Ports."[8] According to the FDA,[8] guidance documents are recommendations to manufacturers that are nonbinding. A manufacturer may choose alternative approaches if the approach satisfies the requirements of applicable statutes and regulations. It is important to note that the FDA published a guidance document, not a requirements document, and thus each applicant can, at his or her discretion, choose which tests to perform and submit. If the FDA does not believe a manufacturer has done sufficient testing, they may require further testing before granting approval.

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Cylindrical Rounded Spherical

Figure 1. **Port chamber shapes. The images are representations only and are not meant to imply exact chamber shapes and/or volumes.**

The port guidance document[8] contains a set of recommended tests that any new implanted infusion port should be subjected to before submission of 510(k) clearance to market applications and be a part of the application. One of those tests is the port clearance test.[8] This test measures how efficiently the chamber of a port flushes—or clears—using a simulated blood solution containing a measurable contaminant. This value is known as the CFV. Our study examined the port clearance test to explain why such a test is both necessary and important.

Methods

To better understand the port clearance test as it relates to ports from various manufacturers, the test was administered on ports with varying chamber shapes. Ports from 3 leading port manufacturers were tested. They were selected because they provide a wide range of chamber shapes, from cylindrical to rounded to spherical (Figure 1), yet are all of similar size and currently commercially available ports. The images in Figure 1 are representations only and are not meant to imply exact chamber shapes and/or volumes.

The port clearance test was developed based on FDA guidance[8] and is available on the FDA website (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationand%20Guidance/GuidanceDocument/UCM081374.pdf). The FDA document suggests creating 2 different impedance solutions, a filling solution of 150 ohms and a flushing solution that has an impedance less than the filling solution; filling the port with the filling solution, then injecting the flushing solution at a constant rate.[8] The results produce a record of impedance dilution, clearance time, and clearance volume for a given flow rate.[8,9] Similarly, one can arrive at the same results by using an alternative approach that measures the change in conductivity between the 2 solutions. Conductivity, measured in micromhos per centimeter for this study, is a measure of how well a solution conducts electricity. The filling solution selected was a saline/glycerin/salt mixture based on the FDA guidance document.[8] It is composed of distilled water and 45% glycerin by weight mixed with 2.9 g/L sodium chloride.[8,9] This mixture approximates the viscosity of blood and meets the resistance recommendation set forth in the guidance document. The flushing solution selected was deionized water. Both beakers of solution were placed in a water bath at 37°C ± 2°C to ensure temperature equilibrium.

To measure the conductivity of these solutions, and therefore, accurately monitor the conductivity change that occurs when the flushing solution replaces the filling solution, a conductivity cell/meter attached to the end of the catheter was used. Before testing, the conductivity of both solutions was measured. The glycerin/saline/salt solution measured 160 µmho/cm and the deionized water measured 0 µmho/cm.

Before testing began, all ports were conditioned in the water bath at 37°C ± 2°C. A port was then connected to the conductivity cell via the catheter, filled with the filling solution, and allowed to equilibrate. It is important to note that all catheter internal diameters and lengths were the same (1.25 mm and 6 in, respectively). This was done to prevent the catheter dead space volumes from influencing the CFV. Next, a reading was taken from the conductivity meter and recorded as the start conductivity. A 20-gauge noncoring needle set was then attached to a 60-mL syringe, filled with flushing solution, and mounted on a syringe pump. The needle set was purged/primed and then used to puncture the port septum at an orientation of 90° with respect to the port base. The syringe pump was set to a constant flow rate (5, 10, or 20 mL/min) and allowed to deliver the flushing solution into the port until the conductivity meter read the measured conductivity of the flushing solution. This was recorded as the end conductivity. The total volume of flushing solution pumped was recorded as the clearance volume. From these recorded values, it was also possible to calculate delay time (ie, the amount of time elapsed between the onset of

Table 1. **Clearance Volume Data for Flow Rate of 5 mL/min**

Port	Chamber shape	Outlet pin orientation	Clearance volume (mL)	Clearance time (s)
Sample 1	Spherical	Tangential	2.42 ± 0.06	29.09 ± 0.73
Sample 2	Rounded	Tangential	5.68 ± 0.49	68.16 ± 5.86
Sample 3	Cylindrical	Centered	8.01 ± 0.54	96.17 ± 6.44

Note: Values are given as mean ± SD.