Securement Strength and Motion Reduction Properties of a New Novel Engineered Stabilization Device

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Introduction

The use of catheter securement devices to stabilize and secure central venous catheters (CVCs) and peripherally inserted central catheters (PICCs) is recommended by national organizations such as the Centers of Disease Control (CDC) and Infusion Nursing Society (INS). Research has shown that the use of catheter securement devices helps "preserve the integrity of the access device, minimize catheter movement, and prevent catheter dislodgment and loss of access[1]. Studies have also shown that "pathogenesis of CRBSI occurs via migration of skin flora through the percutaneous entry site[2]." Catheter movement in or out of the insertion site (micropistoning) helps facilitate access for skin organisms to migrate into the site and down the external lumen of the catheter potentially causing infection[3]. "Sutureless securement devices avoid disruption around the catheter entry site and may decrease the degree of bacterial colonization[2]." During the life of the central line, there are many situations that can result in catheter movement. Movement of the catheter can occur inadvertently during standard line maintenance such as: disinfection, flushing, access of the port, and routine dressing changes. Catheter movement can also occur by movement of an IV pole, unintentional drop of an IV fluid bag, or snag of the IV line and/or catheter. Whether the movement of the catheter is minimal as in micropistoning or large enough to cause the catheter tip to migrate, both can potentially be problematic for the patient resulting in complications, infection or premature catheter removal. The 2016 Infusion Therapy Standards of Practice recommends the use of an Engineered Stabilization Device (ESD) to stabilize and secure catheters but no details are provided as to which type of stabilization device is preferred.

Purpose

The purpose of this study was to research catheter securement strength and motion reduction properties of a new novel mechanical Engineered Stabilization Device compared to commonly used catheter securement devices.

Methods

A laboratory simulation study was used to compare the strength, durability and securement properties of the novel ESD to four commonly used catheter securement devices. Ten (10) samples of each securement device were subjected to a Catheter Micro-Pistoning Movement Test and a 90 Degree Pull Force Test[4].

Catheter Securement Devices studied:

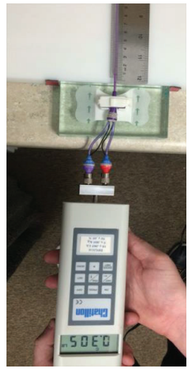
- TIDI® GripLock® Catalog No.: 3300MWA - "Device 1"
- Centurion® Wing Guard® Catalog No.: WG711XT – "Device 2"
- Bard® StatLock® Catalog No.: PIC022 – "Device 3"
- 3M® PICC/CVC Securement Catalog No.: 1839-2100 – "Device 4"
- New Novel Engineered Stabilization Device, Starboard Medical™ Clik-FIX™ Catalog No.: WCS-1000 – "Device 5"

Strength and Securement Tests Performed:

Catheter Micro-pistoning movement test:

To research movement of the catheter in and out of the insertion site, aka "pistoning" a catheter micro-pistoning movement test was performed. A 5 French dual lumen power injectable PICC catheter was threaded through a simulated vein and stabilized on a clean glass block with the securement device according to the respective manufacturer's directions for use. Bio-occlusive dressing was not applied over the securement device. The glass was cleaned with isopropyl alcohol and allowed to dry prior to each application of each securement device tested. The hub of the catheter was attached via a luer lock connector to a force gauge meter (Chatillion DFGS). To simulate a light tug on the catheter, the force gauge was intermittently moved away from the securement point creating a pull force between 2 to 4 lbs. The movement, pistoning of the catheter away from the simulated insertion point, was measured in millimeters and recorded. The system is shown in Figure 1.

Figure 1. Micro-Pistoning Movement Test



90 Degree Pull Force Test:

To stimulate a pull/snag on an IV line or an unintentional IV fluid bag drop, a 90 Degree Pull Force Test[4] was utilized to measure and record the pull force in pounds required to dislodge a PICC catheter from the securement device or complete removal of the securement device from the glass block. The test utilized the variable speed Pull/Push test stand which included the Chatillion TCM-1000, Force gauge Chatillion DFGS, Pull Test fixture, luer lock to catheter connection, and a glass block. To attach the catheter to the force gauge meter and assure the lumens of the catheter would not break or stretch, the lumens of the catheter were reinforced with wire by strapping the catheter hub and catheter wing to the wire with tightly wrapped thread and adhesive. A 5 French dual lumen power injectable PICC catheter was stabilized on a clean glass block with the securement device according to the respective manufacturer's directions for use and placed inside the pull test fixture. The securement devices were not covered with a bio-occlusive dressing. The glass was cleaned with isopropyl alcohol and allowed to dry prior to each application of each securement device tested. The hub of the catheter was attached via a luer lock connector and connected to the force gauge Chatillion DFGS. The system is shown in Figure 2. The constant pull speed (Pull speed: 2.4 inches/minutes or 1 mm/sec) was activated and at the point of catheter dislodgement from the securement device, or removal of the device from the glass block; the peak force was displayed on the force gauge and recorded in pounds (lbs.).

Figure 2. 90 Degree Pull Force Test



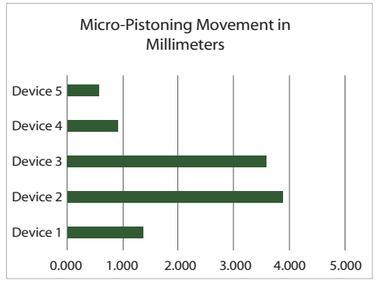
Results

Results from the Catheter Micro-Pistoning Movement Test showed that when a pull force is applied on the catheter above the securement point there is catheter movement below the securement point for each device tested. The amount of movement, however, varied by type of catheter securement device. The mean movement in millimeters for each securement device tested are shown in Table 1 and graphed in Figure 3.

Table 1. Summary of statistics of Micro-Pistoning Movement Test

Micro-Pistoning Movement (millimeters)			
Sample	**N**	**Mean**	**SD**
Device 1	10	1.350	0.580
Device 2	10	3.900	0.568
Device 3	10	3.600	0.516
Device 4	10	0.889	0.220
Device 5	10	0.550	0.158

Figure 3. Micro-pistoning Movement in Millimeters



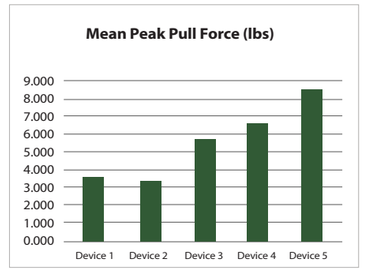
The new novel ESD (Device 5) exhibited the least amount of catheter movement in and out of the insertion site when subjected to a pull force on the catheter above the securement point. Device 3, the current market leading mechanical securement device, allowed 3.6mm of movement at the insertion site which is 6.5 times more movement than the novel ESD (Device 5). Studies have suggested catheter movement at the insertion site of greater than 5mm can lead to tip malposition and movement greater than 1 cm can lead to significant complications[5]. Device 2 and Device 3 exhibited the most pistoning during this test with the maximum nearing 5mm in movement. The novel ESD (Device 5) significantly reduced movement at the insertion site when subjected to the micropistoning test exhibiting a mean movement of only 0.55mm. Device 1 and Device 4 also demonstrated stabilization properties to minimize pistoning.

Results of the 90 Degree Pull Test show the Novel ESD (Device 5) exhibited the highest mean peak pull force of 8.326 lbs. with minimal standard deviation. The minimum peak pull force to failure for the Novel ESD (Device 5) was 7.56 lbs., which was significantly better than the other devices tested. For Device 4, 6.477 lbs. was the mean peak pull force required to reach failure and the failure mode was not removal of the catheter from the securement device but rather removal of the entire securement device from the glass block. Device 4, however, had the greatest standard deviation from all devices tested. 1 sample removed from the glass block with as little at 1.765 lbs. pull force while another required 9.62 lbs. force. Device 3, the current market leading mechanical securement device, failed at mean peak pull force of 5.696 lbs. Device 1, a commonly used tape based alternative to mechanical securement, lifted apart at the Velcro and allowed for complete catheter removal from the device with a mean pull force of 3.62 lbs. Similarly, Device 2 a silicone guard stretched allowing completed dislodgement of the catheter at a mean pull force of 3.335 lbs. Figure 4. illustrates graphically the average peak force (lbs.) required to dislodge the catheter from the securement device or entirely remove the securement device from the glass block. Table 2. provides a summary of the data collected.

Table 2. Summary of statistics of 90 Degree Pull Force Test

Peak Pull Force (lbs)			
Sample	**N**	**Mean**	**SD**
Device 1	10	3.620	0.995
Device 2	10	3.335	0.365
Device 3	10	5.696	0.961
Device 4	10	6.477	2.666
Device 5	10	8.326	0.562

Figure 4. Mean peak pull force required for device failure.



Limitations

The results of the study are limited as they were not performed on catheterized patients but rather in a laboratory setting with testing apparatus designed to simulate the forces the catheter and device would be exposed to in the clinical setting. It would not be possible to conduct this type of testing on actual patients due to the many risks and complications that could result.

Conclusion

This study demonstrates that there are significant differences in the securement and stabilization properties of the various catheter securement devices available for use today. Mechanical securement devices that feature an engineered design specifically made to latch over or strap in the catheter wing performed better in this study. Alternatives, such as tape based and silicone housing systems, did not secure the catheter as effectively as the active mechanical securement device. The new novel ESD (Device 5) stabilized the catheter better than the other securement devices showing less pistoning in and out of the insertion site during the micro-pistoning movement test and better securement during 90 Degree Pull to failure testing. The novel ESD investigated appears to be a promising alternative to existing securement devices.

Disclosures

No disclosures

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