CLIK-FIX CATHETER SECUREMENT
WHITE PAPERS AND STUDIES

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CLIK-FIX™ DEVICE DURABILITY – NUMBER OF ACTIVATIONS UNTIL FAILURE

Background

Catheter securement devices used to secure peripherally inserted central catheters and central venous catheters are typically placed at time of catheter insertion. The winged hub of the central catheter is placed into the securement device and the device is locked. At the next dressing change, the catheter securement device will be unlocked and the catheter wing removed from the device. Typical use will not require the catheter securement device to be opened and closed during the duration of use. However, the hinges on the locking mechanisms of catheter securement devices support a critical patient lifeline, as such they should be durable and secure. Even though the ability to open and close the catheter securement device is not typically required until the next dressing change, having a device designed to withstand the pressures that may occur during securement of the catheter is an important product feature.

Purpose

To test the strength and durability of two leading catheter securement devices when subjected to multiple device activations.

Methods

Ten samples of the Bard® StatLock® (PIC0220) Catheter Securement Device hereinafter "Competition" and the Starboard Medical™ Clik-FIX™ (WCS-1000) Catheter Securement Device were each placed on a clean glass block. Following the respective manufacturer's directions for use, a commonly utilized dual lumen power injectable 5 French PICC catheter was placed into each securement device. The catheter was properly secured in the device and then the catheter was removed from the securement device. The process of locking in the catheter and unlocking the catheter is considered 1 activation. Each catheter securement device was repeatedly activated until the device failed. The number of activations until failure were recorded for each of the securement devices tested.

Results

The activations until failure test demonstrated there are significant differences in the durability and strength of the hinge design between the two securement devices tested. The Clik-FIX catheter securement device displayed the highest mean number of activations until failure, 147 activations. Device 1, failed at a mean number of activations to failure of 8. The results collected are shown in Figure 1 (Clik-FIX WCS-1000 Data) and Figure 2 (Competition) below:

Figure 1. Clik-FIX Activations until Failure

Clik-FIX Sample	Activations	Comment
1	123	hinge broke
2	185	device did not break
3	163	hinge broke
4	145	hinge broke
5	120	hinge broke
Mean	**147.2**	
Std. Dev.	**27.43**	

Figure 2. Competition Activations until Failure

Competition Sample	Activations	Comment
1	2	1 hinge broke
2	5	1 hinge broke
3	16	both hinges broke
4	6	1 hinge broke
5	12	1 hinge broke
Mean	**8.2**	
Std. Dev.	**5.67**	

Conclusion

The activations until failure test demonstrated there are significant differences in the durability and strength of the hinge design between the two securement devices tested. The Clik-FIX device was able to tolerate 147 activations prior to the hinges failing. The competition, a commonly used securement device, failed at an average of 8 activations demonstrating the hinges are less tolerant to stress. The strength and durability of catheter securement devices is an important characteristic to review when securing central venous catheters. This study demonstrated the Clik-FIX catheter securement device provides superior durability during repeated activation testing.

FLOW RATE THROUGH THE CATHETER WITH AND WITHOUT SECUREMENT DEVICE

FLOW RATE THROUGH THE CATHETER WITH AND WITHOUT SECUREMENT DEVICE

Introduction

The primary objective of catheter securement devices is to properly secure the catheter without changing the characteristics of the catheter itself. Flow rate is a critical characteristic of IV catheters. The catheter securement device cannot restrict the flow of IV fluids to the patient.

Objective

Verify that the catheter securement device does not restrict flow through the catheter under both gravity and pressure administration systems.

Method

Two catheters were tested under both gravity fed and pressure driven conditions. The gravity administration system consisted of a reservoir open to the atmosphere with a 1 meter head height above the termination of the catheter. The pressure driven administration setup maintained constant hydrostatic pressure in order to generate the measured flow rate. Both systems used water as the test fluid. The fluid volume was collected into the graduated cylinder over a constant time interval. The volume was then divided by time to determine flow rate. The device tested is the Clik-FIX™ PICC and Central Catheter Securement Device (WCS-1000). Five data points were taken for each catheter in both open and secured configurations.

Results

The flow rate data for the gravity administration setup is given in liters per hour (ml/m). The flow rate data for the pressure administration setup is given in milliliters per second (ml/s).

Gravity Administration Setup

Arrow® PICC with Chlorag+ard® Technology Double-Lumen 5.5Fr	
Mean Flow Rate Unsecured(ml/m)	7.24 ± 0.09
Mean Flow Rate Secured(ml/m)	7.18 ± 0.05

Bard® PowerPICC® Dual Lumen 5Fr	
Mean Flow Rate Unsecured(ml/m	7.08 ± 0.08
Mean Flow Rate Secured(ml/m)	7.12± 0.11

Pressure Administration Setup

Arrow® PICC with Chlorag+ard® Technology Double-Lumen 5.5Fr	
Mean Flow Rate Unsecured(ml/s)	4.22 ± 0.05
Mean Flow Rate Secured(ml/s)	4.18 ± 0.04

Bard® PowerPICC® Dual Lumen 5Fr	
Mean Flow Rate Unsecured(ml/s)	4.21 ± 0.05
Mean Flow Rate Secured(ml/s)	4.34 ± 0.02

Conclusion

The flow rates with and without securement match closely for both the gravity fed and pressure driven systems. The locking mechanism of the Clik-FIX™ PICC and Central Catheter Securement Device (WCS-1000) does not restrict flow through the catheter.

SECUREMENT STRENGTH AND MOTION REDUCTION PROPERTIES OF A NEW NOVEL ENGINEERED STABILIZATION DEVICE

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 detail is 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 variable 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.

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

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

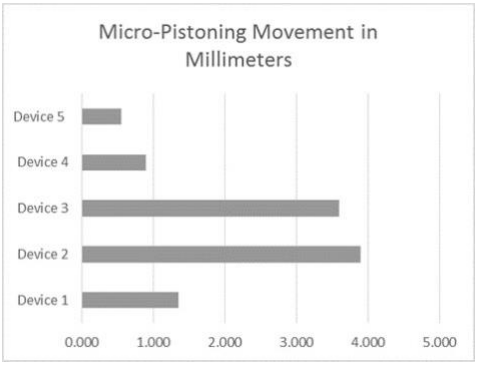

Figure 3: Micro-pistoning Movement in Millimeters

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 .5 cm 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 .5cm 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. The actual pull tests are shown in Video 1. for Device 3 and Video 2 for Device 5.

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

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

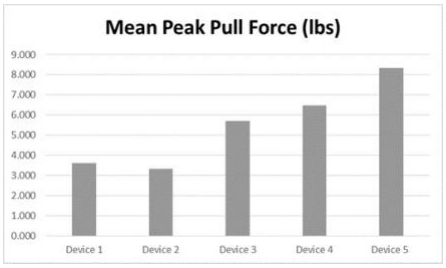

Figure 4. Mean peak pull force required for device failure

Conclusion

This study demonstrates that there is a difference 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.

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.

Citations

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SIZE AND PROFILE OF ACTIVE MECHANICAL SECUREMENT DEVICES

SIZE AND PROFILE OF ACTIVE MECHANICAL SECUREMENT DEVICES

Background

Catheter securement devices used to secure peripherally inserted central catheters and central venous catheters are often scrutinized for their size and profile. The general school of thought is that a device that is low profile may help minimize the risk of site disturbances from bumping or jostling and a small surface area is better because it is less cumbersome. The problem is that general school of thought is not necessarily true. In clinical applications, it is well known that the larger the surface area for adhesive placement, the better the adhesion. Catheter securement aimed at reducing dislodgement, micro-movements within the intima of the vein and micropistoning at the insertion site must secure and hold the catheter well and many of the currently marketed low-profile tape-based securement systems are lacking in that respect.

Purpose

To present the actual difference in profile and surface area of a commonly used PICC and central catheter securement device to a new innovative active mechanical securement device.

Methods

Samples of the Bard® StatLock® (PIC0220) Catheter Securement Device with moving posts – hereinafter "Device 1" and the Starboard Medical™ Clik-FIX™ (WCS-1000) Catheter Securement Device were each measured in nine (9) specific locations with a digital caliper. The measurements were recorded and compared.

Measurement Sites

The measurement sites are described in the list below and depicted in Figures 1-4 below.

1. Height of device when locked from skin surface to highest point.
2. Height of device when locked from skin surface to top of cover.
3. Length of device footprint.
4. Width of adhesive pad.
5. Length of adhesive pad.
6. Length of locking device
7. Width of locking device
8. Height of top of catheter hub to skin when the catheter's positioned at zero insertion point and secured in the catheter securement device
9. Height of angle from hub/catheter junction to skin when the catheter's positioned at zero insertion point and secured in the catheter securement device.

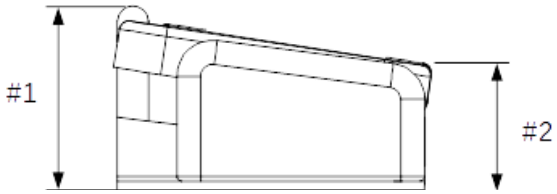

Figure 1. Measurements 1 & 2

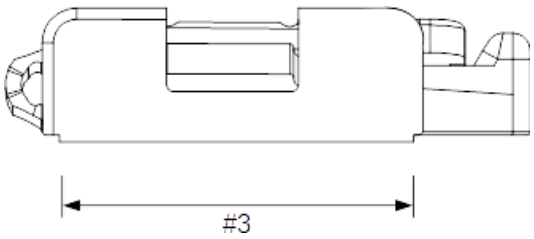

Figure 2. Measurement 3

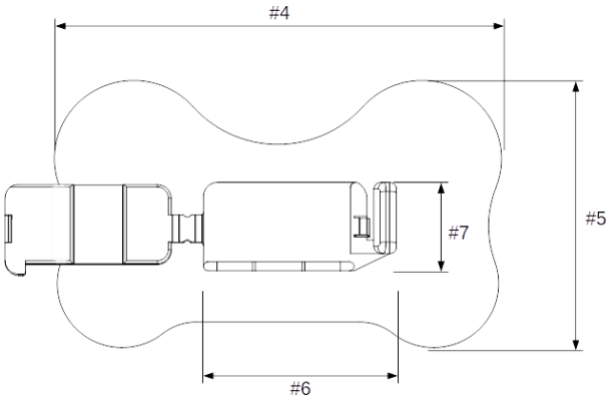

Figure 3. Measurements 4, 5, 6 & 7

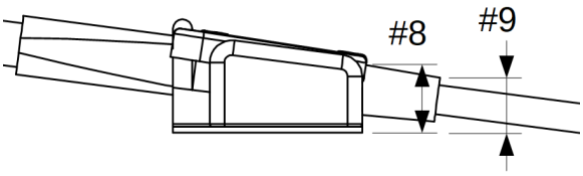

Figure 4. Measurements 8 & 9

Results

Profile, Footprint and Catheter Height - In Millimeters

Measured Location	Clik-FIX	Device 1	Variance
1	10	9	+1
2	7	9	-2
3	26	29	-3
4	79	78	+1
5	46	34	+12
6	36	29	+7
7	16	20	-4
8	6	8	-2
9	5	7	-2

The measurements reveal that the differences in profile and footprint of the two devices are minimal. The highest point on the Clik-FIX device is at the location where the posts raise to anchor the catheter wings to accommodate a variety of catheters. At this point, the Clik-FIX device is only 1mm taller than the Device 1; yet at the lowest point the Clik-FIX device is 2mm shorter than Device 1, demonstrating the profile of the Clik-FIX and Device 1 are nearly the same. The securement pad of each device is very similar in width, but the length of the Clik-FIX device is larger to maximize the surface area on the skin, allowing the use of a less aggressive adhesive.

Measurement 6 and 7, the length and width of the locking device, also show minor differences between the two devices. The Clik-FIX base is 7mm longer, but 4mm shorter in width than Device 1's base. However, the length of the device footprint at measurement 3 shows that the Clik-FIX is actually 3mm shorter. The most important profile measurement with a catheter securement device is the height of the angle from the skin to the top of the catheter. While secured in the device at a simulated zero insertion point, the space created between the skin surface and top of catheter was measured in two locations. Location 8 was the height between the skin and the top of the catheter hub. Measurement 9 consisted of the height between the skin surface and the top of the catheter/hub junction. The Clik-FIX device was measured to be 2mm lower at both positions.

Conclusion

The difference in profile and surface area of the two securement devices are minimal. The adhesive pad on the Clik-FIX offers a slightly larger surface area in order to provide a better adhesion. A smaller surface area version is available for patients with sensitivities. The measurements taken at Location 8 and 9 also show that the Clik-FIX Catheter Securement Device secures the catheter closer to the skin, minimizing the gap between the catheter and skin surface to reduce the risk of inadvertent snagging or dislodgement.

BIBLIOGRAPHY

REVIEW OF CLINICAL STUDIES COMPARING VAD SECUREMENT DEVICES

BIBLIOGRAPHY – REVIEW OF CLINICAL STUDIES COMPARING VAD SECUREMENT DEVICES

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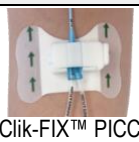
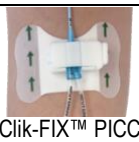
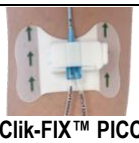
Griffin, Rochelle. "Out With the Old or In With the New: Catheter Securement, What Should We Use?" AVA 2018 Presentation, 2018	**StatLock®**	 Clik-FIX™ PICC Central Securement	 **Clik-FIX™ PICC Central Securement**
Lange, Victor. Securement Strength and Motion Reduction Properties of a New Novel Engineered Stabilization Device, The Journal for the Association of Vascular Access, December 2016 Volume 21, Issue 4, Page 257	**StatLock®**, GripLock®, WingGuard®, **3M® PICC/Central Securement**	 Clik-FIX™ PICC Central Securement	 **Clik-FIX™ PICC Central Securement**
Rutledge et al. Catheter securement systems: comparison of two investigational devices to a sutureless securement device, a securement dressing, and sutures in a pig model. Intensive Care Medicine Experimental (2015) 3:24	StatLock®, 3M™ Tegaderm®, Sorbaview® Shield	3M™ PICC/CVC Securement device + 3M™ Tegaderm™	3M™ PICC/CVC Securement device + 3M™ Tegaderm™
Ventura R, et al. Clinical evaluation of a securement device used on midline catheters. British J Nurs. 2016 Jul 28;25(14):S16-22. doi:10.12968/bjon.2016.25.14.S16. Abstract	StatLock®, GripLock™,	3M™ PICC/CVC Securement device + 3M™ Tegaderm™	3M™ PICC/CVC Securement device + 3M™ Tegaderm™
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