When the dressing is compromised... how well does the securement device stabilize?

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Introduction

As much as 90% of hospitalized patients will receive IV therapy during their hospital stay.[1] Research has shown that almost 50% of vascular access devices fail before the completion of treatment.[1] Catheter movement and dislodgement are the most common causes of vascular access device failure.[2] Catheters are often subjected to pulls and tugs during their life with the patient. These forces come from different angles and different intensities; therefore, devices used to stabilize catheters should be tested to tolerate these variable forces.

The most common cause of catheter dislodgement is the patient themselves pulling on the catheter. Other causes are tangling of the IV tubing with patient movement, transfer of the patient, moving the IV pump/pole, improper catheter care and maintenance, inadequate securement, and compromised dressing integrity.[3] Most concerning are those centered on the physical aspects of catheter stabilization. If compromised, any pull or tug on the catheter or tubing can lead to catheter movement, migration, and dislodgement. CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections recommend using securement devices to reduce the risk of infection and migration of skin flora into the insertion site. Migration of skin flora can occur when the catheter moves, even as little as a micro-motion. Thus, methods to protect and stabilize catheters, particularly peripherally inserted central catheters (PICCs), should address these unintended but expected situations.

Compromised or disrupted transparent semipermeable membranes (TSMs) are of concern to our team as the dressing itself is often the primary method used to secure the catheter. Disruption of the TSM is extremely common, even when all typical protocols are followed. 67% of TSM dressings fail before their scheduled change.[4] Disruption can be caused by an abundance of reasons: wear and tear, hair regrowth, humidity, patient temperature, clammy or oily skin, various bodily fluids like sweat, blood, pus, and device adhesive properties.[5,6] Frequently, a catheter is secured only with a TSM and not coupled with a securement device. This practice may lead to catheter movement and complications. Research has shown that non-occlusive dressings were identified as the major lapse in CVC care and a risk factor for catheter-related bloodstream infection.[4,6]

Although dressings are necessary, they should not be used alone. The Infusion Nurses Society (INS) recommends to "use a securement method... in addition to the primary dressing, to stabilize and secure VADs. Inadequate securement can cause unintentional dislodgement and complications requiring premature removal." They also recommend to "maintain asepsis during VAD dwell time by the use and management of sterile dressings and appropriate securement devices."[7]

Previous research has shown that TSM dressings are likely to fail between 50-72% of the time.[4,5,6] As such, the underlying ASD (adhesive securement device) ability to properly secure the catheter without the aid of transparent dressing is of utmost importance. Previous studies on catheter securement devices have focused on user evaluation surveys and/or device testing; the ASD and TSM are used in conjunction, making it difficult to ascertain which device (TSM or ASD) is the primary form of catheter stabilization. Research on securement device performance without the use of a TSM is lacking.

We noted that previous research on securement device stabilization was completed using only one specific pull force angle rather than many.[8,9,10] We know that during infusion therapy, inadvertent pulls or tugs on the patient's catheter and/or IV tubing will not be consistent or at the same angle every time. Our research aims to provide more clinically relevant data by simulating pulls on the catheter from multiple directions, not just one.

Our study aims to evaluate the catheter stabilization characteristics of several commercially available ASDs without the use of a TSM for their ability to secure and stabilize when subjected to multiple pull force angles, micromotion at the insertion site, and adhesive peel strength. Evaluation of the stabilization properties of the ASD without the dressing will answer the question:

When the dressing is compromised, how well does the securement device stabilize?

Purpose

The purpose of this study is to generate evidence comparing the performance and durability of commercially available adhesive securement devices (ASDs) for their ability to secure and stabilize peripherally inserted central catheters (PICCs) in situations where the transparent semipermeable membrane (TSM) may be compromised. To simulate the worst-case scenario of TSM disruption, we studied each ASD's performance without the use of covering TSM dressing. The specific aims of our study were to:

1. Test the ASD for its ability to secure and stabilize the catheter when subjected to 4 different pull force angles to simulate real-life clinical situations
2. Test the ASD for its ability to minimize catheter micro-motion at the insertion site
3. Test the ASD for its adhesive peel strength properties

This simulation study examines the catheter stabilization properties of ASDs when the dressing is compromised.

Method

The following ASDs, including 2 novel devices and 3 common devices (Table 1), were tested to assess catheter securement/stabilization, micro-motion, and adhesive strength in a simulated use study. The devices below were received in their original sterile packaging.

Devices Tested

Image	Device #	Manufacturer	Brand	Product Code	Lot #
	Device #1	Starboard Medical™	Clik-FIX™	WCS-1000	2018
	Device #2	Starboard Medical™	Clik-FIX™	WCS-1006	2021
	Device #3	BD™	Statlock™	PIC0220	JUFQ0551
	Device #4	3M™	3M PICC/CVC	1877-2100	202108AH
	Device #5	TIDI®	Grip-Lok®	3300M	43638629

Table 1

Pull-Strength Testing Method

To simulate conditions of catheter dislodgement, 40 samples of each ASD were used to secure a Bard™ Dual Lumen PowerPICC™ (5 French) on simulated skin according to each ASD's directions for use. To simulate the worst-case scenario of dressing disruption, a TSM was not utilized.

Each device was adhered to a flat glass block cleaned and prepped with alcohol and left to dry. Research for a simulated skin alternative found none of the current or past material alternatives used by others "provide a standardized surface that produces data predictive of adhesion to skin over time."[11] A glass block was chosen as the surface to simulate skin in this study. It provides a constant and standardized surface that can be thoroughly cleaned between each device application, minimizing variables that could affect our testing and results. The glass block was fastened to the base of a vertical test stand. After properly securing each ASD, the lumens of the PICC catheter were attached to a digital force gauge mounted to the motorized vertical test stand. To preserve the integrity of the catheters for testing, each lumen was inserted into a custom-made Luer connector attached to the force gauge with equal distribution of the pull force on each lumen (Figure 1).

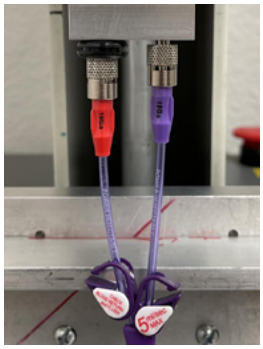

Figure 1
Custom-made Luer connector attached to the force gauge

Ten minutes after placement of the ASD on the simulated skin surface and placement of the PICC within the ASD, the secured PICCs were attached to the pull test equipment, and the pull force profile was observed and recorded. In total 40 samples of each ASD were tested; 10 samples were utilized for each of the 4 different pull test angles. To effectively simulate more clinically relevant pulls and tugs on the PICC or IV tubing, pull-strength testing was conducted by using a straight pull force at 0°, 45°, and 90°, and a 45°/45° side pull (Figure 2). The peak axial pull force measurement was recorded when the ASD failed to no longer secure the PICC.

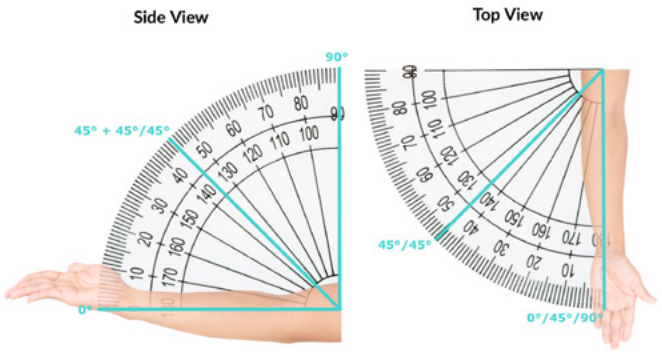

Figure 2
Visualization of the 4 chosen pull-test angles

Micro-Motion Testing Method

To determine the ASD's ability to reduce catheter micromotion, 10 samples of each ASD were tested to determine the maximum amount of PICC micro-motion when pulled with a 3 lb. force. Each device was first attached to a clean testing board. The catheter was inserted into a simulated vein, then inserted into the securement device according to the manufacturer's instructions. Reference points on the catheter were used to determine the micro-motion movement of the catheter inside the simulated vein when lead weights (3 lbs. in total) were attached to the lumens (Figure 3).

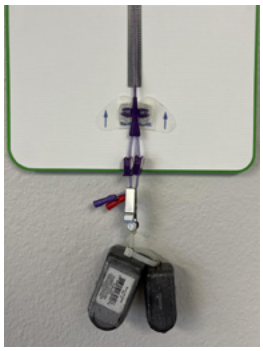

Figure 3
Micro-motion board setup after weights are added

Peel Testing Method

To test the ability of each ASD's skin-contacting adhesive, a peel strength test was performed. Adhesive peel strength is the force required to peel the device from the application surface (ASTM D3330 - Standard Test Method for Peel Adhesion). 10 samples of each ASD were prepared by removing all rigid plastic parts from the device to eliminate any variables that could interfere with the peel testing. If required, each device was cut down in size to have approximately the same adhesion surface area. Each device was then adhered to a clean simulated skin surface and attached to a motorized test stand with a digital force gauge, which pulled perpendicularly away from the surface at a 90° angle and constant speed (Figure 4).

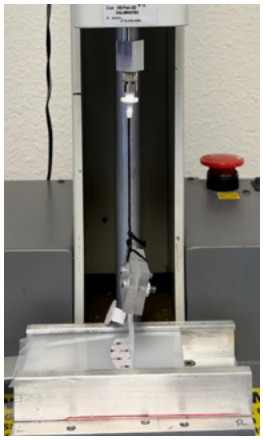

Figure 4
Visualization of peel-test

The peel strength was recorded with a custom data recording and graphing application, which collected peel force in pounds per second over the length of time it took to peel the entire device from the test surface. This data was plotted on a graph of force (lbs.) vs. time (seconds). The area under the curve was calculated to determine the overall peel strength of each device, which was recorded. This method of measurement was chosen because it is the most accurate way to evaluate the peel strength of materials with varying geometries.

Results

Our findings align with those of Rutledge, Lange, and Gibson, who found that the stabilization properties of various securement devices can vary greatly. The results of our testing show significant differences in catheter securement, stability, and adhesive strength between the ASDs tested in this study. Results show that the two novel devices (Device #1 and #2) displayed the highest mean peak

axial pull force required to dislodge the catheter from the device at every angle tested (Chart 1).

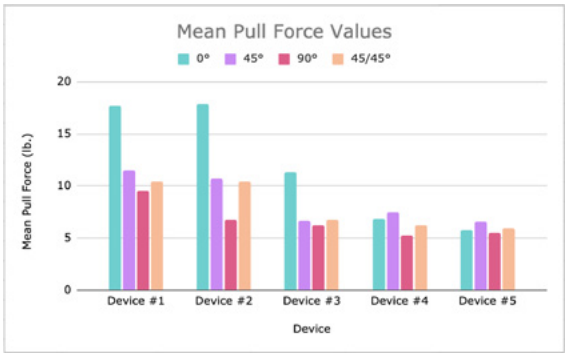

Chart 1
Pull-Strength Test Results

The mean peak axial pull force required to dislodge the PICC catheter from the ASDs at each pull force angle tested is shown in Table 2.

Mean Peak Pull Force Values (lb)				
Device	**0°**	**45°**	**90°**	**45°/45°**
1	17.682	11.4945	9.5665	10.474
2	17.843	10.709	6.794	10.4525
3	11.3045	6.693	6.236	6.7895
4	6.8855	7.522	5.272	6.2455
5	5.766	6.594	5.486	5.987

Table 2

For the 0° pull test, which would simulate a pull on the catheter away from the insertion site and level with the patient's skin, (Figure 5) Device #2 had the highest mean peak axial pull force at 17.84 lb. while Device #5 had the lowest mean peak axial pull force at 5.77 lb. However, at the 45° pull test, Device #1 had the highest mean peak axial pull force at 11.49 lb. Device #5 still performed lower than the other devices. For each ASD, the 90° pull test was the most problematic, causing each device to allow for PICC dislodgement at pull forces less than those of the other angles tested. At 90°, Device #1 had the highest mean peak axial pull force at 9.57 lb. while Device #4 had the least at 5.27 lb.

Figure 5
0° Pull-Strength Test Example Footage

The 45°/45° pull tests simulate what we believe to be the most common type of pull that a catheter would receive. It is a side pull at a 45° angle. (Figure 6) This pull test demonstrated that Device #1 had the highest mean peak axial pull force at 10.47 lb. Device #5 again had the least at 5.99 lb.

Figure 6
45°/45° Pull-Strength Test Example Footage

Micro-Motion Results

Under the conditions of a simulated 3 lb. tug, the catheter secured with Device #1 had the least amount of micro-motion movement at 0.46 mm. The catheter secured in Device #3 had the most micro-motion movement at 4.75 mm, 10x more movement than seen with Device #1. Device #5, which showed the least stabilization strength in the pull tests, performed better than Device #2, #3, and #4 in the micro-motion test. The micro-motion test used only a 3 lb. drop weight rather than a higher pound pull force which may explain the differences in device outcomes. All measurements were converted from inches to millimeters (1 inch = 25.4 mm). The mean PICC micro-motion movement for each device is shown in Table 3.

Mean Micro-Motion Values (mm)	
Device	**Catheter Micro-Motion Movement**
1	0.46
2	1.37
3	4.75
4	2.51*
5	0.89

Table 3
*device had to be taped down to test board to prevent lifting

Figure 7 shows visualizations of the micro-motion test. The red lines show an approximation of the change in location of the zero-point marker on the catheter when subjected to a 3 lb. pull force.

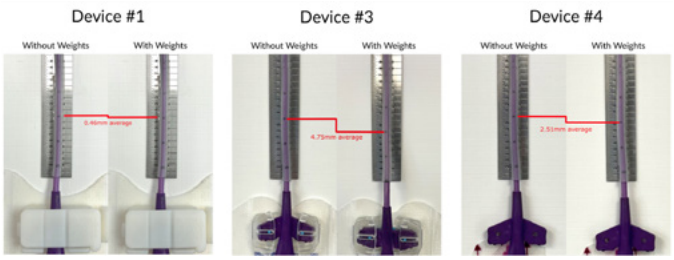

Figure 7

Peel Test Results

The results of the adhesive peel strength test varied widely (Chart 2).

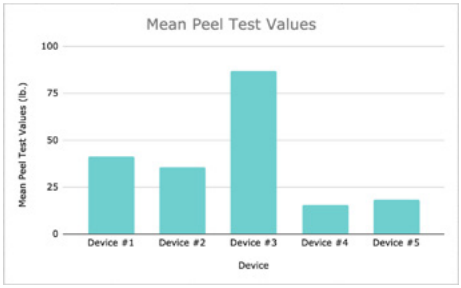

Chart 2

The adhesive peel strength of a device is not hard to measure, but it is hard to determine which strength is best for the patient's skin, especially since skin conditions vary. If adhesive sticks too well, you risk causing mechanical trauma to the skin surface during removal. On the other hand, if the adhesive sticks too light, you run the risk of the device lifting or falling entirely off the patient - Figure 8 displays how the testing was performed.

Figure 8
Adhesive Peel Test Example Footage

Our testing found that the mean adhesive peel strength of Device #3

(86.8591 lb./sec.) was significantly higher than that of the other ASDs tested. This was expected, as this device recommends using multiple alcohol prep pads to remove the adhesive. Device #4, which is marketed as a gentle silicone adhesive, had the lowest at 15.339 lb./sec., and Device #5 also demonstrated a peel strength on the low side at 18.1938 lb./sec. Devices #1 and #2 had peel strength test values in the mid-range, 41.4573 lb./sec. and 35.8504 lb./sec., respectively. The mean peel test values required to remove each device from the simulated skin surface completely are shown in Table 4.

Mean Peel Test Values (lb/sec)	
Device	**Peel Strength**
1	41.4574
2	35.8504
3	86.8591
4	15.339
5	18.1938

Table 4

Overall, this study shows significant differences in performance and stabilization characteristics of the various ASDs tested. The devices considered novel in this study (Device #1 and Device #2) demonstrated significantly better pull force values and micro-motion prevention properties than the leading ASDs tested in this study. The adhesive peel strength of Device #1 and Device #2 tested in the mid-range, suggesting it is neither too strong nor too weak.

Conclusion

Taking all three tests into consideration (pull strength, micro-motion, and peel strength), Device #1 and Device #2 showed the highest pull strength values at 17.68 lb. and 17.84 lb. respectively, minimal micromotion, and moderate adhesive peel strength (not too aggressive nor too weak).

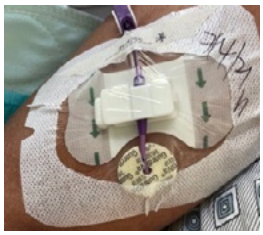

Figure 9
Device #1 being used on a patient

This study confirmed that the catheter securement, stabilization, and adhesive strength properties of the ASDs tested are not equal. How well they hold and stabilize the catheter greatly varies.

Based on our findings, we have recommended implementing Device #1 and Device #2 in our Mobile PICC insertion services program. Figure 9 shows Device #1 on a patient. We have found they are simple to use, hold the catheter well, and are less cumbersome to remove than the previous ASD.

Proper securement of catheters requires the use of both an ASD and a TSM. These two tools work together to protect and stabilize the catheter and reduce the risk of complications. TSMs are known to disrupt, become compromised, and be less effective. When this occurs, the primary ASD's ability to properly secure the catheter is exceedingly essential.

Thus, as this testing has shown, it is important to physically test the stabilization properties of ASDs used on patients to have the confidence that they are appropriately securing the catheter.

Discussion

Many of us who insert and care for vascular access devices have been using the same catheters, dressings, and securement devices for years. Often, these devices are chosen by the hospital through contracts and teams. Once selected, changing to something new is not only challenging but usually forbidden because more recent technology is not on contract. Our research and the research of others[9,10] have shown there are significant differences in the stabilization and performance characteristics of securement devices. These differences may significantly improve patient care. There is a considerable body of evidence that supports the use of securement devices to reduce catheter complication risk. Catheter securement has been shown to decrease the risk of infection, migration, phlebitis, and dislodgement[12], but most of the research supporting complication reduction was done years ago with the Statlock device (Device #3 in this study). Both the INS and CDC recommend the use of securement devices. Our laboratory testing has shown that there are newer ASDs superior to the ones we currently use. Our study utilized methods to test the stabilization performance of ASDs in a manner that provides more information than a clinical use study could provide. We feel it is vital that both physical performance testing and clinical evaluation are performed when making device selection. As clinicians, we should all be more vocal about the need to review and evaluate new technologies that may improve patient care and outcomes.

Limitations

Due to the nature of this research, it was not conducted on catheterized patients. The study was performed in a laboratory with testing equipment and fixtures to simulate conditions where a PICC secured in an ASD could be tugged or pulled. The laboratory nature of our testing lacked the variable conditions that may be present in the clinical setting. The sample size in each of the tests could have been higher. 60 samples of each ASD in total were tested, but since we conducted 4 different pull test angles, a micro-motion test, and a peel strength test, only 10 samples of each device were used in each test.

We are currently performing clinical testing and gathering feedback on the newer products (Device #1 and Device #2).

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