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A Randomized Controlled Trial to Compare the Complications of 2 Peripheral Intravenous Catheter-Stabilization Systems

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ABSTRACT

An open-label, prospective, randomized, noninferiority study was conducted at a large academic, Magnet-designated, Level I trauma center to compare the peripheral intravenous catheter securement-related complication rates of 2 different stabilization systems. The control stabilization system included the StatLock device with a nonwinged catheter, and the investigational stabilization system included a closed catheter system with a specially designed Tegaderm dressing. Data from 302 subjects indicated that the investigational stabilization system was noninferior or similar to the control stabilization system with respect to the overall securement-related complications. The cost of the investigational stabilization system was approximately 75% of the cost for the control stabilization system.

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Peripheral intravenous (PIV) catheters are used on almost every patient in the hospital for the delivery of fluids, electrolytes, and/or medications. However, inadequately secured PIV catheters pose a risk for complications that can impact quality patient care. The features of the PIV catheter and stabilization device used are important considerations, as they relate to the success of PIV catheter dwell time¹ and the occurrence of patient complications^{2,3} and also have nursing implications.⁴ The Infusion Nurses Society's *Infusion Nursing Standards of Practice*⁵ recommends catheter stabilization to preserve PIV catheter-site integrity, and products used for stabilization should be evaluated for effectiveness, such as the ability to immobilize the catheter, durability, ease of use, and cost.⁴

Peripheral intravenous catheter-related complications can be caused by several risk factors not limited to the skill and insertion technique of the nurse, vein quality, irritating medication solutions, type or size of the PIV catheter, extended dwell time, and inadequate stabilization.^{4,6} When a PIV catheter is not properly secured, motion and micromotion within the vessel cause injury to the vein. This damage to the vein is a primary cause of phlebitis, a distressing complication of PIV therapy.^{4,7,8} Additional complications of inadequate stabilization of the PIV catheter are infiltration, leaking at the insertion site, pain, infection, and dislodgment.⁴ The results of these complications can be serious if another vein cannot be immediately accessed or if the infiltrated infusate causes tissue necrosis. In addition, an unscheduled restart of another PIV catheter is a downstream consequence of poor stabilization.² Unscheduled restarts cause a delay in patient treatment, patient discomfort, patient dissatisfaction, safety concerns, nursing interruptions, and additional costs.⁹ Actual costs associated with PIV catheter restarts include materials and nursing resources; yet intangibles such as treatment of patient complications and patient dissatisfaction may

be far more costly.^{2,9} A study using the Press Ganey hospital satisfaction survey indicated that unnecessary PIV catheter restarts can also have a negative impact on hospital patient satisfaction scores.¹⁰ The material and labor cost savings associated with longer dwell times, fewer restarts, and fewer complications have been shown to offset the added cost of the stabilization device.^{7,9,11}

Stabilization of PIV catheters is, therefore, a vital component in preserving the integrity of the access device and the prevention of catheter migration and loss of vein access.⁵ Peripheral intravenous catheter design, catheter-stabilization devices, and transparent film dressings can help to reduce catheter movement and subsequent rates of complications. Yet the methods of stabilization can vary dramatically even within a single institution.¹ Traditionally, PIV catheters have been secured with non-sterile medical tape, tape plus transparent semipermeable membrane dressings, or tape and gauze.^{7,8,12} For catheters secured with traditional tape or tape plus transparent semipermeable membrane dressings, the published rates of phlebitis (2.3%-67%),^{6,13,14} dislodgment (16%-42%),⁷ and infiltration (22%-36%)^{2,6,7,13} are highly variable. The lack of standard definitions and protocols in these studies has contributed to this variability.

The *Infusion Nursing Standards of Practice* indicates that manufactured catheter-stabilization devices are the preferred method of stabilization over other methods and should be used whenever possible.⁵ According to Alexander et al, "the FDA [Food and Drug Administration] defines a *catheter stabilization device* as a device with an adhesive backing that is placed over a needle or catheter and is used to keep the hub of the needle or the catheter flat and securely anchored to the skin."^{4(p430)} However, the Infusion Nurses Society does not recommend a certain stabilization device or provide specifications for one. The Bard StatLock catheter-specific stabilization device (C.R. Bard, Covington, GA) is one of the devices most often used and studied by the US health care community.^{2,3,7,8} In a review of descriptive product trials for 10,164 subjects, Schears² reported a 76% decrease in unscheduled restarts and a decrease in phlebitis rates from 3.6% to 0.7% with StatLock device stabilization versus traditional stabilization.² Similarly, in a descriptive study of more than 600 subjects, catheter survival rate at 96 hours was 52% for catheters stabilized with a StatLock device and 8% to 9% when stabilized with 1 of 2 tape-stabilization systems.³ Hospitals use varying types of PIV catheters, and the combination of the catheter with the type of stabilization device can impact its efficacy.

A closed catheter system (BD Nexiva Closed IV Catheter System, Becton, Dickinson and Company, Franklin Lakes, New Jersey) combines a PIV catheter with a built-in stabilization platform and a preattached extension tube exiting the hub at a 45-degree angle. McNeill et al¹ evaluated the closed catheter system in combination with a foam-bordered transparent absorbent

and found a decrease in restarts from a pretrial rate of 62% in which there was no standard stabilization protocol to 28% with the dressing stabilization protocol. More recently, a new transparent dressing (3M Tegaderm IV Securement Dressing, designed for the BD Nexiva Closed IV Catheter System, 3M Health Care, St Paul, Minnesota) has been specifically designed to accommodate the BD Nexiva Catheter System. It is a breathable, transparent, adhesive film dressing with borders and a reinforced notch that fits around the 45-degree angle extension tubing, helping to secure both the tubing and the catheter.

The combination of a catheter and stabilization device is important to minimize patient complications. Studies that have tested the use of the StatLock device have largely been designed as product trials without randomization or control group comparisons.^{2,3,7} Since these descriptive studies did not describe the type of catheter or type of stabilization device, it is not known whether the results could be generalized to all catheter types and their respective stabilization devices. It is unknown if a modified dressing partnered with a catheter that has a built-in stabilization platform can provide similar catheter stabilization as other devices and reduce the costs associated with PIV catheter therapy. No randomized controlled studies have been published that compared 2 catheter-stabilization device systems, so a study of this strength is needed to provide guidance for clinical practice.

STUDY PURPOSE

This study reports the findings from a randomized controlled trial comparing 2 different PIV catheter-stabilization systems. The purpose was to (1) compare the percentages of securement-related complications and other complications of 2 PIV catheter-stabilization systems, and (2) assess the potential cost implications of each stabilization system.

METHODS

Study Design

The study design was a single-center, open-label, prospective, randomized, noninferiority study comparing 2 catheter-stabilization systems. A noninferiority study is intended to show that a new treatment has at least as much efficacy as a reference treatment or is not worse by an amount determined prior to the study.¹⁵

The study was conducted at a large academic, Magnet-designated, Level I trauma center located in the Midwest. Subjects were recruited from September 2008 through December 2009. Patient enrollment and data collection were conducted by hospital-employed venous access device (VAD) team nurses. This VAD team consisted of 16 registered nurses specifically trained in insertion and

maintenance of PIV catheters and central catheters. The VAD team does not typically insert all PIV catheters at this medical center but is consulted for difficult insertion of PIVs if the primary nurse determines a need for intervention. This team inserts approximately 18,000 PIV catheters per year, and both catheters were being used at this medical center before the study. All team members served as data collectors for this study. Before the study initiation, the VAD nurses received video and live training with return demonstration on the proper technique for application and removal of both stabilization devices and appropriate documentation of study variables. The study was approved by the Advocate Health Care institutional review board, and all subjects received informed consent. The study supplies were provided by the study sponsors.

Subject Selection

The convenience sample included medical-surgical patients admitted to the hospital with an anticipated 96-hour need for a PIV catheter. The VAD team was notified by the primary nurse when a PIV catheter insertion was needed, and the VAD team member would assess the patient for study-inclusion criteria (Table 1). Subjects were eligible whether or not it was their initial PIV catheter insertion. Subjects could neither wear more than 1 stabilization system if they required multiple PIV

sites nor be reenrolled in the study when a PIV catheter was restarted, or if they were readmitted. Subjects were randomized using a computer-generated randomization process. The randomization assignment was not provided to the VAD nurse until the subject had been assessed and the site determination had been made. The investigator and staff were not blinded because of obvious differences in the stabilization systems.

Study enrollment was projected to be a sample size of 400 subjects. A sample size of 200 subjects per group would provide 80% power to detect noninferiority of 2 study groups, with expected differences in proportions of 0% and an assumed proportion in the control group of 20%. This sample size estimation was based on using a 2-group large sample normal approximation test of proportions with a 1-sided 0.05 significance and a noninferiority margin of 10%.

Study Procedures

Before PIV catheter insertion, the site was prepared with 2% chlorhexidine gluconate with 70% isopropyl alcohol skin antiseptic. The majority of the catheters inserted were 20 gauge in size and the other sizes, 22 and 18 gauge, made up the minority. Additional means of securing the PIV dressings to the skin were not allowed, and the tape used to secure the tubing to the arm could not overlap the edge of the dressings.



TABLE 1

Study Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
At least 18 y of age, unless an emancipated minor	Is a current participant or a past participant in this study
An inpatient who requires peripheral IV therapy (catheter) for an anticipated 96 h or 4 d	If the new PIV site will be placed below an old infusion site or at an area of flexion (eg, wrist, antecubital fossa)
Has an available insertion site on the hand or arm	Has a documented or a known sensitivity to medical adhesive products, eg, transparent film adhesive dressings or StatLock device
Demonstrates cooperation with medical devices and/or treatments	Has dermatitis, burns, lesions, or tattoos at or near the insertion site
Able to provide written informed consent	Is diaphoretic at the time of catheter insertion
	Requires the application of topical antibiotics or ointments under the dressing
	Has an IV site that requires a gauze pad or a tackifier, eg, Benzoin
	Is pregnant
	Has a condition that in the opinion of the investigator or staff nurse would make the patient unsuitable for enrollment in the study

Abbreviations: IV, intravenous; PIV, peripheral intravenous.

Control Group

The control group catheter and stabilization protocol included the insertion of a nonwinged B. Braun Introcan Safety Catheter (B. Braun, Bethlehem, PA) to which an extension tubing was attached (Figure 1). The Bard StatLock IV Ultra Stabilization Device was applied according to the manufacturer's instructions. After the StatLock device was placed, a transparent dressing was used to cover the insertion site, and the extension tubing was secured to the skin.

Investigational Group

The investigational group catheter and stabilization protocol included the insertion of a BD Nexiva Closed IV Catheter System with a built-in stabilization platform and extension tubing with 2 split-septum access ports (Figure 2). After the catheter was inserted, a 3M Tegaderm IV Securement Dressing, designed for the BD Nexiva Closed IV Catheter System, was applied, and the extension tubing was secured to the skin.

The duration of each subject's participation in the study was up to 96 hours or 4 days. Baseline data collection included sex, age, medical diagnosis, reason for PIV catheter insertion, vein condition, location of PIV site, difficulty of insertion, exposure to blood, and ease of application of the stabilization device. The study coordinator used a stopwatch to time the application of the stabilization device (this did not include the catheter insertion time) and documented this time and number of insertion attempts. Daily assessments were completed every 24 hours \pm 4 hours by the VAD nurse to evaluate catheter stabilization and patency, performance of the stabilization device, and any complications. A securement-related complication was defined by removal of the stabilization device due to phlebitis, infiltration, leakage, dislodgment, or poor adherence (Table 2). Skin condition, presence of stabilization device edge lift (adherence), complaints of itching at the PIV site, and patient comfort with the



Figure 2 Investigational group catheter-stabilization system. (Courtesy of 3M.)

catheter-stabilization system were also monitored daily. The primary nurse notified the VAD nurse if the subject experienced any PIV-related complications and if the catheter required removal. When the catheter-stabilization system was removed, the VAD nurse recorded the reason for removal, ease of removal, any presence of adhesive residue on skin or catheter, skin redness or blisters, and the VAD nurse's overall satisfaction with the catheter and stabilization device. Once the subject completed the study, the primary nurse was responsible for communicating any postinfusion adverse events to the study investigator.

DATA ANALYSES

Comparative Analyses

The appropriate statistical tests were used to compare the study groups with respect to the demographic and the baseline catheter-related characteristics, the relationship between complications and PIV insertion site location, and the nurse's satisfaction with the PIV catheter and stabilization system. In addition, a multinomial logistic regression model was used to examine the influence of the study group, insertion site location, and vein condition on the number of insertion attempts. All statistical tests were carried out using SASTM version 9.2. In general, *P* values \leq .05 were considered statistically significant.



Figure 1 Control group catheter-stabilization system. (Courtesy of 3M.)

**TABLE 2**

Definition of Securement-Related and Other Complications

Complication	Definition
Phlebitis due to catheter movement ^a	Presence of pain, tenderness, warmth, erythema, or streak formation at or near the PIV insertion site
Infiltration ^a	Presence of edema, blanching, coolness, or pain, without the presence of erythema at or near the PIV insertion site
Leakage at insertion site ^a	Presence of fluid at the insertion site
Dislodgment ^a	Migration of the PIV catheter outside the vein
Poor adherence ^a	The PIV catheter is patent and remains in the vein, but the stabilization device has significant edge lift that requires removal and replacement with nonstudy dressing
Other	Phlebitis due to medication
	Less than 5% of the events that led to the stabilization device removal include skin reaction to dressing adhesive, discomfort with wearing the StatLock device, excessive blood under the dressing, IV clotted, subject pulled out catheter, IV leaking at tubing to hub, and medical order

Abbreviations: IV, intravenous; PIV, peripheral intravenous.

^aSecurement-related complications.

Survival Data and Survival Analysis

In this study, the time from insertion of the PIV catheter to the occurrence of a complication or the end of the study observation period was captured. A *complication* was any event that necessitated the removal of only the stabilization system or both the stabilization system and the catheter. These data are called survival data and require special methods for their analyses. A subject whose observation finished without a complication was termed as *censored case*. Survival analysis methods took into account the censored cases to produce appropriate statistical inferences.

Several different statistical methods were used in this study. To determine noninferiority of the 2 different study groups with respect to securement-related complication rates, a Cox regression model was used with a noninferior hazard ratio (HR) defined as 1.5. The Cox model accounts for the varying length of time each subject was at risk of a complication and allowed for the addition of variables (such as study group and catheter location) that may have influenced the time to the occurrence of a complication. The model estimated an HR, which was defined in this study as the instantaneous risk of a complication occurring in the investigational group divided by the instantaneous risk in the control group. The 2-sided 90% Wald confidence interval was computed for the HR. This confidence interval displayed the upper bound of a 1-sided 95% confidence interval to which the noninferiority and superiority tests were linked.

A noninferior HR of 1.5 meant that if the hazard rate of the investigational group was 1.5 or less times the hazard rate of the control group, then the investigational group could be declared as noninferior or similar to the control group. A catheter-restart rate of 20% has been reported for StatLock device users,² and it was believed that a restart rate of 30% would be acceptable relative to the StatLock device's performance, partially accounting for the 10% noninferiority margin mentioned before. This was approximately equivalent to an HR of 1.5 (0.3/0.2).

To estimate complication rates at various time points, the Actuarial Life Table method was used. Complication rates were estimated for (1) any securement-related complication (defined as catheter dislodgment, infiltration, leakage at insertion site, poor adherence of stabilization system, or phlebitis due to movement), (2) phlebitis due to medication, and (3) any complication (securement- or nonsecurement-related). To test for differences between study groups with respect to these various complication rates, the Cox regression model was used, which adjusted for PIV site location.

RESULTS

Subject Disposition

Three hundred twenty-nine subjects were screened for participation in the study; 302 met inclusion criteria and were randomized to a study group. A total of 150 subjects were randomized to the investigational group,

and 152 subjects were randomized to the control group (Figure 3). While the study protocol justified a sample size of 400 subjects, a decision was made to terminate the study after enrolling 302 subjects due to enrollment issues and the project timeline; however, this decision did not affect the statistical validity of the results.

Subjects were anticipated to require 4 days (96 hours) of PIV catheter use. The mean (\pm SD) length of wear time (the time from stabilization system application to its removal) was 52 (\pm 31) hours for the investigational device and 52 (\pm 32) hours for the control device. The wear times for all subjects ranged from 0.2 hours to 122.6 hours. Fifty-two percent of the subjects randomized had their PIV catheter systems intact for at least 48 hours, and 13% had their systems intact for at least 96 hours. The wear time of the stabilization system was a surrogate measure for the catheter dwell time because the majority of catheters and stabilization systems were removed at the same time. In addition, at least 24 subjects (8% of randomized subjects) were missing assessments at the time of stabilization system removal.

Subject and PIV Catheter Characteristics

There were no significant differences between study groups with respect to gender, age, or medical diagnoses. See Table 3 for the entire summary of demographic and catheter insertion characteristics. The median age of the sample was 63 years, and 58% were female. Vein condition, reason for intravenous (IV) insertion, and location of the PIV insertion site did not differ significantly between

study groups. Overall, 89% of the subjects had veins classified as soft, and 66% of subjects needed the PIV for both hydration and medication administration.

The mean number of insertion attempts was 1.12 for the investigational group and 1.19 for the control group. The number of insertion attempts (1, 2, 3, and \geq 4) was significantly different in the 2 treatment groups: first-attempt success rate of 90.7% with the investigational group compared with 82.2% with the control group ($P = .036$). This difference remained significant after adjusting for treatment group, insertion site location, and vein condition using a multinomial regression model ($P = .020$).

The nurses' exposure to blood during catheter insertion was significantly different between study groups ($P < .001$). There was one catheter insertion (<1%) in the investigational group that resulted in the nurse being exposed to blood, and there were 44 catheter insertions (29%) in the control group that resulted in the nurse being exposed to blood. No additional detail was available to describe the blood exposure in the investigational group, and it is possible that there was an error in coding.

PIV Location and Specific Complications

The distribution of the PIV insertion location was not significantly different between the 2 treatment groups overall; the control group had a higher proportion of PIVs in the hand and a lower proportion of PIVs in the mid-forearm than the investigational group (Table 3). Among the 5 most frequent complications, there was a significant

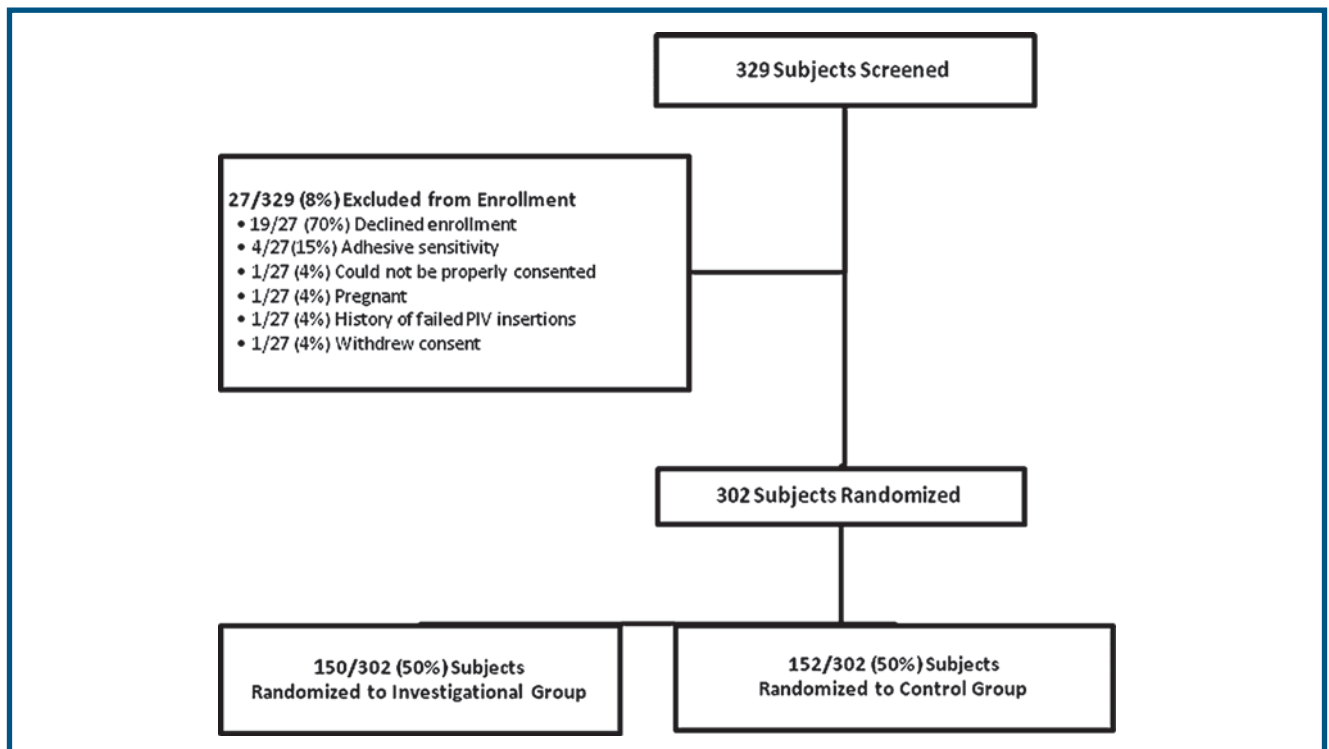


Figure 3 Subject disposition.

**TABLE 3**

Demographic and Catheter Insertion Characteristics

Variable	Categories	Investigational Group (N = 150)	Control Group (N = 152)	P ^a
Gender	M	66 (44%)	60 (39%)	.484
	F	84 (56%)	92 (61%)	
Age (y)	N	150	152	.691
	Mean	60	60.8	
	SD	16.53	17.12	
	Median	62	64	
	Min	18	18	
	Max	89	95	
Primary reason for IV insertion	Other	1 (0.7%)	1 (0.7%)	.801
	Fluids (hydration)	25 (16.7%)	25 (16.4%)	
	Medication administration	19 (12.7%)	21 (13.8%)	
	Blood products	0 (0.0%)	1 (0.7%)	
	Fluids and medication	101 (67.3%)	97 (63.8%)	
	Fluids and blood	1 (0.7%)	1 (0.7%)	
	Medication and blood	0 (0.0%)	1 (0.7%)	
	Saline lock	0 (0.0%)	3 (2.0%)	
Vein condition	Soft	131 (87.3%)	137 (90.1%)	.562
	Hard (cord-like)	1 (0.7%)	2 (1.3%)	
	Rolling	17 (11.3%)	13 (8.6%)	
	Soft and rolling	1 (0.7%)	0 (0.0%)	
Location of IV	Hand	30 (20.0%)	46 (30.3%)	.099
	Lower forearm	38 (25.3%)	34 (22.4%)	
	Mid forearm	71 (47.3%)	56 (36.8%)	
	Upper forearm	11 (7.3%)	16 (10.5%)	
Number of insertion attempts	1	136 (90.7%)	125 (82.2%)	.036
	2	12 (8.0%)	25 (16.4%)	
	3	0 (0.0%)	2 (1.3%)	
	≥4	2 (1.3%)	0 (0.0%)	
Exposure to blood during insertion	No	149 (99.3%)	108 (71.1%)	<.001
	Yes	1 (0.7%)	44 (28.9%)	

Abbreviation: IV, intravenous.

^aP values based on either the 1-way analysis of variance (age), the Fisher exact test (exposure to blood, vein condition, reason for PIV insertion, location of IV, gender), or the Wilcoxon rank sum test (number of insertion attempts).

**TABLE 4**

Specific Complications by Catheter Site Location

Complication	Location	Investigational Group (N = 150)	Control Group (N = 152)	Total	Location by Treatment P ^a	Complication by Location P ^b
Catheter dislodged	Hand	1 (50%)	9 (64%)	10 (63%)	.625	.002
	Lower forearm	0 (0%)	2 (14%)	2 (13%)		
	Mid forearm	1 (50%)	2 (14%)	3 (19%)		
	Upper forearm	0 (0%)	1 (7%)	1 (6%)		
Poor adherence	Hand	9 (53%)	2 (29%)	11 (46%)	.272	
	Lower forearm	6 (35%)	2 (29%)	8 (33%)		
	Mid forearm	2 (12%)	3 (43%)	5 (21%)		
	Upper forearm	0 (0%)	0 (0%)	0 (0%)		
Infiltration	Hand	3 (14%)	5 (19%)	8 (17%)	.895	
	Lower forearm	4 (19%)	3 (11%)	7 (15%)		
	Mid forearm	11 (52%)	14 (52%)	25 (52%)		
	Upper forearm	3 (14%)	5 (19%)	8 (17%)		
Leaking at insertion site	Hand	0 (0%)	2 (20%)	2 (17%)	1.000	
	Lower forearm	0 (0%)	2 (20%)	2 (17%)		
	Mid forearm	2 (100%)	4 (40%)	6 (50%)		
	Upper forearm	0 (0%)	2 (20%)	2 (17%)		
Phlebitis due to medication	Hand	1 (13%)	0 (0%)	1 (11%)	1.000	
	Lower forearm	0 (0%)	0 (0%)	0 (0%)		
	Mid forearm	5 (63%)	1 (100%)	6 (67%)		
	Upper forearm	2 (25%)	0 (0%)	2 (22%)		

^aP value based on the Fisher exact test.^bP value based on the Pearson χ^2 test.

relationship between the PIV insertion location and the complication type ($P = .002$) (Table 4). The complication of dislodgment tended to occur more frequently in the hand, and the complications of infiltration, leaking from the insertion site, and phlebitis due to medication tended to occur more frequently in the mid-forearm.

Group Comparisons of Complications

When examining the securement-related complications (based on the Cox regression analysis), the investigational group was shown to be significantly noninferior to the control group. Specifically, the Cox regression model gave an HR estimate of 0.740 (90% confidence interval: 0.530-1.034). An HR of 0.74 means that the instantaneous risk of a securement-related complication in the investigational group was 74% of that for the control group. In other words, the risk of a securement-related complication was reduced by 26% in the investigational group compared

with the control group. The HR observed was significantly less than the predefined noninferior margin of 1.5 (one-sided $P < .001$) but not significantly different from 1.0 ($P = .138$). The same conclusions were reached when PIV location was added into the regression model. The analysis showed that the investigational group was significantly noninferior to, or at least as effective as, the control group when looking at any type of complication.

Estimation of Complication Rates

The probability of a securement-related complication increases the longer the stabilization device is worn, or conversely, the complication-free survival rate for the stabilization device decreases the longer the device is worn. In Figure 4, the Kaplan-Meier plot illustrates the estimated survival rates or how the proportion of subjects free of any securement-related complication changes with device wear time. The securement-related complication rates are simply

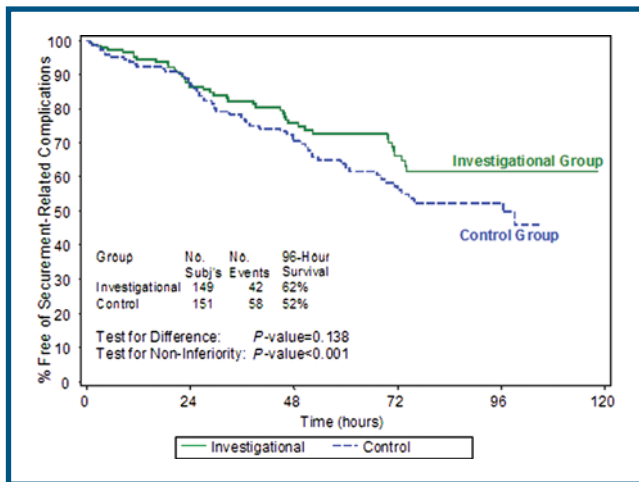


Figure 4 Survival curves.

the reflection of the survival rates (survival rate = 100% – complication rate). The probability of a securement-related complication occurring by 48 hours is 23% for the investigational group and 29% for the control group, and by 96 hours the probability increases to 38% for the investigational group and 48% for the control group (Table 5). These failure rates were not significantly different between the 2 study groups. When adding all types of complications into the survival analysis, the probability of any complication occurring by 48 hours is 29% for the investigational group and 33% for the control group, and by 96 hours it is 48% for the investigational group and 53% for the control group. Although the investigational group shows a tendency to have lower complication rates than the control group, the study groups were not significantly different.

Estimates of various cumulative complication rates are presented in Table 5. The estimates of the HRs and the P values from the Cox regression model after adjusting for PIV location are also presented in Table 6. When examining specific complications, there were significant study group differences observed for 3 complications. The investigational group showed significantly lower rates of dislodgments and showed significantly higher rates of poor adherence and phlebitis than the control group. Every case of documented phlebitis was receiving an irritating solution through the PIV site. These medications included potassium chloride, antibiotics, steroids, and IV-push morphine sulfate or some combination of these.

Nurse Satisfaction With the PIV Catheter and Stabilization System

Overall nurse satisfaction with ease of use of the catheter system was significantly higher for the investigational catheter (56% compared with 36% for the control catheter; $P \leq .001$). Overall nurse satisfaction with the stabilization system was also higher for the investigational group but was not significant. The investigational

group was rated significantly higher for ease of stabilization system application and removal. The incidence of adhesive residue left on the catheter and skin after stabilization system removal was minimal (<10%) and not significantly different between the 2 groups. Minimal redness (2%) and no blisters were observed in both groups at the time of the stabilization system removal (Table 7).

Material Cost of the Stabilization Systems

When comparing the costs of the 2 stabilization systems, there are common and unique cost elements associated with the systems. The IV start kit and the antimicrobial skin preparations were the common elements of both stabilization systems. The unique elements that determined the cost difference between the 2 systems are identified in Figure 5. The cost of the investigational system with its customized securement dressing was approximately 75% of the cost for the control system (\$5.65 vs \$7.56), resulting in a cost savings of \$1.91 per PIV catheter insertion.

DISCUSSION

Inadequately secured PIV catheters can pose patient safety issues that contribute significantly to catheter-related complications. In this single-center, open-label, prospective, randomized, noninferiority study, a PIV catheter protocol using a closed system catheter and investigational stabilization dressing was compared with a control PIV catheter with stabilization. The performance of the investigational stabilization device when used in combination with the closed IV catheter system was not inferior and therefore considered at least as equivalent to or no worse than the more widely used control catheter-stabilization system as evaluated by overall complication rates.

Previously published evaluations of stabilization devices have been compared to the traditional method of tape securement,^{1-3,7} and no other trial has compared 2 types of specifically designed catheter-stabilization systems using a randomized design. Findings from these previous studies demonstrate that the control stabilization device used in this study performed better than traditional tape securement in reducing complications and unscheduled catheter restarts. Therefore, it is reasonable to deduce that the investigational stabilization system in this study will also perform better than the traditional method of tape securement. Furthermore, the findings of this trial expand the concept of a manufactured stabilization device as recommended by the Infusion Nurses Society,⁵ which can and should include a stabilization platform and a dressing specifically designed for stabilization.

The rates of catheter dislodgment were lower for the investigational catheter-stabilization system with dislodgment rates estimated to be 2% for the investigational

**TABLE 5**

Estimates of Cumulative Complication Rates^a

Event Leading to Stabilization Device Removal	Investigational Group Estimate of Failure Rate (95% CI)	Control Group Estimate of Failure Rate (95% CI)
Up to 24 h		
Catheter dislodgment	1% (0%-5%)	5% (2%-10%)
Poor adherence without catheter removal	6% (3%-11%)	Unestimable
Infiltration	7% (4%-13%)	6% (3%-12%)
Leakage at insertion site	Unestimable	1% (0%-6%)
Any securement-related complication	13% (9%-20%)	12% (8%-19%)
Phlebitis due to medication	1% (0%-6%)	1% (0%-5%)
Any complication	16% (11%-23%)	14% (10%-21%)
Up to 48 h		
Catheter dislodgment	2% (0%-7%)	11% (6%-18%)
Poor adherence without catheter removal	11% (7%-19%)	3% (1%-9%)
Infiltration	12% (7%-19%)	15% (10%-23%)
Leakage at insertion site	Unestimable	3% (1%-9%)
Any securement-related complication	23% (17%-32%)	29% (22%-38%)
Phlebitis due to medication	4% (2%-11%)	1% (0%-5%)
Any complication	29% (22%-37%)	33% (26%-42%)
Up to 72 h		
Catheter dislodgment	2% (0%-7%)	12% (7%-20%)
Poor adherence without catheter removal	14% (9%-22%)	9% (4%-18%)
Infiltration	20% (13%-29%)	22% (15%-31%)
Leakage at insertion site	Unestimable	9% (5%-18%)
Any securement-related complication	32% (25%-42%)	43% (35%-53%)
Phlebitis due to medication	7% (4%-15%)	1% (0%-5%)
Any complication	40% (32%-50%)	48% (39%-57%)
Up to 96 h		
Catheter dislodgment	2% (0%-7%)	12% (7%-20%)
Poor adherence without catheter removal	17% (10%-27%)	9% (4%-18%)
Infiltration	20% (13%-29%)	24% (16%-34%)
Leakage at insertion site	6% (2%-22%)	14% (8%-26%)
Any securement-related complication	38% (29%-49%)	48% (39%-58%)
Phlebitis due to medication	10% (5%-21%)	1% (0%-5%)
Any complication	48% (39%-59%)	53% (44%-63%)

Abbreviation: CI, confidence interval.

^aEstimates of failure rate are based on the Actuarial Life Table method with intervals of every 24 hours. The failure rate provided is the estimate at the beginning of the (24-48)-, (48-72)-, (72-96)-, and (96-120)-hour intervals. The 95% confidence interval is based on the log-log method.

**TABLE 6**

Comparison of Complication Rates

Event Leading to Stabilization Device Removal	HR: Investigation/Control After Adjusting for PIV Catheter Location (95% Wald confidence interval)	P ^a (2-Sided Test HR≠1)
Catheter dislodgment	0.16 (0.04-0.72)	.017
Poor adherence without catheter removal	2.59 (1.07-6.28)	.035
Infiltration	0.78 (0.44-1.38)	.390
Leakage at insertion site	0.23 (0.05-1.04)	.056
Any securement-related complication	0.76 (0.51-1.14)	.187
Phlebitis due to medication	8.04 (1.02-63.59)	.048
Any complication	0.85 (0.59-1.22)	.384

Abbreviations: HR, hazard ratio; PIV, peripheral intravenous.

^aP value based on the type 3 Wald χ^2 test.

system compared with 11%–12% for the control systems for dwell times of 48–96 hours. Lower or similar levels of dislodgments have been reported previously: 2%¹² and 12%⁷ for the control stabilization device. In this study, dislodgment occurred more frequently when the PIV was located in the hand than in any other forearm location. This is a reasonable observation given the high range of motion possible with the hand. However, nurses should take into account the combination of the catheter location and the securement system when inserting PIV catheters. If dislodgments can be prevented by the use of a catheter-stabilization system that allows for movement without dislodgment, it should be prudently considered.

Of interest is the significantly higher rate of stabilization device failure due solely to poor adherence for the investigational dressing. The 48- and 96-hour failure rates due to poor adherence ranged from 11% to 17% for the investigational group and 3% to 9% for the control group. When poor adherence occurred in the investigational group, the stabilization device was removed, but the catheter remained in place and was monitored up to 96 hours of wear time, suggesting that the adherence did not impact the dwell time of the catheter. The protocol in this study prohibited any additional tape applied to the edges of either stabilization device, which nurses would typically use to resolve or minimize poor adherence. Previous studies have not included poor adherence as a complication leading to securement failure; it was included in this study because of the investigational nature of the dressing.

Phlebitis reported in this study was classified as being due to either movement or medication. No cases of phlebitis due to movement (mechanical phlebitis) were reported. The daily site monitoring and removing the sys-

tem at first signs of infiltration may have minimized mechanical phlebitis in this study. However, the rates of chemical phlebitis or phlebitis due to medication in this study were higher for the investigational group (4%-10% vs 1% for up to 48-96 hours). Although it is unknown whether the medications or catheter movement initially brought on the development of phlebitis, these cases of phlebitis occurred in subjects who were receiving irritating solutions intravenously through the study PIV site. The rates of phlebitis observed in this study were similar to or lower than previously reported: 7.3%,⁶ 11.7%,¹⁶ 0%,⁷ and 3.3%.¹⁴

There were no differences between groups for infiltration rates found in this study; the infiltration rates by 48 to 96 hours were 12% to 20% for the investigational system and 15% to 24% for the control system. Previous studies have reported lower rates of infiltration with catheter stabilization, such as 2%,⁷ 7.5%,¹⁷ and 12.2%.⁶ The same definition of infiltration was not used in every study, and only Catney et al⁶ used an infiltration rating based on the measured size of infiltration. Infiltration in this study was not classified according to a scale, so the extent of the infiltration was unknown. Because of the daily monitoring by the VAD nurses in addition to the primary nurse, there may have been more attention to the care and monitoring of the PIV than would occur naturally, and it is unknown whether infiltrates were identified more readily.

This study is one of the first to investigate complications related to stabilization, using a statistical method that accounts for the varying wear times of the stabilization devices and/or the varying catheter dwell times. The dwell times for the stabilization system observed in this study ranged widely, from less than an hour to

**TABLE 7**

Nurse Satisfaction With Catheter and Stabilization System

Variable Description	Categories	Investigational Group	Control Group	P ^a
Overall satisfaction with ease of the use of catheter	Unknown	2 (1.3%)	11 (7.2%)	<.001
	Very good	84 (56.0%)	55 (36.2%)	
	Good	45 (30.0%)	50 (32.9%)	
	Acceptable	15 (10.0%)	28 (18.4%)	
	Poor	4 (2.7%)	7 (4.6%)	
	Very poor	0 (0.0%)	1 (0.7%)	
Overall satisfaction with stabilization system	Unknown	2 (1.3%)	11 (7.2%)	.161
	Very good	84 (56.0%)	64 (42.1%)	
	Good	30 (20.0%)	43 (28.3%)	
	Acceptable	16 (10.7%)	18 (11.8%)	
	Poor	15 (10.0%)	15 (9.9%)	
	Very poor	3 (2.0%)	1 (0.7%)	
Ease of catheter insertion	Easy	115 (76.7%)	110 (72.4%)	.082
	Somewhat difficult	28 (18.7%)	40 (26.3%)	
	Moderately difficult	6 (4.0%)	1 (0.7%)	
	Very difficult	1 (0.7%)	1 (0.7%)	
Ease of stabilization device application	Unknown	1 (0.7%)	1 (0.7%)	<.001
	Very easy	76 (50.7%)	39 (25.7%)	
	Easy	65 (43.3%)	59 (38.8%)	
	Reasonable	6 (4.0%)	49 (32.2%)	
	Difficult	2 (1.3%)	4 (2.6%)	
Ease of stabilization device removal	Unknown	16 (10.7%)	22 (14.5%)	.0037
	NA	1 (0.7%)	0 (0.0%)	
	Very easy	90 (60.0%)	64 (42.1%)	
	Easy	35 (23.3%)	57 (37.5%)	
	Reasonable	5 (3.3%)	8 (5.3%)	
	Difficult	3 (2.0%)	1 (0.7%)	

^aP based on the Wilcoxon rank sum test.

122 hours, with 40% of the randomized subjects leaving the study before 96 hours because of hospital discharge or discontinuation of IV therapy. Adjusting failure rate computations using survival analysis to take into account the changing number of subjects at particular times was necessary so that correct statistical inferences could be made. Published complication rates have been based on nonrandomized studies that did not take catheter dwell times into account, and therefore these studies may have

given misleading failure rates that do not address the time-sensitive nature of failure rates. In addition, setting this statistical precedence makes sense if it is desired to compare complication or failure rates across studies.

Catheter-stabilization complications like catheter dislodgment, leakage, infiltration, and phlebitis result in additional nursing and material costs. The higher level of first-attempt success and lower blood exposure no doubt contributed to the higher level of nurse satisfaction

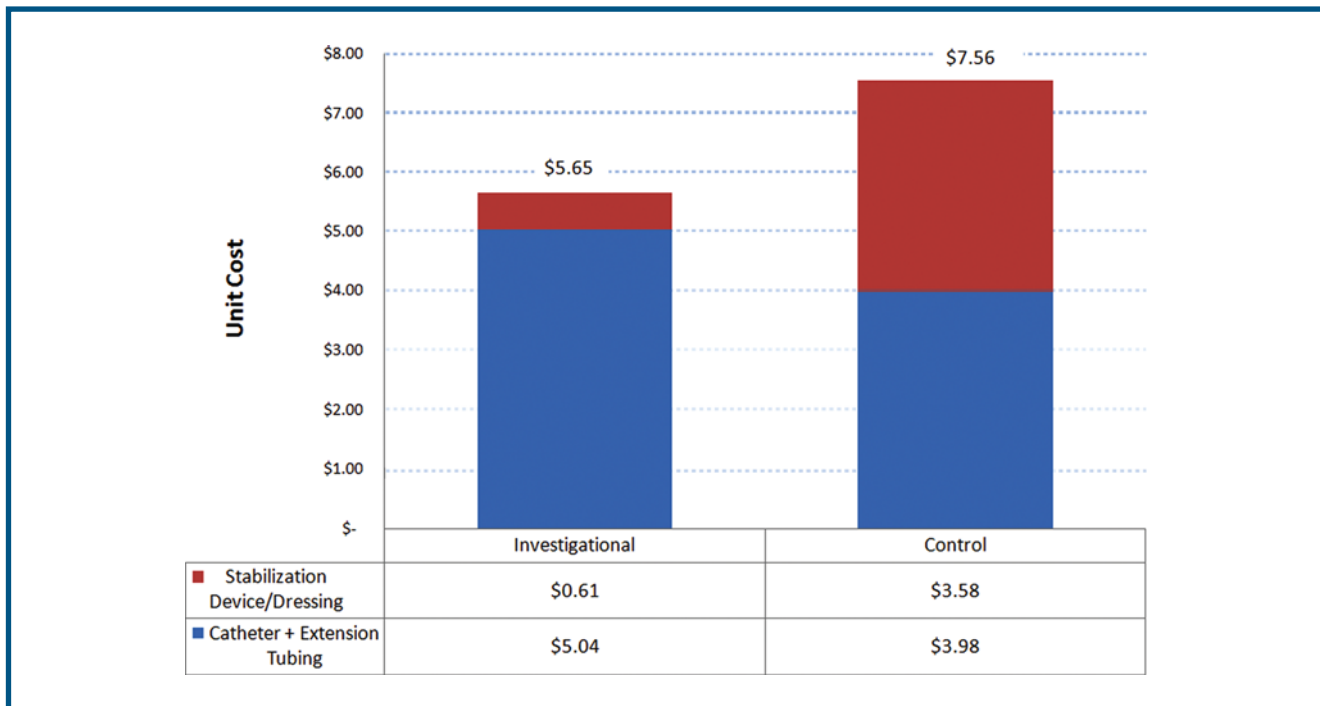


Figure 5 Unique system elements of PIV catheter-stabilization systems. Material costs for components were obtained from GHX Market Intelligence (formerly Health care Products Information Services or HPIS), 2009.

reported with the investigational catheter. In addition, the specially designed stabilization dressing used in the investigational group did not leave significant residue on the skin or catheter upon removal, and minimal or no redness were observed on the skin, which perhaps also contributed to the level of the nurse satisfaction reported.

An estimated 46 000 patients are admitted annually for acute care at the study site. Considering that each patient would likely need at least 1 PIV during his or her hospitalization, treating all of these patients with the investigational stabilization system rather than the control stabilization system could reduce supply costs by nearly \$88,000. This conservative cost-savings estimate does not account for labor and material costs associated with unsuccessful first insertion attempts, unscheduled restarts due to complications, routine PIV catheter changes, or the PIV catheter insertions for patients treated in the emergency department or outpatient areas. Neither blood exposure nor nursing time was monetized because there was a clear difference in supply costs.

LIMITATIONS

This study had several limitations identified after protocol implementation. The overall type, acuity, and number of enrolled subjects were limited by the subject recruitment process and the requirement that each subject should have an anticipated need of a PIV catheter for at least 96 hours. The recruitment process relied heavily upon the primary nurse to alert the VAD team of a

patient needing a PIV catheter; however, the primary nurse most often contacted the VAD team when unable to insert the PIV catheter herself rather than for every patient requiring a PIV catheter. These limitations may have created a group of subjects with higher acuities, which could partially account for the higher rates of infiltration and phlebitis compared with what has been previously reported in other studies.^{7,12,17}

The PIV catheter-insertion history and previous complication history were not tracked. These data could have provided rationale and/or confirmation for the observed differences in complication rates. Alternatively, excluding patients with a previous history of an infiltration or phlebitis could have reduced the overall securement-related complication rates and increased the mean catheter dwell. The feasibility of conducting this type of study with a large sample size in a practical setting necessitated keeping the study protocol as close to the standard of care as possible. Lastly, the results of this study can be generalized only when the investigational stabilization dressing is used with the Nexiva Catheter System.

CONCLUSIONS

Nurses are frequently called upon when hospitals are evaluating new products for use. Several factors can affect the choice of a product, including efficacy, patient comfort and satisfaction, safety, nursing time, ease of use, and cost. This study found the investigational catheter-stabilization system effective and safe for both the patient and the

nurse, and nurses found it easier to use than the control. Literature reports the benefits of using a stabilization system to minimize the complications associated with PIV catheters, and this study has validated these findings.

The securement-related and overall complication rates observed for the investigational group were shown to be noninferior to, or no worse than, the control group. The securement-related complication rates up to 72 hours were estimated to be 32% in the investigational group and 43% in the control group and for 96 hours were estimated to be 38% in the investigational group and 48% in the control group. The overall complication rates up to 72 hours were estimated to be 40% in the investigational group and 48% in the control group and for 96 hours were estimated to be 48% in the investigational group and 53% in the control group.

The Nexiva Closed IV Catheter System and the Tegaderm IV Securement Dressing for the Nexiva Catheter System were rated more favorably than the B. Braun non-winged catheter and the StatLock stabilization device. The nursing staff preference combined with the similar performance in preventing complications and the cost savings provide strong evidence to conclude that the Nexiva Catheter System with the specifically designed Tegaderm dressing is an attractive and sensible alternative to current PIV stabilization practices.

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