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A New Force-Activated Separation Device for the Prevention of Peripheral Intravenous Restarts

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ABSTRACT

The high failure rate (46%) of peripheral intravenous catheters (PIVCs) is well-documented. There is limited research examining the effect of forces/pulls on PIVC complications. New breakaway connectors called force-activated separation devices (FASD) separate when a damaging force is placed on a PIVC. In a randomized, controlled trial, patients were assigned 1:1 to a control group receiving PIVC standard of care (SOC) or SOC with FASD added to the catheter. The primary outcome was total mechanical complications requiring a PIVC restart. Secondary outcomes were delay in therapy, PIVC restarts, and adverse events. Outcomes were compared in an intention-to-treat analysis (N = 302) and per-protocol analysis (N = 287). There were less total mechanical complications in FASD compared with SOC (22 vs 41, respectively; $P < .01$). The treatment group was a predictor of total delay in therapy (minutes), indicating a greater estimated total delay in therapy in SOC than FASD (B = 69.53; 95% CI, 28.32–110.73; $P = .001$). There were more adverse events in SOC (127) than FASD (76; $P = .001$). Results were consistent in the per-protocol analysis. Use of a FASD showed a reduction in total mechanical complications. These results support use of the FASD as a safer and time-saving alternative to current SOC.

Key words: delay in therapy, force-activated separation device, mechanical complication, peripheral intravenous catheter

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This article was funded by Lineus Medical, grant ID No. 126709.

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DOI: 10.1097/NAN.0000000000000455

Peripheral intravenous catheter (PIVC) insertion is the most commonly performed invasive procedure, with 60% to 90% of all hospitalized patients requiring a PIVC. With more than 350 million PIVCs sold annually in the United States, only 235 million are successfully placed, with 33% of PIVCs inserted on the first attempt using a traditional approach.[1-3] For a device with more than a century of use, PIVCs have a poor failure rate.[1] Even in major hospitals with dedicated intravenous (IV) access teams that would be expected to have better-than-average results, the PIVC failure rate in prospective randomized trials is at best 36% and at worst 63%, with a mean of failure rate of 46%.[1] The 4 most common complications that lead to PIVC failure include: infiltration, occlusion, phlebitis, and dislodgement.[1]

The cost of a PIVC replacement has been reported to be approximately $64.84.[4] With 235 million PIVCs placed annually, a 46% mean failure rate would equate to 108 million failed PIVCs. At a cost of $64.84 per replacement, the cost of PIVC failure in the United States is estimated to be more than $7 billion annually.[1-4]

The impact of pulls and forces on PIVC failure rates is an area that has not been addressed. One type of PIVC failure is when it completely dislodges, potentially as a result of many pulls and tugs caused by patient activities of daily living. Bench testing has shown that PIVC securements completely pull off when approximately 8 lb of force is placed on the IV catheter.[5] What is not clear is the impact that forces below this 8 lb threshold have on PIVC failure rates. An animal study[6] with small and large patients has indicated that a device that separates at 4 lb of force could aid in the reduction of PIVC mechanical complications.

There are several companies currently working on a new class of safety devices to protect PIVCs from damaging forces. The new devices have the following in common: separate or break away when a certain threshold of force is applied to the PIVC; connect into the PIVC using ISO (80369-7) standard Luer connectors; and have valves that shut off the flow of fluids when the device separates. This new class of devices is called force-activated separation devices (FASDs).

This study examined the rate of PIVC complications requiring a PIVC restart using the FASD compared with the current PIVC standard of care (SOC). The primary outcome was a comparison of the total combined number of mechanical complications requiring IV restart (ie, dislodgement, infiltration, phlebitis, and occlusion combined complications). The secondary outcomes were each individual mechanical complication (ie, dislodgement, infiltration, phlebitis, and occlusion individual complications), number of PIVC restarts, total adverse events (AEs), and total delay in therapy time (minutes).

METHODS

Trial Overview

This study was a single-hospital, multiunit, randomized, unblinded, controlled trial that was conducted at Hartford Hospital. The FASD, used in this study was provided by Lineus Medical (Fayetteville, AR), as well as an unrestricted grant. The study was registered at clinicaltrials.gov (NCT04469218) and performed following Good Clinical Practices ICH E6R2 under approval by the Hartford HealthCare Institutional Review Board as a nonsignificant risk device study.

Patients

Patients eligible were those ≥18 years of age with a PIVC projected to have continuous IV fluids or intermittent infusions for a minimum of 24 hours in 1 of 6 prespecified units (neurology, neurology step down, 2 medical units, and 2 cardiology units). Patients were excluded from eligibility if they were <18 years of age, were on comfort care only or expected to have <24 hours of survival, required >1 PIVC at the time of enrollment, or were enrolled in a different investigational drug or device study at the time of enrollment.

Trial Procedures

New admitted patients were screened for enrollment eligibility on a daily basis. Once consent was given, the patient was considered to be enrolled into the study. Each patient was assigned a deidentified case/study number. A randomization schedule was created before study initiation by a computer random number generator with a treatment allocation ratio of 1:1. As each eligible patient was enrolled, they were assigned a treatment based on the randomization order.

If the patient was enrolled in the FASD arm of the study, an FASD (Figure 1A) was installed into their current PIVC administration line (Figure 1B) and in subsequent replacement PIVCs. If the patient was enrolled in the SOC/control arm, the patient received the current SOC for PIVCs (Figure 1C) at Hartford Hospital. All PIVCs in the study were inserted by a dedicated vascular access team (VAT) using a

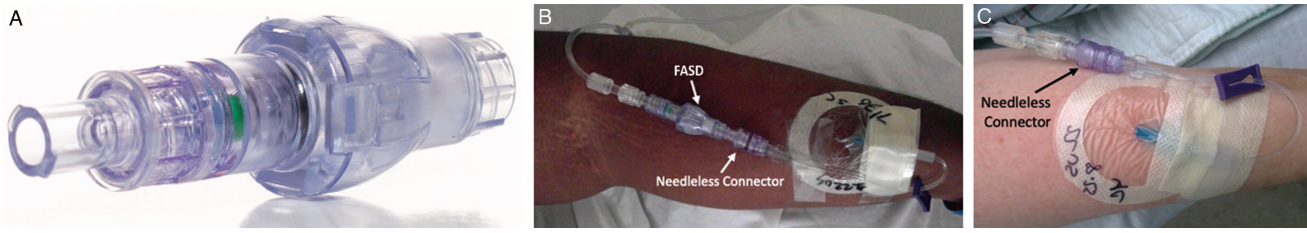

Figure 1 A, FASD. B, FASD group patient. C, Control group patient. Reprinted with permission from Lineus Medical. *Abbreviation: FASD, force-activated separation device.*

bundled approach (PIV5Rights®).[7] The bundled approach for IV therapy was implemented at Hartford Hospital in 2018 and aims to improve inefficiencies in staffing, insertion and placement methods, supplies and technology, and review/assessment of quality of patient care. Insertion and placement methods focus on the use of ultrasound when needed, avoiding placement in points of flexion, and the use of a 22-gauge, 1.75-inch catheter, antireflux needleless connector, and a chlorhexidine transparent securement dressing. A detailed description of each of the PIV5Rights steps has been published previously.[7]

The FASD separated at 4 ± 1 pounds of force. When an FASD separated, it was discarded, and a new, sterile FASD was installed in the patient's IV administration set by the primary care nurse. When an IV complication occurred, the nurse called the VAT, and the patient was put in the queue for a PIVC insertion. Delays in therapy, as well as all mechanical complications, were documented by the primary care nurse on an event log kept in each patient's room. When the patient's primary care nurse became aware of the event (ie, IV complication or FASD separation), the nurse documented the mechanical complication type and clock time, which represented the start time for the delay in therapy. When the event was resolved and the catheter or separated FASD was replaced, the clock time was noted again, which represented the end time for the delay in therapy. Delay in therapy time for each event was calculated as the duration between the start and end clock times. Of note, failed PIVC insertion attempts were not considered IV complications in this study.

All of the patients remained in the study for a maximum of 7 days or if one of the following events occurred prior: transitioned from the acute care facility, PIVC access was discontinued, IV fluids/intermittent infusions were discontinued, patient withdrew from the study, or patient was transferred to a unit not listed as a study unit.

Statistical Analysis

A sample size estimate was conducted at 80.0% power to detect a 17.5% difference in total mechanical complications between groups. A minimum of 101 patients per treatment group was needed (accounting for 10% attrition) to reject the null hypothesis that the proportions of mechanical complications were equal, with α established at $P < .05$.

Identical statistical analyses were performed for the intention-to-treat (ITT) and the per-protocol (PP) populations. The ITT population consisted of all patients who were screened, randomized, and successfully enrolled in the study as part of the index study procedure. The PP population consisted of all patients in the ITT population who were successfully enrolled in the study and were not withdrawn from the study because of a major protocol violation or other issues that would cause inaccurate or biased data collection. Figure 2 includes the reasons for patient exclusion from the PP population.

All of the data were checked for normality of distribution and to ensure that all test assumptions were met. Baseline characteristics were compared between treatment groups using an independent samples *t* test for continuous variables and χ^2 analysis for categorical variables. To test the primary outcome, proportions of the total and individual mechanical complications for dislodgement, infiltration, and phlebitis were compared between groups using a χ^2 analysis or Fisher exact test (if cell counts were <5). For secondary outcomes, infusion time was examined as a binary variable (≥6 and <6 hours) and compared between treatment groups using a χ^2 analysis with total number of infusions as the denominator. The number of PIVC restarts was examined using a negative binomial regression analysis, with treatment group and total therapy time as independent variables. Total therapy time was added to the model so that the number of PIVC restarts could be examined while controlling for total therapy time. The total delay in therapy time (minutes) caused by mechanical complications (including FASD separations in the FASD group) was examined among patients with delay in therapy >0 minutes (due to >5% of patients having 0 minutes) using a linear regression analysis with treatment group and total time enrolled used as independent variables. Analyses were performed with SPSS version 26.0 (IBM Corp, Armonk, NY), with 2-sided *P* values <.05 established as the level of statistical significance.

RESULTS

Patient Characteristics

From July 2020 to December 2020, 302 patients were enrolled and randomized to FASD (n = 151) or SOC (n = 151), representing the ITT population. The PP population consisted of 287 patients (FASD n = 143, SOC n = 144; Figure 2). Overall, patients were middle aged and overweight according to body mass index, with the majority being non-Hispanic, white males. There were no differences in patient characteristics between groups (Table 1). The median time enrolled in the study was 32.4 hours (interquartile range = 49.5 hours).

IV Therapy Characteristics and Nonmechanical Complications

The total number of PIVC status reviews performed during the study is shown in Table 2. There were significantly more infusions lasting ≥6 hours in the FASD group than in the SOC group ($P < .001$). There were no differences (all $P > .05$) between the FASD and SOC groups in the proportion of patients who had fluid leakage, blood leakage, or a dressing change, respectively. There were no patients with hematomas attributed to IV infusion in either group.

Outcomes

There was a significant difference between groups for the primary outcome, total combined number of dislodgements, infiltrations, and phlebitis ($P < .01$). There were no significant differences between groups when each

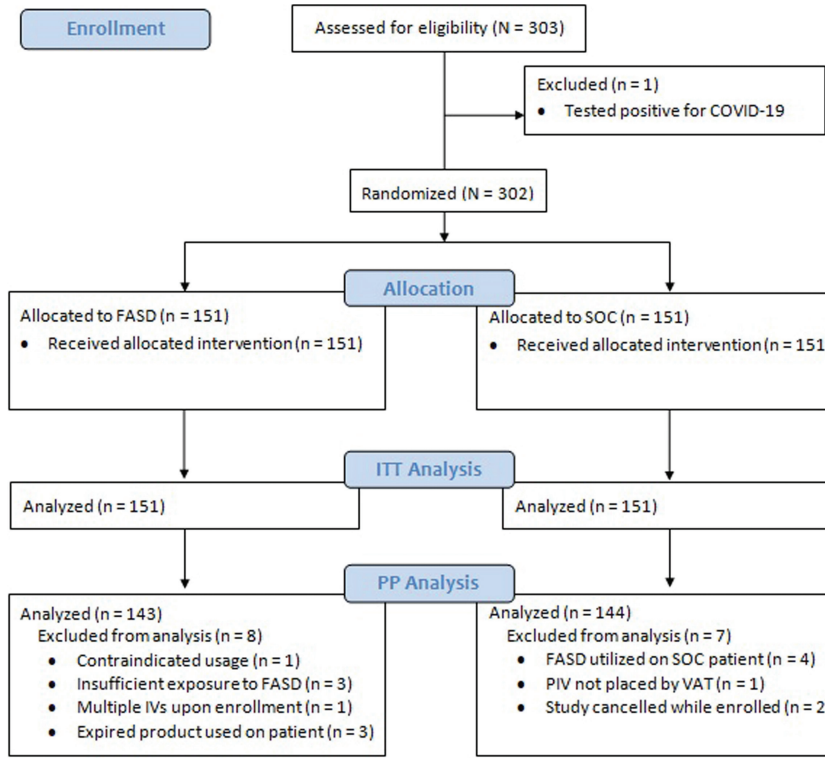

Figure 2 Patient enrollment. *Abbreviations: FASD, force-activated separation device; ITT, intention-to-treat; IV, intravenous; PIV, peripheral intravenous; PP, per protocol; SOC, standard of care; VAT, vascular access team.*

of the mechanical complications were compared individually (all $P > .05$). All of the mechanical complications requiring a PIVC restart are shown in Table 3.

Treatment group was not a significant predictor of the number of PIVC restarts (odds ratio [OR] = 1.516; 95% CI, 0.812–2.833; $P = .192$), when controlling for time enrolled (minutes) in the study. These results for PIVC restart were consistent in the PP population (OR = 1.401; 95% CI, 0.74–2.64; $P = .298$). Treatment group was a significant predictor of total delay in therapy when controlling for total time enrolled in the study, indicating a greater estimated total delay in therapy in the SOC group than in the FASD group (β coefficient [B] = 69.53; 95% CI, 28.32–110.73; $P = .001$). These results for total delay in therapy were consistent in the PP population (B = 66.52; 95% CI, 25.06–107.99; $P = .002$).

Safety

The FASD group experienced 46% fewer total mechanical complications (dislodgement, infiltration, phlebitis, and occlusion combined) requiring PIVC restart than the SOC group. When mechanical complications requiring a PIVC restart are reviewed individually, FASD patients experienced 58% fewer cases of phlebitis, 50% fewer dislodgements, and 45% fewer infiltrations, as shown in Table 3. The replacement rate for FASDs in patients who experienced an FASD separation was 16.7%.

Safety was also evaluated by examining all AEs. There were no air emboli, stroke, infection, sepsis, or catheter-related infections in the ITT or PP populations. In the ITT population, there were significantly more overall AEs in the SOC (127) than in the FASD (76) group ($P = .001$). This was consistent in the PP population (125 vs 75 AEs, respectively; $P = .001$). However, there were no differences in the proportion of patients with an AE between the SOC (43.0%) and FASD (33.1%) groups ($P = .075$). This was consistent in the PP population (44.4% vs 34.3%, respectively; $P = .078$).

DISCUSSION

The current study found that there was a significant reduction in overall mechanical complications in the FASD group compared with current SOC. In addition, the treatment group was associated with total delay in therapy when controlling for total time enrolled in the study, indicating a greater estimated total delay in therapy in the SOC group than in the FASD group. These results were consistent in both the ITT and PP populations and support the use of the FASD as both a safer and time-saving alternative to the current SOC.

The vascular access products and related protocols used at the study site were based on a previous study by the same principal investigator that showed that supply and process interventions could lower PIVC complication rates.[7] As a result of these supply and process optimization efforts, the baseline complication rate ranges observed in the control groups documented in the meta-analysis by Helm et al[1] are higher than the SOC group in the current

TABLE 1

Patient Characteristics

Variable	Intention-to-Treat Analysis					Per-protocol Analysis				
	FASD (n = 151)	SOC (n = 151)	Total (N = 302)	χ^2 or 95% CI	*P* Value	FASD (n = 143)	SOC (n = 144)	Total (N = 287)	χ^2 or 95% CI	*P* Value
Age, y[a]	59.7 ± 15.7	60.4 ± 16.1	60.1 ± 15.9	-4.31, 2.88	.696	59.9 ± 15.5	59.9 ± 15.9	59.9 ± 15.7	-3.59, 3.71	.973
Minimum	21	18	18			21	18	18		
Maximum	90	95	95			90	90	90		
Gender[b]				.057	.812				.200	.655
Female	55 (36.4)	57 (37.7)	112 (37.1)			50 (35.0)	54 (37.5)	104 (36.2)		
Male	96 (63.6)	94 (62.3)	190 (62.9)			93 (65.0)	90 (62.5)	183 (63.8)		
Race[b]				3.373	.497				3.726	.444
White (Hispanic)	23 (15.2)	29 (19.2)	52 (17.2)			21 (14.7)	29 (20.1)	50 (17.4)		
White (non-Hispanic)	105 (69.5)	106 (70.2)	211 (69.9)			100 (69.9)	99 (68.8)	199 (69.3)		
Black or African American	21 (13.9)	16 (10.6)	37 (12.3)			20 (14.0)	16 (11.1)	36 (12.5)		
Asian	1 (0.7)	0 (0.0)	1 (0.3)			1 (0.7)	0 (0.0)	1 (0.3)		
Not provided or unknown	1 (0.7)	0 (0.0)	1 (0.3)			1 (0.7)	0 (0.0)	1 (0.3)		
Height, cm[a]	170.1 ± 10.6	170.5 ± 10.8	170.3 ± 10.7	-2.82, 2.07	.763	170.2 ± 10.6	170.6 ± 10.9	170.4 ± 10.8	-2.99, 2.08	.724
Weight, kg[a]	88.8 ± 24.8	87.8 ± 25.8	88.3 ± 25.3	-4.72, 6.84	.719	88.8 ± 24.5	88.3 ± 26.2	88.5 ± 25.4	-5.44, 6.46	.866
Body mass index, kg/m^2[a]	30.5 ± 7.4	30.2 ± 8.6	30.3 ± 8.0	-1.48, 2.19	.702	30.5 ± 7.3	30.3 ± 8.7	30.4 ± 8.0	-1.68, 2.10	.830

Abbreviations: FASD, force-activated separation device; SOC, standard of care.

[a]Continuous variables presented as mean ± SD.

[b]Categorical variables presented as frequency (%).

TABLE 2

Peripheral Intravenous Catheter Status Reviews Performed and Infusion Time

	Intention-to-Treat Analysis					Per-protocol Analysis				
	FASD (n = 583)	SOC (n = 795)	Total[a] (N = 1378)	χ^2	*P* Value	FASD (n = 573)	SOC (n = 768)	Total[a] (N = 1341)	χ^2	*P* Value
Infusion time				58.530	<.001				52.411	<.001
<6 h	130 (22.3)	334 (42.0)	464 (33.7)			128 (22.3)	316 (41.1)	444 (33.1)		
≥6 h	453 (77.7)	461 (58.0)	914 (66.3)			445 (77.7)	452 (58.9)	897 (66.9)		

Abbreviations: FASD, force-activated separation device; SOC, standard of care.
[a]N represents number of infusions (denominator).

study (36%–63% vs 27.1% SOC, respectively). Even in this more challenging, lower complication environment, use of an FASD showed meaningful reductions for infiltration, dislodgement, and phlebitis complication rates. The low rate of occlusion in both groups was likely attributed to the antiflux needleless connector that is used as standard protocol at the hospital at which this study took place. In addition, we did not anticipate the FASD to have any impact on occlusion because occlusion is not a pull force–derived complication.

The current study suggests that the 24 FASD separations in the FASD group could have led to the avoidance of mechanical complications, because the SOC group had 41 complications and the FASD group had 22 complications, a 46% reduction. In addition, >70 minutes of delay in therapy was potentially avoided whenever a PIVC replacement (mean delay in therapy time = 78.4 minutes) was prevented by an FASD separation (mean delay in therapy time = 6.8 minutes). However, FASDs were replaced by the patient's primary care nurse. If primary care nurses would have also replaced PIVCs instead of the VAT, there would have likely been a lower mean delay in therapy time for PIVC restarts.

Clinical Implications

This study further validates previous studies showing that an FASD that separates at 4 lb can effectively reduce PIVC mechanical complications with a reasonable replacement rate of the FASD of 16.7%. The 4-lb separation force of this FASD seems to strike the right balance among effectively

TABLE 3

Mechanical Complications: Force-Activated Separation Device vs Standard of Care

	Intention-to-Treat Analysis					Per-protocol Analysis				
Variable	FASD (n = 151)	SOC (n = 151)	Total (N = 302)	χ^2	*P* Value	FASD (n = 143)	SOC (n = 144)	Total (N = 287)	χ^2	*P* Value
Mechanical complications, frequency										
Dislodgement	4	8	12	–	.277	4	8	12	–	.278
Infiltration	11	20	31	2.414	.120	11	18	29	1.480	.224
Phlebitis	5	12	17	2.684	.101	5	12	17	2.673	.102
Occlusion	2	1	3	–	1.000	2	1	3	–	1.000
Total	22	41	63	6.146	.013	22	39	61	4.994	.025
Patients with a mechanical complication, frequency (%)										
Dislodgement	4 (2.6)	7 (4.6)	11 (3.6)	–	.357	4 (2.8)	7 (4.9)	11 (3.8)	–	.363
Infiltration	11 (7.3)	16 (10.6)	27 (8.9)	1.017	.313	11 (7.7)	15 (10.4)	26 (9.1)	.646	.421
Phlebitis	5 (3.3)	11 (7.3)	16 (5.3)	2.376	.123	5 (3.5)	11 (7.6)	16 (5.6)	2.339	.126
Occlusion	2 (1.3)	1 (0.6)	3 (1.0)	–	1.000	2 (1.3)	1 (0.6)	3 (1.0)	–	1.000
Total[a]	21 (13.9)	30 (19.9)	51 (16.9)	2.948	.086	21 (14.7)	30 (20.8)	51 (17.8)	1.856	.173

Abbreviations: FASD, force-activated separation device; SOC, standard of care.
Mechanical complications represent those that required an IV restart. Fisher exact test was used for any comparisons with a cell count <5.
[a]The breakdown for number of patients with mechanical complications does not add up to the "total" because the "total" is the total number of patients with at least 1 mechanical complication.

reducing PIVC mechanical complications, not creating new extended delays in therapy, and helping nurses save time rather than adding to their workload.

Breakaway connectors are used on laptop charging cords, at gas station fuel pumps, and in other everyday, practical applications, and therefore it is appropriate that a breakaway connector (ie, FASD) be used on medically critical PIVCs. PIVC complications have remained a persistent problem despite securements becoming larger and stronger, suggesting that robust securement alone cannot prevent traumatic forces from causing mechanical PIVC complications. In the 2019 follow-up to the pivotal Accepted but Unacceptable: Peripheral IV Catheter Failure study, Helm describes trauma as, "any force that shifts the short peripheral catheter within the vein causing tissue injury or mechanical loss of the catheter."[5(p149)] Even when securement maintains full adhesion to the skin during a traumatic force on the PIVC, the elasticity of skin allows tenting that moves the catheter within the vein, causing endothelial cell injury or mechanical loss of the catheter. If minimizing intravascular catheter movement is the goal, devices that prevent traumatic forces from ever reaching the securement should be used.

Financial Impact

Costs of PIVC failures leading to restarts are estimated to be more than $7 billion annually.[1-4] Therefore, the 46% reduction in PIVC restarts found in this study compared with the current SOC would equate to over $3.2 billion in annual savings to the US health care system. This financial savings does not include the corresponding reduction in needlesticks, wasted nursing hours replacing failed PIVCs, and the likely improved patient satisfaction that would accompany avoiding additional needlesticks. With >32 million inpatient admissions receiving a PIVC in the United States every year, reducing PIVC failure has the potential to impact millions of patients annually.[8]

STRENGTHS AND LIMITATIONS

The current study had several strengths. It was well powered, with a randomized, controlled design. The patient population was diverse, enhancing generalizability of the results. All PIVCs were placed by the VAT using a bundled approach, which enhanced consistency of placement methods across both groups.

The reduction in complication rates was for patients expected to stay overnight in the hospital and may not hold true for other areas of the hospital, such as emergency departments or outpatient facilities. Although the standardization of the skill level of nurses across groups was a strength of the study, the same study done at a facility without a VAT may have different results. However, it is possible that having a VAT led to lower overall complications, making it more difficult to detect differences between groups. Nevertheless, differences were still found between groups for the total number of mechanical complications. Finally, cost analyses presented were based on economic data calculations represented in the references noted.

CONCLUSION

The use of an FASD prevented traumatic forces from causing mechanical complications that require a PIVC restart. A reduction in total complications, including infiltration, dislodgement, and phlebitis, was shown among patients using FASD. The current results support use of the FASD as a safer and time-saving alternative to the current SOC.

Future studies are needed to examine the use of FASDs with diverse patient populations across different facilities that include varying skill levels of PIVC placement. Future research should assess whether FASDs can have a similar impact on pediatric patients with PIVCs, as well as the use of central venous catheters in both adults and children. Examining the use of FASDs at different facilities (eg, outpatient), as well as other areas of the hospital (eg, emergency department), with providers who have varying skill levels in PIVC placement will enhance the generalizability of these devices.

ACKNOWLEDGMENTS

The authors thank the study coordinators and nurses for their contributions to the study.

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