Fewer peripheral intravenous catheter complications in hospitalized dogs when force-activated separation devices are used versus not used in a randomized controlled clinical trial

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OBJECTIVE
To determine whether the use of a force-activated separation device (FASD) lowers the incidence risk of peripheral intravenous catheter (PIVC) complications in hospitalized dogs.

ANIMALS
367 dogs that were hospitalized and received IV fluids between January 11 and March 25, 2021.

PROCEDURES
A prospective, randomized controlled clinical trial was performed. Dogs hospitalized and receiving IV fluids for at least 24 hours were randomized to the FASD group or control group. PIVCs were placed following a standardized protocol. Dogs in the FASD group had the FASD device attached to their PIVC according to manufacturer instructions. For both groups, all PIVC complications were documented, and each complication was classified as extravasation, phlebitis, dislodgement, occlusion, or line breakage.

RESULTS
Results from 367 dogs (FASD group = 180, control group = 187) underwent analysis. The proportion of PIVC complications was significantly \( P = .004 \) lower for the FASD group (8.9% [16/180]) versus the control group (24.6% [46/187]). Following adjustment for differences in hospitalization time, the odds of a dog in the FASD group having a PIVC complication was approximately one-third the odds of those in the control group (OR, 0.33; 95% CI, 0.17 to 0.63; \( P = .001 \)).

CLINICAL RELEVANCE
Results indicated that the use of a FASD in hospitalized dogs receiving IV fluids is warranted to lower the incidence of PIVC complications and may also limit patient discomfort, owner expense, and staff time devoted to managing PIVC complications. Further research investigating its use in cats and other species should be considered.

Intravenous catheters (IVC) play a critical role in the treatment of hospitalized patients, however, IVC complications may occur. Peripheral intravenous catheter (PIVC) complications, including phlebitis, occlusion, extravasation, and dislodgement, may result in consequences for the patient.\(^1\) These consequences may include catheter-related bloodstream infections, pain, tissue damage, and failure to deliver prescribed treatments in a timely fashion.\(^1\) Owners are responsible for the costs associated with replacing a PIVC in veterinary medicine, so PIVC complications can also lead to additional costs to the client.

The PIVC complication rate in humans has been reported to be 35% to 67%;\(^1,2\) however, there is very limited veterinary literature regarding PIVC complications. In 1 veterinary study,\(^3\) 21.4% (9/42) of hospitalized cats suffered a PIVC complication, which included phlebitis, extravasation, removal of the catheter by the patient, occlusion, and formation of edema. In another study,\(^4\) 23.2% (111/478) of all IVCs placed were documented to have bacterial colonization. In a recently published study,\(^5\) PIVCs were removed due to complications in 43% (33/76) of dogs and 52% (21/40) of cats.
Force-activated separation devices (FASD) are placed between the intravenous fluid (IVF) administration set and the t-port and function to limit harmful forces from being placed on the PIVC, which can lead to complications. They are designed to separate when 4 lb of force is exerted on the device. When the device separates, valves on both sides of the device close, which stops the flow of fluids from the infusion pump, and stops the flow of blood from the PIVC end. An FASD (SafeBreak Vascular; Lineus Medical) has been approved for use in humans. The use of this FASD resulted in 46% fewer PIVC complications in human patients. The use of a FASD has not been evaluated in veterinary patients. The objective of the study reported here was to determine whether the use of a FASD lowers the incidence risk of PIVC complications in hospitalized dogs. We hypothesized that PIVC complications, including phlebitis, extravasation, and dislodgement, would be less common for dogs in the FASD group versus the control group.

Materials and Methods

This prospective, randomized clinical trial was approved by the Institutional Animal Care and Use Committee and the Clinical Review Board at the Colorado State University Veterinary Teaching Hospital. Owner consent for use of the FASD was not required by the Clinical Review Board. All dogs hospitalized in the Intermediate Care Unit (IMCU) or the Critical Care Unit (CCU) between January 11 and March 25, 2021, with a PIVC in place were evaluated for enrollment in the study. To be included in the study, a PIVC must have been placed at the Colorado State University Veterinary Teaching Hospital, and the dog must have received IVFs via an infusion pump for at least 24 hours. Dogs were excluded if they were not expected to have a PIVC in place for at least 24 hours, if they stopped receiving IVFs before 24 hours, or if they were receiving blood products, as the product has not been FDA approved for use with blood products.

All PIVCs were placed by technicians, students (under direct supervision), or veterinarians. Our institutional protocol for PIVC placement requires personnel to wear examination gloves, clip the hair circumferentially around the limb, and aseptically prepare the skin over the vessel with swab stick prepared with chlorhexidine gluconate 3.15% and isopropyl alcohol 70% (Prevents swab stick; Professional Disposables International Inc). Once the PIVC was placed, it was secured to the patient using medical tape (Johnson & Johnson), which covered the insertion site. This was followed by a layer of brown gauze (Jorgensen Laboratories, Inc), which was then covered by medical tape. A standard t-port (Vedco Inc) was attached to the catheter and secured to the patient with medical tape. Dogs were only fitted with an Elizabethan collar if the dog’s behavior warranted its use.

A randomization schedule was created with a random number generator prior to the study. Each dog enrolled in the study was randomly assigned to either the FASD group or the control group based on the randomization schedule. Dogs in the FASD group had the device installed between the IVF administration or extension set and the standard t-port (Figure 1).

Figure 1—Representative image of a force-activated separation device installed between the IV fluid extension set and t-port for 1 of 180 client-owned dogs that were randomized to the device treatment group (vs the control group; n = 187) and that had been hospitalized for ≥ 24 hours of IV fluid therapy in a clinical trial between January 11 and March 25, 2021.

All FASDs were replaced as long as the PIVC remained in place. Technicians were trained on the use of the FASD prior to the start of the study. This study was not blinded.

All PIVC complications in the FASD group and control group were documented on a data collection sheet. Information collected included the dog’s medical record number, age, sex and neuter status, breed, body weight, reason for hospitalization, and length of hospitalization. In addition, the type of complication was classified as dislodgement, phlebitis, extravasation, occlusion, or line breakage. Dislodgement was defined as the complete removal of the PIVC from the dog’s limb. Phlebitis was defined as redness, swelling, pain, or oozing at the PIVC insertion site. Phlebitis was graded using the previously published Visual Infusion Phlebitis Scale. Extravasation was defined as infusion of infusate into the subcutaneous space and surrounding soft tissues. Occlusion was defined as loss of patency and an inability to flush the PIVC. Line breakage was defined as breakage of the standard t-port via separation of the line from the male or female adaptor port. Technicians were trained on classifying PIVC complications based on definitions prior to the start of the study. If the patient was witnessed removing the catheter by chewing, this was not documented as a catheter complication. When a PIVC complication occurred, the PIVC was removed and a new PIVC was placed if further treatment was required. Each
subsequent PIVC was also monitored for complication and included in the overall analysis of PIVC complication incidence risk. All device separations in the FASD group were also documented.

PIVC maintenance at our institution included monitoring the limb for redness, heat, swelling, and signs of pain and palpating the limb proximal and distal to the PIVC site. This was performed approximately every 8 hours by trained technicians. In addition, students and veterinarians evaluated the catheter sites as part of their physical examinations, which occur at least twice daily. Technicians and students performed treatments throughout the day, and if any concerns with the PIVC were noted or the IVF pump was alarming, the PIVC is evaluated. The medical tape and brown gauze were only removed to evaluate the insertion site if there was a concern.

Statistical analysis
All analyses were performed with standard software (SPSS Statistics version 26.0; IBM Corp). Results for patient characteristics were compared between the groups using independent samples t test for normally distributed continuous variables and the Mann-Whitney U test for nonnormally distributed data. A χ² test of proportions or Fisher exact test (when cell counts were < 5) was used to compare categorical variables between the groups for patient characteristics and the rate of PIVC complications. Multivariate logistic regression was performed for the total PIVC complications to determine whether treatment group (categorical coding of 1 for FASD group and 0 for the control group) predicted having a PIVC complication while adjusting for duration of hospitalization. Assumptions for performing logistic regression model were assessed. Multicollinearity was examined to confirm that independent variables were not highly correlated. Linearity of the logit was assessed and determined using Box Tidwell transformation. Omnibus tests of model coefficients and residuals were examined to confirm that independent variables were not highly correlated. Linearity of the logit was assessed and determined using Box Tidwell transformation. In addition, residuals were examined to identify if any cases were extreme outliers.

Results
There were 379 dogs evaluated for inclusion in the study. Twelve dogs were excluded for not being hospitalized for at least 24 hours. A total of 367 dogs were included in the analysis. Dogs were hospitalized in either the Critical Care Unit (62.7% [230/367]) or Intermediate Care Unit (37.3% [137/367]). There were 180 dogs randomized to the FASD group and 187 dogs to the control group (Table 1). The FASD and control group patient characteristics were similar; however, hospitalization was longer (P = .04) for dogs in the control group (median, 3.0 days; range, 1.0 to 15.0 days) versus the FASD group (median, 3.0 days; range, 1.0 to 9.0 days).

There were a total of 62 PIVC complications reported in this study, including 16 in the FASD group and 46 in the control group (Table 2). The PIVC complication incidence risk was significantly (P ≤ 0.001) lower in the FASD group (8.9% [16/180]), compared to the control group (24.6% [46/187]). Similarly, the proportion of dogs that had 1 or more PIVC complications was significantly (P = .004) lower for the FASD group (8.9% [16/180]) versus the control group (19.3% [36/187]).

Phlebitis was the most commonly reported complication in this study (20/62 [32.2%]; Table 2). Line breakage (14/62 [22.6%]), extravasation (13/62 [21.0%]), dislodgement (12/62 [19.4%]), and occlusion (3/62 [4.8%]) were also reported. Use of the FASD was associated with less frequent line breakage (P = .002), phlebitis (P = .036), and dislodgment (P = .038), but not in extravasation (P = .314) or occlusion (P = .250). When adjusting for length of hospitalization, there remained a significant difference in the PIVC complication incidence risk between the 2 groups (P = .001) and in the number of patients with a PIVC complication between the 2 groups (P = .006). When the length of hospitalization was adjusted for in covariate analysis, being in the control group remained a significant predictor of having a PIVC complication (Table 3). After adjust-

Table 1—Comparisons of descriptive statistics to identify potential differences in patient-related characteristics for 367 client-owned dogs that had been hospitalized for ≥ 24 hours of IV fluid therapy with a peripheral intravenous catheter (PIVC) in place and had been randomly assigned to the force-activated separation device (FASD) group (n = 180) versus the control group (187) in a clinical trial between January 11 and March 25, 2021.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total (n = 367)</th>
<th>FASD (n = 180)</th>
<th>Control (n = 187)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)a</td>
<td>6.71 ± 5.00</td>
<td>6.74 ± 4.68</td>
<td>6.68 ± 5.32</td>
<td>.915</td>
</tr>
<tr>
<td>Body weight (kg)a</td>
<td>22.61 ± 14.16</td>
<td>23.02 ± 13.60</td>
<td>22.21 ± 14.71</td>
<td>.585</td>
</tr>
<tr>
<td>Breed size</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small, ≤ 5 kg</td>
<td>36 (9.8)</td>
<td>39 (9.4)</td>
<td>27 (14.5)</td>
<td>.136</td>
</tr>
<tr>
<td>Medium, 5 to 19.9 kg</td>
<td>122 (33.2)</td>
<td>56 (31.1)</td>
<td>66 (35.3)</td>
<td>.395</td>
</tr>
<tr>
<td>Large, 20 to 39.9 kg</td>
<td>169 (46.0)</td>
<td>90 (50.0)</td>
<td>79 (42.2)</td>
<td>.38</td>
</tr>
<tr>
<td>Giant, &gt; 40 kg</td>
<td>40 (10.9)</td>
<td>17 (9.4)</td>
<td>23 (12.3)</td>
<td>.818</td>
</tr>
<tr>
<td>Unit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CCU</td>
<td>230 (62.7)</td>
<td>113 (62.8)</td>
<td>117 (62.6)</td>
<td>.967</td>
</tr>
<tr>
<td>IMCU</td>
<td>137 (37.3)</td>
<td>70 (37.4)</td>
<td>67 (37.2)</td>
<td>.967</td>
</tr>
<tr>
<td>Hospitalization (d)b</td>
<td>3.0 (1.0 to 15.0)</td>
<td>3.0 (1.0 to 9.0)</td>
<td>3.0 (1.0 to 15.0)</td>
<td>.04</td>
</tr>
</tbody>
</table>

Data reported as number and percentage unless otherwise indicated.

aData reported as mean ± SD.

bData reported as median and range.

CCU = Critical care unit. IMCU = Intermediate care unit.
ing for length of hospitalization, the odds of a dog in the FASD group experiencing a PIVC complication was approximately one-third the odds of those in the control group (OR, 0.33; 95% CI, 0.17 to 0.63; \( P = .001 \)). Omnibus tests of model coefficients and Hosmer-Lemeshow test both indicated that the models were an acceptable fit.

In the FASD group, 54% (97/180) of dogs had a device separation. There were 327 separations documented in 97 dogs, with an average of 3.4 separations (range, 0 to 12 separations) per patient. Thirty-nine dogs had more than 3 separations, which was most commonly seen in anxious or active dogs. When dogs with more than 3 device separations were excluded from statistical analysis, the PIVC complication incidence risk in the FASD group was 5.6% and there was an average of 1.6 separations per dog (data not shown).

**Discussion**

Results of the present study supported our hypothesis that PIVC complications would be less common for dogs in the FASD group versus the control group. In this study, the PIVC complication incidence risk in the control group was 24.6% (46/187), compared to 8.9% (16/180) in the FASD group. The use of the FASD was associated with less frequent line breakage, dislodgement, and phlebitis, which were the 3 most commonly reported PIVC complications in the control group. There are many potential causes of phlebitis, but micromotion of the PIVC and subsequent skin irritation is likely a key contributor. The FASD may have been able to minimize the occurrence of phlebitis by reducing the micromotion of the PIVC. The use of the FASD did not lessen the incidence of occlusion and extravasation, which were the least commonly reported complications, representing 17.4% (8/46) of PIVC complications reported in the control group. Similarly, in the human study, occlusion complications were not less common with the use of the FASD. This was likely because occlusion is not a complication that occurs due to force on the PIVC. The FASD used in this study (SafeBreak Vascular; Lineus Medical) has been FDA approved for use in humans. Veterinary hospitals use many human medical products, which enabled us to easily adapt this product to use in veterinary patients. The FASD is inserted between the standard t-port and IVF administration or extension set. However, the product was designed to separate under 4 lb of force based on human data. It is unclear whether this is the ideal force for vete-

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**Table 2**—Comparisons of the numbers and types of PIVC complications identified for the FASD group (16 complications in 16 dogs) versus the control group (46 complications in 36 dogs) described in Table 1.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total (n = 367)</th>
<th>FASD group (n = 180)</th>
<th>Control group (n = 187)</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PIVC complication, frequency</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Line breakage</td>
<td>14</td>
<td>1</td>
<td>13</td>
<td>.002</td>
</tr>
<tr>
<td>Dislodgement</td>
<td>12</td>
<td>2</td>
<td>10</td>
<td>.038</td>
</tr>
<tr>
<td>Phlebitis</td>
<td>20</td>
<td>5</td>
<td>15</td>
<td>.036</td>
</tr>
<tr>
<td>Extravasation</td>
<td>13</td>
<td>8</td>
<td>5</td>
<td>.314</td>
</tr>
<tr>
<td>Occlusion</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>.25</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>16</td>
<td>46</td>
<td>&lt; .001</td>
</tr>
</tbody>
</table>

**Table 3**—Results of the multivariate logistic regression to identify potential predictive variables associated with PIVC complications in the 367 dogs described in Table 1.

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR</th>
<th>95% CI for OR</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total mechanical complications:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment group</td>
<td>0.327</td>
<td>0.171 to 0.625</td>
<td>.001</td>
</tr>
<tr>
<td>Length of hospitalization (days)</td>
<td>1.43</td>
<td>1.233 to 1.659</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>Patients with a mechanical complication:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment group</td>
<td>0.4</td>
<td>0.207 to 0.771</td>
<td>.006</td>
</tr>
<tr>
<td>Length of hospitalization (days)</td>
<td>1.341</td>
<td>1.147 to 1.568</td>
<td>&lt; .001</td>
</tr>
</tbody>
</table>

*Categorical coding: Treatment group (FASD = 1, Control = 0).*
nary patients, which can vary substantially in size and weight. There were no specific adverse events related to the use of the device in our study.

Ninety-seven dogs in the FASD group had a device separation, with an average of 3.4 separations/dog. There were 20 dogs that had more than 5 device separations, which is likely not financially feasible because each time the device separates, it needs to be replaced. These were usually very active dogs. To account for the financial feasibility of the device, when dogs with more than 3 separations were excluded from statistical analysis, the PIVC complication incidence risk in the FASD group was 5.6% (8/143; data not shown). In this population of dogs with greater than 3 separations excluded, 41.3% (59/143) of dogs had a separation, with an average of 1.6 separations/dog (data not shown). When the present report was written, the cost to the client for replacing a PIVC at this institution was $60.90 and was $8.90 for a SafeBreak Vascular (Lineus Medical) device.

PIVC complications have been documented in the human literature to be associated with many risk factors, including PIVC dwell time, size of PIVC, insertion site, type of dressing, gender, and type of infusion or medications administered. In 1 veterinary study that evaluated PIVC complications in cats, PIVC gauge, patient temperament, catheter location, and infusion of irritant medications were not associated with PIVC complications. Further research investigating risk factors for PIVC complications in veterinary patients is needed. In addition, research investigating other techniques for reducing the PIVC complication rate, especially for occlusion and extravasation, is needed. For instance, checklists have been used in many different areas of human and veterinary medicine to reduce the risk of complications. In humans, the use of a simple checklist for placement of IVCs was shown to reduce the incidence of catheter-related bloodstream infections. Similarly, the use of a surgical checklist was documented to reduce the incidence of surgical complications in a university veterinary hospital.

There were a number of limitations in the present study. Although different complications were defined, there is some subjectivity in determining the type of PIVC complication. In addition, individuals may have failed to document complications or they may have incorrectly classified them. Even though our institution has a specific protocol for PIVC placement, there is inevitably some variability in how they are placed, which may affect the complication rate. Similarly, our hospital’s PIVC placement protocol may vary from protocols at other institutions, which may affect the generalizability of this study. In addition, despite randomization, dogs in the control group were hospitalized significantly longer than the FASD group. This was a concern because results from human studies have suggested that the length of hospitalization may be a risk factor for PIVC complications. However, when length of hospitalization was adjusted for in the covariate analysis, being in the control group remained a significant predictor of having a PIVC complication. Thus, patients in the control group were still more likely to have a PIVC complication when the difference in the length of hospitalization is accounted for. Dogs that were witnessed chewing their PIVCs were not included as complications in the present study because this complication already has a solution through the use of an Elizabethan collar. There are many potential risk factors for PIVC complications that were not evaluated in the present study. For instance, increased staff handling of the PIVC due to the number of IV medications given may be a risk factor for PIVC complications, but this was not evaluated in this study. Further evaluation of risk factors for PIVC complications is needed. Finally, the lack of blinding is an important limitation of this study.

In conclusion, PIVC complications were less common for dogs in the FASD group, significantly lowering the incidence risk of PIVC complications from 24.6% (46/187) in the control group to 8.9% (16/180) in the FASD group. This human product was easy to adapt for use in veterinary patients, and there were no adverse events reported with its use. Reducing PIVC complications is imperative as it ensures that the dog receives all prescribed treatments in a timely manner, but it also may reduce the risk for venous depletion, reduce client costs, and minimize pain for the dog. Further research evaluating the use of this device in cats and other species is warranted.

Acknowledgments

The SafeBreak Devices used in this study were provided by Lineus Medical. There are no conflicts of interest to report.

References