Uroliths can occur anywhere in the urinary tract, but most commonly in the urinary bladder (urocystoliths) and urethra (urethroliths). Patients in need of a cystotomy experience stranguria, hematuria, discomfort, urinary tract infections, and even urinary obstruction in more severe cases. A common method for removing smaller urocystoliths during a cystotomy is to perform normograde and/or retrograde lavage via a urinary catheter. This technique allows small urocystoliths to be flushed out of the urethra or into the urinary bladder, respectively. Another frequently used method involves scooping out the smaller urocystoliths with common tablespoons and teaspoons, the same kind typically used for food preparation. Oftentimes, as urocystoliths are removed, the urinary bladder itself becomes increasingly contracted, which creates challenges for maneuvering effectively within its lumen. Additionally, a small incision in the bladder gives little visualization of where the urocystoliths are and how many are left. As a result, incomplete removal of urocystoliths is not uncommon and may require subsequent operation. Generally, urinary bladder size is attributable to patient weight as it relates to urine production. Normal canines produce 20–100 mL of urine per kilogram of body weight each day. Therefore, the manipulation of surgical

OBJECTIVE
Current cystotomy methods often implement the use of off-label devices, resulting in urocystolith extraction difficulty and potentially leading to postoperative complications and discomfort for the patient. The objective of this study was to create 3 novel 3-D printed cystotomy spoons that offer a dedicated solution for removing urocystoliths from a patient’s urinary bladder.

ANIMALS
Clinical use of the 3 novel 3-D printed cystotomy spoons were ultimately evaluated in 4 dogs and 1 cat that presented for urocystolith removal at 3 different veterinary hospitals in northwest Arkansas.

METHODS
The novel cystotomy spoons were designed using SolidWorks, 3-D printed with a Dental Surgical Guide resin, and underwent prototype testing that included chlorhexidine soaking, autoclave sterilization, 3-point bend testing, and Finite Element Analysis. The efficiency of the spoons was then evaluated through a limited proof-of-concept study utilizing a postoperative questionnaire for the participating clinicians.

RESULTS
Practitioner feedback indicated positive experiences using 1 or more of the novel 3-D printed cystotomy spoons while performing a cystotomy surgery. However, successful use of the spoons was ultimately limited to dogs in the 23 to 34 kg weight range.

CLINICAL RELEVANCE
Novel 3-D printed cystotomy spoons have the potential to mediate urocystolith extraction difficulty and reduce postoperative complications. Additionally, this research demonstrates how veterinarians might develop custom 3-D models and prints to meet patient-specific needs. As such, further development could impact the standard of healthcare and the veterinary industry by promoting the use of additive manufacturing in veterinary medicine.

Keywords: urinary bladder, cystotomy, urocystolith, urinary tract-small animal, urinary tract-surgery
instruments within the lumen of a urinary bladder in a small patient is more difficult than in larger patients. Thus, off-label spoons, such as tablespoons and teaspoons, can be too large or too thick to maneuver effectively within the urinary bladder, especially in small patients. On the other hand, currently available gall bladder cystotomy spoons may be too small for the effective and timely removal of some urocystoliths. The typical cystotomy surgical time for canines is 1.26 ± 0.50 hours, with the difficulty in extracting smaller urocystoliths potentially increasing the period of time anesthesia is administered to the patient. In addition to time and cost concerns, prolonged anesthesia can cause animal harm, and potentially “may cause a significant delay in gastric emptying and predispose to postanesthetic GI complications.”

3-D printing is a rapid prototyping technology, in which objects are created in a layer-by-layer process, using materials such as plastics, metals, ceramics, powders, liquids, and even biological tissues. The geometry of the part to be printed is created in Computer Aided Design (CAD) software such as SolidWorks, AutoCAD, etc., and prepared with a slicing software before being sent to the printer. 3-D printing permits the rapid (timespans of several hours) and relatively cheap production and testing of complex geometries, without the often prohibitively high cost and long development times associated with conventional manufacturing, such as custom machining, injection molding, and drop forging. Although the use of 3-D printing technology is quickly proliferating in the human medicine realm, it is still gaining a foothold in veterinary medicine. However, veterinary clinical applications for 3-D printing are being reported across academic institutions and veterinary hospitals. The technology has been considered beneficial to patients according to the clinical experience of veterinary surgeons. 3-D printing provides veterinary medicine with a “powerful tool” to facilitate surgical planning, enhance the teaching of students and clients, and has been shown useful for research purposes. Therefore, additive manufacturing is capable of being multifunctional and advantageous to veterinary researchers, businesses, practicing veterinarians, and patients. 3-D printing for veterinary practices, especially coupled with subsequent measurement and validation techniques, can provide opportunities for critical advances and improvements to veterinary medicine and the health and well-being of companion animals.

The following is a description of the engineering process followed for the creation of 3 novel 3-D printed cystotomy spoons and the subsequent prototype testing and proof-of-concept trials. Ultimately, this report provides a guide for veterinary professionals to follow when designing and producing custom devices.

**Methods**

**Design and fabrication process**

During the development process, the dimensions of the novel 3-D printed cystotomy spoons were strategically designed to maneuver gently and more effectively inside a small incision in a contracted urinary bladder. As such, the cystotomy spoons were designed to have smaller dimensions than the common off-label devices in an attempt to mitigate the instrument-to-patient urinary bladder size variable. Observed use of off-label devices, such as traditional tablespoons, indicated that the standard curvature of the spoon head had insufficient surface area contact with the lumen and appeared too large and thick compared with the patient’s urinary bladder. Therefore, straight edges were incorporated into the 3-D printed cystotomy spoon heads with the intent to provide increased surface area contact between the spoon and urinary bladder tissue. In theory, this alteration allows for more effective extraction of urocystoliths adhering to the lumen of the urinary bladder. Additionally, these straight edges of the new cystotomy spoon heads are projected to allow more urocystoliths to be extracted in a single scoop. For patient safety, the straight edges of the cystotomy spoons have slightly rounded corners, which decreases the sharpness, with the goal of preventing damage to the mucosa of the urinary bladder.

The cystotomy spoons, considered in 3 different geometries, vary in size and the placement of 1 or 2 straight edges (Figures 1 and 2). Spoon #1 has 2 straight edges on the left side of the spoon head. Spoon #1 was designed to maintain surface area contact while holding the spoon at different angles. Spoon #1 has a shallow depth to provide the appropriate access to maneuver effectively through the incision while extracting urocystoliths. Spoon #2 has a relatively smaller head with symmetrical straight edges. This spoon was designed to maneuver gently into the neck of the urinary bladder to extract urocystoliths that are migrating to the urethra. Spoon #3 has 1 straight edge placed on the left side of the spoon head and has a relatively large depth and width. The design of Spoon #3 was chosen to maintain surface area contact but to also be able to extract a large amount of urocystoliths in each scoop.

The novel cystotomy spoons were modeled in SolidWorks (Dassault Systèmes) and subsequently 3-D printed using a Form 2 printer and Dental Surgical Guide Resin (Formlabs). This resin was chosen due to its characteristic Class I biocompatibility and ability to withstand the heat and pressure of autoclave sterilization. Dental Surgical Guide Resin is often used by dental professionals in the operating room and can remain in the mouth for up to 24 hours. The biocompatibility confirms there are no adverse effects in relation to cytotoxicity, sensitivity, irritation, acute toxicity, and genotoxicity. To ensure biocompatibility, all Formlabs protocols for printing and postprocessing were followed. After printing was complete, the cystotomy spoons were bathed in a Form Wash (Formlabs), which cleans the finished prints in an agitated bath of 99% isopropyl alcohol, for 20 minutes to remove any excess uncured resin. The cystotomy spoons dried for 30 minutes and were postcured by exposure to UV light and heat for 30 minutes at 60 degrees Celsius in a Form Cure. All
spoons were designed with identical thickness in the handles and scoops, ensuring consistent printing and curing and, therefore, consistent Young’s Modulus across spoon models. The spoons were then manually removed from the support bridges and polished carefully with fine sandpaper to remove any remaining sharp edges/points.

Overview of prototype testing

In a veterinary clinical setting, the cystotomy spoons would frequently be subjected to repeated autoclave sterilization and cold sterilization using chlorhexidine solution. Therefore, the cystotomy spoons were tested for durability by creating 3 experimental groups to test for detrimental effects on the spoons’ material. The first group contained 4 prototypes of Spoon #1, in which 1 was a control, and 3 were soaked in 50% chlorhexidine solution for increasing amounts of time. The second group contained 4 prototypes of Spoon #2, in which 1 was a control, and 3 were subject to increasing numbers of repeated autoclave cycles. The third group contained 4 prototypes of Spoon #3, in which 1 was a control, and 3 were subjected to combined chlorhexidine soaking and autoclave treatments. The spoons were weighed before and after sterilization and/or soaking to evaluate for absorbed/trapped moisture. After treatment, measurement of shear strength was performed on all experimental groups by performing a 3-point bend test with an Instron Series 4466 load frame (Instron). The Instron applies force to the cystotomy spoons to evaluate the load needed to elicit failure of the spoon’s structural integrity. Finite element analysis (FEA) was then conducted to validate the bend-test findings and subsequently to estimate strength in the use-case typical to a cystotomy. Lastly, the 3-D printed cystotomy spoons were distributed to 7 veterinary clinics to conduct a proof-of-concept study. The cystotomy spoons were to be used in animals requiring a cystotomy, with client consent. The study included a postoperative questionnaire to determine patient parameters and overall veterinarian experience with the spoons and individual spoon preference after using one or more of the 3-D printed cystotomy spoons while performing a cystotomy.

The authors would like to note that appropriate approvals were sought from both the University of Arkansas Institutional Animal Care and Use Committee and its Institutional Review Board before the initiation of this project. However, after careful evaluation of the project plan, each committee determined that formal approval was not needed, either because (1) the animals were privately owned and current patients of the area veterinarians and client...
consent would be obtained before the discretionary use of the novel spoons by the veterinarians and (2) no data collected from the practitioner postsurgical questionnaire would reveal any personal information about the practitioner or the client.

**Chlorhexidine exposure**

Given that instruments are commonly cleaned and disinfected in chlorhexidine before autoclave sterilization, the first experimental group was conducted with Spoon #1 by soaking the instruments in 50% chlorhexidine (300 mL) and 50% water solution (300 mL). Soak times were for periods of 1 hour, 12 hours, and 24 hours. The solution was left to rest while soaking with no agitation. The spoons were allowed to thoroughly dry before the 3-point bend test with their weights measured 2, 12- and 24-hours postsoaking, as well as immediately before bend testing.

**Autoclave cycles**

The second experimental group was conducted with Spoon #2 by repeatedly autoclaving the cystotomy spoons in a Primus autoclave (MPS5-A-MSSD, Spire Integrated Solutions). Spoons were autoclaved at 121 °C and 18.1 PSI for 30 minutes per the resin manufacturer’s recommendations. Spoons were autoclaved for 1 cycle, 5 cycles, and 10 cycles before being allowed to fully cool and dry before the 3-point bend test. Spoon weights were measured before and after sterilization, before bend testing.

**Chlorhexidine exposure and autoclave cycles**

The third experimental group was a combination of the first and second groups, which consisted of Spoon #3 used for autoclave sterilization and chlorhexidine soaking. The combination of increments was as follows: 1 autoclave cycle followed by 1-hour soaking, 5 autoclave cycles followed by 12-hours soaking, and lastly 10 autoclave cycles followed by 24-hours soaking. The weights of the spoons were recorded before and after sterilization, before bend testing.

**3-point bend test**

After sterilization cycling, the cystotomy spoons were subjected to a 3-point bend test to determine shear strength. Bend testing was performed with an Instron Series 4466 load frame (Instron). The spoons’ integrity was tested using a 1/2-inch diameter cylindrical upper anvil attached to a 50-kg load cell. The spoons were loaded on the top edge of the scoop section by the cylindrical anvil and supported underneath the scoop by v-shaped lower anvils, spaced approximately 34 inches apart. The handles of the spoons were held manually (Figure 3) until sufficient force was applied to the scoop that they remained held by the grip fixtures. The deflector was lowered with a constant cross speed of 200 mm/min until the spoon ruptured. Recorded data included the applied load and corresponding displacement of the cystotomy spoons.

**Statistical analysis**

After bend testing, the statistical significance of the various treatments’ effects on mechanical behavior was determined by 2-sided, unpaired Student’s t-tests. Each treatment group consisted of a different spoon model, and each t-test compared these treatment groups with their corresponding, untreated counterparts. For example, the autoclave treatment group, which utilized Spoon #2, was compared against the untreated Spoon #2 control. The null hypothesis is that there is no significant difference between treated and untreated, whereas the alternative hypothesis is that a significant difference is present. Statistical significance is considered to be when $P < .05$.

**Finite element simulation**

Additionally, a FEA of the spoons was conducted to verify the findings from the shear strength tests using the Instron Series 4466 and demonstrate that the cystotomy spoons are sufficiently robust and able to withstand cystotomy use. FEA is a computational analysis tool used to predict how structures or materials will respond to real loading applications. The FEA utilizes the CAD model’s geometry, discretizing it into a mesh with interconnected vertices for which the model’s mechanical behavior, including stress and deformation, is computed. All computational analysis was conducted using SolidWorks and all simulations were treated as static. Models for the 3-point bend fixture hardware were prepared and appropriately mated together with the spoon models in a Solidworks assembly (Figure 3). The fixtures were modeled as American Iron and Steel Institute 1045 cold rolled steel (205 GPa Young’s Modulus) while the spoon was modeled as a custom material, initially with a Young’s Modulus of 1,500 MPa. The lower supporting grip fixture was held steady while the upper deflector was constrained to travel only in the vertical direction by applying a roller/slider fixture. The bottom face of the spoon head was constrained to lie tangent to both lower supports, and the rear-most face of the handle was locked with a
fixture to prevent under-constrained motion and ensure simulation stability. A uniformly distributed force equal to the average experimental load at failure was applied downwards to the upper deflector that was then pressed against the spoon. No penetration contact sets were applied between the deflector and spoon as well as the spoon and lower supports. The assembly was meshed using a 4-point Jacobian mesh. The mesh size, which impacts the quality and accuracy of the simulation results, was gradually decreased, and the simulation was rerun until the results stabilized.

To obtain a reasonable estimate of the Young’s Modulus for the Dental Surgical Guide resin, which was not provided by the manufacturer, and furthermore varies as a function of cure time and temperature, the Instron data for the Spoon #3 control group was used to iterate the FEA simulation until the obtained displacement matched the experimental results. This was done by applying the average experimental loading with a reasonable estimate for Young’s Modulus, running the simulations, and checking whether the resulting displacement was larger or smaller than the experimental. The Young’s Modulus was then incremented accordingly (increasing Young’s Modulus to reduce the simulated displacement), and the simulation was rerun. This process was repeated until a good match (<1% difference) was obtained between simulation and experimental displacements. Once a reasonable estimate for Young’s Modulus was obtained (2,450 MPa), that value was used to run similarly set-up simulations for the Spoon #1 and #2 models. The loading force and desired displacement used in the FEA were taken to be equal to half the average load and displacement of the 3-point bend tests at failure rather than the full failure points as some variability was present in the ultimate breaking strength of the printed spoons. The half-failure conditions are within the linear region of the stress-strain curve, so they represent an appropriate interpolation.

The physical 3-point bend test described above allowed for pre- or poststerilization testing as well as validation of the FEA results; however, it does not sufficiently predict the loading present during actual cystotomy use. To avoid the necessity of creating specialized fixturing and test equipment, an additional FEA was conducted in which the spoon handle is held stationary as fixed geometry up to a point 1/4 inch behind the spoon head, with the head itself bearing a downwards, uniformly distributed force of 11 Newtons (2.5 pounds). This configuration is reminiscent of a “scooping” action being applied to the spoon. The same Young’s Modulus found previously was used for this analysis.

Proof-of-concept study
The cystotomy spoons (1 copy of each spoon type; 3 spoons total) were distributed to 7 veterinary clinics in northwest Arkansas, ranging in size from 1 to 9 veterinarians per practice for a proof-of-concept study. Over the course of 6 months, utilization or attempted utilization of the novel cystotomy spoons was documented by 3 of the veterinary clinics. The participating patients were dogs and cats currently in need of cystotomy surgery. The use of the cystotomy spoons was at the sole discretion of the attending veterinary surgeon, and there was no specific requirement for the surgeon to utilize all or any of the spoon types provided by the researchers. Owner consent was obtained before the use of the spoons via an informative consent form that the owners signed before their pet’s scheduled procedure. The cystotomy spoons were then subjected to autoclave sterilization before surgery according to standard clinic practices. A practitioner postoperative questionnaire was provided to each attending veterinary surgeon to collect appropriate findings on their experience with and the efficacy of the cystotomy spoons. The questionnaire requested the species, breed, age, and weight of the patient, which cystotomy spoon(s) were used during the cystotomy, if the veterinarian resorted to other conventional methods of extraction, and asked the veterinarian to rate the overall experience associated with the use of the spoons. Patient weight was used to assess the patient’s urinary bladder size. The questionnaire also determined parameters such as previous history and composition of urocystoliths, diagnostic imaging evaluation, and total surgical time. The specific criteria that were used to evaluate the performance of the 3-D printed cystotomy spoons included: patient weight, an estimate of total surgical time and urocystolith extraction time, complete removal of urocystoliths, spoon preference, and overall experience implementing the cystotomy spoons. The full-length questionnaire and owner consent form are provided elsewhere (Supplementary Materials S1 and S2). Note that insufficient responses were received to determine the statistical significance of spoon preferences and the results are considered more qualitative.

Results

Chlorhexidine exposure
The 50% chlorhexidine solution treatment did not appear to compromise spoon strength or rigidity (P = .84) as the applied load and resulting displacements at failure remained relatively unchanged, regardless of soak time. Each spoon decreased in weight slightly after soaking. However, the difference in weight does not appear to become consistently larger when soaked for longer periods of time (Table 1).

Autoclave cycles
Repeated sterilization by autoclave cycling did not significantly diminish the load-bearing abilities of the spoons (P = .37), with neither large increases nor decreases in failure load/displacement (Table 1). As with the soaked treatment group, a small decrease in spoon weight was observed in the single and 5-cycle spoons; however, an increase was seen for 10-cycle spoons. Decreases are again likely due to trace material removal, where a minor increase may be due to insufficient drying time to allow for the removal of absorbed moisture.
Combined chlorhexidine exposure and autoclave cycles

Combined autoclave cycling and chlorhexidine soaking did not appear to seriously degrade the spoons in terms of failure load or resulting displacement ($P = .24$). Increased variability was seen in the combined treatment group compared with the autoclave and soaking groups alone, likely due to the geometry of the spoon used (Spoon #3) and the fact that spoons were positioned manually on the Instron machine. Small decreases in spoon weight were observed for the combined treatment group as well (Table 1).

Finite element simulation

A Young’s Modulus of 2,450 MPa was found to most accurately mimic the deformation observed for Spoon #3’s control group with an error of 0.8%, with mesh convergence and Young’s Modulus optimization shown elsewhere (Supplementary Table S1). Simulated displacement results for the 3-point bend setup using this Young’s Modulus showed good agreement with experimentally measured displacements of Spoon #1’s geometry, having a difference of less than 3%, validating the use of FEA. Using this same modulus, the more representative “scooping” load case (Figure 4), which utilizes a 2.5-pound loading force, was found to generate von Mises stresses upwards of 78% of the half-failure experimental measurements (Table 2), even with such a relatively large loading force.

Proof-of-concept study

Attempted use of the cystotomy spoons occurred a total of 5 times across 3 veterinary clinics. All patients in need of cystotomy surgery participating in the study were canines, except for 1 feline. Three of the cystotomy surgeries (2 canines and 1 feline) did not ultimately utilize the 3-D printed cystotomy spoons because the spoons were too large for the intended patient’s urinary bladder. These 2 canine breeds were a miniature dachshund and Yorkshire terrier mix both in the weight range of $\leq 11$ kg. The Yorkshire terrier mix was within the age range of 4–7 years old, while the miniature dachshund was over 12 years old. The feline was a domestic shorthair, within the age range of 4–7 years old, and within the $\leq 11$ kg weight range.

The cystotomy surgeries where the 3-D printed cystotomy spoons were implemented included 2 canines. The breeds were a terrier mix and blue heeler, both weighing between 23–34 kg, within an age range of 4–7 years old, had no previous history of uroliths, and the type of urolith removed was struvite. The terrier mix was diagnosed with a urinary tract infection and the veterinarian sent the uroliths

<table>
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<th>Treatment</th>
<th>Cycles</th>
<th>Soak time (hours)</th>
<th>Initial weight (g)</th>
<th>Final weight (g)</th>
<th>Load (kgf)</th>
<th>Displacement (mm)</th>
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<td>2.677</td>
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<tr>
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<td>2.644</td>
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<tr>
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<td>13.09</td>
<td>3.967</td>
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<tr>
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<td>2.933</td>
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<tr>
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<td>3.051</td>
<td>3.034</td>
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<td>2.439</td>
</tr>
</tbody>
</table>

Spoons used for chlorhexidine, autoclave, and combined treatment were models 1, 2, and 3, respectively.

Table 1—Conditions for chlorhexidine soaking, autoclave sterilization, and combined chlorohexidine and autoclave treatment along with results of subsequent 3-point bend tests.

Table 2—Results of the finite element analysis (FEA) for a more realistic “scooping” load-case.
A reliable tool is required. Currently, access to the technology is limited. Therefore, an economically viable solution for performing advanced cystotomies is needed. Practitioners do not routinely perform laparoscopic procedures, and veterinarians have reported difficulties using conventional cystotomy spoons to retrieve urocystoliths. The information gained regarding the discontinuation of the use of the novel cystotomy spoons was unexpected, as they are commonly present in companion animals, requiring surgical intervention by veterinarians. Unfortunately, general veterinary practitioners do not routinely perform laparoscopic-assisted or other advanced cystotomies due to a lack of access to the technology. Therefore, an economical and reliable tool is required. Currently, there are no commercially available instruments that have been developed or labeled for the removal of urocystoliths in veterinary patients. As a result, 3 models of novel cystotomy spoons were designed and produced by 3-D printing, which dramatically accelerated prototyping and reduced cost compared with more conventional manufacturing methods.

Initial clinical feedback from 2 veterinarians who were able to utilize the spoons during cystotomy surgeries indicated a preferred and favorable experience while using 1 or more of the novel cystotomy spoons compared with off-label devices such as a tablespoon. Prototype testing, as well as simulation, show the spoons to be robust to both intended use as well as likely sterilization methods. As indicated by the veterinarians’ responses to the questionnaire, Spoon #2 was the most utilized. Its current shape and size are ideal for extracting millimeters in size urocystoliths sticking to the lumen and at the neck of the urinary bladder, where it narrows into the urethra (Figure 2). Both surgeries took 0–20 minutes to remove the urocystoliths, which is a positive predictor for time efficiency. Additionally, both veterinarians stated that they discontinued the use of the cystotomy spoons to retrieve some larger urocystoliths by hand or with forceps. The veterinarian on the terrier mix’s case rated the overall experience using the cystotomy spoons as “excellent,” while the blue heeler’s veterinarian rated the overall experience as “good.”

**Discussion**

Urocystoliths are commonly present in companion animals, requiring surgical intervention by veterinarians. Unfortunately, general veterinary practitioners do not routinely perform laparoscopic-assisted or other advanced cystotomies due to a lack of access to the technology. Therefore, an economical and reliable tool is required. Currently, there are no commercially available instruments that have been developed or labeled for the removal of urocystoliths in veterinary patients. As a result, 3 models of novel cystotomy spoons were designed and produced by 3-D printing, which dramatically accelerated prototyping and reduced cost compared with more conventional manufacturing methods.

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**Acknowledgments**

This work was sponsored by grants from the University of Arkansas Bumpers College of Agriculture, Food, and Life Sciences and the Honors College, as well as the Arkansas Research Alliance.

The authors declare that there were no conflicts of interest.
The authors would like to thank the following veterinary clinics of northwest Arkansas for their participation in the proof-of-concept study: Faithful Friends Animal Clinic of Rogers, Smithers Animal Hospital of West Fork, Crossover Veterinary Clinic of Fayetteville, Best Friends Animal Hospital of Fayetteville, Animal Medical Center of Rogers, Wedington Animal Hospital of Fayetteville, and Animal Medical Clinic of Fayetteville. The authors also wish to thank Dr. Janeal Yancy for her support with 3-point-bend testing, as well as Diane D’Angelo and the late David D’Angelo for their assistance in the development of the prototype drawings.

References


Supplementary Materials

Supplementary materials are posted online at the journal website: avmajournals.avma.org.