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## Abstract

Bladder stones, also known as uroliths, are not an uncommon condition in domestic dogs. To remove these uroliths, which occur in various sizes, shapes, and compositions, veterinarians will perform a surgical procedure called a cystotomy. A cystotomy consists of creating a small incision into the lumen of the urinary bladder and the utilization of various methods to extract the uroliths. For general veterinary practitioners, the laparoscopic-assisted technique is unavailable. As a result, the methods available for urolith extraction are often limited to flushing the stones out by inserting a urinary catheter through the urinary tract and the use of off-label devices such as the standard tablespoon, teaspoon, or gallbladder spoon. Many times, these methods still make it difficult to remove all of the uroliths, especially the small ones that can be millimeters in size. Remaining uroliths can cause post-operative complications and discomfort to the patient. Three novel 3D-printed surgical spoons have been designed to find a dedicated solution to the difficulty of removing all uroliths from a patient's bladder. Thus, the objective and innovation of this research could impact the standard of health care for companion animals and the veterinary industry. The novel surgical spoons were designed on a Computer-Aided Software, 3D-printed, and laboratory tested through cycles of autoclave sterilization, chlorhexidine solution soaking, and shear strength measurement using three-point-bend tests on an Instron Series 4466. Finite Element Analysis was conducted, validated using the Instron measurements, and subsequently used to estimate strength in the case of a cystotomy. Clinical trials at numerous veterinary clinics in Northwest Arkansas showed favorable experiences using one or more of the 3D-printed novel surgical instruments while performing a cystotomy compared to other traditional methods.

*Keywords:* Cystotomy, 3D-Printing, Veterinary

## Introduction

Uroliths are referred to as bladder stones and can occur anywhere in the urinary tract, but most commonly in the urinary bladder and urethra. Uroliths form when the urine becomes heavily concentrated with microscopic precursors such as mineral solutes and crystalloids. Uroliths are considered precursors that have grown to macroscopic size (Brown, 2013). Uroliths are not formed unless certain environmental conditions of the urinary bladder are present, which include~~s~~ “high concentrations of urolith-forming constituents,” favorable pH levels, and occurrence of urinary tract infections. Decreased water consumption, protein content in diets affecting the urine, and genetics also play a role in the formation of uroliths (Brown, 2013).

The common types of uroliths vary in mineral compositions, formation, and treatment. Struvite uroliths are comprised of magnesium, ammonium, and phosphate. Struvite urolithiasis forms in urine with a higher pH level and in animals with concurrent urinary tract infections. To prevent struvite urolithiasis, dietary strategies such as reducing magnesium, ammonium, phosphate, and protein levels can be implemented. Urate uroliths are comprised of uric acid or urate and urolithiasis form in pets with a liver shunt or Dalmatians and English Bulldogs with a genetic defect that disrupts the ability to regulate dietary purines. The treatment options for urate urolithiasis are decreasing dietary ammonia levels in liver shunt patients and purine diets in dogs with a genetic predisposition. Lastly, calcium oxalate uroliths are comprised of calcium oxalate and form in concentrated urine. There is debate whether reducing protein, calcium, and oxalate levels in the diet are effective and safe in treating companion animals with calcium oxalate uroliths (Gardiner, 2018).

Furthermore, according to a study conducted by the Canadian Veterinary Urolith Centre, breed and sex may serve as predisposing factors to urolithiasis. Urolithiasis describes the deposits of urinary calculi, or uroliths, in the bladder or any other part of the urinary tract. Of 16,647 canine uroliths, 43.8% were struvite and 41.5% were oxalate. Struvite urolithiasis was reported as most common in female canines, while oxalate and urate urolithiasis were most common in male canines. Struvite uroliths were most common in mix breeds, “followed by shih tzu, bichon frise, miniature schnauzer, Lhasa apso, and Yorkshire terrier.” Oxalate uroliths were most common in the “miniature schnauzer, bichon frise, Lhasa apso, shih tzu, and Yorkshire terrier.” Lastly, urate urolithiasis was most common in Dalmatians (Houston, Moore, Favrin, & Hoff, 2004).

In veterinary medicine, a cystotomy surgery is the most common method to remove uroliths from the urinary bladder. Patients in need of a cystotomy experience difficulty urinating (stranguria), blood in the urine (hematuria), discomfort, urinary tract infections, and even urinary blockage and obstruction in more severe cases. For a cystotomy, the patient is anesthetized, and an incision is made into the lumen of the urinary bladder. The surgical time, in hours, is “1.26 ± 0.50” (Arulpragasam, S. P., Case, J. B., & Ellison, G. W., 2013). The length of time to complete this surgery is largely attributed to the difficulty in removing smaller uroliths from the bladder, which may result in the patient receiving a greater amount of anesthesia. A small incision in the bladder gives little visualization of where the stones are and how many are left. A common method for removing these smaller uroliths is to insert a catheter through the entire urinary tract and flush out the small, almost glass like, uroliths. Another common method is to scoop out the small uroliths with “bladder spoons” (Rawlings, Mahaffey, Barsanti, & Canalis, 2003). The tissue of the urinary bladder contracts when an incision is made, creating an additional challenge of maneuvering effectively within the lumen of the urinary bladder tissue. Thus, “bladder spoons” such as tablespoons and teaspoons can be too large or too thick to maneuver effectively within the bladder. These are the issues behind the reasoning for the creation of new, specially shaped, 3D-printed surgical spoons, especially since 3D-printing is growing exponentially in medical practices (Ventola, 2014).

The development of the 3D-printed surgical spoons aims to give general veterinary practitioners access to an alternate tool for use in cystotomy surgery that will yield improved efficacy of urolith removal in dogs by reducing surgical time and decreasing the likelihood of leaving uroliths behind in the urinary bladder. The novel surgical instruments can also help clients save money by reducing the overall surgical anesthetic time. By decreasing surgical time, the veterinarian also has more allotted time for other surgeries and tasks of the day, which can have a positive impact on the veterinary practice as a whole.

The surgical spoons are targeted for use in cystotomy surgeries in order to improve the efficiency of urolith removal and overall improve the health of our companion animals. Moreover, the innovation could have significant benefits to the veterinary industry in how veterinarians and researchers approach veterinary medicine. 3D-printing for veterinary practices, especially coupled with subsequent measurement and validation techniques, can open opportunities for critical advances and improvements to veterinary medicine and the health and well-being of companion animals.

## Literature Review

### Cystotomy Surgery

During a cystotomy, it is crucial that all the uroliths are removed, especially small ones that can cause "lower urinary tract obstruction" in the urethra if left untreated (Appel, Otto, & Weese, 2012). Obstruction can cause severe discomfort and require surgical intervention to stabilize the patient. Veterinarians will often require an image to be taken of the lower abdomen by a radiograph or ultrasound to confirm removal was complete. It is believed by some veterinarians that neglecting to take a diagnostic image is considered failure in the standard of care (Grant, Harper, & Werre, 2010). Failure to remove all uroliths is a breach in veterinary care because the uroliths can cause post-operative complications and can leave an animal in urinary discomfort. In fact, studies have reported that uroliths were left behind in 20% of dogs after cystotomy (Langston, Gisselman, Palma, & McCue, 2010). Complications may include urolith recurrence as well as urinary tract infection. (Pinel, Monnet, & Reems, 2013). Some veterinarians will also administer anti-inflammatory and antibiotic therapy to the patient if infection is suspected or as a preventative measure (Franz et. al, 2009). The mere composition of some uroliths, such as calcium oxalate stones, can make recurrence more likely (Bartges, et. al, 1999). Veterinarians commonly battle recurring urolith cases and resort to a urinary prescription diet in an effort to reduce the onset of new uroliths.

The difficulty in extracting uroliths increases the period of time anesthesia is administered to the patient and cost to the client. In fact, prolonged anesthesia can cause an animal harm (Gaynor, et. al, 1999). For instance, prolonged anesthesia and surgery "may cause a significant delay in gastric emptying and predispose to post-anesthetic GI complications" (Boscan, P., Cochran, S., Monnet, et al., 2014). As a solution to these issues, this research aims to protect the health of the patient by decreasing anesthetic time, post-operative complications, and cost to the client through the use of one or more of the novel surgical spoons.

### 3-D Printing

Three-dimensional (3D) printing is accomplished with computer-aided design software (CAD) and a 3D-printer “similar to traditional inkjet printers;” however, the result is a 3D object. 3D-printing is a method in which “objects are made by fusing or depositing materials—such as plastic, metal, ceramics, powders, liquids, or even living cells—in layers” (Ventola, 2014). The geometry of the part to be printed is created in CAD software such as SolidWorks, AutoCAD, etc. This geometry is saved into a compatible file format, most typically a .STL (standard tessellation language) file, whereby the object’s surface is described as a set of triangles that mesh the surfaces. This file is used by a slicer program, often specific for a given 3D-printed, which uses the surface information to generate layer-by-layer instructions in the form of g-code for the 3D-printer to execute. The electronic instructions include dimensions, but also convey color and texture to the 3D-printer (Ventola, 2014).

Advances in medical 3D-printing technology has led to innovations in several fields of healthcare. In fact, the material used in this research is primarily used by dental professionals to deliver better customized treatment to patients. 3D-printing has allowed healthcare professionals the ability to learn, perform tasks more efficiently, and bring ease to their patients. For example, healthcare professionals are printing a variety of medical devices and anatomical models. Current medical devices that have been produced with 3D printing technology include orthopedic and cranial implants, surgical instruments, dental restorations, and prosthetics (Center for Devices and Radiological Health, 2020).

Although the use of 3D-printing technology is quickly proliferating the human medicine realm, it is still gaining a foothold in veterinary medicine. One paramount 3D-printing accomplishment in the veterinary profession was Dr. Michelle Oblak at Ontario Veterinary College printing a “customized part of the skull of a dog with a massive brain tumor” (Gyles, 2019). The 3D-printed anatomical model enabled her to be well-prepared in the operating room. Other uses of 3D-printing in veterinary medicine have been for academic purposes such as printing “models of selected domestic animal bones or organ specimens” for veterinary students enrolled in gross anatomy courses (Benjamin, 2020).

3D-printing, also known as additive manufacturing, has become a technique used in industry production, yielding optimization in manufacturability, product design, and planning. The benefits of 3D-printing are freedom of design, fast prototyping, and mass customization (Ngo, T. D., Kashani, A., Imbalzano, G., Nguyen, K. T., & Hui, D., 2018). Customization can also be independent of production volume and is beneficial for manufacturing complex or specific parts in a timely manner. With conventional manufacturing processes, product complexity increases cost, production time, and decreases production rates. 3D-printing materials have become stronger and more durable regardless of complexity, providing functional prototypes that are more cost effective and time efficient compared to conventional manufactured prototypes. Thus, reducing time-to-market, final product functionality, elimination of labor and capital costs (Conner, B. P., Manogharan, G. P., et al., 2014).

Mass customization by additive manufacturing is currently implemented by companies such as Invisalign and New Balance. New Balance has printed customized track and field spikes for consumers. As machine costs decrease and processing speeds increase, it is clearly possible that shoes will be printed in-store while the consumer waits (Conner, B. P., Manogharan, G. P., et al., 2014). With additive manufacturing becoming more competitive and advantageous compared to conventional manufacturing, businesses will likely convert their manufacturing processes to 3D-printing in the near future.

With the collaboration of University of Arkansas Biomedical Engineering and Animal Science faculty, 3D-printing a veterinary medical device has become the focus of this research. The 3D-printed veterinary medical device is a set of novel surgical spoons intended to provide a dedicated solution to the difficulty in removing uroliths and provide an improvement in the standard of care for companion animals.

## Development Plan and Design Process

During the development process, the dimensions of the novel 3D-printed surgical spoons were strategically designed to maneuver gently and more effectively inside a small incision in a contracted bladder. The surgical spoon heads were designed with straight edges to allow more surface area contact between the spoon and bladder tissue and to more effectively extract millimeter in size uroliths sticking to the lumen of the bladder. The standard curvature of a traditional tablespoon head lacks the ability to make sufficient surface area contact with the lumen. Thus, the straight edges of the spoon heads will allow more uroliths to be extracted in one scoop rather than multiple scoops with a traditional tablespoon. The straight edges of the surgical spoons are beveled in order to prevent damage to the tissue of the bladder.

To facilitate a more efficient and complete removal of the uroliths, the surgical spoons were also designed with appropriate thickness, depth, width, and length. The dimensions of each surgical spoon are shown in Figures 1-3. The three surgical spoons vary in the placement of one or two straight edges. Spoon 1, referenced in Figure 1, has a relatively smaller head with symmetrical straight edges. Spoon 2, referenced in Figure 2, has one straight edge placed on the left side of the spoon head and has a larger depth and width compared to Spoon 1. Spoon 3, referenced in Figure 3, has two straight edges on the left side of the spoon head, has a smaller depth than Spoon 1, and has a greater length than Spoon 2.

## 3D-Printing

The novel surgical spoons were sketched and designed on a Computer-Aided Design program called SolidWorks. The material of the 3D-printed surgical spoons is distributed by FormLabs, Inc. and is a photopolymer resin made of methacrylic esters and photoinitiators and is commonly referred to as Dental Surgical Guide Resin. The 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. Thus, making the resin ideal for use within the urinary bladder.

In order to ensure biocompatibility, the Dental Surgical Resin manufacturer's instructions were followed. After printing was complete, the surgical spoons were then bathed in a Form Wash, which cleans the finished prints in an agitated bath of 99% isopropyl alcohol, for 10-20 minutes to remove any excess uncured resin. Once the surgical spoons dried after 30 minutes, they were post-cured by exposure to UV light and heat for 30 minutes at 60 degrees Celsius in a Form Cure. The spoons were then removed from the support bridges and polished carefully (Form Labs, Inc., 2020).

## Prototype Testing

In a veterinary clinical setting, the surgical spoons will most often be subjected to 50% chlorhexidine disinfectant and repeated autoclave sterilization. Chlorhexidine is an anti-septic and anti-microbial topical solution used to soak instruments and is applied to a patient's skin in preparation for surgery. As a result, the surgical spoons were tested for durability and maximum shear strength by creating three experimental groups using 50% chlorhexidine solution for soaking, repeated autoclave cycles, and measurement of shear strength by the Instron Series 4466.

The first experimental group was conducted with Spoon 3 by soaking the instruments in a 50% chlorhexidine (300 mL) and 50% water solution (300 mL) ranging in increments of one hour, 12 hours, and 24 hours. The control group was not soaked. The second experimental group was conducted with Spoon 1 by repeatedly autoclaving the surgical spoons in increments of one cycle, 5 cycles, and 10 cycles. The control group was not autoclaved. According to the manufacturer's recommendations, the appropriate autoclave cycle for Dental Surgical Guide Resin is 30 minutes at 121 degrees Celsius. The third experimental group was a combination of the first and second groups, which consisted of Spoon 2 used for autoclave sterilization and chlorhexidine soaking. The combination of increments are as follows: one autoclave cycle and one-hour soaking, 5 autoclave cycles and 12 hours soaking, and lastly 10 autoclave cycles and 24 hours soaking. The control group was not autoclaved or soaked. The weights of the spoons were recorded before and after all treatments. The spoons were allowed to dry and were weighed 2 hours, 12 hours, and 24 hours post soak, followed by subsequent shear strength testing.

The surgical spoons were then subjected to a 3-point bend test to determine shear strength in accordance with the International Organization for Standardization and the American Society for Testing and Materials (ASTM) documents for Dental Surgical Guide Resin. The ASTM documents followed were "Standard Test Method for Tensile Properties of Plastics" (ASTM

D638-14, 2014) and “Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials” (ASTM D790-17, 2017).

The machinery used was an Instron Series 4466. Each spoon’s integrity was tested using a ½ -inch diameter cylindrical deflector attached to a 50-kilogram load cell. The spoons were loaded on the top edge of the scoop section by the ½ inch diameter cylindrical deflector and supported underneath the scoop by v-shaped lower supports, grip fixtures, spaced approximately ¾ inches apart. The handles of the spoons were held manually until sufficient force was applied to the scoop that they remained held by the grip fixtures. The deflector was lowered with a cross speed of 200 mm/min until the spoon ruptured. The setup for the 3-point bend test with the Instron is illustrated in Figure 4a. Recorded data included the applied load and corresponding displacement of the surgical spoons. The load determines how much shear force in kilograms can be applied to the surgical spoon before rupture occurs. The displacement is the overall vertical deflection of the surgical spoon in millimeters before rupture occurs. The experimental group values and control group values were compared to determine if the surgical spoons can withstand the weight of uroliths and will not rupture inside the urinary bladder or abdominal cavity.

Additionally, a Finite Element Analysis (FEA) of the spoon was conducted to verify the findings from the shear strength tests using the Instron Series 4466 and demonstrate that the surgical spoons are sufficiently robust and able to withstand cystotomy use. The FEA model validates the displacement and load values for different spoons applied at different places of the spoon as well as with different handle fixation protocols. 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 an assembly. The fixtures were modeled as AISI 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 1500 MPa. The lower supporting grip fixture was held steady by locking several of its faces with a fixture. The upper deflector was constrained to travel only in the vertical direction by applying a roller/slider fixture to several of its faces. The bottom face of the spoon head was constrained to lie tangent to both of the 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 which 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 was gradually decreased, and the simulation rerun until the results stabilized. The FEA computational setup is illustrated in Figure 4b.

In an effort to obtain a reasonable estimate of the Young's Modulus, which is not provided by the manufacturer, and furthermore varies as a function of cure time and temperature, the Instron data for the Spoon 2 model 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 then experimental. The Young's Modulus was incremented accordingly and the simulation 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 (2150 MPa), that value was used to run similarly setup simulations for the Spoon 1 and Spoon 3 models, the results of which are shown in Table 1. 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. The failure points were not used as some variability was present in the ultimate breaking strength of the printed spoons. The half-loading conditions are within the linear region of the stress-strain curve, so they represent an appropriate interpolation. Percent error was is shown for the 3-point bending vs. FEA displacements in Table 2.

The physical 3-point bend test described above allowed for validation of the Finite Element Analysis results; however, it is not sufficient in predicting the stress factors within the surgical spoons during cystotomy use. Therefore, an additional Finite Element Analysis was conducted in which the spoon handle is held stationary as fixed geometry up to a point ¼ inch behind the spoon head, with the head itself bearing a downwards uniformly distributed force of 11 Newtons (2.5 pounds). This simulation setup appropriately represents the clinical use of the surgical spoons and is shown in Figure 5 and 6.

**Clinical Trials**

Clinical trials were conducted to determine if the surgical spoons were advantageous in extracting uroliths and if the attending veterinarian preferred the use of the 3D-printed surgical spoons compared to other cystotomy methods. The surgical spoons were distributed to veterinary clinics in Northwest Arkansas. The participating patients were dogs currently in need of a cystotomy surgery. Owner consent was obtained prior to the use of the surgical spoons. The surgical spoons were then subjected to autoclave sterilization before surgery. A practitioner post-operative questionnaire was written in order to collect appropriate findings of the efficacy of the surgical spoons. The questionnaire determined the species, breed, age, and weight of the patient, which surgical spoon(s) were used during the cystotomy, if the veterinarian resorted to other conventional methods of extraction, and to rate the overall experience. The questionnaire also determined parameters such as previous history and composition of uroliths, diagnostic imaging evaluation, and length of surgery. See Appendix F for the full-length questionnaire. The surgical spoons were used a total of five times across several veterinary clinics. Analysis of recorded parameters will prove if there is a difference in surgical time and preferred method of extraction between the favored 3D-printed surgical spoon and other cystotomy methods.

## Results and Discussion

### Prototype Testing

The 50% chlorhexidine solution experimental group was soaked in increments of 1 hours, 12 hours, and 24 hours and allowed to dry for 2 hours, 12 hours, and 24 hours post-soaking. The control was not chlorhexidine soaked. The weight of each spoon was also determined at this time. The treatment did not appear to follow a trend. Each spoon decreased in weight after soaking. However, the difference in weight does not appear to become consistently larger when soaked for a longer period of time. The minute loss of weight can be attributed to trace amounts of uncured resin dissolving from the novel surgical spoons. The load and displacement were fairly consistent with this treatment, indicating a trend. If the spoon weighed more, then the load and displacement would be greater regardless of time spent soaking. However, Spoon 3 soaking for 24 hours had a larger displacement in millimeters compared to Spoon 3 soaking for 1 hour, which could be explained by a longer soaking period causing the spoon to become less rigid. Regardless, the small changes in weight could be attributed to human error associated with curing, washing the residual resin off of the spoons, and positioning the spoon within the Instron. The decreases in weight and load and displacement values are shown in Table 4.

The autoclave experimental group was autoclaved in cycles of once, five times, and 10 times and had a control that was not autoclaved. This treatment did not have a trend, perhaps because of trapped moisture. Spoons were allowed time to dry but were stored in Ziploc bags before final weight was taken. The control, Spoon 1 autoclaved for 0 minutes, required the greatest amount of force to break (i.e. greatest load). The data demonstrates spoon weight increased slightly immediately following multiple autoclave cycles. However, the final weight prior to breaking shows that each spoon's weight returned closer to its starting weight prior to rupture, which occurred several days after autoclaving to allow time for drying. The data does not show a consistent trend with spoon weight nor load and displacement. Therefore, indicating the autoclave treatment has no adverse effect to the novel surgical spoons. The weight, load, and displacement values are illustrated in Table 4.

The combination experimental group was first subjected to autoclave cycles and then chlorhexidine soaking treatments. The spoons were autoclaved once and soaked for one hour, autoclaved five times and soaked for 12 hours, and autoclaved 10 times and soaked for 24 hours. There was a control group that was neither autoclaved nor chlorhexidine soaked. This treatment appears to follow a trend; each spoon decreased in weight after autoclaving and soaking. However, the difference in weight does not appear to become consistently larger when autoclaved and soaked for a longer period of time. This indicates that if any uncured resin remains on the spoon, it will be removed during the first soaking cycle. There appears to be no further loss of resin the longer the spoon is soaked in chlorhexidine. All spoons were allowed to dry before the final weight was taken. The displacement measurements for this treatment were fairly consistent as well. If the final weight of the spoon was smaller, then the displacement was smaller. However, the load of the spoons did not follow a clear trend. The load appears to decrease with longer periods of treatment, but there is not a consistent decline. A possible explanation could be the weight of the spoon compensating for the treatment of the spoon, when analyzing load. Spoon 2 autoclaved for 10 cycles and soaked for 24 hours weighed the most, and still had a fairly high load, but the displacement was the lowest of the treatment. In comparison, Spoon 2 autoclaved for 5 cycles and soaked for 12 hours weighed less and had a smaller load, but had a larger displacement. See Table 4 for values of weight, load, and displacement for the combination experimental group.

In conclusion, the treatments of autoclaving, soaking, and the combination of both have an effect on the weight of the spoon. The majority of the spoons demonstrated a decrease in weight after treatments. However, none of the spoons exceeded a difference in weight more than approximately 0.1 grams. In reference to the soaking and combination treatments, the weight of the spoon has an effect on the load and appears to compensate for when the maximum treatment option has been applied to the spoon. If a spoon has a smaller weight, the treatments have a greater effect on the spoon's load. There appears to be an effect on the displacement of most of the spoons after treatments, demonstrating the spoons become less rigid as treatment continues. A change in rigidity can be attributed to loss of uncured resin, which would account for a weight difference. Possible sources of error include the absence of a clamp to hold the spoon in place while using the Instron to measure load and displacement, moisture retention due to a portion of spoons being stored in a Ziploc bag after treatment, and failure to remove all trace amounts of uncured resin.

The Finite Element Analysis yielded results that determined the resin in conjunction with the design of the surgical spoons can withstand repetitive autoclave cycles and chlorhexidine solution soaking as seen in the clinical setting. Most importantly, the simulation yielded results indicating the surgical spoons can withstand weights much greater than the magnitude of a large urolith. The conclusions of the loaded-spoon simulations, which are more representative of how the spoons are intended to be used in a gentle scooping and lifting maneuver of a cystotomy surgery, show that the maximum stresses are well below those of the 3-point bend tests and only at 50% of the fracture load. Additionally, the 11 Newtons (2.5 pounds) loading conditions are significantly higher than the surgical spoons would ever experience in typical surgical use, rendering this analysis as a worst-case scenario. The simulation concludes that the surgical spoons as currently designed and manufactured are well within expected safety parameters for surgical use. See Table 3 for the FEA results of the loaded-scoop simulation.

## Clinical Trials

All patients in need of cystotomy surgery participating in the clinical trials were canines, with the exception of one feline. Three of the cystotomy surgeries did not utilize the 3D printed surgical instruments, two of which were canines and one feline. The two canine breeds were a miniature dachshund and Yorkshire mix both in the weight range of 0-24 pounds. The Yorkshire mix was within the age range of 4-7 years old, while the miniature dachshund was within the age range of over 12 years old. The feline was a domestic short hair, within the age range of 4-7 years old, and within the 0-24 pounds weight range. The cystotomy surgeries that implemented the 3D printed surgical spoons included two canines. The breeds were Terrier Mix and Blue Heeler, both weighing between 50-74 pounds, 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 to a lab for analysis. The total length of surgery for the Terrier Mix was between 21-40 minutes, while the Blue Heeler's surgery lasted between 41-60 minutes. The allotted time to remove the uroliths for both canines was between 0-20 minutes and all uroliths were removed. The veterinarian on both cases requested a diagnostic image after the cystotomy procedure. The veterinarian conducting surgery on the Blue Heeler preferred Spoon 1 the most, while the Terrier Mix's veterinarian preferred Spoon 3 and also used Spoon 1. Both veterinarians discontinued use of the surgical spoons to retrieve uroliths by hand or with forceps. The veterinarian on the Terrier Mix's case rated the overall experience using the surgical spoons as "excellent," while the Blue Heeler's veterinarian rated the overall experience as "good."

As indicated by the veterinarians' responses to the questionnaire, Spoon 1 was the most utilized. The veterinarians resorted to manual extraction and use of forceps to remove remaining uroliths, which is common in the presence of large uroliths that will not fit in the scoop of a spoon. It would only make sense to extract uroliths of this size with such methods. Both surgeries took 0-20 minutes to remove the uroliths, which is an indication of time efficiency.

The veterinarians were unable to perform surgery with the 3D-printed surgical spoons on canines and the feline that were in the weight range of 0-24 pounds, such as the Yorkshire, Yorkshire mix, miniature dachshund, and domestic short hair due to the smaller size of the urinary bladder. The incision made on a urinary bladder for a small breed or feline is approximately ½ inches. An incision of this size is too small for any of the surgical spoons to pass through, serving as a limitation of the research. The cystotomy surgeries that implemented the 3D printed surgical spoons were on patients in the weight range of 50-74 pounds, indicating the current dimensions of the surgical spoons are ideal for medium-size animals and possibly large-size animals.

## Conclusion

Uroliths present in companion animals commonly, requiring surgical intervention by veterinarians. Unfortunately, general veterinarians do not routinely perform laparoscopic-assisted cystotomies due to lack of access to the technology. Veterinarians have been accustomed to using off-label devices such as gallbladder spoons, tablespoons, and teaspoons to remove uroliths. Owing to the growing use of 3D-printing in veterinary medicine, these surgical spoons now provide a dedicated solution to the difficulty in removing uroliths. By limiting the difficulty level of extracting uroliths through the use of the 3D-printed surgical spoons, clients will save money treating their pets' urinary condition and patients will receive less anesthesia and experience a decrease in post-operative complications. Veterinarians will also benefit from the decreased surgical time.

Technological advances in the veterinary industry has improved the quality of healthcare for companion animals. Within the past decade technology such as ultrasound machines and magnetic resonance imaging have surfaced in veterinary clinics. It is likely that 3D-printers will make an appearance in veterinary clinics and hospitals in the foreseeable future. Thus, allowing veterinarians to print customized surgical instruments, anatomical models, and orthopedic prosthetics for immediate use.

As the research progresses, the surgical spoons will be downsized in order to accommodate for smaller breeds of canines, felines, and exotics according to weight range as veterinarians have expressed need for such sizes in surgical spoons. Perhaps, one day veterinarians will 3D-print the novel surgical spoons in-clinic according to their patient's parameters. Nonetheless, the overall experience of 3D-printing for surgical purposes has yielded a fruitful advantage to veterinary medicine that is expected to continue to grow at an exponential rate.

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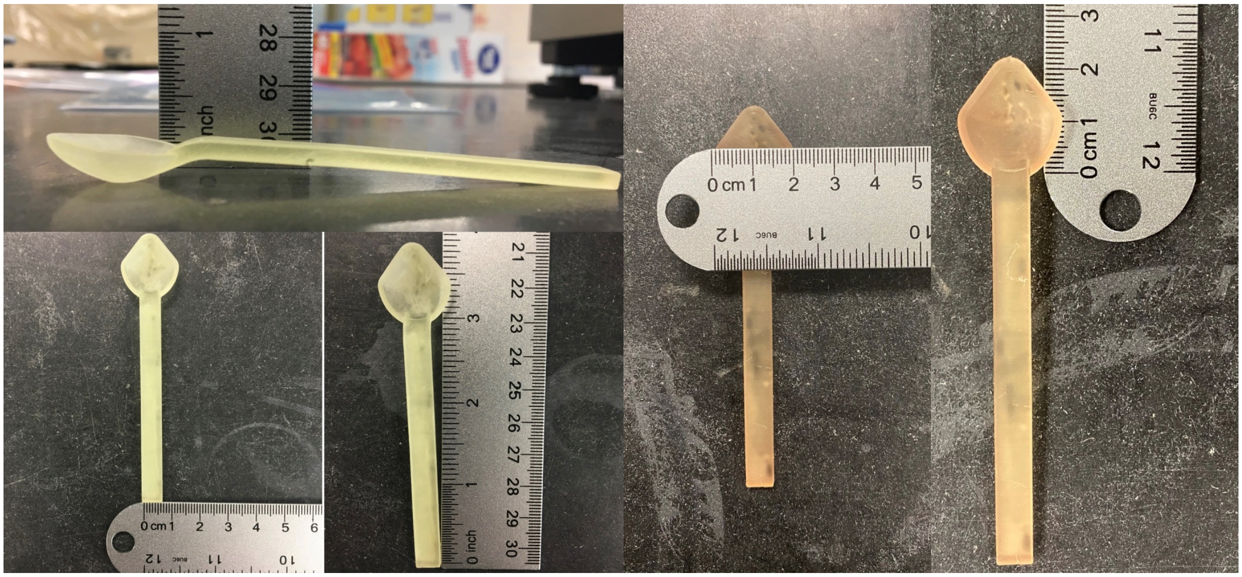
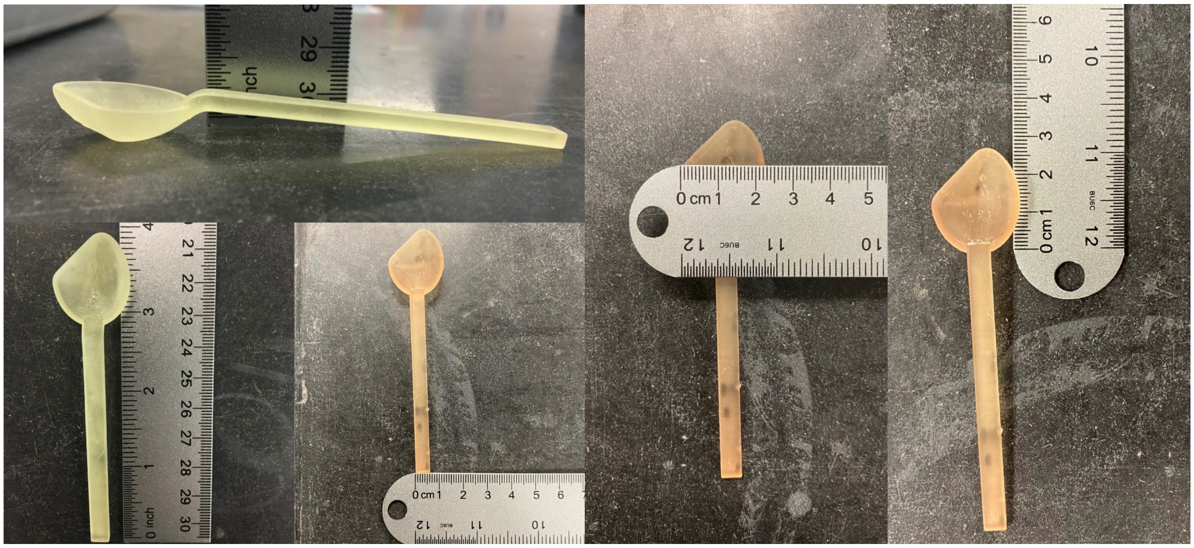
## Appendix A: Spoon Measurements

**Figure 1**



Measurements for Spoon 1 which includes a) depth of the scoop of the spoon head and highest point of the handle b) width of the spoon handle c) length of the entire spoon d) the width of the spoon head e) the length of the spoon head.

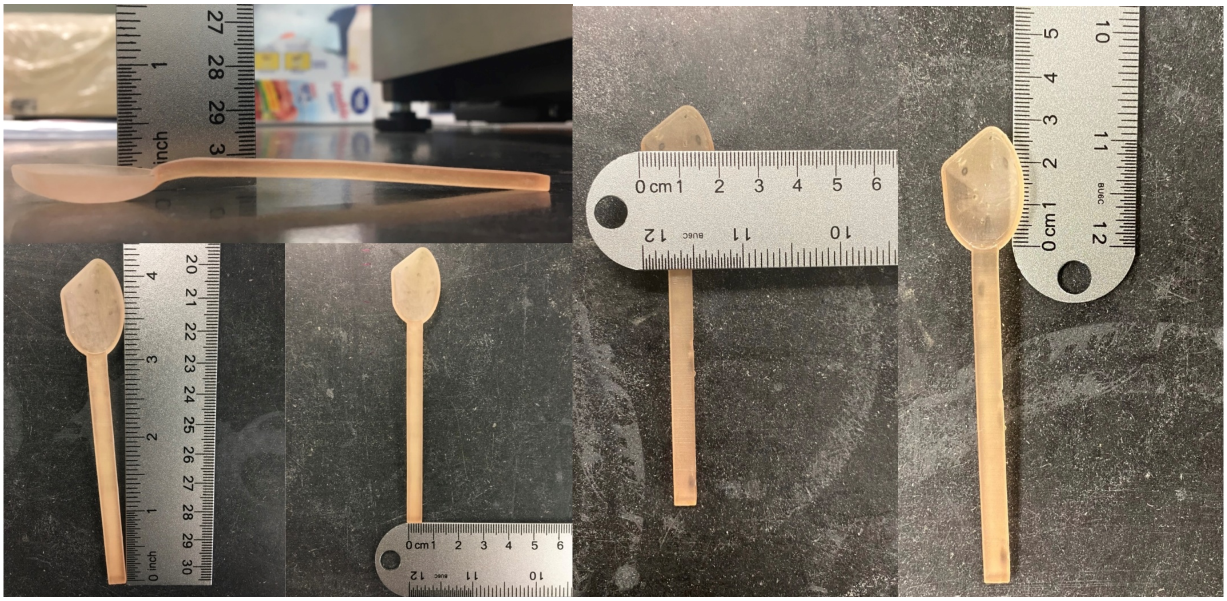
**Figure 2**



Measurements for Spoon 2 includes a) depth of the scoop of the spoon head and highest point of the handle b) width of the spoon handle c) length of the entire spoon d) the width of the spoon head e) the length of the spoon head.

## Appendix A: Spoon Measurements

**Figure 3**



Measurements for Spoon 3 includes a) depth of the scoop of the spoon head and highest point of the handle b) width of the spoon handle c) length of the entire spoon d) the width of the spoon head e) the length of the spoon head.

# Appendix B: Finite Element Analysis

**Figure 4**

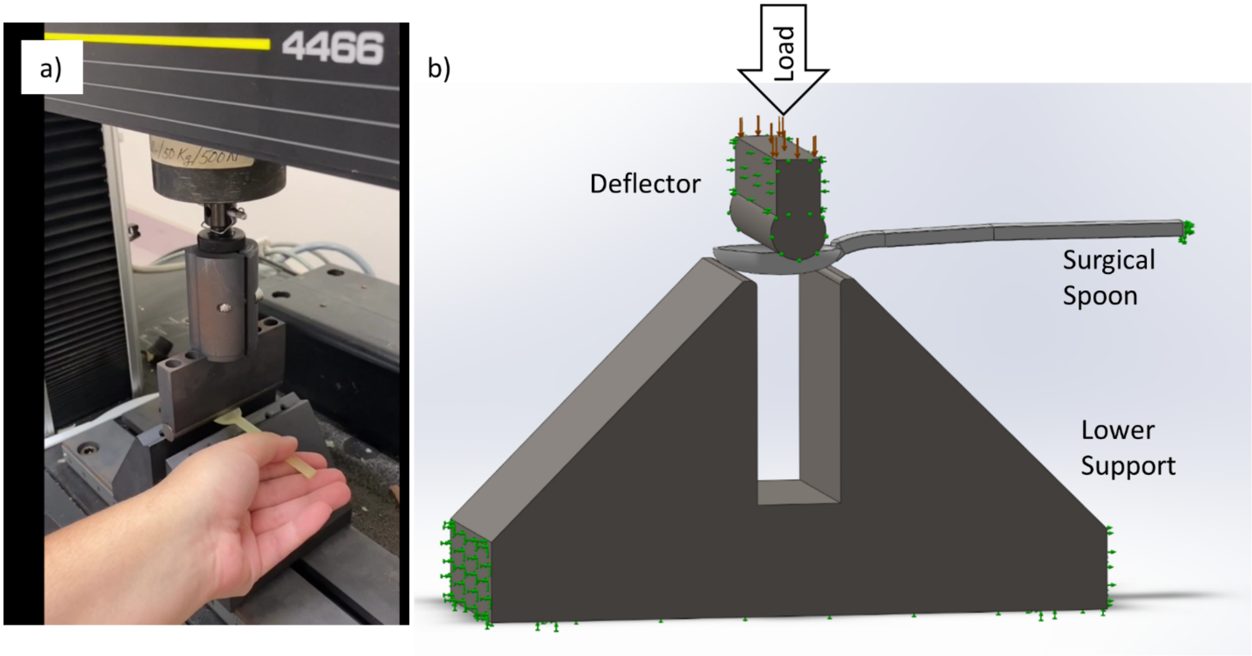


**Table 1**

| **Displacement (mm)** | **Young's Modulus (Mpa)** | **% Error** | **Mesh Elements** |
|---|---|---|---|
| 2.266 | 1500 | 39.7 | 11875 |
| 2.287 | 1500 | 41.0 | 24000 |
| 1.193 | 3000 | 26.5 | 24000 |
| 1.417 | 2500 | 12.6 | 24000 |
| 1.705 | 2050 | 5.1 | 24000 |
| 1.631 | 2150 | 0.6 | 24000 |

Spoon 2 “Calibration” for Young’s Modulus. Results are obtained via FEA at 50% average maximum load. Percent error is calculated against the average experimental displacement.

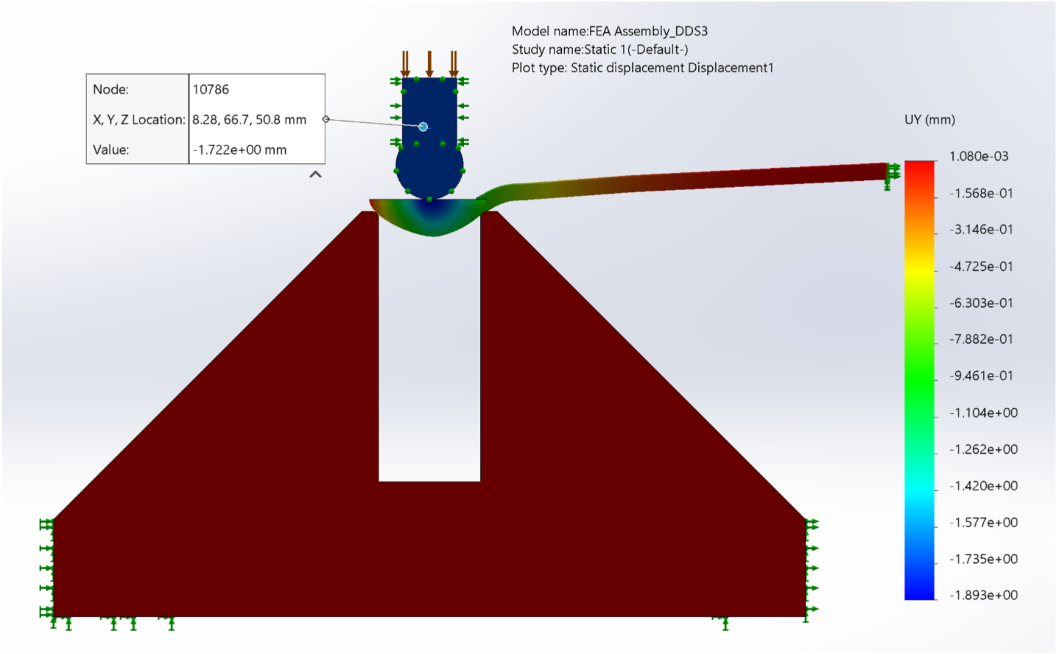
## Appendix C: Finite Element Analysis Continued

**Table 2**

| Model | Failure Load (Kgf) | Failure Displacement (mm) | FEA Load (Kgf) | Expected FEA Displacement @ 50% Loading (mm) | Actual FEA Displacement (mm) | % Error | FEA Maximum Stress (Mpa) |
|---|---|---|---|---|---|---|---|
| Spoon 1 | 14.38 | 3.47 | 7.19 | 1.735505873 | 0.6103 | 64.834 | 51.37 |
| Spoon 2 | 17.89 | 3.24 | 8.95 | 1.622061097 | 1.631 | 0.5511 | 112.8 |
| Spoon 3 | 17.35 | 4.09 | 8.67 | 2.045485857 | 1.722 | 15.815 | 108.9 |

FEA results and % error values for FEA vs experimental displacement.

**Figure 5**



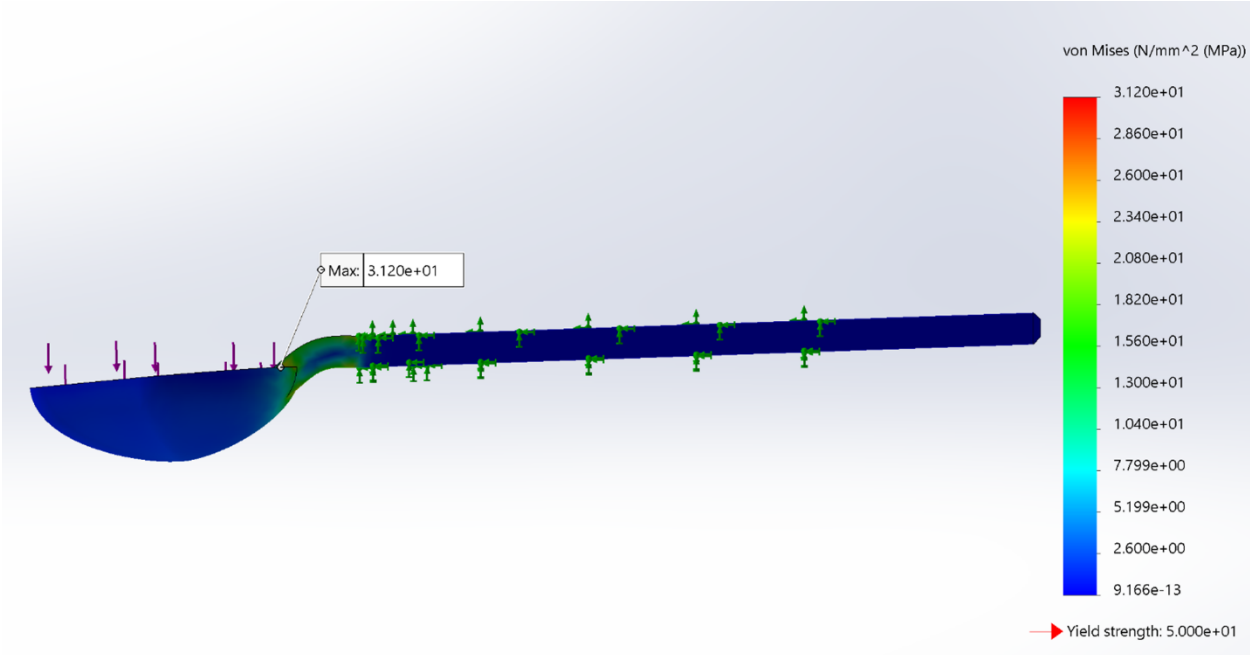
Model name:FEA Assembly_DDS3
Study name:Static 1(-Default-)
Plot type: Static displacement Displacement1

| | |
|---|---|
| Node: | 10786 |
| X, Y, Z Location: | 8.28, 66.7, 50.8 mm |
| Value: | -1.722e+00 mm |

Example of 3-point bend simulation results with Spoon 3. The purple arrows indicate loading while the green arrows show fixed/constrained geometry. The superimposed color plot represents the displacement in the vertical direction. A probe value is shown on the upper deflector to correspond to the recorded displacement from the Instron experimental testing.

## Appendix D: Finite Element Analysis Continued

**Figure 6**



Example of loaded-scoop simulation results. Purple arrows indicate loading while green arrows show fixed geometry. The color plot superimposed upon the deformed spoon geometry represents von Mises stress in MPa.

**Table 3**

| Model | Maximum Displacement (mm) | Maximum Stress (Mpa) | % of Stress @ Half Failure Load |
|---|---|---|---|
| Spoon 1 | 2.224 | 31.20 | 60.7 |
| Spoon 2 | 4.648 | 91.61 | 81.2 |
| Spoon 3 | 1.212 | 35.98 | 33.0 |

FEA results for loaded-scoop FEA simulations.

## Appendix E: Prototype Testing Table

**Table 4**

| | **Pre Weight (g)** | **Post Auto Weight (g)** | **Post 2 Hr Soak Weight (g)** | **Post 12 Hr Soak Weight (g)** | **Post 24 Hr Soak Weight (g)** | **Final Weight (g)** | **Load (kg)** | **Displacement (mm)** |
|---|---|---|---|---|---|---|---|---|
| **Spoon 1 Auto 0** | 2.9494 | | | | | 2.9476 | 39.37 | 3.559 |
| **Spoon 1 Auto 1** | 2.94 | 2.9376 | | | | 2.933 | 17.58 | 2.45 |
| **Spoon 1 Auto 5** | 2.9474 | 2.9775 | | | | 2.956 | 16.79 | 11.45 |
| **Spoon 1 Auto 10** | 2.9477 | 2.9633 | | | | 2.9416 | 19.23 | 3.149 |
| **Spoon 3 Soak 0** | | | | | | | | |
| **Spoon 3 Soak 1** | 2.678 | | 2.678 | | 2.6768 | 2.6767 | 13.5 | 3.035 |
| **Spoon 3 Soak 12** | 2.653 | | 2.6471 | 2.6451 | 2.6439 | 2.6439 | 12.03 | 2.881 |
| **Spoon 3 Soak 24** | 2.6556 | | 2.6573 | 2.6552 | 2.6542 | 2.6537 | 13.09 | 3.384 |
| **Spoon 2 Combo 0** | 3.169 | | | | | 3.1675 | 21.33 | 9.07 |
| **Spoon 2 Combo 1/1** | 3.169 | 3.07 | 3.0698 | | 3.0687 | 3.0677 | 24.13 | 9.3 |
| **Spoon 2 Combo 5/12** | 3.0506 | 3.0514 | 3.0526 | 3.0489 | 3.0452 | 3.0336 | 17.66 | 8.85 |
| **Spoon 2 Combo 10/24** | 3.22 | 3.2272 | 3.2281 | 3.2246 | 3.2227 | 3.2074 | 19.91 | 8.67 |

## Appendix F: Practitioner Post-Operative Questionnaire

1. What was the species of the cystotomy patient?

2. What was the breed of the cystotomy patient?

3. How much did the patient weigh?
   A. 0-24 lbs
   B. 25-49 lbs
   C. 50-74 lbs
   D. 75-100lbs
   E. Greater than 100 lbs

4. How old was the patient?
   A. 0-3 years old
   B. 4-7 years old
   C. 7-10 years old
   D. Over 10 years old

5. Did the patient have a diagnosed urinary tract infection (UTI) at the time of surgery?
   A. Yes
   B. No
   C. Unknown

6. Did this patient have a previous history of developing bladder stones? If yes, what kind?
   A. Calcium oxalate
   B. Silica
   C. Struvite
   D. Other
   E. No Previous History

7. What type of stones do you suspect were removed today via cystotomy?
   A. Calcium oxalate
   B. Silica
   C. Struvite
   D. Other
   E. Not Sure

8. Will you be sending the stones to a lab for analysis/identification?
   A. Yes
   B. No
   C. Not sure

9. How long was the total length of the surgery (from open to close), in minutes?
   A. 0-20 minutes
   B. 21-40 minutes
   C. 41-60 minutes
   D. Over 60 minutes

10. How long did it take you to remove all of the stones?
   A. 0-20 minutes
   B. 21-40 minutes
   C. 41-60 minutes
   D. Over 60 minutes

11. Were all stones removed from the patient?
   A. Yes
   B. No
   C. Not Sure

12. Was a diagnostic image taken of the patient to visualize remaining stones during or after the cystotomy?

13. Did you utilize any of the 3D-printed surgical spoons provided?
   A. Yes
   B. No

14. If any of the spoons were useful in removing the bladder stones, which spoon did you prefer the most? (see attached photo of spoons for guidance).
   A. Spoon #1
   B. Spoon #2
   C. Spoon #3

15. If you would prefer to use a combination of spoons, which combination was most desirable for this case?
   A. Spoon #1 and #2
   B. Spoon #1 and #3
   C. Spoon #2 and #3
   D. All spoons were equally utilized and desirable.

16. During the cystotomy, did you have to discontinue use of a 3D-printed spoon(s) and revert to another method to remove the stones? If yes, which method?
   A. Yes
   B. No

17. If the answer to the above question (#15) is yes, please briefly describe the method and/or instrument you used to successfully remove the stones.

18. Overall, how would you rate your experience using the 3D-Printed surgical spoons?
    A. Excellent
    B. Good
    C. Average
    D. Poor
    E. Very Poor