Urodynamic effects of a percutaneously controlled static hydraulic urethral sphincter in canine cadavers

Christopher A. Adin, DVM; James P. Farese, DVM; Alan R. Cross, DVM; Mary K. Provitola, BS; Jeffrey S. Davidson; Hope Jankunas, BS

Objective—To describe a percutaneously controlled static hydraulic urethral sphincter (SHUS) and evaluate urodynamic effects of the SHUS in canine cadavers.

Sample Population—Cadavers of 6 adult female dogs.

Procedure—Cadavers were obtained immediately after dogs were euthanatized. Baseline maximal urethral closure pressure (MUCP) and cystourethral leak point pressure (CLPP) were measured by use of a urethral pressure profilometer. An SHUS system was constructed by use of a silicone vascular occluder and subcutaneous infusion port. The SHUS system was then placed around the pelvic urethra in each cadaver. Measurements of MUCP and CLPP were repeated after varying occlusion of the SHUS (0%, 25%, and 50% occlusion). Baseline MUCP and CLPP values were compared with values obtained at 0%, 25%, and 50% occlusion of the SHUS by use of repeated-measures ANOVA.

Results—Mean ± SD MUCP for canine cadavers was 7 ± 1.3 cm H_2O at baseline, which increased to 127 ± 53 cm H_2O after 50% occlusion of the SHUS. Mean CLPP was 11 ± 8.6 cm H_2O at baseline, which increased to 73 ± 38 cm H_2O after 50% occlusion of the SHUS. Mean MUCP and CLPP were significantly associated with the amount of occlusion.

Conclusions and Clinical Relevance—The SHUS had positive effects on MUCP and CLPP in canine cadavers. Therefore, additional evaluation of the SHUS in live dogs is warranted. (*Am J Vet Res* 2004; 65:283–288)

Urethral sphincter mechanism incompetence (USMI) is evident after hysterectomy in 13.6%[1] to 20.1%[2] of dogs. Surgical intervention is an option in dogs that fail to respond to pharmacologic treatment. Techniques described for use in dogs with USMI are similar to those used in humans and have achieved static resistance to urine leakage by altering the anatomic position of the bladder neck and pelvic urethra,[3-6] via urethral bulking,[7-9] or through urethral sling procedures.[10,11] Although many techniques have good short-term efficacy, surgery alone has produced poor long-term results, with restoration of continence in only 14% to 56% of dogs in large clinical studies.[4-6] The current lack of an effective surgical technique for dogs with incontinence that is refractory to medical treatment is an important issue because failure of surgical treatment often leads to a decision to euthanatize such dogs. Thus, although there are a number of surgical techniques available for dogs with USMI, there remains a need for a simple method to control urine leakage when other methods have failed.

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From the Department of Small Animal Clinical Sciences, College of Veterinary Medicine, University of Florida, Gainesville, FL 32610-0126.
Address correspondence to Dr. Adin.

Our laboratory group has investigated the use of a **hydraulic urethral sphincter (HUS)** as an alternative surgical treatment for dogs with USMI. **Patient-controlled hydraulic urethral sphincters (PCHUSs)** have been in use in humans with refractory USMI for > 30 years.[12-14] The PCHUS has been used most commonly in men with severe iatrogenic USMI secondary to surgery or radiation therapy for prostatic neoplasia.[12,13] In addition, there have been several reports[15-17] of the use of PCHUSs in women with refractory USMI after failure of less invasive techniques. The PCHUS has been highly effective in control of urine leakage, with a mean social continence of 91.5% and mean patient satisfaction of 84.5%.[12] This high success rate in the restoration of continence is balanced by a relatively high revision rate as a result of mechanical failure or implant-related problems, such as atrophy, erosion, or infection of the urethra.[16] Complications are rarely life-threatening and most commonly involve formation of cutaneous fistulas or recurrence of incontinence attributable to loss of coaptation between the atrophied urethra and surrounding cuff.[18,19] Surgical revision and replacement of the device in another location on the urethra are highly successful (83%) in restoring continence in people with urethral atrophy.[18] Implant-associated infection is rare (incidence of 1% to 3%) and typically associated with surgical contamination, rather than urinary tract infection.[19] Urodynamic analysis of cadavers and clinical patients is of assistance in determining the minimal degree of urethral compression required to maintain continence, which decreases the risk of atrophy or erosion of the urethra.[20-22]

Several practical concerns have prevented direct application of the PCHUS system in dogs with USMI. First, the PCHUS system currently used in humans must be manually deflated by compression of a control assembly implanted in the scrotum or labia majora. It is anticipated that use of dynamic, manually controlled devices would be difficult in dogs. Second, the complexity of the PCHUS leads to major expense and is a concern even in the treatment of humans. The PCHUS costs > $5,000, and costs for surgical placement are $12,000 to $15,000/patient.[14]

The purpose of the study reported here was to design an affordable, **static HUS (SHUS)** system and evaluate the urodynamic effects of that SHUS system in canine cadavers. We hypothesized that because of a lack of neuromuscular activity, baseline urodynamic values in canine cadavers would be lower than those reported in live dogs. Furthermore, we hypothesized that progressive occlusion of the SHUS would allow improvement of these urodynamic variables in the cadavers. Knowledge of urodynamic effects of the SHUS should be of benefit when planning urethral compression required in subsequent studies of live dogs.

Materials and Methods

Sample population—Cadavers of 6 healthy adult female dogs were obtained immediately after the dogs were euthanatized for reasons unrelated to the study reported here. Dogs weighed between 17 and 21 kg (mean ± SD, 18.8 ± 1.6 kg). All procedures were approved by the University of Florida Institutional Animal Care and Use Committee.

Construction of the SHUS system—A percutaneously adjustable SHUS system was constructed by use of 30 cm of the infusion line from an 8-mm-diameter inflatable silicone vascular occluder[a] connected to a biocompatible subcutaneous infusion port[b] (**Fig 1**). The vascular occluder was an incomplete ring consisting of a reinforced synthetic polyester back that was lined with a silicone membrane. After placement of the occluder around a cylindrical structure, the ring of the occluder was completed by placing suture through preexisting holes, and the silicone cuff on the inner aspect of the occluder was then inflated. Thus, the biocompatible subcutaneous infusion port enabled adjustment of urethral compression by percutaneous injection or aspiration of fluid from the SHUS.

Injection volume and percentage occlusion—After the SHUS system was assembled, the incomplete ring of the noninflated 8-mm hydraulic occluder was closed by tying a strand of 3-0 polypropylene suture material through the preexisting holes (Fig 1). A 22-gauge, noncoring needle[c] was used for all injections to minimize damage to the silicone membrane of the infusion port. Lactated Ringer's solution was injected and aspirated multiple times to remove air bubbles from the SHUS system. Once cleared of air, the noninflated occluder was placed on a flatbed scanner and digital images were obtained prior to inflation. The occluder was then inflated with incremental 0.1-mL injections of lactated Ringer's solution, and digital images were obtained for each increment until the internal lumen of the occluder was completely obliterated by the inflated occluder. Complete inflation of the occluder was performed twice. For each increment of each inflation, the internal aspect of the occluder lumen was traced for each of the stored digital images, and the resulting **luminal area (LA)** was calculated by use of a computer software program.[d] Percentage occlusion after each injection was calculated by use of the following equation: Percentage occlusion = ([LA noninflated occluder – LA inflated occluder]/LA of the noninflated occluder) × 100. Data were tabulated for the volume injected and resulting percentage occlusion to enable investigators to achieve planned stages of luminal occlusion.

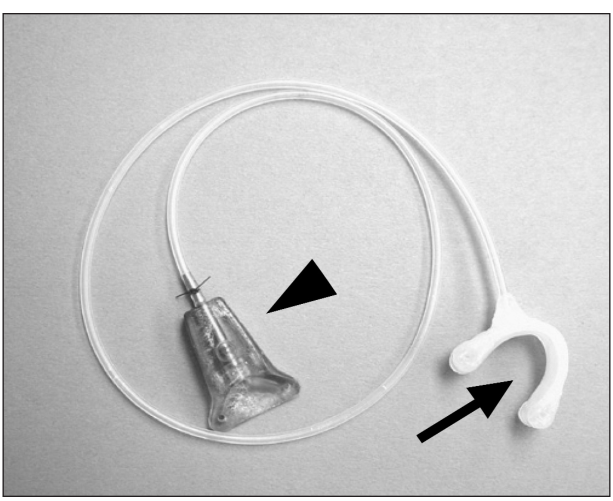

Figure 1—Photograph of the static hydraulic urethral sphincter device that was created by connecting an 8-mm-diameter vascular occluder (arrow) to a subcutaneous injection port (arrowhead). After the occluder was placed around the proximal portion of the urethra, the ring of the vascular occluder was completed by placing suture through preexisting holes, and the silicone cuff on the inner aspect of the occluder was then inflated.

Urodynamic analysis—Immediately after the dogs were euthanatized, each cadaver was placed in left lateral recumbency and baseline values for **urethral pressure profilometry (UPP)** and **cystourethral leak point pressure (CLPP)** were measured, as described elsewhere.[7] Briefly, a 6-F double-lumen UPP catheter[e] was connected to a urethral pressure profilometer.[f] The catheter tip was held at the approximate height of the external urethral meatus during calibration of the pressure transducer. A recording catheter was inserted into the bladder, and all residual urine was evacuated. The catheter was withdrawn at a rate of 1 mm/s concurrent with constant-rate infusion of lactated Ringer's solution (10 mL/min). Pressures were recorded on a strip chart and used to calculate functional profile length and **maximal urethral closure pressure (MUCP)**.[7,23] The CLPP was measured by use of a protocol similar to that described for the UPP, except that the dual-lumen UPP catheter was maintained in the bladder throughout CLPP measurement and lactated Ringer's solution was infused at a constant rate of 35 mL/min while intravesicular pressure was recorded on a strip chart. The CLPP was defined as the intravesicular pressure required to cause visible urine flow from the vestibule.

Placement of the SHUS—Each cadaver was positioned in dorsal recumbency. Ventral midline laparotomy was performed, and the urinary bladder was exteriorized and retracted cranially to expose the proximal portion of the urethra. A 1.5-cm section of the proximal portion of the urethra located approximately 2 cm caudal to the trigone was dissected from the surrounding connective tissue. The outer urethral circumference was estimated by passing a piece of suture material around the urethra and measuring the length of that piece of suture. The SHUS was placed around the urethra, and the ring was closed by use of a single suture of 3-0 polypropylene. The bladder was returned through the midline incision; we were careful to avoid kinking of the SHUS on the pubic bone as the bladder returned to its normal position. The infusion line exited the abdominal cavity through the midline incision in the linea alba, and the infusion port was maintained in the subcutaneous tissues. The abdominal incision was closed by use of 2-0 polypropylene in a simple continuous suture pattern, and the skin was closed with 3-0 nylon in a cruciate suture pattern.

Following implantation of the SHUS, cadavers were returned to left lateral recumbency and UPP and CLPP recordings were obtained at 0% occlusion. We used the data described previously for percentage occlusion after injection of incremental volumes of lactated Ringer's solution to determine the amount of solution to inject into the subcutaneous infusion port to obtain 25% occlusion (0.10 mL) and 50% occlusion (0.20 mL) of the SHUS. Measurements of UPP and CLPP were recorded at each stage of occlusion.

Statistical analysis—A simple regression plot was performed for percentage occlusion versus volume injected into the 8-mm hydraulic occluder. Data for MUCP and CLPP were compared between baseline and 0%, 25%, and 50% occlusion by use of repeated-measures ANOVA. Values of $P < 0.05$ were considered significant. Statistical calculations were performed by use of a computer software program.[g]

Results

Injection volume and percentage occlusion—Luminal area of the 8-mm vascular occluder was highly correlated with the volume of fluid injected into the infusion port (R^2, 0.98; **Fig 2**).

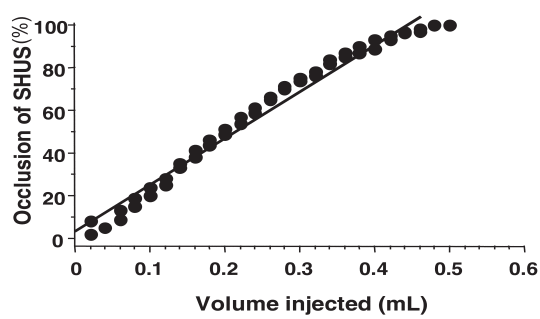

Figure 2—Scatterplot and regression line for percentage occlusion of the static hydraulic urethral sphincter (SHUS) versus volume injected. Lactated Ringer's solution was injected in 0.1-mL increments, and the corresponding occlusion of the SHUS was measured. Volume injected and percentage occlusion was highly correlated (R^2, 0.98).

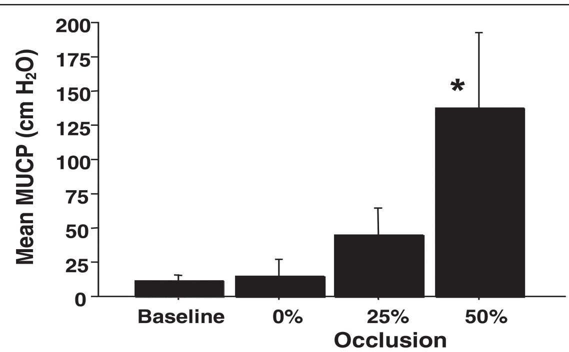

Figure 3—Mean ± SD maximal urethral closure pressure (MUCP) for canine cadavers at baseline and 0%, 25%, and 50% occlusion of the SHUS. *Value differs significantly ($P < 0.001$) from baseline value.

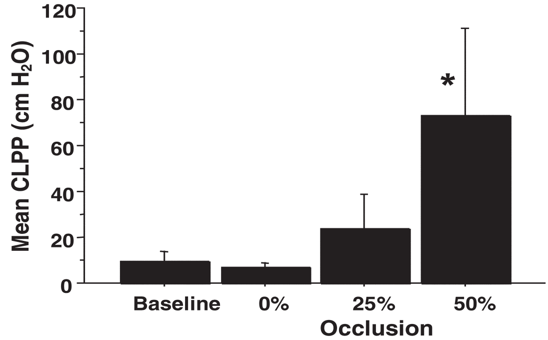

Figure 4—Mean ± SD cystourethral leak point pressure (CLPP) for canine cadavers at baseline and 0%, 25%, and 50% occlusion of the SHUS. *Value differs significantly ($P < 0.001$) from baseline value.

Placement of the SHUS system—Placement of the SHUS around the pelvic urethra required minimal technical skill and was accomplished without the need for specialized equipment. Injection into the subcutaneous port was performed without difficulty in all 6 cadavers. Mean ± SD urethral circumference for the 6 canine cadavers was 21 ± 5 mm.

Urodynamic analysis—Mean ± SD functional profile length for the 6 cadavers was 7.3 ± 2.2 cm. Mean baseline values for MUCP and CLPP were 7 ± 1.3 cm H_2O and 11 ± 8.6 cm H_2O, respectively. After placement of the SHUS around the urethra, mean MUCP increased from 11 ± 9 cm H_2O at 0% occlusion to 27 ± 16 cm H_2O at 25% occlusion and to 127 ± 53 cm H_2O at 50% occlusion (**Fig 3**). There was a significant ($P < 0.001$) association between mean MUCP and percentage occlusion of the SHUS. Similarly, mean CLPP increased from 7 ± 2 cm H_2O at 0% occlusion to 24 ± 15 cm H_2O at 25% occlusion and to 73 ± 38 cm H_2O at 50% occlusion (**Fig 4**). There was a significant ($P < 0.001$) association between mean CLPP and percentage occlusion of the SHUS.

Discussion

To the authors' knowledge, the study reported here was the first in which the urodynamic effects of a procedure in canine cadavers were evaluated, although a similar study[20] was performed to evaluate the urodynamic effects of the PCHUS in fresh bladder-urethra specimens from porcine cadavers. Similar to the findings in our study, results of that study[20] revealed that progressive increases in cuff pressure were associated with increases in detrusor leakage pressures. The validity of the use of porcine cadavers was subsequently supported by a study[21] documenting similar urodynamic effects in live human patients after application of the PCHUS. Similar to the study[20] in porcine cadavers, we believed that preliminary evaluation of the percutaneously adjustable SHUS could be performed in canine cadavers because the SHUS works by direct compression of the urethra and is not dependent on neuromuscular activity. Our hypothesis was that fresh canine cadavers would have anatomic characteristics similar to those of live dogs, whereas neuromuscular activity involved in urine retention would be ablated, causing subnormal MUCP and CLPP values at baseline. Consistent with our hypothesis, MUCP and CLPP values that we obtained in canine cadavers were much less than the values reported in clinically normal dogs sedated with xylazine hydrochloride during another study[7] in which investigators used the same urethral pressure profilometer, catheter and technique. Unfortunately, cadavers cannot provide information on the incidence of urethral atrophy, erosion, or implant-associated infection, so evaluation of the incidence of these complications must be conducted in live animals.

Analysis of results of our study also confirmed our hypothesis that a simple, percutaneously controlled HUS could be used to improve urodynamic variables in canine cadavers. Although they will never supersede objective evaluation of clinical outcome in dogs with naturally developing USMI, urodynamic variables have served as 1 of the few objective means of comparing the effects of medical or surgical treatment in controlled studies[4,7,24-33] and have been reported consistently in the veterinary literature. Studies[7,20,25-27,29,30] of diagnostic or surgical techniques for USMI are often performed in clinically normal animals or on cadavers, making it impossible to quantify the degree of incontinence. Consequently, studies[7,20,25-27,29] have often relied on urodynamic variables to describe the mechanism of action of medical and surgical interventions for USMI. Evaluation of intraoperative and postoperative urodynamic variables has also been recommended specifically during use of the PCHUS in human patients.[21,22] A positive correlation has been found between maximum urethral pressure and urethral leakage in humans in which the PCHUS is used,[21] and intraoperative measurement of MUCP and CLPP has been used to titrate inflation of the cuff to the minimum pressure that is required to achieve control of urine leakage.[22] On the basis of these considerations, we elected to use MUCP and CLPP to quantitatively assess the effect of the SHUS on passive resistance to urine flow in this initial study of canine cadavers.

Comparison between urodynamic values obtained at various institutions is often complicated by a lack of standardization in profilometry techniques.[23] It has been observed that functional profile length is the most reproducible of the urodynamic variables, whereas MUCP is dependent on many factors, including drug administration, sedation or anesthesia, position of the dog during measurement, speed of catheter withdrawal, and size of catheter.[23] To remove variations based on technique, we adhered to recommendations for standardization of UPP and CLPP measurements reported elsewhere.[7,23] In another study,[7] investigators used the same technique and equipment as we used in our study and found that continent female dogs sedated by administration of xylazine had mean ± SD MUCP of 18 ± 7 cm H_2O and CLPP of 8 ± 7 cm H_2O. After placement of the SHUS in canine cadavers in the study reported here, mean MUCP and CLPP exceeded those values at 25% and 50% occlusion. Thus, use of the SHUS in cadavers allowed us to achieve pressures for urodynamic variables that equaled or exceeded those obtained in sedated, continent female dogs. We cannot extrapolate the quantitative changes in MUCP and CLPP values obtained by use of the SHUS in canine cadavers to the situation for live dogs with intact neuromuscular activity. However, it is likely that a device that causes direct urethral compression will cause similar qualitative increases in MUCP and CLPP in live dogs and that, similar to the situation in human patients, clinical efficacy will be related to the degree of cuff inflation.

The SHUS system that was designed for this study has several favorable characteristics. The occluder consisted of medical-grade silicone appropriate for long-term implants, the system could be applied in a simple procedure, and the cost of the required components was < $300. One of the most notable advantages of the SHUS is the ability to percutaneously adjust urethral resistance by inserting a needle into the subcutaneous infusion port and injecting or removing fluid from the occluder. Testing by the manufacturer has certified that the injection ports will not leak after up to 1,500 punctures with a 22-gauge noncoring needle. Use of a noncoring needle also prevents clogging of the needle tip with a piece of the silicone membrane during insertion. Data collected in the preliminary phase of this study relate the volume injected into the SHUS to the percentage occlusion of the lumen (Fig 2). This information will allow surgeons to reliably predict the percentage occlusion of the system by measuring the amount of fluid injected into the infusion port. The PCHUS system used in humans is not typically adjusted after surgery, but it is available with the pressure reservoir in 5 preset pressure ranges (41 to 50, 51 to 60, 61 to 70, 71 to 80, and 81 to 90 cm H_2O).[12] Cuff pressure could be measured percutaneously by puncturing the subcutaneous injection port of the SHUS reported here but would increase complexity of operation of the device.

The PCHUS system currently used in humans is available in cuff lengths of 4 to 11 cm and is placed such that the internal diameter of the artificial sphincter approximates the circumference of the urethra.[12] The vascular occluder that was used in the SHUS system in the study reported here was available in various sizes, ranging from 2 to 20 mm in internal diameter and 1.3 to 12.6 cm in length. Urethral circumference was measured in the cadavers during the placement procedure. On the basis of the measurements obtained, the 8-mm internal diameter occluder (2.5 cm in length) was considered to be the closest to a standard size that could be used in the medium-sized canine cadavers in the study. We attempted to standardize body weight of the cadavers such that a single occluder size could be used during this study. However, application of the SHUS system would be possible in miniature and large-breed dogs by use of appropriately sized occluders.

The placement technique was technically simple and could be performed by a veterinarian with minimal experience in soft tissue surgical techniques. The infusion line connecting the cuff to the subcutaneous injection port exited through the midline abdominal incision for expedience in this cadaver study. In future studies in live animals, it may be preferable that the infusion line exit through a separate, small paramedian incision in the abdominal wall to prevent complications with healing of the midline abdominal incision or with kinking of the infusion line as it exits the incision.

Our primary concern in clinical application of the SHUS in dogs is atrophy or erosion of the urethra attributable to chronic compression of urethral tissues. The incidence of erosion associated with the manually operated PCHUS has been reduced in humans by use of a narrow-backed cuff design and by delaying inflation of the HUS to allow restoration of urethral blood supply during the healing period.[12] Nocturnal deactivation is recommended[34-38] but is not performed by many patients with severe incontinence.[39] Prior radiotherapy of the pelvic region in patients with prostatic neoplasia causes fibrosis and hypovascularity of the urethra, contributing to postoperative urethral erosions and infection in men who use the PCHUS for incontinence after prostatectomy.[34-38] Use of the PCHUS as a primary treatment in women has been associated with a much lower rate of revision, with none of 27 patients having erosions during long-term monitoring in 2 retrospective studies.[40,41] By virtue of the information available from the aforementioned studies performed in human patients, our intent in future application of the SHUS system in live dogs would be to percutaneously inflate the cuff after the healing period is complete and adjust the occluder to the minimum percentage occlusion that is required to prevent urine leakage but still allow natural urination. Thus, the SHUS would be applied in static mode to slightly increase urethral resistance to passive urine flow, similar to the static compression caused by urethral bulking procedures or urethral slings. It is anticipated that the rate of urethral erosions in female dogs without a history of pelvic irradiation or neoplasia may be lower than those reported in men who use the PCHUS. In addition, we anticipate that continence may be restored in female dogs with USMI at a lower amount of urethral compression than is typically required in men with severe incontinence secondary to prostatic surgery or irradiation, decreasing the risk of urethral erosions.

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[a]OC8 vascular occluder, In Vivo Metric, Ukiah, Calif.
[b]M-ISC-S-5, DaVinci Biomedical Research Products, South Lancaster, Mass.
[c]22-gauge × ¾-inch Huber-point needle, Access Technologies, Skokie, Ill.
[d]Public domain National Institutes of Health Image program. Available at http://rsb.info.nih.gov/nih-image/. Accessed Dec 12, 2002.
[e]Dual-lumen CMG/UPP catheter, Life-Tech Inc, Houston, Tex.
[f]Uroflow cystometer 2118, Richard Wolf Medical Instruments Corp, Rosemont, Ill.
[g]StatView 5, SAS Institute Inc, Cary, NC.

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