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| 1  | Title: Long-term outcome of female dogs treated with static hydraulic urethral sphinc-             |
|----|--|
| 2  | ter for urethral sphincter mechanism incompetence  |
| 3  |  |
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| 9  |  |
| 10 | Short title: Outcome of dogs treated with static hydraulic urethral sphincter                      |
| 11 |  |
| 12 | The purpose of the study was to report the postoperative outcome, complications and long-          |
| 13 | term follow-up of the use of a static hydraulic urethral sphincter (SHUS) for the management       |
| 14 | of urethral sphincter mechanism incompetence (USMI) in female dogs. Medical records were           |
| 15 | reviewed to extract information on long-term (>365days) outcome data. Telephone owner              |
| 16 | questionnaire was performed to assess post-operative urinary continence scores (scale 1 to         |
| 17 | 10, where 10 is complete continence) and the presence and frequency of complications.              |
| 18 | Twenty female dogs were included. Mean (±SD) time to follow-up was 1205.1 (±627.4)                 |
| 19 | days. Median continence score/10 (range) was 3.5 (2-6) preoperatively, and 9.0 (7-10) at the       |
| 20 | last follow up. Median continence score was significantly higher at all-time points post-          |
| 21 | operatively compared to before surgery (P<0.001). Complete continence was achieved in              |
| 22 | 90% of bitches. Minor complications occurred in 13 bitches and included dysuria (8), bacte-        |
| 23 | rial cystitis (8), longer urination time (10), incisional seroma (5), urinary retention (3), hema- |
| 24 | turia (2) and pain when urinating (2). Major complications occurred in one dog (SHUS re-           |
| 25 | moved 28 months after placement). Continence scores were sustainably improved in the               |

- long-term. Complications were mostly minor. Urinary tract infection (UTI) were the most
  common but resolved with conventional antibiotic treatment.
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- 29

30 Introduction

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Urinary incontinence in dogs is commonly seen in veterinary practice. <sup>1</sup> USMI is the 32 most common cause of acquired urinary incontinence in female dogs,<sup>1</sup> and it is also seen, less 33 commonly, in males.<sup>2</sup> USMI is a multifactorial condition. Contributory factors include ure-34 35 thral tone, urethral length, bladder neck position, hormonal status, neutering status, obesity, 36 body size and breed.<sup>3</sup> Medical management with  $\alpha$ -adrenergic agonists, such as phenylpro-37 panolamine (PPA) or ephedrine, increases sympathetic bladder neck tone and has been shown 38 to increase maximal urethral closure pressure in cases of urethral sphincter mechanism incompetence.<sup>4</sup> It has been shown to improve urinary incontinence in acquired USMI in up to 39 40 85% of dogs. However, between 15 and 27% of female dogs with USMI cases remain refractory to medical management with PPA.<sup>45</sup> The same percentage of refractory cases is also 41 found following treatment with estriol.<sup>6</sup> 42 Surgical management of USMI is recommended when medical management fails or if long-43

term medical management is not an option. Several different procedures are described for controlling USMI in bitches including colposuspension, <sup>7 8 9</sup> urethropexy <sup>10 11</sup> or a combination of both, <sup>12</sup> urethral submucosal injections with either collagen, <sup>13 14 15</sup> polytetrafluoroethylene (PTFE) <sup>16</sup> or extracellular matrix bioscaffold, <sup>17</sup> transobturator vaginal tape inside out , <sup>18 19</sup> Dacron coated Silastic sheet urethral sphincter, <sup>20</sup> and most recently, SHUS. <sup>21 22 23,24</sup> Complications reported with these techniques include persistent incontinence (immediate or delayed), dysuria, urinary obstruction, haematuria and recurrent UTI. <sup>8 11 13 13 15 14 23 21</sup> 51 The Static Hydraulic Urethral Sphincter (also known as artificial urethral sphincter) is 52 a silicone device surgically placed around the urethra. It can be incrementally inflated post-53 operatively, via a subcutaneous port, to progressively compress the proximal urethra and achieve continence. Should dysuria result, the SHUS can also be partially or fully deflated.<sup>22</sup> 54 55 SHUS has been investigated in bitches that have ongoing or recurrent incontinence after surgery. A preliminary in vivo experimental study, <sup>25</sup> followed by a clinical pilot study in four 56 spaved bitches, <sup>22</sup> showed good results up to two years post-operatively, with all dogs 57 achieving full continence at last follow-up at 26 to 30 months. A larger study (27 dogs, in-58 59 cluding three male dogs) was published by the same institution and improved incontinence scores were seen in all dogs, with a median follow up of 12.5 (6-19) months. <sup>23</sup> This series 60 61 also reported minimal complications. The authors of the present study have also previously 62 reported high success rates and low complication rates for this technique at their institution but only with a short-term follow-up;<sup>21</sup> several reports have defined long-term follow-up as 63 follow- up of 12 months and over. <sup>26 7</sup> To our knowledge, no studies to date have described 64 65 long-term follow-up (> 12 months) of female dogs treated for USMI with SHUS implanta-66 tion. The primary aim of this study was therefore to report the long-term (>12 months) outcome 67 of SHUS for the control of USMI in female dogs. A second aim was to document any long-68 69 term complications and therefore assess the ongoing safety of the SHUS in dogs with 70 naturally occurring disease. 71 72 73 74

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## 85 Material and Methods

86 Inclusion criteria

87 The study was approved by our institutional Ethical Review Committee. Clinical records and 88 histories were reviewed for female dogs presenting to the authors institution between January 89 2009 and December 2015 for evaluation of urinary incontinence. History, physical examina-90 tion, routine biochemical and haematological analysis, abdominal ultrasound, urinalysis, 91 urine culture, intravenous contrast urography (IVU) and contrast retrograde vaginourethro-92 cystogram  $\pm$  cystoscopic examination were performed in all dogs to rule out other causes of 93 urinary incontinence. Dogs that were presented with concurrent UTI were treated with antibi-94 otics selected according to anti-microbial susceptibility testing. USMI was diagnosed if the 95 incontinence persisted after negative urine culture and imaging of the urogenital tract dis-96 closed no significant anatomical abnormalities other than an intrapelvic bladder neck location 97 consistent with USMI. Inclusion criteria included all females in which a SHUS was placed 98 for the treatment of USMI where adequate records were available. Animals were excluded if 99 their follow-up was less than 12 months. Long-term follow-up was assessed by a question-100 naire to owners and or referring veterinarian.

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### 102 Surgical Procedure

All dogs were investigated and treated at the author's institution and surgery was performed by a board-certified surgeon or a surgical resident under the direct supervision of a board-certified surgeon. Surgery was performed as previously described. <sup>21</sup> <sup>22</sup>

106

#### 107 *Postoperative care*

108 Dogs were administered 0.2 to 0.3 mg/kg methadone intravenously (IV) or intramus-109 cularly (IM) q 4 hr or 0.01 to 0.02 mg/kg buprenorphine IM or subcutaneously q 6 hr to q 8 110 hr postoperatively as required (based on pain assessment) and 0.1 mg/kg meloxicam<sup>b</sup> q 24 hr 111 orally postoperatively for analgesia. Perioperative antibiosis was administered in the form of 112 potentiated amoxicillin<sup>c</sup>, 20 mg/kg q 2 hr during anaesthesia, followed by five days of 20 113 mg/kg potentiated amoxicillin<sup>d</sup> orally in some dogs. The sphincter was not inflated at the time 114 of placement.

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116 Follow-up

117 Follow-up intervals varied and any procedures performed at these examinations were dictated by the needs of each individual dog. Typically dogs were requested to return to the 118 119 institution for a routine re-examination six to eight weeks postoperatively. At this re-120 examination the overall continence rate was assessed, and the presence and severity of dysu-121 ria, stranguria, haematuria, wound inflammation or infection and length and character of mic-122 turition were determined by close questioning of the owners and direct observation of the dog 123 urinating by the examining veterinary surgeon. Remaining follow-up examinations were per-124 formed by referring veterinarians or the institution as required.

125 Dogs exhibiting dysuria, pain on urination or suspicion of UTI on routine re-126 examination or on communication with the owner were admitted for repeat urinary tract ul-127 trasound examination. Postoperatively, only dogs which remained incontinent had urine sam-128 pled for culture and sensitivity. A urine sample was obtained by cystocentesis and was sub-129 mitted for urinalysis and/or urine bacterial culture and antibiotic sensitivity. Where UTI (pos-130 itive bacterial culture or active sediment on urinalysis) was identified, treatment was instigat-131 ed with appropriate antibiotics based on susceptibility testing, where possible, until a nega-132 tive urine culture was obtained. Upon documentation of a negative urine culture, and if the 133 animal was still showing signs of incontinence, the SHUS was inflated by one injection of 134 0.1 to 0.5 mL of sterile isotonic (0.9%) sodium chloride (NaCl) into the port following a pro-135 tocol, previously described.<sup>21</sup>

Complications were identified and categorized as major or minor using criteria similar to those previously published. <sup>21</sup>Briefly, major complications included those requiring replacement of the SHUS system. Minor complications were defined as those that did not necessitate replacement of the SHUS, and were often self-limiting.

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141 Follow-up questionnaire

142 Owners and referring veterinarians were contacted and asked to complete a telephone 143 questionnaire(s) assessing the postoperative progress of the dogs (December 2015). Where 144 owners could not be contacted, questionnaires were completed where possible based on refer-145 ring veterinarian records. Continence levels were scored using a scale ranging from 1 (con-146 stant leakage) to 10 (complete continence), before surgery and at set time points postopera-147 tively (at discharge, six and 12 months postoperatively, and at the time of the last questionnaire). Details of the scale are given in the appendix 1. Scores of <8 were classified as 'in-148 149 continent', whereas scores of 8 or more were classed as 'continent'. Scores were dichoto150 mized this way for easier interpretation in terms of clinical relevance, based on what owners' 151 perceive to be acceptable levels of continence. Additionally, owners were asked to grade in 152 severity (0-3) any complications pertaining to urination noted following surgery, or related to 153 the implants. A score of 0 indicated that no complications were seen, and scores of 1, 2 and 3 154 indicated mild, moderate and severe complications, respectively. The significance of a mild, 155 moderate or severe events was illustrated by giving precise examples to owners when com-156 pleting the questionnaire over the phone. Finally, owners were asked to score their satisfac-157 tion with their dog's outcome from 1 (very unsatisfied) to 10 (very satisfied), and asked 158 whether they would have the procedure performed again if they had another dog with the 159 same problem. Where dogs were euthanized or died before being contacted, owners were 160 asked to answer the questionnaire based on their latest recollection of their dog's status (at 161 the time of death).

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#### 163 Statistical analysis

Statistical analysis was performed by use of a commercial software.<sup>f</sup> Data were tested for 164 165 normality using Kolmogorov-Smirnov tests; age, body weight and time to follow-up were 166 normally distributed and were reported as the mean (SD); duration of hospitalization, owner satisfaction scores and continence scores were not normally distributed and reported as medi-167 168 an (range). A Friedman test for repeated measures was first performed to assess any overall 169 difference between the repeated continence scores on each subject, pre-operatively with those 170 at discharge, 6 months, and 12 months and at last follow-up. Given an overall significance, 171 differences between paired time points were then assessed using a paired-samples sign 172 test. *P* value <0.05 was considered significant.

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### **Results**

Twenty female dogs met the inclusion criteria. Eighteen were 18 spayed and two en-tire. Table 1 shows the signalment, preoperative treatment, diagnostic imaging findings and cuff size used along with their respective volumes of total inflation. Mean age was 61.0 months (±24.0) and median weight was 27.7 kg (9.6 - 62.7 kg). All included spayed female dogs were first noticed to be incontinent soon after routine ovariohysterectomy (days to weeks). Seventeen of the twenty dogs had either failed to respond completely to medical management with one or more of a combination of PPA, estriol or ephedrine, or had initially responded but then become incontinent despite medication. None of the dogs had experi-enced adverse effects attributable to medication. Dog 13 did not receive any medical treat-ment for USMI prior to surgical treatment as the owner wished to pursue surgery only. Dogs two and 10 were selected for surgery despite adequate medical control of incontinence due to difficulties with administering medication. Physical examination and diagnostic imaging re-vealed urogenital abnormalities in 11/20 dogs (Table 1). No dog had a UTI at the time of sur200 gery, based on the results of urinalysis and bacteriology assessment. Median pre-operative201 continence score was 3.0 (2-6).

No intraoperative complications were encountered during surgery, and all dogs were urinating without difficulty the following day, although 12/20 remained incontinent at discharge (Table 2). Median immediate postoperative continence score (8.0 (2-10)) was significantly higher than median pre-operative score (P<0.001). Median postoperative hospitalization time was 2 days (1 to 3 days).

Median continence scores at 6- and 12-months postoperatively were 8.5 (4-10) and 207 208 9.0 (5-10) respectively. These were both significantly higher than preoperatively scores 209 (P<0.001). Mean time at latest follow-up was 1205.4 days (627.4) (Table 2). At this time, 210 80% of dogs (16) were continent without any other treatment, 10% of dogs (two) were 211 continent and on continued medical therapy (dogs 3 on 1mg estriol q 24 hr and PPA and dog 212 14 on PPA and estriol) and two dogs were judged incontinent based on lower continence 213 scores (both had continence scores of 7). Continence score was 9.0 (7-10) and was signifi-214 cantly higher than pre-operatively (P < 0.001). Communication was not possible with the 215 owners of four dogs (dogs 9, 13, 19 and 20) at the time of latest follow-up and therefore, in-216 formation were gathered through communication with the referring veterinarian. Over the study period, 4/20 dogs (dogs 1, 2, 6 and 12) were euthanized for reasons unrelated to USMI. 217 218 All of these dogs had a follow-up time >12 months before euthanasia.

Regarding management of ongoing incontinence, one dog (dog 8) received a course of PPA to control persistent post-operative incontinence, as the authors were reluctant to inflate the cuff in this dog due to concurrent dysuria. Dysuria resolved without treatment after several weeks and incontinence subsequently resolved with inflation of the SHUS and cessation of the PPA. Seven of the 20 dogs (35%) did not require any inflation of the SHUS. Thirteen required inflation and four of these dogs required subsequent deflation of the cuff, due to

urinary retention (dog 1), severe dysuria (dogs 2 and 6), or urethral obstruction (dog 11). Two
dogs (dogs 1 and 2) had their cuff completely deflated, and two dogs (dogs 6 and 11) had partial deflation (see Table 2 for details).

228 Minor complications were reported in 13/20 dogs (65%) and are further detailed in 229 Table 3. Complications were experienced at a variety of times postoperatively. All complica-230 tions, with one exception, were minor. One dog (dog 1) experienced a major complication 231 event and required surgical intervention for SHUS removal 28 months postoperatively due to 232 persistent post-operative stranguria. Seven dogs had postoperative UTIs. One additional dog 233 (dog 10) had a UTI before (but not at the time of surgery) and after surgery. E.coli infection 234 was initially identified in this dog, which was sensitive to and treated with amoxicil-235 lin/clavulanic acid. Persistent recurrent dysuria was reported post-operatively and this was 236 treated presumptively by the referring veterinarian with amoxicillin/clavulanic acid. Culture 237 and sensitivity was then performed six days postoperatively; Multi-drug resistant (MDR) 238 Escherichia coli, Enterobacteriae and Pseudomonas spp. were identified which were sensitive 239 to amoxicillin/clavulanic acid. For all other dogs where a UTI was suspected based on clini-240 cal signs, urinalysis and a positive response to antibiotics, no culture and sensitivity infor-241 mation was available. Pain surrounding the subcutaneous port, which was responsive to an-242 algesia, was noted in two dogs during the first two to three weeks postoperatively.

Median owner satisfaction score was 9.5 (5-10). All but one owner, who said he was unsure (dog 15, satisfaction score of 8) said that they would have the procedure performed again if they had another dog with the same problem. We also noted lack of compliance with our recommendations (i.e. owner unwilling to come back for cuff inflation) from two owners. Those were the dogs with the lower continence scores at follow up (continence score of 7).

248

249 **Discussion** 

250 This retrospective study reports the long-term outcome of SHUS for the management 251 of USMI in female dogs, with a longer time to follow-up (mean 40 months) than has previously been described (26-30 months<sup>22</sup>; 13.5 months; <sup>21</sup> 12.5 months; <sup>23</sup> 32 months<sup>24</sup>). It is 252 253 important to document long-term efficacy of surgical techniques for USMI, as, for example, 254 dogs treated with urethral injections of collagen showed good initial success, but over half of dogs become incontinent approximately 12-16 months postoperatively <sup>14 15</sup> and PTFE injec-255 256 tions had an initial 100% success rate but many dogs developed recurrent incontinence over time.<sup>14</sup> It is vital that veterinarians have a good understanding of the likely outcomes of the 257 258 technique and are aware of the possible short- and long-term complications. The long-term 259 continence rate is higher (90% with 2 cases having medical management) than for colposuspension (53% and 37% being improved or more responsive to medical treatment), <sup>7</sup> ure-260 thropexy (56%) <sup>11</sup> or combination of both (70%) <sup>12</sup> or urethral bulking agents (68%); <sup>14</sup> mean 261 follow up in the latter two studies was comparable to this study at around three years. Fur-262 263 thermore, the two dogs classed as incontinent (continence scores <8) did not have a proper 264 cuff management due to lack of owner compliance. Avoiding the financial costs associated 265 with ongoing medical management and expensive repeat surgery is a benefit of SHUS 266 placement compared to other techniques (only one dog required repeat surgery in this study). Another major benefit of the SHUS that is not possible with any other reported technique is 267 268 the flexibility provided by the ability to inflate or deflate the SHUS at any stage following 269 surgery, in a conscious dog with minimal equipment. Importantly, owner satisfaction scores 270 were very high in this study and all but one owner agreed that they would have the same treatment performed again. This is similar to owner satisfaction reported in an other study <sup>23</sup> 271 272 where 24/27 owners were satisfied or very satisfied with the procedure. 273 In the authors' experience the surgical procedure is simple to perform and requires

274 minimal additional specialized equipment, apart from the implants and a non-coring Huber

275 needle. Certain aspects of the technique, however, require special attention. Care must be 276 taken to avoid bubble formation in the system and to ensure adequate slack is left in the tub-277 ing to avoid kinking of the SHUS at the urethra. Secure attachment of the tubing to the injec-278 tion port is also particularly important. Finally, close monitoring of the dog for at least 24 279 hours postoperatively for ease and character of urination is essential.

SHUS can be used to treat dogs with incontinence due to multiple different causes other than USMI <sup>24</sup> and in males dogs with USMI. <sup>23</sup> We have purposely decided to restrict this study to the female population of dogs treated for USMI (which is the most common cause of incontinence seen in our hospital). We believed that adding male dogs or dogs presented for urinary incontinence due to conditions other than USMI would add variability and have weakened the conclusions of the present report.

286 Ninety percent of our dogs (where two are being managed medically) achieved continence at long term follow up, similar to Currao et al. study<sup>24</sup> where all 18 dogs had signifi-287 288 cantly improved continence scores immediately after SHUS placement, and 67% with conti-289 nence scores > 9 at long term follow up. A median continence score of 9 out of 10 at last follow-up was reported by Reeves et al.<sup>23</sup> In Rose et al. study<sup>22</sup> all dogs were continent after 290 291 the placement of the SHUS (including one dog on medical management for a few months to maintain a continence score 9 out of 10) and were continent at mean latest follow-up of 30 292 293 months without complications. The two dogs on medical management post-operatively in this 294 study achieved good continence scores, despite not being responsive to medical management 295 before surgery. They were not completely continent as their owners decided to not pursue 296 further inflations and decided to continue with medication; the authors believe it is likely that 297 medications could have been stopped if further cuff inflation had been performed. Despite the SHUS being left uninflated at the time of surgery (only a small residual 298

299 primer volume was used to fill the tubing and injection port), 85% dogs showed improved

300 continence immediately after surgery. A period of 6-8 weeks was allowed between surgical 301 placement and inflation of the SHUS based on previous recommendations in human and veterinary studies. <sup>22 27</sup> This is proposed to allow adequate revascularization of the dissected 302 303 ure thra and minimize the risk of ure thral atrophy and erosion. The immediate postoperative improvement in continence seen in this study was also appreciated in previous reports. <sup>22 23</sup> It 304 305 is hypothesized that this occurs due to the passive increase in urethral tone created by the presence of the semi-rigid backing on the urethral part of the implant. <sup>22 23</sup> Similar to our re-306 sults (7 dogs, 35%) 33% of dogs reported by Currao et al.<sup>24</sup> did not require inflation to 307 308 achieve continence.

309 Only one major complication was reported in the current case series, (one dog that 310 had to have the SHUS removed) in agreement with previous reports of the SHUS technique. <sup>22 23</sup> One or more minor complications occurred in 65% dogs, a lower incidence than in our 311 previous study (81.8%).<sup>21</sup> This report included the first 11 dogs of the current study, suggest-312 313 ing that complication rate has improved with more experience of the technique. Although complications were encountered more commonly than reported with other techniques, <sup>7 11</sup> 314 315 they were minor and self-limiting. Only one dog required further surgery to remove the cuff, 316 28 months after it was placed. This dog was moderately persistently stranguric despite com-317 plete deflation of the cuff. Postoperative or post-cuff inflation stranguria was seen in seven 318 additional cases. Deflation of the SHUS was performed, resulting in resolution of stranguria 319 in all dogs without further intervention. This is a similar experience to stranguric dogs previously reported.<sup>22</sup> The severity of the stranguria and the presence of urinary retention were 320 321 considered when determining whether cuff deflation was indicated. It was thought in retro-322 spect that stranguria was caused by overinflation of the cuff in dog 1, where 33% of the total cuff volume was instilled initially. In subsequent dogs, a more gradual SHUS inflation (10 to 323 324 20% increments) was therefore performed to reduce the risk of stranguria, in line with the

recommendations by Rose et al.<sup>22</sup> Reeves et al.<sup>23</sup> reported mild stranguria seven to ten days 325 after surgery in five dogs, which responded to non-steroidal anti-inflammatories in all 326 327 animals. Stranguria and anuria are reported complications of colposuspension and ure-328 thropexy, requiring postoperative catheterisation in the case of colposuspension and repeat surgery and suture removal in urethropexy.<sup>711</sup> Martinoli et al. reported dysuria in some dogs 329 where both techniques were combined.<sup>12</sup> When these complications occur following SHUS 330 placement, this study shows that they are more easily and less invasively managed than with 331 332 the two aforementioned techniques.

333 The most common complication in this population appeared to be post-operative UTIs. According to a study by Wong et al., dogs that had one or two single events of UTI 334 335 documented were consider to have uncomplicated UTIs which may even have been related to USMI.<sup>28</sup> Olin and Bartges proposed that all dogs with UTIs related to USMI would be called 336 complicated.<sup>29</sup> UTIs occurred in eight cases out of 20 dogs (40%), based on a combination 337 338 of urinalysis, positive urine bacterial culture and response to antibiotics. This is a significant 339 proportion of dogs, although two out of eight cases where information was available had single UTIs. Three dogs had multiple (three and over) UTI events and in these animals the au-340 341 thors consider that they had complicated UTIs. Due to lack of records, the nature of these infections (for example if they involved the same organism, or MDR organisms and whether or 342 343 not significant clinical signs were associated) was unknown. All UTIs were successfully 344 treated with antibiotics based on resolution of clinical signs. It is clear that more information 345 is needed regarding the association between SHUS and UTIs as it is possible that some of the 346 cases of UTIs post SHUS placement may simply be related to the higher prevalence of UTIs 347 in incontinent female dogs and not necessarily linked with the presence of the SHUS. Only a more stringent protocol involving routine urine culture and sensitivity irrespective of the 348 349 presence of clinical signs could provide information on the prevalence of subclinical infec-

tions. We can therefore not exclude the presence of subclinical infection in some of the dogs included in this study as only dogs with clinical signs consistent with UTIs were further investigated with urine culture and sensitivity.

353 . Because pain surrounding the subcutaneous port was noted in two dogs during the 354 first two to three weeks postoperatively, the authors modified the port placement technique 355 by moving the location of the port from the medial musculature of the pelvic limb/inguinal 356 region to the paramedian abdominal wall. Pain was not suspected in any subsequent dog, and 357 that location of the port allowed it to be more easily identified on palpation and also likely 358 reduced port movement.

359 Prolonged duration of micturition compared to that preoperatively was reported in 360 50% dogs. This is far less frequent than that noted in a previous study where three out of four animals (75%) presented with this complication.<sup>22</sup> To the authors' knowledge, this is not a 361 362 reported complication following colposuspension or urethropexy and is considered a more 363 severe form of prolonged emptying. The significance of prolonged micturition in these dogs 364 is unknown but may indicate discomfort when urinating, or smaller urethral diameter due to 365 the SHUS placement and rather inelastic fibrous tissue formation around the urethra at this 366 particular level.

367 One dog had a known obstructive episode (managed by slight cuff deflation) and 368 three additional dogs had suspected low-grade ongoing urinary retention. Although urinary 369 retention did not result in obvious additional complications, it is a known risk factor for UTI 370 development. This may contribute to UTI development in dogs treated with SHUS cases, alt-371 hough this case series is too small to allow this association to be evaluated fully. It is now 372 considered prudent to counsel owners regarding the potential postoperative risks of urinary retention. We recommend that the bladder is routinely checked post-micturition (by palpation 373 374 and/or ultrasound examination) by the referring veterinarian every three months during the

375 first year postoperatively and then as required, based on the initial presence or degree of uri-376 nary retention.

377 This study has a number of limitations, primarily due to its retrospective nature. Some 378 data were reliant on owner recall ability and in any case were subjective, despite efforts to 379 classify continence scores and complication severity on numeric scales. Inter-observer varia-380 bility and bias were unavoidable disadvantages of data collection by owner questionnaire. Owner satisfaction would also have depended on pre-existing expectations, influenced by 381 382 preoperative counseling, owner education, understanding of the procedure and expected out-383 come. A contemporaneous record of the continence levels, recorded at the specified time in-384 tervals, would be more reliable. This said, owners' perceptions are increasingly being recog-385 nized as important outcome indicators, rather than using objective scientific criteria alone.<sup>30</sup> 386 Additionally, bacteriuria may have been missed due to clinical signs only prompting further investigations for a possible infection. 387

### 389 Conclusion

390 Overall, SHUS is an effective treatment for USMI in bitches, resulting in a significant 391 improvement in continence scores, in both the short- and long-term (>12 months). This study 392 shows that 90% of dogs achieve continence and that owners were very satisfied with their 393 dogs' outcome. It confirms that a major advantage of the SHUS is that it provides scope for 394 potentially further improving continence postoperatively (without surgery and without further medication) by cuff inflation, although this is not required in all dogs. According to this 395 396 study, long-term management of SHUS does not seem to result in a high incidence of implant 397 -related complications. Results are of importance as they add to the currently limited body of 398 evidence available for veterinarians regarding the use of SHUS. 399

### 401 Footnote list

- 402 a : Prolene, Ethicon, Norderstedt, Germany
- 403 b : Metacam, Boehringer Ingelheim Ltd, Bracknell, UK
- 404 c: Augmentin, GlaxoSmithKline, Brentford, UK
- 405 d: Clavaseptin, Vetoquinol UK Ltd Buckingham, UK
- 406 e: Access Technologies, Skokie, IL
- 407 f: Systat, version 10.0, SPSS Inc, Chicago, Ill
- 408 PPA: phenylpropanolamine
- 409 USMI: Urethral sphincter mechanism incompetence
- 410 UTI: urinary tract infection
- 411 SHUS: static hydraulic urethral sphincter
- 412 PTFE: polytetrafluoroethylene
- 413 IVU: intravenous contrast urography
- 414 IV: intravenously
- 415 IM: intramuscularly
- 416 MDR: multi-drug resistant

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- 1 Table 1: Signalment, preoperative findings and inflation/deflation volumes for SHUS for 20
- 2 female dogs.

| Dog  | Breed            | Body weight<br>(Kg) | Age at<br>surgery<br>(months) | Preoperative treatment | eoperative Imaging<br>eatment findings                 |           |
|------|------------------|---------------------|-------------------------------|------------------------|--|-----------|
| 1    | Irish Setter     | 31.9                | 100                           | PPA                    | Intrapelvic<br>bladder                                 | 12 (1.5)  |
| 2    | Rottweiller X    | 52.3                | 31                            | PPA / estriol          | NSF  | 10 (1.45) |
| 3    | Labrador         | 27.5                | 84                            | Ephedrine              | Intrapelvic<br>bladder                                 | 10        |
| 4    | Irish Setter     | 32                  | 63                            | PPA / estriol          | Intrapelvic<br>bladder                                 | 10 (0.9)  |
| 5    | WHWT             | 9.6                 | 54                            | PPA / estriol          | NSF  | 6(1)      |
| 6    | Border Collie    | 23.5                | 80                            | PPA / estriol          | Pyelectasia<br>and intrapelvic<br>bladder              | 8 (1)     |
| 7    | Springer Spaniel | 14.5                | 88                            | PPA / colpo            | Mild vaginal stricture                                 | 8 (1)     |
| 8    | Dobermann        | 38.3                | 33                            | РРА                    | Intrapelvic<br>bladder and<br>perivulvar<br>dermatitis | 10 (0.8)  |
| 9    | Labrador         | 24.5                | 72                            | PPA / estriol          | NSF  | 10 (0.8)  |
| 10   | Labrador         | 27.9                | 77                            | PPA/ estriol           | NSF  | 10 (1.2)  |
| 11   | Dobermann        | 34.8                | 60                            | PPA / estriol          | NSF  | 10 (2)    |
| 12   | Dobermann        | 27.9                | 72                            | PPA / estriol          | Intrapelvic<br>bladder                                 | 12 (1.5)  |
| 13   | Great Dane       | 62.65               | 23                            | None                   | Intrapelvic<br>bladder                                 | 10 (1.2)  |
| 14   | Boxer            | 24.9                | 60                            | PPA / estriol          | NSF  | 10(1)     |
| 15   | Weimaraner       | 25.6                | 83                            | PPA                    | Intrapelvic<br>bladder                                 | 10 (2)    |
| 16   | Springer Spaniel | 22.5                | 80                            | PPA / estriol          | NSF  | 10 (1.2)  |
| 17   | Mastiff          | 40.1                | 26                            | PPA                    | Intrapelvic<br>bladder                                 | 10 (1.2)  |
| 18   | Labrador         | 25                  | 36                            | PPA / estriol          | NSF  | 10        |
| 19   | Dobermann        | 31.3                | 25                            | Estriol                | Mild renal<br>dysplasia and<br>intrapelvic<br>bladder  | 10        |
| 20   | Collie X         | 25                  | 73                            | PPA / estriol          | NSF  | 10        |
| Mean |                  | 30.1                | 61                            |                        |  |           |
| S.D. |                  | 11.8                | 24.0                          |                        |  |           |

NSF- no significant findings; PPA- phenylpropanolamine; Colpo- colposuspension; WHWT-

4 west highland white terrier; S.D.-standard deviation

- 10
- 11
- 12 Table 2: Owner-rated continence scores, total number and volume of inflations/deflations
- 13 performed and time at last follow-up.

|        | Continence s | core (0-10) | Total    | Total         |                     |   |   |  |
|--------|--------------|-------------|----------|---------------|---------------------|---|---|--|
| Dog    | Pre- op      | Discharge   | 6-months | 12-<br>months | Latest<br>follow-up | number of<br>inflations<br>(total<br>volume of<br>inflation,<br>mL) | number of<br>deflations<br>(total<br>volume of<br>deflation,<br>mL) | Time at<br>last<br>follow-<br>up<br>(days) |
| 1      | 2            | 4           | 4        | 10            | 10 (PTS)            | 3 (0.75)  | 2 (0.75)  | 1279                                       |
| 2      | 4            | 10          | 6        | 7             | 7 (PTS)             | 1 (0.3)   | 1 (0.1)   | 428  |
| 3      | 6            | 8           | 10       | 5             | 9*                  | 4 (0.5)   | 0   | 2044                                       |
| 4      | 3            | 2           | 10       | 10            | 9                   | 0   | 0   | 1884                                       |
| 5      | 3            | 3           | 7        | 7             | 8                   | 1 (0.2)   | 0   | 1853                                       |
| 6      | 6            | 8           | 5        | 9             | 10 (PTS)            | 4 (0.8)   | 1 (0.2)   | 1095                                       |
| 7      | 4            | 10          | 8        | 8             | 8                   | 0   | 0   | 1779                                       |
| 8      | 2            | 6           | 8        | 8             | 9.5                 | 2 (0.4)   | 0   | 1519                                       |
| 9      | 3            | 8           | 8        | 9             | 9                   | 0   | 0   | 1090                                       |
| 10     | 5            | 6           | 10       | 10            | 10                  | 9 (1.05)  | 0   | 790  |
| 11     | 2            | 2           | 4        | 9             | 8                   | 6 (0.65)  | 1 (0.35)  | 454  |
| 12     | 2            | 4           | 10       | 10            | 10 (PTS)            | 5 (0.65)  | 0   | 365  |
| 13     | 6            | 8           | 10       | 10            | 10                  | 0   | 0   | 1424                                       |
| 14     | 2            | 9           | 10       | 10            | 10*                 | 0   | 0   | 808  |
| 15     | 2            | 9           | 8        | 8             | 7                   | 3 (0.5)   | 0   | 806  |
| 16     | 2            | 9           | 10       | 10            | 10                  | 1 (0.15)  | 0   | 559  |
| 17     | 2            | 9           | 9        | 9             | 8                   | 1 (0.15)  | 0   | 1290                                       |
| 18     | 6            | 10          | 9        | 9             | 10                  | 0   | 0   | 2257                                       |
| 19     | 2            | 5           | 9        | 9             | 9                   | 0   | 0   | 2093                                       |
| 20     | 6            | 9           | 8        | 8             | 8                   | 1 (0.15)  | 0   | 365  |
| Median | 3.0          | 8.0         | 8.0      | 9.0           | 9.0                 |   | Mean  | 1205.4                                     |
| Range  | 2-6          | 2-10        | 4-10     | 5-10          | 7-10                |   | SD  | 627.4                                      |

14 PTS=euthanized, \*dogs also receiving medical management

# 16 Table 3: Severity scores (0-3 in increasing severity) of complications following SHUS

# 17 placement.

| Dog | Urinary complications |            |                   |             |             |           |             | Wound / port complications |           |      |         |
|-----|-----------------------|------------|-------------------|-------------|-------------|-----------|-------------|----------------------------|-----------|------|---------|
|     | Stranguria            | Haematuria | Urinary infection |             |             | Pain on   | Longer      | Seroma                     | Infection | Pain | Healing |
|     |                       |            | Score             | When        | Number of   | Urination | micturition |                            |           |      |         |
|     |                       |            |                   | occurred    | events      |           | time        |                            |           |      |         |
| 1   | 2                     | 0          | 1                 | Post        | Single      | 0         | 2           | 1                          | 0         | 0    | 0       |
|     |                       |            |                   | operatively | event       |           |             |                            |           |      |         |
| 2   | 3                     | 2          | 3                 | Post        | Multiple    | 2         | 3           | 0                          | 0         | 0    | 0       |
|     |                       |            |                   | operatively | events      |           |             |                            |           |      |         |
| 3   | 0                     | 0          | 0                 |             |             | 0         | 1           | 0                          | 0         | 0    | 0       |
| 4   | 0                     | 0          | 0                 |             |             | 0         | 0           | 0                          | 0         | 0    | 0       |
| 5   | 0                     | 0          | 0                 |             |             | 0         | 0           | 0                          | 0         | 0    | 0       |
| 6   | 3                     | 0          | 3                 | Post        | Multiple    | 1         | 1           | 0                          | 0         | 1    | 0       |
|     |                       |            |                   | operatively | events      |           |             |                            |           |      |         |
| 7   | 0                     | 0          | 3                 | Post        | Multiple    | 0         | 1           | 1                          | 0         | 0    | 0       |
|     |                       |            |                   | operatively | events      |           |             |                            |           |      |         |
| 8   | 2                     | 0          | 0                 |             |             | 0         | 2           | 3                          | 0         | 0    | 0       |
| 9   | 2                     | 0          | 2                 | Post        | Single      | 0         | 2           | 0                          | 0         | 0    | 0       |
|     |                       |            |                   | operatively | event       |           |             |                            |           |      |         |
| 10  | 0                     | 2          | 2                 | Pre and     | Multiple    | 0         | 0           | 0                          | 0         | 0    | 0       |
|     |                       |            |                   | post        | events      |           |             |                            |           |      |         |
|     |                       |            |                   | operatively |             |           |             |                            |           |      |         |
| 11  | 1                     | 0          | 0                 |             |             | 0         | 2           | 0                          | 0         | 0    | 0       |
| 12  | 1                     | 0          | 0                 |             |             | 0         | 1           | 0                          | 0         | 0    | 0       |
| 13  | 0                     | 0          | 0                 |             |             | 0         | 0           | 0                          | 0         | 0    | 0       |
| 14  | 0                     | 0          | 1                 | Information | Information | 0         | 1           | 0                          | 0         | 0    | 0       |
|     |                       |            |                   | not         | not         |           |             |                            |           |      |         |
|     |                       |            |                   | available   | available   |           |             |                            |           |      |         |
| 15  | 0                     | 0          | 0                 |             |             | 0         | 0           | 0                          | 0         | 0    | 0       |
| 16  | 0                     | 0          | 0                 |             |             | 0         | 0           | 1                          | 0         | 0    | 0       |
| 17  | 0                     | 0          | 0                 |             |             | 0         | 0           | 0                          | 0         | 0    | 0       |
| 18  | 3                     | 0          | 2                 | Information | Information | 0         | 0           | 1                          | 0         | 0    | 0       |
|     |                       |            |                   | not         | not         |           |             |                            |           |      |         |
|     |                       |            |                   | available   | available   |           |             |                            |           |      |         |
| 19  | 0                     | 0          | 0                 |             |             | 1         | 0           | 0                          | 0         | 2    | 0       |
| 20  | 0                     | 0          | 0                 |             |             | 0         | 0           | 0                          | 0         | 0    | 0       |

18 Complication score = 0- none /complete healing, 1- mild, 2- moderate, 3-severe;