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## Comparison of adjustable continence therapy periurethral balloons and artificial urinary sphincter in female patients with stress urinary incontinence due to intrinsic sphincter deficiency

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34 **Comparison of Adjustable Continence Therapy periurethral balloons and**  
35 **artificial urinary sphincter in female patients with stress urinary incontinence**  
36 **due to intrinsic sphincter deficiency**

37

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68 **Abstract**

69 *Objective:* To compare the outcomes of the ACT® device to the ones of the artificial  
70 urinary sphincter (AUS) AMS 800 in the treatment of stress urinary incontinence due  
71 to sphincter deficiency in women

72

73 *Methods:* All the women who underwent a surgical treatment for stress urinary  
74 incontinence due to intrinsic sphincter deficiency from 2007 to 2017 were included in  
75 a single-center retrospective study. The primary endpoint was the functional  
76 outcome. Perioperative functional parameters were compared between the two  
77 groups.

78

79 *Results:*

80 25 patients underwent an ACT® implantation and 36 an AUS implantation. Patients  
81 in the AUS group were younger (62.9 vs. 70.4 years;  $p=0.03$ ) with less comorbidity  
82 (ASA Score=3 in 12.1% vs. 33.3%;  $p=0.005$ ). Operative time and hospital stay were  
83 shorter in the ACT® group (respectively 45.7 vs. 206.1 min;  $p<0.001$ ; 1.7 vs. 7 days;  
84  $p<0.001$ ). There was a higher rate of intraoperative complications in the AUS group  
85 (47% vs. 8%;  $p<0.001$ ) but the rates of post-operative complications were similar  
86 between both groups. The ACT® was associated with an increased risk of urinary  
87 retention (20% vs. 2.8%;  $p=0.04$ ). Results were in favor of AUS for: decrease in USP  
88 stress incontinence subscore (-7.6 vs. -3.2;  $p<0.001$ ), number of pads per 24h (- 4.6  
89 vs. -2.3;  $p=0.002$ ), PGII scale (PGII=1: 61.1% vs. 12%;  $p<0.001$ ) and cure rate  
90 (71.4% vs. 21.7%;  $p<0.001$ ).

91

92 *Conclusion:* In the present series, keeping in mind significantly different baseline  
93 characteristics, AUS implantation was associated with better functional outcomes  
94 than the ACT® in female patients with stress urinary incontinence due to intrinsic  
95 sphincter deficiency but with higher intraoperative complications rate, longer  
96 operative time and length of stay.

97

98 **Keywords (MeSH):** artificial urinary sphincter; urinary incontinence; sphincter  
99 deficiency; surgery

100

101 **Brief summary:** Artificial Urinary Sphincter and periurethral balloons are two options  
102 for female patients with intrinsic sphincter deficiency according to their health status.

103

104 **Introduction**

105

106 Stress urinary incontinence due to intrinsic sphincter deficiency is usually defined as  
107 the combination of a low urethral closure pressure, loss of urethral mobility, and a  
108 negative Marshall/Bonney test (urine leakage on straining or coughing not corrected  
109 by urethral support) [1; 2]. In daily practice, this condition is usually seen in two  
110 different populations: female patients who failed previous anti-incontinence surgical  
111 procedures (recurrent or persistent urinary incontinence after midurethral sling, Burch  
112 colposuspension,....) [3] or patients with neurogenic stress urinary incontinence  
113 (usually due to spinal cord injury or spina bifida) [4]. The management of these  
114 women remains highly controversial, fascial slings and bulking agents being the most  
115 commonly used treatment option in North America [5], while in several European  
116 countries, notably in France, external compression device, such as the Adjustable  
117 Contenance Therapy (ACT®, Uromedia Inc., MN, USA) or the artificial urinary  
118 sphincter (AUS) AMS 800 (American Medical Systems, Minnetonka, MN, USA), are  
119 usually favoured. While several series have assessed the outcomes of various  
120 surgical treatment of intrinsic sphincter deficiency [1], studies comparing two  
121 treatment options are lacking. The aim of this study was to compare the outcomes of  
122 the ACT® device to the one of the artificial urinary sphincter AMS 800 in the  
123 treatment of stress urinary incontinence due to intrinsic sphincter deficiency in  
124 women.

125

126

127

128 **Methods**

129

130 *Study design*

131

132 All the 61 women who underwent a surgical treatment for stress urinary incontinence  
133 due to intrinsic sphincter deficiency from 2007 to 2017 were included in a single-  
134 center retrospective study. Intrinsic sphincter deficiency was defined as the  
135 combination of a low urethral closure pressure (<40 cm H<sub>2</sub>O), loss of urethral  
136 mobility, and a negative Marshall/Bonney test (urine leakage on straining or coughing  
137 not corrected by urethral support). The artificial urinary sphincter AMS 800 was  
138 considered as the standard treatment in these patients during the study period. The  
139 ACT® periurethral balloons became available in our center in 2011 and was used  
140 only in the following cases: moderate incontinence (subjectively defined as pad test <  
141 200 g/24h), patients aged over 80 years and/or morbidly obese and/or lacking  
142 manual dexterity limiting the ability to operate the sphincter pump,...) and/or with  
143 history of previous pelvic radiation therapy and/or patients who refused the  
144 implantation of an artificial urinary sphincter. From 2007 to 2011, all patients were  
145 offered AUS with no alternatives and from 2011 to 2017 patients with the  
146 aforementioned comorbidities and those with moderate incontinence were offered  
147 peri-urethral balloons and the other patients were offered an AUS (but some refused  
148 and preferred to receive peri-urethral balloons). In accordance with national  
149 guidelines [1], no other surgical treatment (e.g. fascial sling, bulking agents,...) was  
150 used to treat intrinsic sphincter deficiency during the study period. Hence, the  
151 inclusion criterion was: all female patients who underwent a surgical treatment for  
152 stress urinary incontinence due to intrinsic sphincter deficiency from 2007 to 2017.

153 The study was approved by the local ethics committee and was conducted following  
154 the principles of the Helsinki declaration. Consent from all study participants was  
155 obtained. The study was not supported by the industry. The primary endpoint was the  
156 functional outcome categorized as: cured (complete continence, i.e. no pads used),  
157 improved (decrease in number of pads per day or in urine leakage assessed through  
158 pad test) or failure (no decrease in number of pads per day or urine leakage  
159 assessed through pad test).

160

161

162 *Adjustable Continence Therapy: device and surgical technique*

163

164 All patients had a negative preoperative urine culture and received 2 g of  
165 Cephalosporin group 2 at the beginning of the procedure as antibiotic prophylaxis.  
166 Patients with a positive preoperative urine culture ( $\geq 10^3$  CFU/mL) received antibiotic  
167 treatment according to the sensitivity of the bacteria isolated from their urine culture  
168 for a minimum period of two days before the implantation.

169

170 The ACT® kit contains two silicone elastomer balloons connected to a titanium port,  
171 a syringe and a ponction needle used to inflate the device through the titanium port.  
172 Balloons are available in 4 lengths from 6 to 9 cm, which will be determined using the  
173 trocar. This last tool is a part of dedicated tools with tipped stylet and a blunt-tipped  
174 stylet,.

175

176 The surgical procedure was performed as previously described by others [1, 6-8].

177 The balloons were placed at each side of the bladder neck using the trocar, which



178 was inserted using an incision in each labia majora, and the devices were pushed  
179 laterally to urethra to their correct position on each side of the bladder neck, slightly  
180 posterior (at 5 o'clock and 7 o'clock) which was controlled by fluoroscopy and flexible  
181 cystoscopy. The balloons were filled with 0.6 ml of an aqueous radiopaque solution  
182 through the titanium port, which was placed subcutaneously in the labia majora. The  
183 trocar was removed after inflation of the device, in order to avoid moving the device  
184 during the removal.

185 A urethral catheter was introduced for up to 12 hours and removed before the patient  
186 was discharged. The procedure was performed as outpatient surgery when deemed  
187 possible.

188

189 ACT implantations were performed by two surgeons with no previous experience of  
190 this surgery before the study period. Inflations of 0.6 ml were performed once a  
191 month from 1 month post-operatively in outpatient clinics without any anesthesia by  
192 injecting into the titanium ports, until a satisfactory improvement was observed and  
193 up to a maximum of 7 ml per balloon.

194

195

#### 196 *Artificial Urinary Sphincter: device and surgical technique*

197 The antibiotic policy used was similar to the one of ACT implantations (see above).

198 The device used was the AMS 800 in all cases. The surgical techniques used were  
199 those previously described and followed the same principles regardless of the  
200 approach [9]. Briefly, the Retzius space was dissected until the bladder neck and the  
201 endopelvic fascia was opened on both sides of the urethra. The bladder neck was  
202 then dissected from the vagina below the periurethral fascia just below the level of

203 the catheter balloon. The surgeon introduced two fingers of his left hand into the  
204 vagina to help the dissection. At the end of the dissection the bladder was filled with  
205 saline stained with methylene blue to verify the integrity of the bladder neck. The  
206 bladder neck circumference was measured using a measuring tape. The cuff was  
207 then positioned around the bladder neck. The pump was implanted in one of the labia  
208 majora and the balloon in the prevesical space. An open approach was used from  
209 2007 to 2012 with a few laparoscopic cases over this period. From 2012 to 2017, all  
210 implantations were performed through a robot-assisted approach. A single surgeon  
211 (AM) highly experienced in functional urology performed all open and laparoscopic  
212 cases. He was then involved as the assistant surgeon on the surgical field for the  
213 robotic implantations while two consecutive surgeons were performing the dissection  
214 at the console: a first surgeon highly-experienced in robotic surgery (SV; > 600 robot-  
215 assisted radical prostatectomy at the beginning of the present study) performed the  
216 first ten cases and a second surgeon, (BP, a young fellow who had performed only  
217 20 robotic procedures before his first robotic AUS implantation) performed the  
218 subsequent cases.

219 The AUS were deactivated at the time of implantation and the urethral catheter was  
220 removed 2 days after surgery, bladder ultrasound was carried out to confirm  
221 adequate bladder voiding after catheter removal. Patients returned 6 weeks later for  
222 activating and learning to use the sphincter.

223

224 *Pre and post-operative assessments*

225

226 All patients underwent a complete work-up before surgery including: urodynamics,  
227 urethrocytoscopy, 3 days bladder diary, and pad test. The preoperative assessment  
228 also comprised a clinical interview, an urogynaecological examination and the  
229 Urinary Symptoms Profile (USP) [10] and the Internation Consultation on  
230 Incontinence Questionnaire Short Form (ICIQ-SF) questionnaires [11] (from 2011 to  
231 2017). Neurogenic stress urinary incontinence was defined as stress urinary  
232 incontinence in a patients with spinal cord injury or spina bifida.

233 Follow-up involved an outpatient visit at 3 months, 6 months and 1 year post-  
234 operatively and then annually with a clinical examination, a 3 days bladder diary and  
235 an uroflowmetry with ultrasound measurement of post-void residual urine volume. An  
236 urodynamic testing was performed 3 months after AUS implantation to measure post-  
237 operative urethral closure pressure but was not performed routinely after ACT®  
238 implantation (only in case of persistent urinary incontinence after inflation of up to 5  
239 ml per balloon).

240 Postoperative complications were graded using the Clavien-Dindo classification [12]  
241 and were reported according to the EAU guidelines [13]. Failure was defined as  
242 explantation of the AUS device and divided into two categories: mechanical failure  
243 (perforation of any parts of the AUS or pump malfunction) and nonmechanical failure  
244 (cuff erosion, infection, pain, insufficient pressure). Hence, failure and continence  
245 status were analyzed separately and failure defined only the impossibility of  
246 maintaining the device in situ. Acute urinary retention was defined as a post-void  
247 residual volume > 150 ml postoperatively spontaneously resolving within the first 3  
248 months after surgery. Chronic urinary retention was defined as the persistence of a  
249 post-void residual volume > 150 ml greater than three months after the implantation.

250 All urinary retentions were managed by clean-intermittent self-catheterizations (4 to 6  
251 per day).

252

253 *Statistical analysis*

254

255 Perioperative and functional parameters were compared between the two groups.  
256 Means and standard deviations were reported for continuous variables, and  
257 proportions for nominal variables. Comparisons between groups were performed  
258 using the  $\chi^2$  test or Fisher's exact test for discrete variables, and Mann-Whitney test  
259 for continuous variables. Change of continuous variables over time was assessed  
260 using the McNemar test. Time to failure were estimated using the Kaplan-Meier  
261 method and compared between both groups using the log-rank test. Statistical  
262 analyses were performed using JMP v.12.0 software (SAS Institute Inc., Cary, NC,  
263 USA). All tests were two-sided with a level of  $p < 0.05$  considered statistically  
264 significant.

265

266

267

268 **Results**

269 *Patients' characteristics*

270

271 Over the study period, 61 patients were screened and all met the inclusion criterion:  
272 25 underwent an ACT® implantation and 36 an AUS implantation. The study flow-  
273 chart is shown in figure 1. The patients' characteristics are summarized in table 1.  
274 Patients in the AUS group were younger (62.9 vs. 70.4 years;  $p=0.03$ ) with less  
275 comorbidity (ASA Score=3 in 12.1% vs. 33.3%;  $p=0.005$ ) and none had a history of  
276 previous pelvic radiation therapy conversely to those in the ACT® group (0% vs.  
277 20%;  $p=0.009$ ). More patients undergoing an AUS implantation had failed previous  
278 midurethral sling (66.7% vs. 40%;  $p=0.04$ ) but the rate of neurogenic stress urinary  
279 incontinence was comparable between both groups (13.9% vs. 4%;  $p=0.39$ ) and the  
280 maximum urethral closure pressure did not differ significantly between the AUS and  
281 ACT® groups (27.3 vs. 28.8 cmH<sub>2</sub>O;  $p=0.61$ ). The proportion of patients who had  
282 undergone a second midurethral sling was also similar in both groups (27.8% vs.  
283 13.6%;  $p=0.21$ ). The reasons for ACT® implantations were as follows: moderate  
284 incontinence in five patients (20%), comorbidities in 10 patients (40%) and 10 patients  
285 were offered an AUS but refused and then underwent implantation of ACT® (40%).  
286 Eight and five patients in the ACT and AUS group respectively had not undergone  
287 any anti-incontinence surgical procedure (32% vs. 13.9%;  $p=0.12$ ).

288

289 *Perioperative outcomes*

290

291 Operative time was shorter in the ACT® group (45.7 vs. 206.1 min;  $p<0.001$ ) and so  
292 was the length of hospital stay (1.7 vs. 7 days;  $p<0.001$ ). There was a higher rate of

293 intraoperative complications in the AUS group (47% vs. 8%;  $p < 0.001$ ). The two  
294 intraoperative complications in the ACT® group were 1 bladder neck injury and 1  
295 vaginal injury. The 17 intraoperative complications in the AUS group were 10 bladder  
296 neck injuries and 7 vaginal injuries. The rates of post-operative complications (40%  
297 vs. 47.2%;  $p = 0.57$ ) and of major post-operative complications (8% vs. 19.4%;  
298  $p = 0.28$ ) did not differ significantly between both groups. There were two Clavien 3a  
299 complications in the ACT® group which were early vaginal erosions associated with  
300 a device infection which required explantation under local anesthesia in both cases.  
301 In the AUS group, seven Clavien 3b complications occurred; 5 device infections and  
302 two large erosions which required all an explantation of the AUS under general  
303 anesthesia. The last major complication in the AUS group was a device infection,  
304 which occurred after a change of a first sphincter that got infected and treated  
305 conservatively. It was almost always associated with a bladder neck injury during the  
306 procedure. No Clavien 4 or 5 complications occurred in both groups. After a mean  
307 follow-up of 44.3 months in the AUS group (vs 22.3 months in the ACT® group;  
308  $p = 0.02$ ) the explantation rate were similar in both groups (19.4% vs. 20%;  $p = 0.99$ ).  
309 All five explantations in the ACT® group were due to non-mechanical failure: It was  
310 due to device infection two cases, to symptoms worsening in two cases and in one  
311 case, ACT® were explanted before implantation of an AUS. Explantations in the AUS  
312 group were due to non-mechanical failure: Five were due to device infections; one to  
313 large vaginal erosion and one was explanted because of a bladder neck erosion.  
314 When a mechanical failure occurred, we managed the situation with a surgical  
315 revision and it has always been done successfully. Time-to-failure is shown in figure  
316 2 (12-months cumulative failure rate: 14% in the AUS group vs 22% in the ACT®  
317 group;  $p = 0.42$ ).

318

319 *Functional outcomes*

320

321 The mean number of inflations in the ACT® group was 2.9 per balloon and the mean  
322 final volume of each balloon was 3.4 ml. In the AUS group a 61-70 cm H<sub>2</sub>O pressure  
323 balloon was used in all except one case (71-80 cm H<sub>2</sub>O) and the median cuff size  
324 was 70 mm. The decrease in USP stress incontinence subscore was significantly  
325 greater in the AUS group (-7.6 vs. -3.2;  $p < 0.001$ ; supplementary figure 1) and so was  
326 the decrease in mean number of pads per 24h (- 4.6 vs. -2.3;  $p = 0.002$ ; see table 3).  
327 The Patient-Global Impression of Improvement (PGII) [14] was better in the AUS  
328 group (PGII=1: 61.1% vs. 12%;  $p < 0.001$ ) as was the rate of patients cured (71.4%  
329 vs. 21.7%;  $p < 0.001$ ). Five patients in the ACT® group required the use of clean-  
330 intermittent self-catheterization postoperatively, at least for some time, compared to  
331 only one in the AUS group (20% vs. 2.8%;  $p = 0.04$ ). Two of the five patients who  
332 experienced urinary retention in the ACT® group complained from this condition so  
333 their balloons were partly deflated and they recovered spontaneous voiding in both  
334 case.

335

336 *Subgroup of persistent/recurrent stress urinary incontinence after midurethral slings*

337

338 In this subgroup, no patients in the ACT® group had undergone previous pelvic  
339 radiation therapy. Mean age was similar in both groups (71.7 vs. 66.4;  $p = 0.23$ ; see  
340 table 4) and the maximum urethral closure pressure of patients who underwent an  
341 AUS or an ACT® implantations were comparable (24.9 vs. 26.4 cm H<sub>2</sub>O;  $p = 0.64$ ).  
342 The proportion of patients who had undergone a second midurethral sling did not

343 differ significantly between both groups (37.5% vs. 10%;  $p=0.21$ ). The rate of intra-  
344 operative complications remained higher in the AUS group (54.2% vs. 10%;  $p=0.02$ ).  
345 The rate of post-operative complications tended to be higher in the AUS group  
346 (54.2% vs. 20%;  $p=0.13$ ). The explantation rate did not differ significantly between  
347 the two groups (30% vs. 25%;  $p=0.99$ ). AUS outperformed ACT® in terms of  
348 functional outcomes with a higher cure rate (66.7% vs. 30%;  $p=0.04$ ) and a greater  
349 decrease in USP stress incontinence subscore (-8 vs. -5.3;  $p=0.003$ ).

350

351



352 **Discussion**

353 According to the International Consultation on Urological Diseases (ICUD), stress  
354 urinary incontinence would affect from 5 to 15% and up to 30% in women over 70-  
355 year old [15].. Two decades ago, the works of Ulmsten and DeLancey has changed  
356 the understanding of stress urinary incontinence by outlining the distinct role of  
357 urethral support and function of urethral muscles [16; 17]. This gave birth to the  
358 concept of intrinsic sphincter deficiency meaning an impaired sphincter functioning  
359 due to loss of elasticity and coaptation [18]. While most of stress urinary incontinence  
360 in female patients is mainly due to urethral hypermobility, the exact proportion of  
361 these women who suffer from some degree of intrinsic sphincter deficiency remain  
362 unknown [1]. The optimal management of women with stress urinary incontinence  
363 due to intrinsic sphincter deficiency is still a matter of debate. While the American  
364 Urological Association (AUA) 2017 guidelines [19] do not mention the role of AUS or  
365 ACT® in their treatment algorithm; the European Association of Urology (EAU) 2017  
366 guidelines consider that they might have a role but that secondary synthetic sling,  
367 colposuspension or autologous sling are first options for women with complicated  
368 stress urinary incontinence [20]. The French Association of Urology (AFU)  
369 recommends AUS as the gold-standard treatment for severe SUI due to intrinsic  
370 sphincter deficiency and ACT® as a possible alternative in these patients [21]. These  
371 heterogeneous recommendations may be explained by the paucity of data in the  
372 literature. To date, no study has compared fascial slings to AUS or ACT®. To our  
373 knowledge, the present series is one of the first to compare two different techniques  
374 of intrinsic sphincter deficiency management in female patients and the first to  
375 compare these two specific devices. In the present study, AUS implantation was  
376 associated with better functional outcomes than ACT® implantation in female

377 patients with stress urinary incontinence due to intrinsic sphincter deficiency but with  
378 higher intraoperative complications rate, longer operative time and prolonged length  
379 of stay.

380 The morbidity of AUS implantation was higher than the one of ACT®, despite  
381 comparable post-operative complications rate. The high morbidity of the AUS in  
382 female patients has often been assumed to be the key factor that has limited its  
383 widespread [4]. This high complication rate might be due to the technically  
384 challenging dissection of the bladder neck, located deep in the pelvis with an  
385 urethral-vaginal septum often difficult to open due to the amount of previous surgical  
386 procedures. In recent years, the use of a robotic approach has been proposed to  
387 facilitate AUS implantation in women [22]. In a preliminary report, robotic AUS  
388 implantation appeared to decrease post-operative complications rate, blood loss and  
389 length of stay with a trend towards lower intraoperative complications compared to  
390 the open approach. Hence, one may assume that the difference we observed in  
391 terms of morbidity between AUS and ACT® may be tempered with a purely robotic  
392 AUS cohort (our cohort included a mix of open, laparoscopic and robotic AUS  
393 implantation).

394

395 It is now widely accepted through the urogynecology community that rather than  
396 looking for an objective cure in every case, physicians should adapt their treatments  
397 to patient's expectation and profile [23]. Our results are of interest in that regard as  
398 AUS, by outperforming ACT® in terms of functional outcomes, might be an  
399 appropriate option for patients with intrinsic sphincter deficiency seeking for cure of  
400 their urinary incontinence. Conversely, with its fair safety profile despite older patients  
401 with more comorbidity and previous pelvic radiation therapy (20%), the ACT® could

402 be a reliable option for patients looking for improvement of their urinary incontinence.

403

404 Another point of interest of this study is that the ACT® was associated with an  
405 increased risk of urinary retention postoperatively. This finding emphasizes an  
406 important point of strength of the AUS, as it is the only therapy of stress urinary  
407 incontinence due to intrinsic sphincter deficiency increasing urethral pressure during  
408 storage while maintaining a low urethral resistance during voiding by opening the  
409 device cuff. Indeed, the mechanism of action of ACT® is similar to the one of other  
410 treatment options such as fascial slings or bulking agents, by creating a permanent  
411 (ie that cannot be relieved) external compression over the urethra to preserve  
412 continence [5]. Long-term data regarding the impact of this increase bladder outlet  
413 resistance on detrusor contractility are lacking [24] but by analogy to what is seen in  
414 men with long-lasting benign prostate obstruction, one could assume that this  
415 external compression treatment options (i.e. ACT®, bulking agent or fascial sling)  
416 may lead to detrusor underactivity in the long-term. The benefits of ACT over bulking  
417 agents or fascial slings in that regard is that the obstruction can be fully relieved, as  
418 outlined in our series, by deflating the balloons.

419

420 Our study had several limitations that should be emphasized. Firstly, its retrospective  
421 and nonrandomized design could have partly flawed our results, notably because of  
422 an obvious selection bias with patients' characteristics differing in both groups, which  
423 we aimed to balance by performing a subgroup analysis. Another limitation is the  
424 relatively small sample size of our series, which may lead to a lack of statistical  
425 power and which prevented to perform multivariate analyses. We reported the early  
426 experience of a medium volume center for the two techniques and our findings may

427 have differed if coming from a tertiary volume center with a larger experience in AUS  
428 and ACT® implantations. There is still no consensus regarding the definition of  
429 intrinsic sphincter deficiency and the one we used in this study could therefore be a  
430 matter of debate. The various approaches used in the AUS group (i.e. open,  
431 laparoscopic, robot-assisted) might have been a confounder when analysing  
432 perioperative outcomes. Despite these drawbacks, we believe that the comparative  
433 data we provide are of value while the optimal management of SUI due to intrinsic  
434 sphincter deficiency remains to be determined.

435

### 436 **Conclusion**

437 In the present series, the patients in the two groups differed significantly in age, ASA  
438 score, history of pelvic radiation therapy and history of previous midurethral sling,  
439 which might have biased our findings. AUS implantation was associated with better  
440 functional outcomes than the ACT® in female patients with stress urinary  
441 incontinence due to intrinsic sphincter deficiency but with higher intraoperative  
442 complications rate, longer operative time and length of stay. Post-operative  
443 complications and explantation rates were similar between both groups. Future  
444 prospective randomized trials are needed to better define treatment algorithms of  
445 female patients with stress urinary incontinence due to intrinsic sphincter deficiency.

446

447

448 **Abbreviations**

449 ACT : Adjustable Continence Therapy

450 AMS: American Medical System

451 ASA : American Society of Anesthesiologists

452 AUA : American Urological Association

453 AUS : Artificial Urinary Sphincter

454 EAU : European Association of Urology

455 ICIQ-SF: Internation Consultation on Incontinence Questionnaire Short Form

456 ICUD : International Consultation on Urological Diseases

457 PGII: Patient-Global Impression of Improvement

458 SUI : Stress Urinary Incontinence

459 USP : Urinary Symptoms Profile

460

461 **References**

462

463 1. Cour, F., L. Le Normand, J.-F. Lapray, J.-F. Hermieu, L. Peyrat, R. Yiou, L. Donon,  
464 L. Wagner, A. Vidart, and the French committee of female urology. “[Intrinsic  
465 sphincter deficiency and female urinary incontinence].” *Prog Urol* 25, no. 8 (June  
466 2015): 437–54. doi:10.1016/j.purol.2015.03.006.

467

468 2. Costa, Pierre, Gregoire Poinas, Kamel Ben Naoum, Khalid Bouzoubaa, Laurent  
469 Wagner, Laurent Soustelle, Michel Boukaram, and Stéphane Droupy. “Long-Term  
470 Results of Artificial Urinary Sphincter for Women with Type III Stress Urinary  
471 Incontinence.” *European Urology* 63, no. 4 (April 2013): 753–58.  
472 doi:10.1016/j.eururo.2012.03.008.

473

474 3. Lo, Tsia-Shu, Leng Boi Pue, Yiap Loong Tan, and Pei-Ying Wu. “Risk Factors for  
475 Failure of Repeat Midurethral Sling Surgery for Recurrent or Persistent Stress

476 Urinary Incontinence.” *International Urogynecology Journal* 27, no. 6 (June 2016):  
477 923–31. doi:10.1007/s00192-015-2912-5.

478

479 4. Chartier-Kastler, Emmanuel, Philip Van Kerrebroeck, Roberto Olanas, Michel  
480 Cosson, Eric Mandron, Emmanuel Delorme, and François Richard. “Artificial Urinary  
481 Sphincter (AMS 800) Implantation for Women with Intrinsic Sphincter Deficiency: A  
482 Technique for Insiders?” *BJU International* 107, no. 10 (May 2011): 1618–26.  
483 doi:10.1111/j.1464-410X.2010.09610.x.

484

485 5. Nadeau, Geneviève, and Sender Herschorn. “Management of Recurrent Stress  
486 Incontinence Following a Sling.” *Current Urology Reports* 15, no. 8 (August 2014):  
487 427. doi:10.1007/s11934-014-0427-0.

488

489 6. Vayleux, B., F. Luyckx, S. Thélu, J. Rigaud, O. Bouchot, G. Karam, and L. Le  
490 Normand. “[Adjustable Continence Therapy in women, middle term follow-up and a  
491 new technique for balloon positioning].” *Progres En Urologie: Journal De*  
492 *l’Association Francaise D’urologie Et De La Societe Francaise D’urologie* 20, no. 7  
493 (July 2010): 520–26. doi:10.1016/j.purol.2010.01.010.

494

495 7. Phé, Véronique, Kien Nguyen, Morgan Rouprêt, Vincent Cardot, Jérôme Parra,  
496 and Emmanuel Chartier-Kastler. “A Systematic Review of the Treatment for Female  
497 Stress Urinary Incontinence by ACT® Balloon Placement (Uromedica, Irvine, CA,  
498 USA).” *World Journal of Urology* 32, no. 2 (April 2014): 495–505.  
499 doi:10.1007/s00345-013-1117-0.

500

501 8. Kocjancic, Ervin, Simone Crivellaro, Stefania Ranzoni, Daniele Bonvini, Barbara  
502 Grosseti, and Bruno Frea. “Adjustable Continence Therapy for Severe Intrinsic  
503 Sphincter Deficiency and Recurrent Female Stress Urinary Incontinence: Long-Term  
504 Experience.” *The Journal of Urology* 184, no. 3 (September 2010): 1017–21.  
505 doi:10.1016/j.juro.2010.05.024.

506

507 9. Peyronnet, Benoit, Sébastien Vincendeau, Lauranne Tondut, Karim Bensalah,  
508 Mireille Damphousse, and Andréa Manunta. “Artificial Urinary Sphincter Implantation  
509 in Women with Stress Urinary Incontinence: Preliminary Comparison of Robot-

510 Assisted and Open Approaches.” *International Urogynecology Journal* 27, no. 3  
511 (March 1, 2016): 475–81. doi:10.1007/s00192-015-2858-7.

512

513 10. Haab, François, François Richard, Gérard Amarenco, Patrick Coloby, Benoit  
514 Arnould, Khadra Benmedjahed, Isabelle Guillemin, and Philippe Grise.  
515 “Comprehensive Evaluation of Bladder and Urethral Dysfunction Symptoms:  
516 Development and Psychometric Validation of the Urinary Symptom Profile (USP)  
517 Questionnaire.” *Urology* 71, no. 4 (April 2008): 646–56.  
518 doi:10.1016/j.urology.2007.11.100.

519

520 11. Avery, Kerry, Jenny Donovan, Tim J. Peters, Christine Shaw, Momokazu Gotoh,  
521 and Paul Abrams. “ICIQ: A Brief and Robust Measure for Evaluating the Symptoms  
522 and Impact of Urinary Incontinence.” *Neurourology and Urodynamics* 23, no. 4  
523 (2004): 322–30. doi:10.1002/nau.20041.

524

525 12. Dindo, Daniel, Nicolas Demartines, and Pierre-Alain Clavien. “Classification of  
526 Surgical Complications.” *Annals of Surgery* 240, no. 2 (August 2004): 205–13.  
527 doi:10.1097/01.sla.0000133083.54934.ae.

528

529 13. Mitropoulos, Dionysios, Walter Artibani, Markus Graefen, Mesut Remzi, Morgan  
530 Rouprêt, Michael Truss, and European Association of Urology Guidelines Panel.  
531 “Reporting and Grading of Complications after Urologic Surgical Procedures: An Ad  
532 Hoc EAU Guidelines Panel Assessment and Recommendations.” *European Urology*  
533 61, no. 2 (February 2012): 341–49. doi:10.1016/j.eururo.2011.10.033.

534

535 14. Yalcin, Ilker, and Richard C. Bump. “Validation of Two Global Impression  
536 Questionnaires for Incontinence.” *American Journal of Obstetrics and Gynecology*  
537 189, no. 1 (July 2003): 98–101.

538

539 15. *Incontinence*. Paul Abrams, Linda Cardozo, Saad Khoury, Alan Wein. 5th Edition  
540 2013. ISBN : 978-9953-493-21-3

541

- 542 16. DeLancey, John O. L. "The Pathophysiology of Stress Urinary Incontinence in  
543 Women and Its Implications for Surgical Treatment." *World Journal of Urology* 15, no.  
544 5 (October 1, 1997): 268–74. doi:10.1007/BF02202011.
- 545
- 546 17. Petros, Peter E. Papa, Ulf I. Ulmsten, and John Papadimitriou. "The Autogenic  
547 Ligament Procedure: A Technique for Planned Formation of an Artificial Neo-  
548 Ligament." *Acta Obstetricia et Gynecologica Scandinavica* 69, no. S153 (January 1,  
549 1990): 43–51. doi:10.1111/j.1600-0412.1990.tb08031.x.
- 550
- 551 18. McGuire, E. J. "Diagnosis and Treatment of Intrinsic Sphincter Deficiency."  
552 *International Journal of Urology: Official Journal of the Japanese Urological*  
553 *Association* 2 Suppl 1 (April 1995): 7–10; discussion 16–18.
- 554
- 555 19. AUA Guidelines. Kathleen C. Kobashi, MD, FACS, FPMRS; Michael E. Albo, MD;  
556 Roger R. Dmochowski, MD; David A. Ginsberg, MD; Howard B. Goldman, MD;  
557 Alexander Gomelsky, MD; Stephen R. Kraus, MD, FACS; Jaspreet S. Sandhu, MD;  
558 Tracy Shepler; Jonathan R. Treadwell, PhD; Sandip Vasavada, MD; Gary E.  
559 Lemack, MD. [http://www.auanet.org/guidelines/stress-urinary-incontinence-\(sui\)-new-](http://www.auanet.org/guidelines/stress-urinary-incontinence-(sui)-new-(aua/sufu-guideline-2017))  
560 [aua/sufu-guideline-2017\)](http://www.auanet.org/guidelines/stress-urinary-incontinence-(sui)-new-(aua/sufu-guideline-2017))
- 561
- 562 20. EAU guidelines. F.C. Burkhard (Chair), J.L.H.R. Bosch, F. Cruz, G.E. Lemack,  
563 A.K. Nambiar, N. Thiruchelvam, A. Tubaro Guidelines Associates: D. Ambühl, D.  
564 Bedretdinova, F. Farag, B.B. Rozenberg [https://uroweb.org/guideline/urinary-](https://uroweb.org/guideline/urinary-incontinence/)  
565 [incontinence/](https://uroweb.org/guideline/urinary-incontinence/)
- 566
- 567
- 568 21. Recommandations AFU - Prog Urol, 2010, 20, suppl. 2  
569 [http://www.urofrance.org/base-bibliographique/traitement-de-lincontinence-urinaire-](http://www.urofrance.org/base-bibliographique/traitement-de-lincontinence-urinaire-feminine-non-neurologique)  
570 [feminine-non-neurologique](http://www.urofrance.org/base-bibliographique/traitement-de-lincontinence-urinaire-feminine-non-neurologique)
- 571
- 572 22. Fournier, Georges, Pierre Callerot, Maxime Thoulouzan, Antoine Valeri, and  
573 Marie-Aimee Perrouin-Verbe. "Robotic-Assisted Laparoscopic Implantation of  
574 Artificial Urinary Sphincter in Women with Intrinsic Sphincter Deficiency Incontinence:



575 Initial Results.” *Urology* 84, no. 5 (November 2014): 1094–98.  
576 doi:10.1016/j.urology.2014.07.013.

577

578 23. Riss, Paul, and Julia Kargl. “Quality of Life and Urinary Incontinence in Women.”  
579 *Maturitas* 68, no. 2 (February 2011): 137–42. doi:10.1016/j.maturitas.2010.11.006.

580

581 24. Siddiqui, Zain A., Hamid Abboudi, Ruairidh Crawford, and Shahzad Shah.  
582 “Intraurethral Bulking Agents for the Management of Female Stress Urinary  
583 Incontinence: A Systematic Review.” *International Urogynecology Journal*, February  
584 21, 2017, 1–10. doi:10.1007/s00192-017-3278-7.

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Fig. 1 Study flow-chart

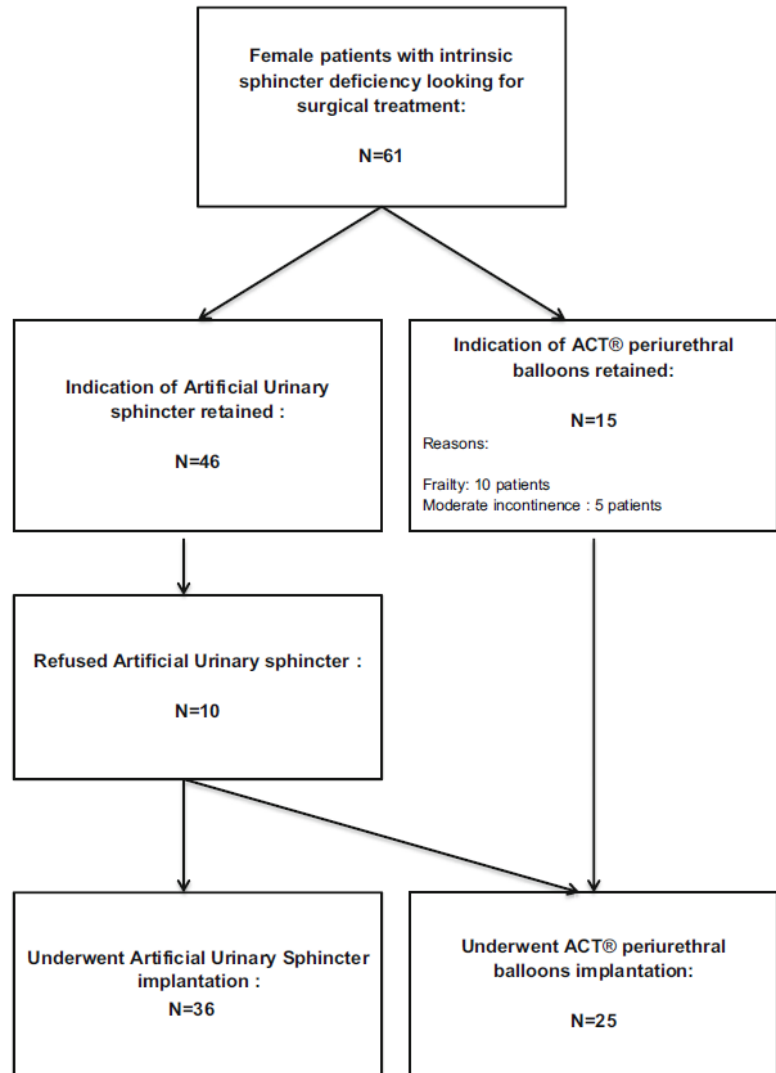
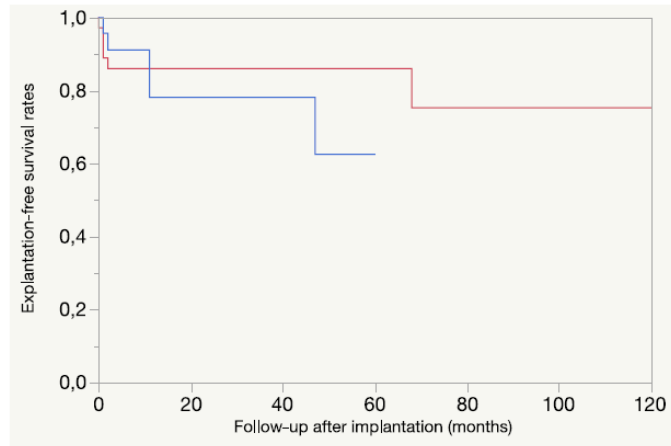


Fig. 2 Time to failure comparison



		20 months	40 months	60 months	80 months	100 months	120 months
ACT N= 25	Number at risk	11	6	3	0	0	0
	Number of failure	4	0	1	0	0	0
AUS N=36	Number at risk	24	17	11	6	3	3
	Number of failure*	5	0	0	1	0	0

— ACT®

— Artificial urinary sphincter

Log-rank test : p=0.42

\* 1 failure occurred at 126 months

**Table 1 : Patients' characteristics**

	<b>ACT® N=25</b>	<b>Artificial urinary sphincter N=36</b>	<b>p-value</b>
<b>Mean age (years)</b>	70.4 (± 3.1)	62.9 (± 2.5)	<b>0.03*</b>
<b>Body Mass Index (kg/m<sup>2</sup>)</b>	26.1 (± 1.4)	28.6 (± 3.1)	0.10
<b>ASA score</b> 1 2 3	0 (0%) 16 (66.7%) 8 (33.3%)	10 (30.3%) 19 (57.6%) 4 (12.1%)	<b>0.005*</b>
<b>History of pelvic radiation therapy</b>	5 (20%)	0 (0%)	<b>0.009*</b>
<b>History of any previous pelvic surgery</b>	19 (76%)	28 (77.8%)	0.87
<b>History of previous midurethral sling</b>	10 (40%)	24 (66.7%)	<b>0.04*</b>
<b>Neurogenic stress urinary incontinence</b>	1 (4%)	5 (13.9%)	0.39
<b>Maximum urethral closure pressure (cmH<sub>2</sub>O)</b>	28.8 (± 2.7)	27.3 (± 2.3)	0.61

**\* :statistically significant**

**Table 2 : Perioperative outcomes**

	<b>ACT® N=25</b>	<b>Artificial urinary sphincter N=36</b>	<b>p-value</b>
<b>Operative time (min)</b>	45.7 (± 7.7)	206.1 (± 7.7)	<b>&lt;0.001*</b>
<b>Length of hospital stay (days)</b>	1.7 (± 1)	7 (± 0.9)	<b>&lt;0.001*</b>
<b>Intra-operative complications</b>	2 (8%)	17 (47%)	<b>&lt;0.001*</b>
<b>Post-operative complications</b>	10 (40%)	17 (47.2%)	0.57
<b>Major post- operative complications (Clavien ≥ 3)</b>	2 (8%)	7 (19.4%)	0.28
<b>Explantation</b>	5 (20%)	7 (19.4%)	0.99

**\* : statistically significant**

**Table 3: Functional outcomes**

	<b>ACT® N=25</b>	<b>Artificial urinary sphincter N=36</b>	<b>p-value</b>
<b>Mean number of pads /24h</b> Preoperatively At 6 months	4.5 (± 0.3) 2.2 (± 0.3) <sup>1</sup>	5.2 (± 0.3) 0.6 (± 0.2) <sup>1</sup>	0.14 <b>0.002 *</b>
<b>PGII (6 months)</b> 1 : Very improved 2 : Improved 3 : Slightly improved 4 : Unchanged 5-7 : Woresened	3 (12%) 6 (24%) 8 (32%) 6 (24%) 2 (8%)	22 (61.1%) 5 (13.9%) 2 (5.6%) 6 (16.7%) 1 (2.8%)	<b>&lt;0.001*</b>
<b>Complete continence at 6 months</b>	5 (21.7%)	25 (71.4%)	<b>&lt;0.001*</b>
<b>USP stress incontinence sub-score (/9)</b> Preoperatively At 6 months	7.8 (± 0.5) 4.8 (± 0.7) <sup>1</sup>	8.4 (± 0.5) 0.3 (± 0.5) <sup>1</sup>	0.22 <b>&lt;0.001*</b>
<b>Median follow-up (months)</b>	11 [4-42.5]	37.5 [12.8-65.8]	<b>0.02 *</b>

\* :statistically significant

<sup>1</sup> : statistically significant change from baseline (p<0.05)

**Table 4: Subgroup of recurrent/persistent incontinence after midurethral slings**

	<b>ACT® N=10</b>	<b>Artificial urinary sphincter N=24</b>	<b>p-value</b>
<b>Mean age (years)</b>	71.7 (± 3.3)	66.4 (± 2.1)	0.23
<b>Maximum urethral closure pressure (cmH2O)</b>	24.9 (± 3.5)	26.4 (± 2.5)	0.64
<b>Intra-operative complications</b>	1 (10%)	13 (54.2%)	<b>0.02*</b>
<b>PGII (6 months)</b> 1 : Very improved 2 : Improved 3 : Slightly improved 4 : Unchanged 5-7 : Woresened	1 (10%) 3 (30%) 4 (40%) 1 (10%) 1 (10%)	15 (62.5%) 5 (20.8%) 2 (8.3%) 4 (16.7%) 1 (4.2%)	<b>0.02*</b>
<b>Complete continence at 6 months</b>	3 (33.3%)	16 (66.7%)	<b>0.04*</b>
<b>USP stress incontinence sub-score (/9)</b> <i>Preoperatively</i> <i>At 6 months</i>	7.8 (± 0.5) 3.5 (± 0.6) <sup>1</sup>	8.4 (± 0.5) 0.4 (± 0.5) <sup>1</sup>	0.22 <b>0.003*</b>
<b>Explantation</b>	3 (30%)	6 (25%)	0.99

\* :statistically significant

<sup>1</sup> : statistically significant change from baseline (p<0.05)