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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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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 H₂O), 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 International 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 χ^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 cmH₂O; $p=0.61$). 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 H₂O pressure
323 balloon was used in all except one case (71-80 cm H₂O) 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 H₂O; $p = 0.64$).
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

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462

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Fig. 1 Study flow-chart

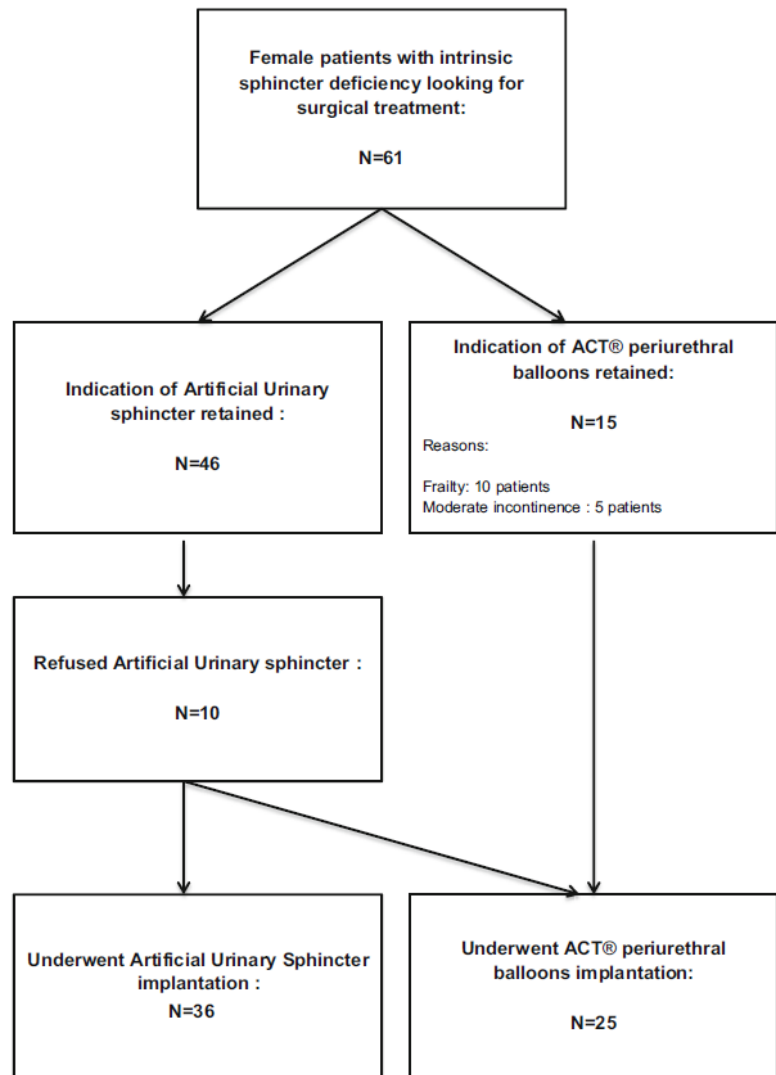
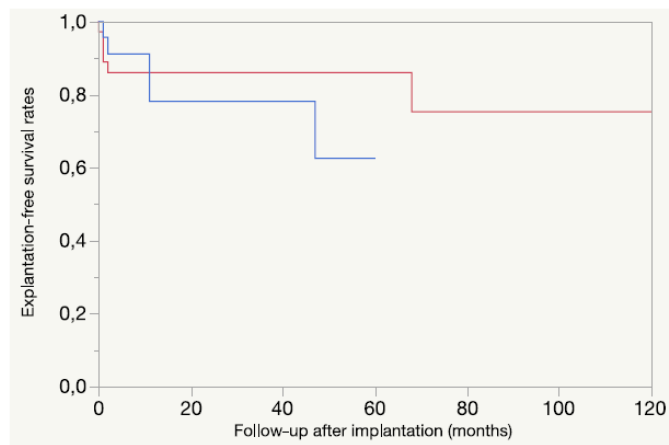


Fig. 2 Time to failure comparison



		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

	ACT® N=25	Artificial urinary sphincter N=36	p-value
Mean age (years)	70.4 (± 3.1)	62.9 (± 2.5)	0.03*
Body Mass Index (kg/m²)	26.1 (± 1.4)	28.6 (± 3.1)	0.10
ASA score 1 2 3	0 (0%) 16 (66.7%) 8 (33.3%)	10 (30.3%) 19 (57.6%) 4 (12.1%)	0.005*
History of pelvic radiation therapy	5 (20%)	0 (0%)	0.009*
History of any previous pelvic surgery	19 (76%)	28 (77.8%)	0.87
History of previous midurethral sling	10 (40%)	24 (66.7%)	0.04*
Neurogenic stress urinary incontinence	1 (4%)	5 (13.9%)	0.39
Maximum urethral closure pressure (cmH₂O)	28.8 (± 2.7)	27.3 (± 2.3)	0.61

* :statistically significant

Table 2 : Perioperative outcomes

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

*** : statistically significant**

Table 3: Functional outcomes

	ACT® N=25	Artificial urinary sphincter N=36	p-value
Mean number of pads /24h Preoperatively At 6 months	4.5 (± 0.3) 2.2 (± 0.3) ¹	5.2 (± 0.3) 0.6 (± 0.2) ¹	0.14 0.002 *
PGII (6 months) 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%)	<0.001*
Complete continence at 6 months	5 (21.7%)	25 (71.4%)	<0.001*
USP stress incontinence sub-score (/9) Preoperatively At 6 months	7.8 (± 0.5) 4.8 (± 0.7) ¹	8.4 (± 0.5) 0.3 (± 0.5) ¹	0.22 <0.001*
Median follow-up (months)	11 [4-42.5]	37.5 [12.8-65.8]	0.02 *

* :statistically significant

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

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

	ACT® N=10	Artificial urinary sphincter N=24	p-value
Mean age (years)	71.7 (± 3.3)	66.4 (± 2.1)	0.23
Maximum urethral closure pressure (cmH2O)	24.9 (± 3.5)	26.4 (± 2.5)	0.64
Intra-operative complications	1 (10%)	13 (54.2%)	0.02*
PGII (6 months) 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%)	0.02*
Complete continence at 6 months	3 (33.3%)	16 (66.7%)	0.04*
USP stress incontinence sub-score (/9) <i>Preoperatively</i> <i>At 6 months</i>	7.8 (± 0.5) 3.5 (± 0.6) ¹	8.4 (± 0.5) 0.4 (± 0.5) ¹	0.22 0.003*
Explantation	3 (30%)	6 (25%)	0.99

* :statistically significant

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