



Surgery in Motion

Robot-assisted AMS-800 Artificial Urinary Sphincter Bladder Neck Implantation in Female Patients with Stress Urinary Incontinence

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Abstract

Background: Widespread adoption of the AMS-800 artificial urinary sphincter (AUS) in female patients has been hampered by the surgical morbidity of its implantation through an open approach.

Objective: To describe a standardized technique of robotic bladder neck AUS implantation in female patients, and to report the perioperative and functional outcomes obtained by multiple surgeons with this technique.

Design, settings, and participants: We retrospectively reviewed the charts of all female patients who underwent robotic AUS implantation for urinary incontinence due to intrinsic sphincter deficiency between March 2012 and March 2017 in five institutions. Most of the 10 surgeons involved were not highly experienced in female AUS implantation and/or in robotic surgery.

Surgical procedure: The AUS is implanted at the bladder neck through a transperitoneal robotic approach. The finger placed by the assistant surgeon in the vagina is paramount to expose the vesicovaginal space and guide the robotic surgeon throughout the bladder neck dissection.

Measurements: The primary endpoint was the incontinence categorized as complete continence (ie, no pads used), improved incontinence, or unchanged incontinence.

Results and limitations: Forty-nine female patients underwent a robotic AUS implantation. There were eight intraoperative complications (16.3%): five bladder neck injuries and three vaginal injuries. Nine patients experienced postoperative complications (18.3%), but only two were Clavien ≥ 3 (4.1%). After a median follow-up of 18.5 mo, one explantation (vaginal erosion, 2.1%) and three revisions (one mechanical and two nonmechanical failure, 6.1%) were needed. At last follow-up, 40 patients were fully continent (81.6%), six had improved incontinence (12.2%), and three had unchanged incontinence (6.1%).

Conclusions: In this first multicenter series of robot-assisted AUS implantation, our technique appeared feasible, safe, and reproducible with perioperative and functional outcomes in the early learning curve not inferior to those reported in large series of open AUS implantation from tertiary referral centers.

Patient summary: Robot-assisted bladder neck AMS-800 artificial urinary sphincter implantation in female patients with stress urinary incontinence resulting from intrinsic sphincter deficiency is feasible, safe, and reproducible with promising outcomes.

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1. Introduction

While AMS-800 artificial urinary sphincter (AUS) implantation is unanimously recognized as the gold-standard surgical treatment in male patients with severe stress urinary incontinence (SUI) resulting from intrinsic sphincter deficiency (ISD) [1,2], its use in female patients remains very limited in most countries, where pubovaginal slings or bulking agents are favored in these patients [3,4]. Despite good functional outcomes and patient satisfaction rates, AUS has not been used widely in female patients due to the technical difficulty of its implantation via an open retropubic approach and high inherent morbidity [3,5]. A laparoscopic approach has been described in the late 2000s with promising preliminary results in experienced hands [6,7]. More recently, Fournier et al [8] reported their early experience with a robotic approach for female AUS implantation, which may combine minimal invasiveness and lower technical complexity compared with the laparoscopic route. However, reproducibility of robotic AUS implantation in women by multiple surgeons and over consecutive cases has never been assessed so far. The aims of the present study were to describe a standardized technique of robotic bladder neck AUS implantation in female patients, and report the perioperative and functional outcomes obtained by multiple surgeons with this technique.

2. Patients and methods

2.1. Study population

After institutional review board approval, we retrospectively reviewed the charts of all female patients who underwent robotic AUS implantation using a standardized technique between March 2012 and March 2017 (to ensure a minimum 1-yr follow-up) in five institutions. The indication for AUS implantation was type III SUI and ISD defined as a combination of low urethral closure pressure, loss of urethral mobility, and a negative Marshall/Bonney test. The robot-assisted approach was the only approach used for AUS implantation in women during the study period in the five institutions involved. The primary endpoint was the continence status postoperatively categorized as complete continence (ie, no pads used), improved incontinence, or unchanged incontinence.

2.2. Surgical technique

The procedure is performed by two surgeons: a surgeon at the console and another surgeon (or a surgeon in training in some cases) to provide assistance on the surgical field.

2.2.1. Patient positioning, port placement, and robot docking

The patient is placed in a 23° Trendelenburg position. The procedure is performed using a transperitoneal approach with a 0° lens. Five ports are placed (Fig. 1): one 12-mm camera port at the umbilicus, three 8-mm robotic ports (one in the right flank, and two at the lateral edge of right and left rectus abdominis muscles), and an additional 12-mm port in the left flank for the assistant. A minimum of 7 cm space is maintained between each port. The four-arm Da Vinci Si robot is placed in a right-side docking position (Fig. 2). Only three robotic instruments are used for the whole procedure: a bipolar Prograsp forceps in the left robotic arm, scissors in the internal right robotic arm, and a regular Prograsp forceps in the external right robotic arm.

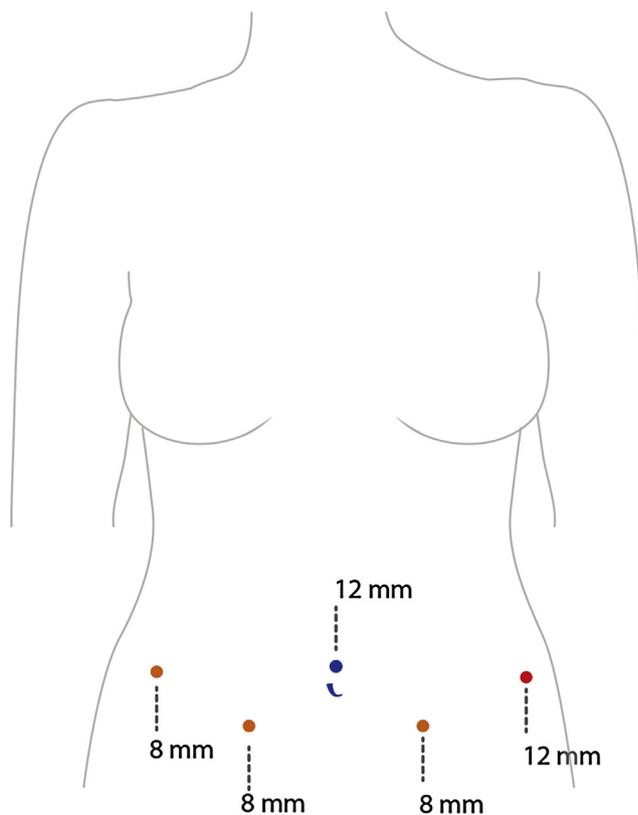


Fig. 1 – Port placement.

2.2.2. Access to the bladder neck

A 14 Fr urethral catheter is inserted and the bladder is filled with 100–300 ml of saline to identify its boundaries. The bladder is dropped down from the abdominal wall, and the Retzius space is dissected until the bladder neck and the endopelvic fascia are individualized. Before starting the dissection of the vesicovaginal space, it is paramount to locate accurately the bladder neck, as in this technique the AUS cuff will be inserted around the bladder neck and not at the level of the urethra. The bladder neck is larger than the urethra, and its wall is thicker allowing the use of a larger cuff, minimizing the risk of erosion. The bladder neck contours are identified thanks to the saline instilled in the bladder, and if needed the catheter balloon can also be gently moved back and forth by the assistant.

2.2.3. Vesicovaginal dissection

Once the space of Retzius has been dissected down to the endopelvic fascia, the assistant surgeon places one finger in the vagina (Fig. 3). This is a key point of this technique. The assistant finger is placed in one of the lateral fornix in order to push it upward and laterally, toward the ipsilateral shoulder. It allows start of the dissection of the vesicovaginal plane “on” the tip of the assistant’s finger, laterally, away from the bladder neck, minimizing the risk of bladder neck injury. The additional benefit of pushing the vaginal fornix laterally is that, after the dissection has been sufficiently initiated, it enables direct vision of the vesicovaginal space posterior to the bladder neck. The plane is initiated with cold scissors. In our early cases, we incised the endopelvic fascia to open it; however, we realized that if the fascia is sufficiently stretched by the assistant finger, it can be opened simply by gently spreading it with the edge of the scissors. This allows to perform a purely blunt dissection of the bladder neck (ie, no incision by electrocautery is used at any point during this step) to minimize the risk of bladder neck or vaginal injury. While performing these subtle moves with the scissors, the perivesical

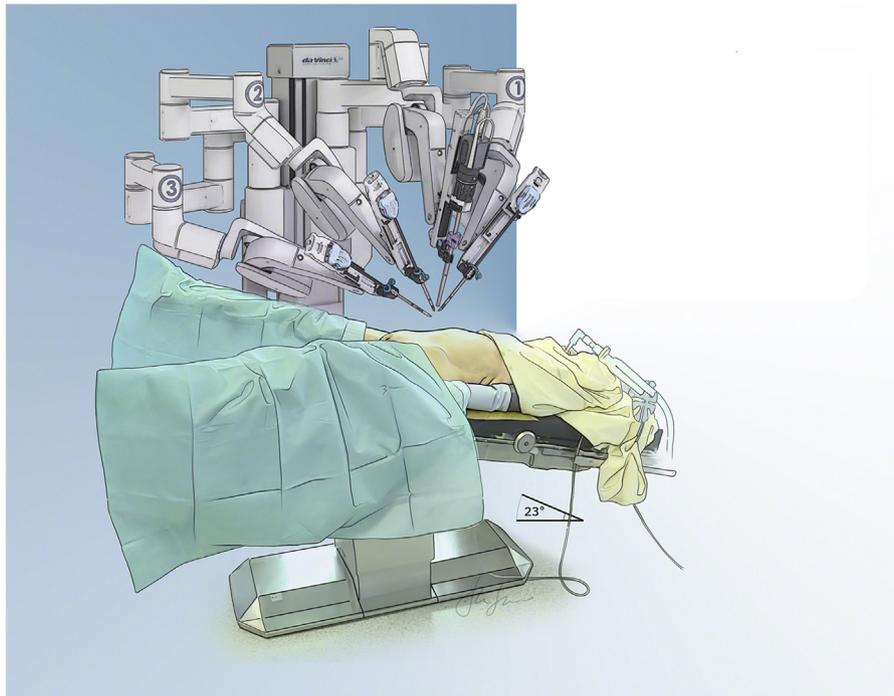


Fig. 2 – Patient positioning and robot docking. The robot is placed tangentially to the patient right leg, oriented toward the pelvis.

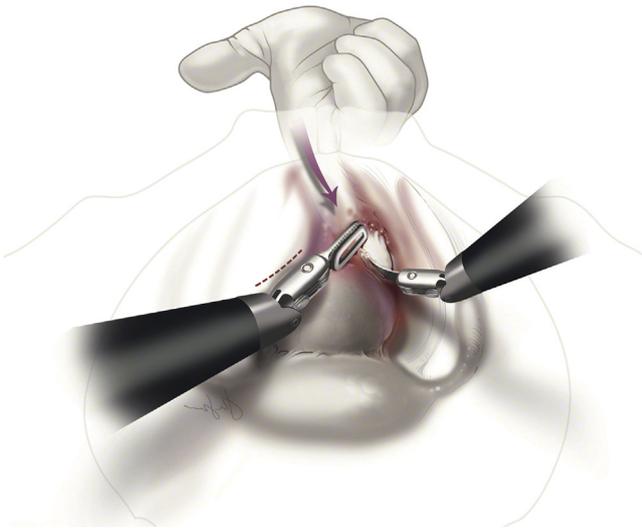


Fig. 3 – Positioning of the assistant finger in the vagina to help in the dissection. The assistant finger is placed in one of the lateral vaginal cul-de-sac, pushing it upward and laterally, toward the ipsilateral shoulder (purple arrow). It is usually helpful to bend the finger slightly (especially if the assistant has long fingers) to push just behind the pubic bone, and not too deeply in the pelvis to make sure that the tip of the finger is at the level of the catheter balloon/bladder neck, in the spot where the dissection of the vesicovaginal space must be started.

fascia is entered and the vaginal wall appears progressively as a shiny white plane (called in France the bald plane, as it looks like a bald head). This is the plane where the dissection around the bladder neck has to be carried out. The breach in the endopelvic fascia is extended cranially and caudally, by cutting with the scissors parallel to the vaginal wall, to avoid traction on the bladder neck and vaginal wall during the dissection and to allow the assistant finger to push more thoroughly. Using the edge of

the scissors, all the small fibers of the endopelvic and perivesical fascia are reclined medially, carrying on the dissection of the white shiny vaginal wall (the “bald” plane). Once the plane has been developed sufficiently, dissection is pursued behind the bladder neck using the Prograsp forceps, “sliding” on the assistant finger while gently opening the blades tangentially to the bladder neck and vaginal walls to separate them (Fig. 4). Once the median line has been reached, the same maneuvers are performed on the other side of the bladder neck. The two dissected spaces are thus joined, with often a remaining “veil” of perivesical fascia to be opened on the tip of the Prograsp forceps after the assistant surgeon has ensured with his/her finger that the vaginal wall is intact and has not been pinched by the tip of the Prograsp forceps (Fig. 5). At the end of the dissection, the bladder is filled with methylene blue to verify the integrity of the bladder neck.

The bladder dome was intentionally opened only in a few cases when the vesicovaginal dissection was felt very challenging, to allow monitoring of the dissection from inside the bladder [9], reducing the risk of bladder neck injury.

2.2.4. Cuff and balloon placement

The bladder neck circumference is measured using a measuring tape introduced through the 12-mm port. The cuff is then introduced through the same 12-mm port and positioned around the bladder neck. The device is manipulated cautiously to avoid any damage. The 61–70 cmH₂O pressure regulating balloon is implanted in the prevesical space via a 3-cm suprapubic incision and filled with saline. The peritoneum is then closed with barbed suture.

2.2.5. Pump placement and connections

The pump is implanted in one of the labia majora by creating a subcutaneous passage starting from the short suprapubic incision used to introduce the balloon and using a long instrument (eg, scissors or Kelly clamp). The connections are made through the suprapubic incision. The incisions are closed. At the end of the procedure, the device is deactivated.

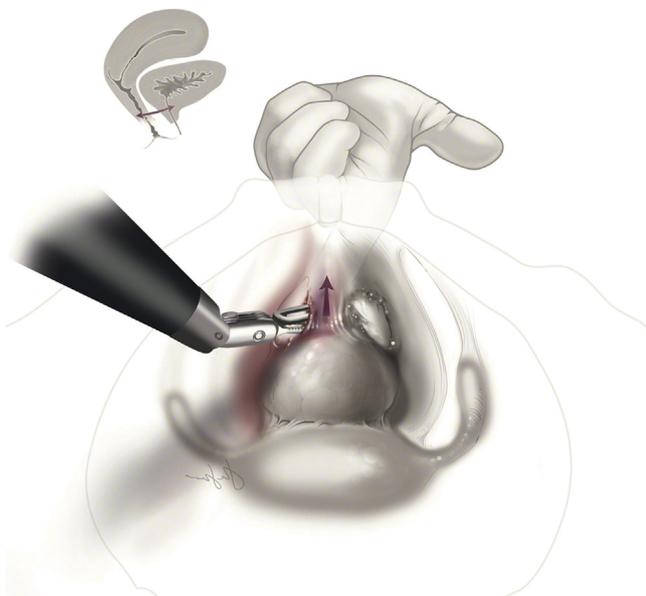


Fig. 4 – Using the Prograsp forceps to end the dissection of the posterior part of the bladder neck. Once the plane has been developed sufficiently, dissection is pursued behind the bladder neck using the Prograsp forceps, “sliding” on the assistant finger while gently opening the blades perpendicularly to the bladder neck and vaginal walls to separate them (red arrow).

2.3. Postoperative management

The bladder catheter is removed on postoperative day 1, except in case of intraoperative bladder neck injury or when the bladder dome had been opened intentionally, where the catheter is left in place for 7–10 d. The patient is discharged after 1–3 d according to surgeon's/institution's habits. The AUS is activated 6 wk after the implantation in the outpatient clinic, and the patient is taught to manipulate the artificial sphincter. For follow-up, the patient is seen in outpatient clinics 4–6 wk after the

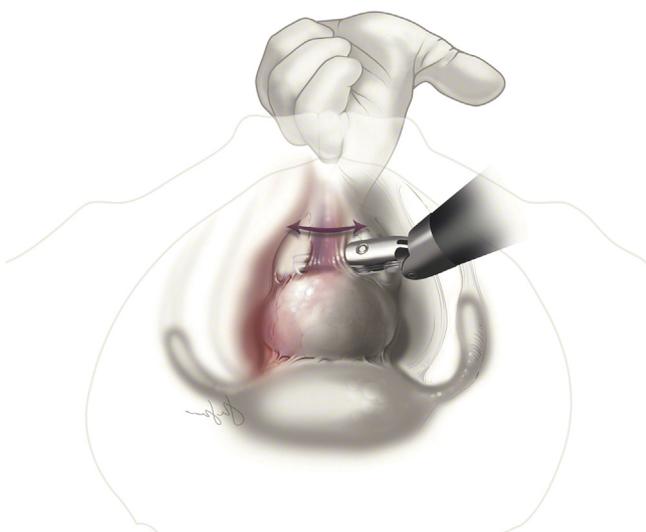


Fig. 5 – Passage behind the bladder neck with the Prograsp forceps completed. The two dissected vesicovaginal spaces dissected are joined, with often a remaining “veil” of perivesical fascia to be opened on the tip of the Prograsp forceps after the assistant surgeon has ensured with his/her finger that the vaginal wall is intact (purple arrow) and has not been “pinched” by the tip of the Prograsp forceps.

activation, at 6 mo, at 1 yr, and then yearly, with no time limit. The follow-up visits involve a clinical interview, a physical examination, an uroflowmetry, and a postvoid residual. Proper use of the device is also checked at each visit.

2.4. Surgeons' experience

Ten surgeons were involved in the robotic part of the procedures reported above. The pioneering surgeon had performed 20 female AUS implantations (either open or laparoscopic) and over 200 robotic procedures (mostly robot-assisted radical prostatectomy [RARP]) at the beginning of the study period. A second surgeon had an experience of 10 open female AUS implantations and over 100 robotic procedures (RARP). Two other surgeons had performed over 200 robotic procedures (RARP) but had no experience with female AUS. The six remaining surgeons had no experience with female AUS implantations, regardless of the approach, and had performed <50 robotic procedures when they performed their first robotic female AUS implantation. In summary, none of the 10 surgeons had performed any robotic AUS implantation and the cases reported herein depict their learning curves.

2.5. Statistical analysis

Means and standard deviations were reported for continuous variables, and proportions for nominal variables. Revision-free survival and explantation-free survival were estimated using a Kaplan-Meier analysis. Statistical analyses were performed using JMP v.12.0 software (SAS Institute Inc., Cary, NC, USA). All the data were reported for the intent-to-treat population (ie, all patients for whom an implantation has been attempted).

3. Results

3.1. Patients characteristics

Forty-nine female patients underwent a robotic AUS implantation by 10 surgeons during the study period (one to 14 procedures/surgeon). The patients' characteristics are summarized in Table 1. The median age was 70.5 yr, and the vast majority of the patients had a history of at least one failed midurethral sling (median = 2). In five patients (10.2%), ISD resulted from an underlying neurological condition (three cauda equina syndrome, one spina bifida, and one spinal cord injury). All these patients were self-catheterizing, and four of them were wheelchair bound. Four patients underwent a concomitant robot-assisted sacrocolpopexy. In these cases, the technique used for AUS implantation was the same and the procedures were staged: sacrocolpopexy as a first step and then AUS implantation.

3.2. Perioperative outcomes

Perioperative outcomes are summarized in Table 2. The bladder dome was opened in 11 procedures in total, mostly during the early cases. The median operative time was 180 min and the median length of hospital stay was 4 d. The mean estimated blood loss was 17.7 (± 49.1) ml. There were eight intraoperative complications (16.3%): five bladder neck injuries and three vaginal injuries. The implantation was completed in all cases (no procedure was stopped due

Table 1 – Patient characteristics

N = 49	
Median age (yr)	70.5 (28–86)
Body mass index (kg/m ²)	27.5 (±4.6)
ASA score	
1	8 (16.3%)
2	31 (63.3%)
3	10 (20.4%)
History of previous anti-incontinence surgery	42 (85.7%)
History of previous midurethral sling	39 (79.6%)
Median preoperative urethral closure pressure (cmH ₂ O)	20 (8–45)
History of pelvic radiation therapy	0 (0%)

ASA = American Society of Anesthesiologists.

to these intraoperative complications). Nine patients experienced postoperative complications within 90 postoperative days (18.3%), but only two were Clavien ≥3 (4.1%): one AUS explantation due to vaginal erosion in a patient with intraoperative vaginal injury and one reoperation for fever and suspicion of device infection, managed by sampling and culture of intraperitoneal fluid and adapted antibiotic therapy for 14 d. The other 90-d complications were four Clavien grade 1 complications (two acute urinary retention, one chronic urinary retention, and one hematoma of the labia majora) and three Clavien grade 2 complications (three urinary tract infections).

3.3. Functional outcomes

After a median follow-up of 18.5 mo, there was no other explantation of the AUS device and the total explantation rate was thus 2% (one out of 49 patients). As mentioned earlier, this explantation was due to early vaginal erosion. Three revisions were performed: one for mechanical failure at 35 mo, one for bladder neck atrophy at 22 mo, and one at 6 mo for difficulty in handling the pump that was too proximal in the labia majora. The revision- and explantation-free survival curves are presented in Fig. 6A and B, respectively. At 3 mo, 40 patients were fully continent (81.6%), six had improved incontinence (12.2%), and three had unchanged incontinence (6.1%). These outcomes were maintained at the latest follow-up. Two female patients had their AUS permanently deactivated because of difficulties handling the pump (in spite of the deactivation, one patient

Table 2 – Perioperative outcomes

N = 49	
Median AUS cuff size (mm)	70 (50–90)
Median operative time (min)	180 (120–300)
Median length of hospital stay (d)	4 (2–9)
Intraoperative complications	8 (16.3%)
Bladder neck injury	5
Vaginal injury	3
Postoperative complications	9 (18.3%)
Clavien 1	4
Clavien 2	3
Clavien 3b	2

AUS = artificial urinary sphincter.

was improved). Three patients developed de novo overactive bladder symptoms in the long run, two managed with intradetrusor botulinum toxin injections, and one managed with posterior tibial nerve stimulation (Table 3).

4. Discussion

The present report suggests that the technique of robot-assisted female AUS implantation described above is feasible, safe, and reproducible. It appeared to be less technically challenging than open AUS implantation; this might help decrease surgical morbidity and could contribute to a wider use of this therapeutic option in women with SUI from ISD. Several assets of the robotic approach may explain the promising outcomes that we observed. First, the bladder neck is located deep into the pelvis and is easier to access with a camera and laparoscopic or robotic instruments than through an open approach. The pneumoperitoneum minimizes bleeding and improves vision. The specific benefits of the robotic approach over the laparoscopic approach are the enhanced dexterity with the Endowrist technology allowing three-dimensional (3D) mobility of the instruments, magnified 3D image, physiological tremor filtering, and motion scaling [10,11], all of which are particularly helpful for the dissection of the

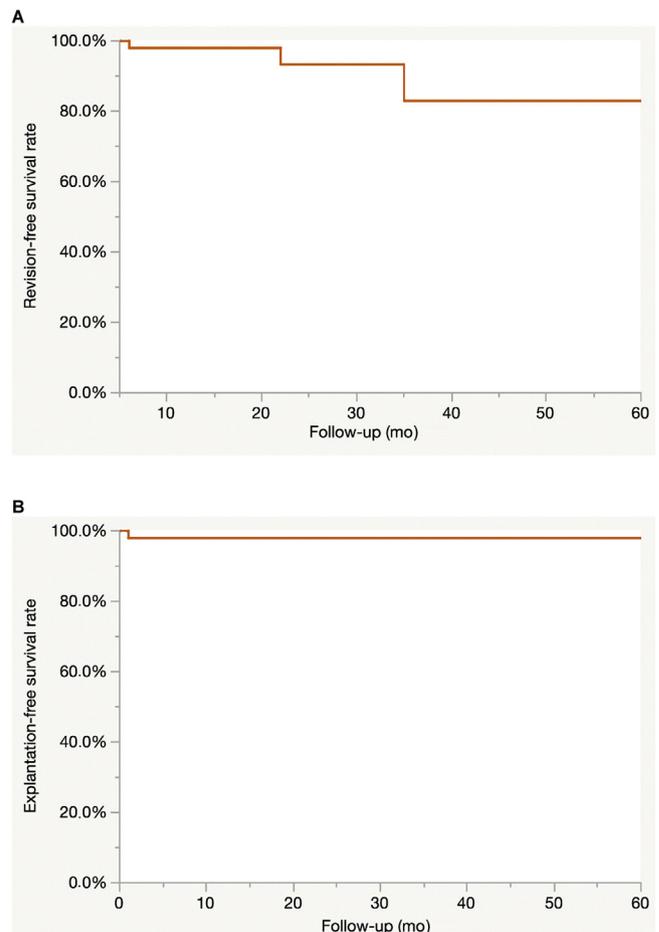


Fig. 6 – Device survival. (A) Revision-free survival. (B) Explantation-free survival.

Table 3 – Functional outcomes

N = 49	
Median follow-up (mo)	18.5 (12–64)
Explantation	1 (2%)
Revision	3 (6.1%)
Functional outcomes	
Cured	40 (81.6%)
Improved	6 (12.2%)
Unchanged	3 (6.1%)
De novo overactive bladder symptoms	3 (6.1%)
Sphincter deactivated permanently due to difficulties in handling the pump	2 (4.1%)

bladder neck, and also for accurate repair of any vaginal or bladder neck injury.

Our technique has slight but noticeable differences from the one described by Biarreau et al [12] in the *Platinum Journal* 3 yr ago. First, our dissection was conducted at the bladder neck rather than at the urethra level, the later being associated with two important caveats: smaller cuffs size and thinner tissue below the cuff, both resulting in an increased theoretical risk of erosion. Another significant difference is that in the technique described by Biarreau et al [12]: the assistant finger in the vagina was not used to push the lateral fornix upward and laterally on either side of the bladder neck. This allows initiation of the dissection of the vesicovaginal plane laterally, away from the bladder neck, and enables direct vision of the space posterior to the bladder neck, facilitating a blunt dissection, thereby minimizing the risk of bladder neck and vaginal injury. The last difference between the two techniques is related to port placement, with no use of 5-mm suprapubic port in our technique. We believe that all these differences could explain the more favorable outcomes obtained with our technique.

Another important key factor explaining the promising outcomes obtained in this series is the collaborative work and great communication between the surgeons involved in this technique. This has certainly allowed shortening of the learning curve, a crucial factor given the facts that the surgeons involved had overall little experience with robotic surgery and AUS implantations, and that none of them had performed any robotic AUS implantation. Hence, the cases reported herein depict their learning curves with robotic AUS implantation. After the start of the procedure by the pioneering surgeon, the other surgeons participating in this work reproduced the pioneering surgeon's technique and kept sharing on a regular basis their mutual experience, and the tips and tricks used to overcome the technical difficulties they faced.

There are considerable discrepancies in the role and use of AUS in female patients from one country to another [13]. While it is considered as the gold-standard treatment in women with SUI resulting from ISD in France [14], AUS should only be regarded as a treatment option of last resort according to the European Association of Urology guidelines

[1] and is not even mentioned as an option in the recent American Association of Urology guidelines [15]. The technically demanding implantation through an open approach (and inherent high rate of complications) has certainly been a significant barrier to the widespread adoption of female AUS by the urological community [5], which might be overcome by the robotic approach allowing easier dissection of the bladder neck and better standardization of the technique. Other drawbacks might have contributed to the limited use of AUS in female patients compared with male patients in many countries. There is a clear lack of high-level evidence studies supporting the use of AUS in female patients compared with other synthetic materials, such as midurethral slings [5,16]. Difficulties in handling the device pump are also more commonly encountered in female than in male patients; newer versions of the AUS, possibly electromechanical and without a pump [17,18], may contribute to the diffusion of AUS implantation in female patients in the future.

The present report has several limitations that should be acknowledged. First, it has numerous biases inherent to its retrospective design. The lack of a control group did not allow a proper assessment of the value of robotic female AUS implantation compared with the open or laparoscopic approaches or other therapeutic options (eg, pubovaginal sling, bulking agents, etc.). The relatively small sample size is another shortcoming of the present series. Last, opening of the bladder dome performed in challenging cases has introduced significant, although isolated, heterogeneity in the technique used, but was part of a “patient's first” policy and has certainly contributed to the safe development of this new surgical technique. Opening of the bladder dome was felt less and less necessary with increasing experience.

5. Conclusions

This report describes in detail a technique of robot-assisted bladder neck AUS implantation in female patients and is the first multicenter series assessing the outcomes of this technique. Despite a limited number of cases performed per surgeon, perioperative and functional outcomes in the early learning curve appeared at least similar to those reported in large series of open AUS implantation from tertiary referral centers. Our findings suggest that this technique is feasible and reproducible by surgeons with various levels of surgical expertise. Further data are needed to confirm the findings of the present report.

Author contributions: Benoit Peyronnet had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Peyronnet, Fournier, Capon, O. Belas, Descazeaud, Manunta.

Acquisition of data: Peyronnet, Allenet, Callerot, Calves, Hascoet, M. Belas. **Analysis and interpretation of data:** Peyronnet, Fournier, Capon, Manunta, Descazeaud, Robert.

Drafting of the manuscript: Peyronnet, Fournier, Capon, Manunta, Descazeaud, Robert.

Critical revision of the manuscript for important intellectual content: M. Belas, O. Belas, Allenet, Callerot, Hascoet, Calves.

Statistical analysis: Peyronnet.

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Supervision: Fournier.

Other: None.

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