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Comparative Outcomes of Robot-Assisted and Open Artificial Urinary Sphincter Implantation in Female Stress Urinary Incontinence

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Abstract

The artificial urinary sphincter represents an effective therapeutic option for stress urinary incontinence resulting from intrinsic sphincter deficiency among women. Nevertheless, adoption of this device remains restricted due to technical challenges and potential risks associated with traditional open surgical implantation. Early investigations using robotic methods have yielded encouraging results; however, only one limited-scale study has directly compared robotic and open techniques. The current investigation seeks to evaluate the outcomes of robotic versus open artificial urinary sphincter placement in women with stress urinary incontinence secondary to intrinsic sphincter deficiency, using a broad, multicenter patient population. Information was retrospectively collected on female patients who underwent either open or robot-assisted implantation of an artificial urinary sphincter between 2006 and 2020 at 12 urology centers. The main endpoint was the frequency of complications within 30 days postoperatively, classified according to the Clavien-Dindo system. Perioperative variables and functional results were contrasted between the robotic and open cohorts. Overall, 135 patients were analyzed, comprising 71 in the robotic cohort and 64 in the open cohort. The open surgery group had higher intraoperative (27.4% vs. 12.7%; P = 0.03) and postoperative (46.8% vs. 15.5%; P < 0.0001) complication rates. A greater proportion of patients in the robotic group attained complete continence (83.3% vs. 62.3%; P = 0.01). Furthermore, the open group demonstrated significantly higher device explantation rates (27.4% vs. 1.4%; P < 0.0001) and revision rates (17.5% vs. 5.6%; P = 0.02). The projected 1-year explantation-free survival was superior in the robotic group (98.6% vs. 78.3%; P = 0.001). Robot-assisted implantation appears to decrease perioperative complications and enhance functional success relative to conventional open implantation in women suffering from stress urinary incontinence.

Keywords: Artificial urinary sphincter, Female, Stress urinary incontinence, Intrinsic sphincter deficiency, Robotic, Robot-assisted

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Introduction

Female stress urinary incontinence (SUI) constitutes a common condition that substantially impairs the quality of life of those affected [1-3]. Outlet resistance in women depends primarily on two distinct mechanisms: the intrinsic urinary sphincters (internal mechanism) and the supportive structures, including the urethral hammock (external mechanism) [4, 5]. Consequently, female SUI arises mainly from two pathophysiological factors:

urethral hypermobility due to extrinsic mechanism failure and intrinsic sphincter deficiency (ISD) resulting from intrinsic mechanism impairment. Intrinsic sphincter deficiency is predominantly observed in individuals who have not responded to prior anti-incontinence surgeries, as well as in particular groups such as elderly, irradiated, or neurogenic patients [6, 7]. Although the artificial urinary sphincter (AUS) has proven to be an efficacious intervention for female SUI linked to ISD, its application has historically been constrained by the technical demands and associated complications of the open surgical approach [8, 9].

Initial research has demonstrated the feasibility and favorable results of employing robotic techniques for AUS implantation in women with ISD-related SUI [10, 11]. Nevertheless, thus far only a single small-scale, single-center investigation has attempted to directly compare outcomes between robotic and open AUS implantation in this population [12]. Accordingly, the objective of the present multicenter study was to assess the comparative outcomes of robotic versus open AUS implantation among women presenting with ISD-dominant stress urinary incontinence.

Materials and Methods

Study design

This retrospective analysis included data from all female patients who underwent either open or robot-assisted implantation of an artificial urinary sphincter for stress urinary incontinence due to intrinsic sphincter deficiency between 2006 and 2020 at 12 specialized urology units. The artificial urinary sphincter was proposed as a treatment choice for all women diagnosed with ISD-related SUI based on a positive cough stress test combined with a fixed or minimally mobile urethra during clinical assessment. All such patients underwent urodynamic evaluation, in which a reduced maximum urethral closure pressure (MUP) served as supporting evidence for ISD [13]. Other therapeutic alternatives presented to these patients included repeat synthetic midurethral sling (MUS) placement, periurethral adjustable continence therapy (ACT) using silicone balloons, or injectable bulking agents, in accordance with national recommendations [14]. Certain participating departments employed an open surgical technique solely for AUS implantation, while others transitioned from open to robotic methods during 2013, 2014, or 2015. Following the adoption of the robotic technique, those departments discontinued open implantations entirely.

At the outset of the study, surgeons performing robotic implantations had minimal or virtually no prior experience (< 20 cases) with artificial urinary sphincter procedures. In comparison, within the open surgery arm, two of the five involved surgeons had already completed more than 20 AUS implantations. All devices used were AMS800 artificial urinary sphincters produced by Boston Scientific® (Marlborough, MA, USA).

The study protocol was approved by the CNIL (Comité National Informatique et Libertés, CNIL 2235498v0) and adhered to the ethical standards outlined in the Helsinki Declaration.

Baseline patient information was systematically recorded in a specialized electronic database. It included the following details for every participant: age at AUS implantation, ASA score, body mass index (BMI), incontinence etiology (neurogenic or non-neurogenic), prior radiotherapy exposure, history of earlier anti-incontinence operations, daily pad count, pad type, preoperative urgency symptoms, maximum free urinary flow rate (Qmax), and post-void residual volume (PVR). In addition, preoperative urodynamic findings, including detrusor overactivity and maximum urethral closure pressure, were documented.

Perioperative management

Before the procedure, urinalysis was performed in all cases. Patients with a positive preoperative urine culture ($\geq 10^3$ CFU/mL) received culture-directed antibiotics commencing 48 hours before surgery. Universal perioperative antibiotic prophylaxis consisted of 2 g cephalosporin or 2 g amoxicillin-clavulanic acid. The sphincter device was left deactivated at the conclusion of surgery.

Urethral catheter removal occurred either in the operating theatre or on postoperative day 1, except when bladder injury was identified, in which case catheterization was extended to 10–14 days.

The artificial urinary sphincter was activated six weeks following the operation.

Surgical techniques

Robot-assisted laparoscopic implantation

Robot-assisted AUS placement was performed via an anterior transperitoneal approach using the Intuitive Da Vinci Si, X, or Xi platform, as previously outlined [15]. In short, the four-arm robot was docked on the patient's right side. The patient was positioned at a 23° Trendelenburg angle while maintaining vaginal accessibility. A 14 French urethral catheter was placed, and five ports were inserted in a straight line at the umbilical level using the conventional arrangement for robotic pelvic operations.

After incising the peritoneum and mobilizing the bladder inferiorly from the anterior abdominal wall to expose the retropubic space, the endopelvic fascia was reached on both sides. Any residual material from previous anti-incontinence surgeries (for example, midurethral slings, Burch colposuspension sutures, or pubovaginal slings)

was removed or divided. The posterior bladder neck was then carefully dissected. The bedside assistant inserted one finger into each anterior vaginal fornix beside the bladder neck to guide blunt robotic dissection of the vesicovaginal plane.

Once the circumferential dissection of the bladder neck was completed, a measuring tape was used to determine the correct cuff size. The cuff was positioned around the bladder neck, after which the pressure-regulating balloon was inserted via a separate 3 cm suprapubic incision. Tubing from the cuff was brought out through the same incision. Finally, a subcutaneous tunnel was fashioned from the suprapubic site into the labia majora for pump placement, and all connections were finalized.

Open implantation

Open artificial urinary sphincter implantation was performed according to the standard technique described by most authors [9]. Following insertion of a 16 French Foley catheter, a Pfannenstiel incision provided abdominal access. Dissection advanced into the retropubic space to reach the bladder neck, and the endopelvic fascia was divided bilaterally alongside the urethra as reported by Costa *et al*. [16]. The balloon of the urethral catheter served as a landmark while the bladder was separated from the vagina beneath the periurethral fascia. The surgeon placed two fingers of the left hand into the vagina to assist the ongoing dissection performed by the right hand.

An on-table leak test using saline and methylene blue was conducted to confirm the absence of bladder injury. Unlike certain earlier descriptions, the bladder dome remained intact in all cases. Circumferential measurement of the bladder neck and device placement were executed identically to the robotic technique outlined above.

Outcomes of interest

The main outcome measure was the rate of postoperative complications occurring within 30 days, graded according to the Clavien-Dindo Classification [17].

Secondary measures comprised: (I) full continence, defined as the complete absence of pad usage; (II) rates of device explantation and need for revision surgery; and (III) explantation-free device survival.

Additional perioperative variables recorded included mean operating time, estimated blood loss, hospital stay duration, and intraoperative complications (vaginal or bladder neck injury). Perioperative and functional results were subsequently compared between the robotic and open surgery groups.

Statistical analysis

Continuous data were presented as mean ± standard deviation, while categorical data were summarized as medians and ranges, and nominal data were expressed as percentages. Between-group comparisons for categorical variables relied on either the χ^2 test or Fisher's exact test, whereas the Mann–Whitney test was employed for continuous variables when suitable.

Estimates of revision-free and explantation-free survival were generated through the Kaplan–Meier approach. The final follow-up date corresponded to the latest available record, obtained either at an outpatient consultation or via a telephone interview conducted to refresh patient information. Cases without any recorded event (neither revision nor explantation) were censored on the date of their most recent contact.

All statistical calculations were executed using JMP version 12.0 (SAS Institute Inc., Cary, NC, USA). Every test was performed as two-sided, and statistical significance was set at a P-value threshold of less than 0.05.

Results and Discussion

Patients' characteristics

Over the entire study period, 135 patients met the inclusion criteria: 71 underwent robotic implantation, and 64 underwent open implantation. The bulk of baseline features showed no notable differences between the two cohorts **(Table 1)**. Median patient age was 66.5 years in the open group and 68 years in the robotic group (P = 0.57). The share of individuals with neurogenic stress urinary incontinence remained comparable across arms (10.9% vs. 6%; P = 0.32). However, a markedly greater percentage of patients in the open group had received prior radiation therapy (6.2% vs. 0%; P = 0.03). In both groups, nearly all participants had a history of at least one earlier anti-incontinence intervention (89% vs. 90.1%; P = 0.95).

Table 1. Population's characteristics.

Characteristic	Open AUS (n = 64)	Robotic AUS (n = 71)	P-value
Median age (years)	66.5 (IQR: 59–74)	68 (IQR: 61–74)	0.57
Average body mass index (kg/m²)	28.5 (± 4.9)	27.2 (± 4.8)	0.13
ASA classification			0.21
• Grade 1	8 (12.9%)	14 (21.2%)	
• Grade 2	36 (58.1%)	40 (60.6%)	
• Grade 3	18 (29%)	12 (18.2%)	
Presence of neurogenic SUI	7 (10.9%)	4 (6%)	0.32

Prior radiation therapy	4 (6.2%)	0 (0%)	0.03
Previous anti-incontinence surgery	57 (89%)	64 (90.1%)	0.95
History of synthetic midurethral sling	47 (74.6%)	57 (80.3%)	0.44
Mean maximum urethral closure pressure (cmH_2O)	25.9 (± 14.5)	22.8 (± 8.2)	0.29
Detrusor overactivity on preoperative urodynamic testing	9 (15.5%)	6 (8.4%)	0.17

Robotic AUS procedures were distributed among centers as follows: Center 1 treated 23 cases; Center 2, 14; Center 3, 12; Center 4, 9; and Centers 5 and 6, each, 4. Center 7 contributed 3 cases, and Center 8 contributed 2 cases. For open AUS procedures, the distribution was: Center 1: 16 cases; Center 2: 15 cases; Center 3: 14 cases; Center 4: 10 cases; Center 5: 9 cases.

Perioperative outcomes

The average operating time was considerably longer for robotic procedures (179.9 versus 126.2 minutes; P < 0.0001). Intraoperative complications, consisting mainly of bladder neck or vaginal injuries, arose more often in the open surgery arm (27.4% versus 12.7%; P = 0.03). Likewise, overall postoperative complication rates proved substantially elevated in the open group (46.8% versus 15.5%; P < 0.0001), including major events classified as Clavien Grade ≥ 3 (17.2% versus 2.8%; P = 0.01). Neither group experienced any Clavien Grade 4 or 5 complications. Estimated intraoperative blood loss reached much higher levels in the open AUS cohort (164.1 versus 16.2 mL; P < 0.0001). Mean hospitalization duration measured 6.5 days in the open group compared with 4.1 days in the robotic group (P = 0.002) **(Table 2)**.

Table 2. Perioperative outcomes.

Outcome measure	Open AUS (n = 64)	Robotic AUS (n = 71)	P-value
Average operative duration (minutes)	126.2 (± 51.8)	179.9 (± 48.5)	< 0.0001
Intraoperative adverse events (vaginal or bladder neck injury)	17 (27.4%)	9 (12.7%)	0.03
Mean intraoperative blood loss (mL)	164.1 (± 194.1)	16.2 (± 37.3)	< 0.0001
Complications within 30 days post-surgery	29 (46.8%)	11 (15.5%)	< 0.0001
Severe postoperative complications (Clavien grade ≥ 3)	11 (17.2%)	2 (2.8%)	0.01
Average hospital stay (days)	6.5 (± 5.6)	4.1 (± 1.9)	0.002

Functional outcomes and device survival

With a median follow-up of 25.5 months in the open group versus 12.2 months in the robotic group, the percentage of patients attaining full continence (zero pads daily) was significantly higher after robotic implantation (83.3% versus 62.3%; P = 0.01). Both device explantation and revision rates occurred at significantly higher frequencies in the open AUS group (explantation rate: 27.4% versus 1.4%; P < 0.0001; revision rate: 17.5% versus 5.6%; P = 0.02) **(Table 3)**. The projected 1-year rate of survival without explantation proved superior in the robotic cohort (98.6% versus 78.3%; P = 0.001) **(Figure 1)**. Conversely, the projected 1-year survival without revision showed no meaningful difference between the groups (86.6% versus 96.2%; P = 0.59) **(Figure 2)**. Every instance of explantation stemmed from either infection or device-related erosion. Detailed etiologies behind revisions were not documented.

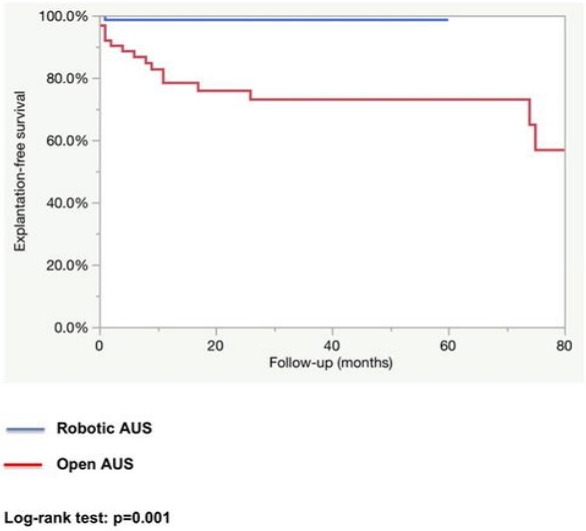

Figure 1. Device explantation-free survival.

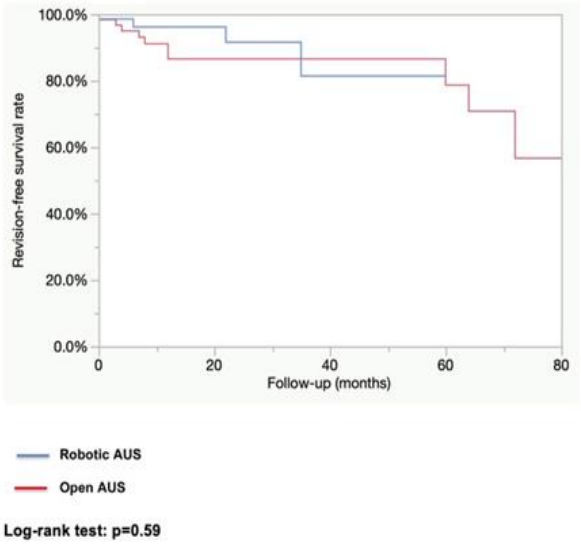

Figure 2. Device revision-free survival.

Table 3. Functional and device outcomes.

Outcome	Open AUS (n = 64)	Robotic AUS (n = 71)	P-value
Complete continence (no pad use)	40 (62.3%)	59 (83.3%)	0.01
Device explantation	22 (27.4%)	1 (1.4%)	< 0.0001
Surgical revision	11 (17.5%)	4 (5.6%)	0.02
Median follow-up duration (months)	25.5 (IQR: 8–55)	12.2 (IQR: 4–22)	< 0.0001

Following the initial placement of an artificial urinary sphincter in a woman in 1973, highly favorable continence outcomes have consistently been reported. Nevertheless, adoption of this device among female patients has remained limited over the decades. This restricted uptake stems partly from the elevated complication rates associated with the technical demands of open surgical implantation. Additional contributing factors include the psychological burden the device imposes on patients and anatomical limitations, particularly regarding pump positioning and manual operation.

The introduction of robotic surgery in the early 2000s has transformed numerous operative procedures [18]. The Da Vinci system from Intuitive stands as the predominant platform in use. Its superior three-dimensional visualization within the pelvis and endowrist instrumentation render it especially advantageous for operating in confined, deep anatomical spaces, making it well-suited for pelvic interventions such as female artificial urinary sphincter placement [19]. The current analysis offers a direct comparison of open versus robot-assisted AUS implantation. Robotic procedures demonstrated reduced perioperative and postoperative complications, decreased explantation rates, and lower intraoperative blood loss. Furthermore, the proportion of patients achieving complete continence proved higher in the robot-assisted cohort. Operative duration was extended in the robotic group, most likely reflecting the novel character of the procedure, the need for technical refinements, and the initial phase of the learning curve at participating institutions.

These findings can be attributed to several inherent benefits of robotic technology. In the traditional open method, dissection of the posterior bladder neck frequently relied on blind palpation and digital guidance with one or two fingers placed vaginally. In contrast, the robotic technique provides magnified three-dimensional visualization, enabling precise dissection under continuous direct view. This approach substantially lowers the likelihood of inadvertent bladder neck or vaginal injury. It facilitates immediate recognition and repair of any such lesions when they arise, rather than allowing undetected damage to progress as often occurs during open surgery.

Unlike conventional laparoscopic tools, the endowrist mechanism delivers seven degrees of freedom comparable to the human wrist in open surgery, representing a major advancement over both open and standard laparoscopic methods [20]. Combined with the instruments' compact size, this technology provides exceptional maneuverability and dexterity within extremely confined pelvic spaces. Such precision is critical during bladder neck dissection, where long, rigid instruments are hindered by the narrow space between the pubic bone and the bladder neck [21]. The presence of pneumoperitoneum during dissection under constant visualization, supported by advanced coagulation devices, likely accounts for the markedly reduced blood loss observed in the robotic arm.

The superior perioperative and postoperative results achieved with robot-assisted implantation, despite surgeons in this group generally possessing less overall experience with the device, highlight the strong teaching potential and enhanced reproducibility offered by the robotic platform. All observations concerning the benefits of robotics presented here derive from our institutional experience and constitute practical recommendations for teams considering adopting robotic AUS implantation in women. Video recording allows key procedural steps to be reviewed intraoperatively and shared remotely via surgical video libraries at any time. Fundamental technical skills can be acquired preoperatively through dedicated simulation platforms. Additionally, Intuitive introduced the dual-console system in 2009, facilitating real-time integrated mentoring and supervision while preserving patient safety and avoiding substantial prolongation of operative time [22, 23]. Telementoring capabilities may further serve as a valuable adjunct for safely disseminating expertise in complex operations such as robotic female AUS implantation.

Accounting for the improved functional results in the robotic group remains more challenging. One plausible hypothesis is that the greater standardization and reproducibility of the robotic technique enable more optimal cuff positioning. Continuous direct vision may permit more accurate dissection around the bladder neck, where tissue thickness is greater, potentially reducing the long-term risk of atrophy and erosion. In addition to curtailing perioperative adverse events and subsequent explantations, precise cuff placement could ensure the device occupies an ideal anatomical position, thereby enhancing overall function.

An alternative consideration is the sequential adoption pattern observed at certain centers, which initially used the open technique before transitioning to robotics. Following this shift, open implantations were discontinued entirely. Consequently, cumulative institutional expertise with female AUS procedures was greater by the time robotic cases were performed.

A further potential factor is the complete absence of patients with prior pelvic irradiation in the robotic cohort, given that radiation exposure has traditionally been viewed as a significant predictor of AUS failure. The scarcity of radiated patients in the robotic group most likely reflects awareness of the heightened risks of cuff-related complications, including erosion, osteitis pubis, and fistula formation when the device is placed around the irradiated bladder neck.

On a broader level, robotic AUS implantation in women has gained increasing acceptance over time, yet the substantial cost of the technology continues to restrict its dissemination. Emerging surgical robotic platforms from additional manufacturers are now entering the market and may help reduce overall costs, including those associated with consumable instruments [24]. Such competition could also stimulate innovation and refinement of the technique. For instance, single-port robotic systems are gaining traction. This innovation enables more focused, anatomy-specific access, as already demonstrated in radical prostatectomy [25, 26]. In the context of AUS implantation, single-port technology could facilitate the development of a standardized preperitoneal route, potentially yielding further improvements in perioperative and postoperative results.

The current investigation presents several limitations that warrant careful consideration when interpreting the results. First, its retrospective design inherently introduces various potential sources of bias. The multicenter setting also introduces heterogeneity, as some centers exclusively used the open technique while others adopted the robotic method at varying rates. In addition, this study exclusively assessed the anterior robotic implantation technique; several groups have reported posterior robotic approaches that were not examined here [27, 28]. Causes of revision surgery were not documented in the database and thus could not be analyzed, representing another drawback. Furthermore, the relatively short- to medium-term follow-up in our series may lead to an underestimation of the true incidence of erosions and revisions in both cohorts. With respect to functional assessment, the evaluation remains limited, as continence status was determined solely by subjective patient self-report of complete dryness (zero pads). The multicenter, retrospective design prevented the collection of comprehensive patient-reported outcome measures using standardized, validated instruments. Lastly, the most notable constraint is likely the shorter median follow-up in the robotic implantation group. This disparity could result in underreporting of long-term explantation and revision events. Consequently, additional research involving larger cohorts and prolonged observation periods would be beneficial to validate the present findings and to better delineate long-term erosion and revision rates, particularly with the robot-assisted technique.

Conclusion

Even when carried out by surgeons with limited prior experience during the initial learning phase, the robot-assisted method appears capable of decreasing perioperative complications linked to artificial urinary sphincter implantation in women relative to the conventional open technique, while also offering the prospect of enhanced functional results, most likely through a substantial reduction in explantation rates. Should these observations be corroborated by future investigations, they could promote wider implementation of the robotic approach for female AUS placement and offer fresh perspectives on the utility of the artificial urinary sphincter in managing stress urinary incontinence among women.

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Ethics statement: This study was approved by the CNIL (Comité National Informatique et Liberté): CNIL number: 2235498v0. The study was conducted in accordance with the principles of the Helsinki Declaration.

On admission, patients are informed of the possibility of using their anonymized data for research purposes. Patients may revoke consent at any time.

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