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ORIGINAL ARTICLE

Complications of the urinary incontinence system ATOMS: description of risk factors and how to prevent these pitfalls

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Abstract

Background We report on our multicentre evaluation of the occurrence and management of complications with the ATOMS device (A.M.I., Austria).

Patients and methods Between 10/09 and 09/18, a total of 187 patients with persistent postoperative stress urinary incontinence received an ATOMS device in Madrid ($n = 101$) or Halle ($n = 86$). This prospective evaluation was carried out consecutively. In addition to complications, patient age, BMI, comorbidities and previous treatments for prostate cancer and urinary incontinence were examined. Statistical analysis was performed with GraphPad Prism 7® (GraphPad Software, Inc., La Jolla, USA); $p < 0.05$ was considered significant.

Results The average age of the overall population was 69.4 years, with a mean CCI of 4.3. In total, 18.2% of the patients had diabetes mellitus, 21.9% were irradiated, and 14.1% and 22.9% underwent previous surgery for urinary incontinence and urethral stricture, respectively. The overall success rate of the device was 80.2%. A total of 51 postoperative complications (51/187, 27.3%) were observed, with 18 grade I (9.6%), 1 grade II (0.5%), 3 grade IIIa (1.6%) and 29 grade IIIb (15.5%) complications. The most serious postoperative complications were primary wound infection (8/187, 4.3%) and long-term cutaneous erosion with subsequent infection (15/187, 8.02%). The main risk factors for complications were previous radiotherapy ($p = 0.003$) and surgery for urethral stricture ($p = 0.017$). No other parameters were significant in bivariate analysis ($p > 0.05$).

Conclusion The most severe complications of ATOMS implantation were primary wound infection and cutaneous erosion, especially in the presence of previous radiotherapy. Particular focus on performing hygienic and accurate implantation techniques is recommended.

Keywords Male stress urinary incontinence · ATOMS · Complications · Risk factors · Management

Background

The implantation of the adjustable transobturator urinary incontinence system (ATOMS, A.M.I., Agency for Medical Innovations, Feldkirch, Austria) to treat persistent male stress urinary incontinence (male SUI) is an established surgical procedure. Mid- and long-term follow-up data [1–7] as well as a meta-analysis of approximately 1393 patients from 20 studies (13 retrospective and 7 prospective studies) have revealed a very good continence success rate, with 67% of patients achieving dryness and 23% of patients showing improvement (> 50% improvement in incontinence compared to baseline) [6]. However, as with any surgical procedure, peri- and postoperative complications are also possible after ATOMS implantation. Unfortunately, no detailed survey exists regarding possible complications, risk factors and management of these complications, and subsequent recommendations to avoid complications. Accordingly, the present multicentre study was conducted to address these issues.

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Patients and methods

Patient population

In the present international multicentre prospective observational study (Madrid, Halle), we evaluated data for 187 patients with persistent male SUI who received an ATOMS between 10/09 and 09/18. Patient consent was obtained for the study. All patients were supervised during an individual incontinence consultation in an outpatient clinic. A prerequisite for surgery was persistent SUI lasting at least 6 months after the primary intervention, as well as failure of conservative treatments (e.g. pelvic floor exercises and biofeedback, electrotherapy, lifestyle modifications and anticholinergic medications). As part of the diagnostic and consultation process, we also evaluated indications for other devices to treat SUI. In the present study, however, only patients who received an ATOMS device were included.

As previously described [4], the preoperative investigation consisted of a detailed medical history (especially regarding radiation and previous incontinence surgery), urinalysis, uroflowmetry, ultrasound with post-void residual volume, 3-day voiding protocol, 24-h pad count, and an urodynamic study to exclude detrusor overactivity as well as a diagnostic cystoscopy to exclude anastomotic stricture and to assess residual sphincter function. The degree of SUI was classified according to the 24-h pad count (grade I: 1–2 pads/day; grade II: 3–5 pads/day; grade III: > 5 pads/day). The surgical procedures were performed routinely, as previously described [1, 2].

Data collection

The average follow-up period of the study was 44 ± 30.9 months, with a minimum of 6 months. During the follow-up period, continence parameters (24-h pad count and 24-h pad test), device parameters (adjustments), pain and quality of life (QoL) ratings [visual analogue scale (VAS) and International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF)], and especially postoperative complications (according to Clavien–Dindo classification [8]) were evaluated. The first follow-up examination was performed in an ambulant setting 4 weeks after ATOMS implantation. The implant fill volume was adjusted at intervals of approximately 4 weeks based on the individual requirements of each patient. After achieving the required continence results, further follow-up examinations were carried out every 12 months.

Statistical analysis

Statistical analysis was performed with GraphPad Prism 7® (GraphPad Software, Inc., La Jolla, United States). Data are presented as the mean ± standard deviation (SD) and range. Statistical significance was considered at $p < 0.05$. Bivariate comparisons were conducted with Student's t tests and Mann–Whitney U tests (metric variables) or χ^2 tests (categorical variables).

Results

The baseline characteristics of the overall population are shown in Table 1. On average, the patients were 69.4 ± 6.6 (46–84) years old, slightly overweight [body mass index (BMI): 28.1 ± 3.9 (19–47) kg/m^2] and with moderate comorbidities [Charlson comorbidity index (CCI): 4.3 ± 1.4 (1–8)], among which 18.2% patients had diabetes mellitus. A total of 21.9% of the patients were previously treated with radiotherapy for prostate cancer, 14.1% underwent previous surgery for urinary incontinence, and 22.9% underwent surgery for urethral strictures. In the overall population, 56.7% of the patients were severely incontinent.

The perioperative and postoperative parameters of the entire population are shown in Table 2. The mean operative time was 64.7 ± 19.3 (30–148) minutes. In total, 55.6% of the patients successfully achieved a 'dry' status (0 or a 'safety pad'/day) and 24.6% an improvement of at least 50% (with 1–2 pads/day), representing an overall success rate of 80.2%. The mean number of pads per day decreased from 6.1 ± 3.6 (1–18) to 0.8 ± 1.3 (0–8); the average number of adjustments was 3.1 ± 2.6 (0–9).

Table 1 Baseline characteristics of the patient population ($n = 187$ patients)

Category	Overall population $n = 187$ pts
Patient age [years] (range)	69.4 ± 6.6 (46–84)
BMI [kg/m^2] (range)	28.1 ± 3.9 (19–47)
ASA score (range)	2.0 ± 0.6 (1–3)
CCI score (range)	4.3 ± 1.4 (1–8)
Diabetes mellitus (%)	34/187 (18.2)
Primary/secondary radiation (%)	42/187 (22.5)
Previous surgery due to SUI (%)	27/187 (14.4)
Previous transurethral resection for urethral stricture (%)	44/187 (23.5)
Preoperative 24-h pad count (range)	6.1 ± 3.6 (1–18)
Preoperative 24-h pad test [ml] (range)	714 ± 521 (40–2500)
Degree of stress urinary incontinence (%)	
SUI I°: 1–2 pads/day	11/187 (5.9)
SUI II°: 3–5 pads/day	70/187 (37.4)
SUI III°: > 5 pads/day	106/187 (56.7)
Preoperative ICIQ-SF score (range)	15.8 ± 3.0 (9–21)
Preoperative VAS score (range)	0.6 ± 1.2 (0–8)

Mean ± standard deviation (range) or percentage

Table 2 Peri- and postoperative parameters of the patient population

Category	Overall population $n = 187$ pts
Operative time [min] (range)	64.7 ± 19.3 (30–148)
Postoperative adjustments (range)	3.1 ± 2.6 (0–9)
Postoperative cushion volume [ml] (range)	18 ± 6.1 (6–25)
Postoperative 24-h pad count (range)	0.8 ± 1.3 (0–8)
Postoperative 24-h pad test [ml] (range)	73 ± 170 (0–1500)
Success rate of the device	
Dry: 0-"safety pad"/day	104/187 (55.6)
Improvement: 1–2 pads/day (> 50% improvement compared to baseline)	46/187 (24.6)
Failure: > 2 pads/day (< 50% improvement compared to baseline)	37/187 (19.8)
Postoperative ICIQ-SF score (range)	2.3 ± 2.1 (0–8)
Postoperative VAS score (range)	0.7 ± 1.1 (0–7)

Mean ± standard deviation (range) or percentage

No intraoperative complications were observed, as expected. Regarding postoperative complications (Table 3), 48 patients had 51 complications (27.3%), including 18 grade I (9.6%), 1 grade II (0.5%), 3 grade IIIa (1.6%) and 29 grade IIIb complications (15.5%). Grade IV and V complications did not occur.

Clavien grade I and II complications

With respect to grade I complications, 7 patients (3.7%) had urinary tract infections in the form of urethral complaints after removal of the transurethral catheter on the first postoperative day, which involved fever in three patients. However, kidney and testis involvement were clinically excluded, and urine cultures were negative. Therefore, perioperative antibiosis (Halle: gentamicin/cefuroxime, Madrid: gentamicin/amoxicillin–clavulanic acid) was continued, and the symptoms declined. Furthermore, two patients (1%) reported slight haematuria, most likely also due to irritation from the transurethral catheter. There was no evidence of urethral leakage. Four patients (2.1%) who received therapeutic anticoagulation (low-molecular weight heparin as a replacement for the original anticoagulation medication) developed scrotal or perineal haematoma (Fig. 1), which spontaneously and gradually resolved with moderate bed rest and local cooling. There was no change in anticoagulation behaviour due to cardiovascular risk. With regard to postoperative pain, we implemented a standardized postoperative analgesic regimen with the use of non-steroidal anti-inflammatory drugs (NSAIDs) during the wound-healing period, which was the first 4 weeks after implantation. Only severe, prolonged postoperative pain, as assessed by a VAS

Table 3 Postoperative complications and their management in the patient population; 51 postoperative complications in 48 patients, overall population $n = 187$ patients

Clavien grade-postoperative complications[a]		*n* (%)	Treatment
Clavien I	Urinary infection (dysuria after catheter removal, 3 cases with fever, negative urine culture)	7 (3.7)	Conservative—spontaneously declining, no change of perioperative antibiotics
	Haematuria after catheter removal	2 (1)	Conservative—spontaneously declining
	Hematoma (scrotal/perineal, under therapeutic anticoagulation)	4 (2.1)	Conservative—spontaneously gradually declining
	Pain (scrotal/perineal pain > 30 days)	4 (2.1)	Conservative—declining under analgesia
	Renal colic	1 (0.5)	Conservative—spontaneous kidney stone discharge
Clavien II	Deep-vein thrombosis	1 (0.5)	Anticoagulation
Clavien IIIa	Urinary retention after catheter removal	3 (1.6)	Re-adjustment and/or suprapubic catheter for 14 days, alternatively transurethral catheter for 2 days
Clavien IIIb	Pain with necessity for device removal (scrotal/perineal pain > 30 days)	3 (1.6)	Device removal
	Wound infection port (< 30 days)	2 (1)	1 × device removal 1 × open wound management + secondary suture
	Wound infection perineal (< 30 days)	6 (3.2)	Device removal
	Subacute erosion of the port (> 30 days)	3 (1.6)	Port replacement
	Erosion and infection of the port capsule (> 30 days)	10 (5.3)	Device removal
	Erosion and infection of the port catheter (> 30 days)	2 (1)	Device removal
	Leakage of the sphincter cushion (> 30 days)	2 (1)	Device change
	Traumatic port catheter disruption (> 30 days)	1 (0.5)	Device change
Sum total		**51 (27.3)**	

[a]Postoperative complications according to Clavien–Dindo classification [8]; presentation in number and percentage; sum total highlighted in bold

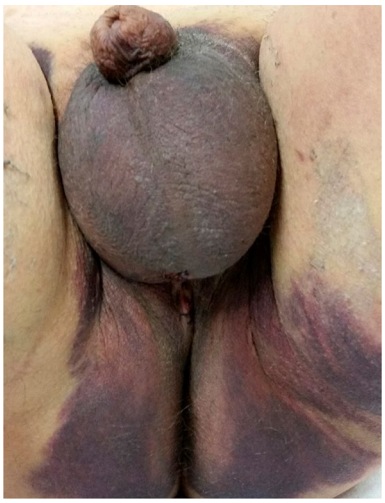

Fig. 1 A complication observed for ATOMS: butterfly perineal haematoma inside the Colles' fascia—Clavien–Dindo grade I

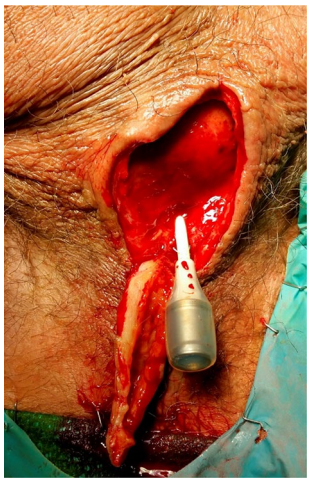

Fig. 2 A complication observed for ATOMS: subacute port erosion that required surgical revision to optimize the port localization—Clavien–Dindo grade IIIb

score higher than 3 and lasting longer than 4 weeks after implantation, was graded as a postoperative complication. In total, seven patients (3.9%) had scrotal or perineal pain; four patients had pain that completely disappeared under prolonged analgesia (Clavien grade I), but in the other three patients (Clavien grade IIIb), the device had to be removed. In the overall population, the mean VAS score at 6 months after implantation was 0.7 ± 1.1 (0–7). Complications of renal colic and deep-vein thrombosis were considered non-systemic and, therefore, a rarity.

Clavien grade IIIa complications

In total, three patients (1.6%) had a grade IIIa complication in the form of acute urinary retention after the transurethral catheter was removed on the first postoperative day. In these cases, the ATOMS sphincter cushion was deblocked to 2 ml, and a temporary urinary drainage was performed. The acute urinary retention was ultimately caused by perioperative wound oedema around the bulbospongiosus muscle as well as suburethral compression by the sphincter cushion. As the placement of a short-term drainage catheter and use of anti-inflammatory analgesics (NSAIDs) supported spontaneous healing, no further intervention was needed.

Clavien grade IIIb complications

Primary scrotal or perineal wound infections occurring within 30 days after implantation were observed in eight patients (4.2%). In a patient with a superficially inguinal port infection, treatment with surgical wound cleaning with secondary sutures was successful. The remaining seven devices were removed. In addition, 12 cases of cutaneous erosion with consecutive infections (6.2%) were observed during long-term follow-up. The erosion involved an inguinal port (first-generation ATOMS) in six patients, the intraoperative manually connectable scrotal port (second-generation ATOMS) in two and the pre-connected, smaller and fully silicone-covered scrotal port (third-generation ATOMS) in the remaining four. For all 12 patients, the ATOMS device had to be removed. Three patients presenting with subacute port erosion (1.6%) required operative revision to optimize the location of the port (Fig. 2). Traumatic port catheter dislocation was also considered non-systemic and, therefore, a rarity. However, in another two patients (1%), unclear leakage of the sphincter cushion was found during long-term follow-up (68 and 76 months, cushion volume 25 ml for both patients), and material fatigue was most likely the cause.

Statistical analysis of the data

A statistical analysis of the factors influencing complications was performed. Previous radiotherapy and resection of a urethral stricture were identified as possible risk factors for these complications (Table 4), with both achieving statistical significance (previous radiation: 27/139 (19.4%) vs. 15/48 (31.3%), $p = 0.003$; previous transurethral resection of a urethral stricture: 28/139 (20.1%) vs. 16/48 (33.3%), $p = 0.017$). The postoperative ICIQ-SF score ($p = 0.062$) and operative time ($p = 0.116$) also tended towards significance. In contrast, none of the other parameters was found to be significant in bivariate analysis. The influence of the port generation (Table 5) and the learning curve (Table 6) were the only other factors with a positive correlation. Regarding port generations and port-associated postoperative complications, we found 1 grade I (1.9%) and 9 grade IIIb

Table 4 Risk factors for postoperative complications in the patient population; 51 postoperative complications in 48 patients, overall population $n = 187$ patients

Category	No postoperative complication $n = 139$ pts	Postoperative complications[a] $n = 48$ pts	Comparison "no postoperative complication" vs. "postoperative complication" p value*
Patient age [years] (range)	69.6 ± 6.8 (46–84)	68.9 ± 6.2 (49–82)	0.270
BMI [kg/m^2] (range)	28.2 ± 3.8 (19–47)	28.1 ± 4.2 (21–38)	0.850
ASA score (range)	2.0 ± 0.6 (1–3)	2.1 ± 0.6 (1–3)	0.720
CCI score (range)	4.3 ± 1.4 (1–7)	4.2 ± 1.3 (1–8)	0.460
Diabetes mellitus (%)	26/139 (18.7)	8/48 (16.7)	0.280
Primary/secondary radiation (%)	27/139 (19.4)	15/48 (31.3)	**0.003**
Previous surgery due to SUI (%)	19/139 (13.7)	8/48 (16.7)	0.150
Previous transurethral resection for urethral stricture (%)	28/139 (20.1)	16/48 (33.3)	**0.017**
Preoperative 24-h pad count (range)	5.4 ± 3.7 (1–18)	5.8 ± 3.4 (2–18)	0.820
Preoperative 24-h pad test [ml] (range)	700 ± 502 (40–2500)	665 ± 577 (80–2500)	0.410
Preoperative ICIQ-SF score (range)	15.8 ± 3.1 (9–21)	15.9 ± 2.8 (10–21)	0.798
Preoperative VAS score (range)	0.64 ± 0.8 (0–5)	0.96 ± 1.9 (0–8)	0.833
Operative time [min] (range)	63.5 ± 17.6 (30–138)	68.1 ± 23.6 (30–148)	0.116
Postoperative adjustments (range)	3.1 ± 2.5 (0–9)	3.1 ± 2.8 (0–9)	0.510
Postoperative 24-h pad count (range)	0.8 ± 1.4 (0–8)	0.6 ± 0.9 (0–3)	0.645
Postoperative 24-h pad test [ml] (range)	68 ± 174 (0–1500)	77 ± 162 (0–800)	0.353
Postoperative ICIQ-SF score (range)	1.9 ± 2.0 (0–8)	3.1 ± 2.1 (0–7)	0.062
Postoperative VAS score (range)	0.7 ± 0.6 (0–2)	1.3 ± 1.6 (0–7)	0.152

[a]Postoperative complications according to Clavien–Dindo classification [8]; mean ± standard deviation (range) or percentage

*Student's t test, Mann–Whitney U test and χ^2 test ($\alpha = 0.05$); significance is highlighted in bold

(17.3%) complications, as well as 1 grade I (9.1%) and 4 grade IIIb (36.4%) complications for IP (52 patients) and SP (11 patients), respectively, but only 1 grade I (0.8%) and 7 grade IIIb complications (5.6%) for SSP (124 patients) (IP/SP $p = 0.0219$, IP/SSP $p = 0.0235$ and SP/SSP $p = 0.0180$). Regarding the influence of the learning curve, we compared the first 25 with the ensuing operations by each surgeon (SM, JA). For the first 25 patients, the total postoperative complication rate was 44%, whereas the rate was only 21.1% for the subsequent surgeries ($p = 0.0211$). In particular, the number of primary wound infections and long-term cutaneous erosions with subsequent infection as well as the need for device removal declined over time.

Discussion

Surgical treatment of male SUI is highly interesting but also challenging in functional urology. On the one hand, the patients are mostly severely impaired [4, 9, 10]; on the other hand, different medical devices in addition to the artificial sphincter have been developed. The effectiveness of these devices for male SUI is dependent on the degree of incontinence and the condition of the patient. These devices include AdVance and AdVanceXP (Boston Scientific, USA), ProACT (Uromedica, USA), Argus Classic and ArgusT (Promedon, Argentina), MRS Remeex (Neomedic, Spain) and ATOMS (A.M.I., Austria), among others [11].

As with any surgical procedure, complications can arise during the implantation of urinary incontinence devices. For the ATOMS device, possible complications have already been reported [1–7], though a more detailed survey of these complications, especially with regard to risk factors and management strategies and subsequent recommendations for prevention, does not exist. For example, Friedl et al. [3] merely defined risk factors for therapeutic failure and found that patients with primary implantation and those without previous radiotherapy had a better therapeutic outcome than did other patients. Angulo et al. [12] also defined patient factors that correlate with a satisfactory outcome, including dryness ($p < 0.0001$), low incidence of urinary incontinence ($p = 0.007$), low postoperative pain ($p = 0.0018$) and no complications ($p = 0.007$). Therefore, the present study was conducted to examine the perioperative and postoperative complications of the ATOMS device, identify their risk factors and provide recommendations to

Table 5 Influence of ATOMS port generations on port-associated postoperative complications in the patient population; 23 port-associated postoperative complications in 23 patients, overall population $n = 187$ patients

Clavien grade	port-associated postoperative complications[a]	Overall $n = 187$ (% of 187 pts)	IP $n = 52$ (% of 52 pts)	SP $n = 11$ (% of 11 pts)	SSP $n = 124$ (% of 124 pts)
Clavien I	Haematoma (scrotal, under therapeutic anticoagulation)	3 (1.6)	1 (1.9)	1 (9.1)	1 (0.8)
Clavien IIIb	Pain with necessity for device removal (scrotal pain > 30 days)	2 (1)	–	1 (9.1)	1 (0.8)
	Wound infection port (< 30 days)	2 (1)	1 (1.9)	1 (9.1)	–
	Incipient erosion of the port (> 30 days)	3 (1.6)	1 (1.9)	–	2 (1.6)
	Erosion and infection of the port capsule (> 30 days)	10 (5.3)	4 (7.7)	2 (18.2)	4 (3.2)
	Erosion and infection of the port catheter (> 30 days)	2 (1)	2 (3.8)	–	–
	Traumatic port catheter disruption (> 30 days)	1 (0.5)	1 (1.9)	–	–
Sum total		**23 (23/187 = 12.3%)**	**10 (10/52 = 19.2%)**	**5 (5/11 = 45.5%)**	**8 (8/124 = 6.5%)**

[a]Port-associated postoperative complications according to Clavien–Dindo classification [8]; *IP* inguinal port (1st ATOMS generation), *SP* intraoperative manually connectable scrotal port (2nd ATOMS generation), *SSP* pre-connected, smaller and fully silicone-covered scrotal port (3rd ATOMS generation); presentation in number and percentage; sum total highlighted in bold

Table 6 Influence of the learning curve on postoperative complications in the patient population; 51 postoperative complications in 48 patients, overall population $n = 187$ patients

Clavien grade	postoperative complications[a]	Overall $n = 187$ (% of 187 pts)	First 25 patients of each surgeon (SM, JA) $n = 50$ (% of 50 pts)	Following patients of each surgeon (SM, JA) $n = 137$ (% of 137 pts)
Clavien I	Urinary infection (dysuria after catheter removal, 3 cases with fever, negative urine culture)	7 (3.7)	3 (6)	4 (2.9)
	Haematuria after catheter removal	2 (1)	–	2 (1.5)
	Haematoma (scrotal/perineal, under therapeutic anticoagulation)	4 (2.1)	2 (4)	2 (1.5)
	Pain (scrotal/perineal pain > 30 days)	4 (2.1)	–	4 (2.9)
	Renal colic	1 (0.5)	–	1 (0.7)
Clavien II	Deep-vein thrombosis	1 (0.5)	–	1 (0.7)
Clavien IIIa	Urinary retention after catheter removal	3 (1.6)	1 (2)	2 (1.5)
Clavien IIIb	Pain with necessity for device removal (scrotal/perineal pain > 30 days)	3 (1.6)	2 (4)	1 (0.7)
	Wound infection port (< 30 days)	2 (1)	1 (2)	1 (0.7)
	Wound infection perineal (< 30 days)	6 (3.2)	4 (8)	2 (1.5)
	Incipient erosion of the port (> 30 days)	3 (1.6)	1 (2)	2 (1.5)
	Erosion and infection of the port capsule (> 30 days)	10 (5.3)	5 (10)	5 (3.6)
	Erosion and infection of the port catheter (> 30 days)	2 (1)	2 (4)	–
	Leakage of the sphincter cushion (> 30 days)	2 (1)	–	2 (1.5)
	Traumatic port catheter disruption (> 30 days)	1 (0.5)	1 (2)	–
Sum total		**51 (51/187 = 27.3%)**	**22 (22/50 = 44%)**	**29 (29/137 = 21.1%)**

[a]Postoperative complications according to Clavien–Dindo classification [8]; presentation in number and percentage; sum total highlighted in bold

prevent these complications. Of the 187 patients included, 51 postoperative complications occurred (27.3%). Specifically, minor complications (grade I–IIIa) occurred in 11.8% of the patients. However, severe complications (grade IIIb) were observed in 15.5% of the patients and usually resulted in the removal or at least a change of the ATOMS device. In general, previous radiotherapy and resection of a urethral stricture were statistically significant risk factors

for complications ($p = 0.003$ and $p = 0.017$, respectively). Previous radiotherapy is known to reduce the therapeutic success of ATOMS [3, 5, 13]. Regardless, no evidence for peri- and postoperative complications, as described above, existed previously. The literature on other urinary incontinence systems, such as the AdVance sling suspension [14], ArgusT [15] and artificial sphincter [16, 17], has not shown a statistically significant association between previous radiotherapy and the occurrence of peri- and postoperative complications or device removal. For instance, Bauer et al. [11] reported a low complication rate (5/24 patients, 20.8%) for the AdVance sling, with comparable complication rates for non-pre-irradiated and pre-irradiated patients. Regarding the ArgusT device, Bauer et al. [15] also found that previous radiotherapy had no negative impact on the success rate (61.9% achieved dryness, 26.2% showed improvement) or safety of the device (19 complications in 42 patients, 45.2%). With regard to the artificial sphincter, Leon et al. [16] showed that previous radiotherapy had no influence on the device removal rate or long-term progression. Similarly, Kretschmer et al. [17] demonstrated that previous radiotherapy had no influence on early complications or the device removal rate immediately after surgery ($p = 0.313$). Nonetheless, there are no studies to date on whether previous urethral stricture resection has an effect on therapeutic success or complications due to a urinary incontinence device, e.g. ATOMS. A detailed analysis of our data revealed that almost half of the patients who previously received radiotherapy had already undergone urethral stricture resection (18/42, 42.9%); thus, an indirect connection between previous urethral stricture resection and radiation is highly likely.

The combined peri- and postoperative complication rate for ATOMS is estimated to be 16.4% (95% CI 12.1–21.2), with major complications such as wound infection, cutaneous erosion and persistent pain accounting for 3% (95% CI 1.65–21.2) of all complications [6]. In accordance with the literature [1–7], we also observed less serious complications, such as postoperative urinary tract infection and haematuria, haematoma, prolonged pain and acute urinary retention (11.8%). Patients with urinary tract infections had urethral complaints after the transurethral catheter was removed, and three patients also had fever. However, the microbiological studies were negative, which may be due to false-negative results owing to pre-existing perioperative antibiosis. Therefore, perioperative antibiosis was maintained according to the schedule until the patient was discharged, and the symptoms spontaneously resolved in all seven patients. Overall, a rather cautious approach for urinary tract infections is advisable. Moreover, slight haematuria is most likely due to urethral irritation due to the transurethral catheter. If preoperative diagnostic results, including diagnostic urethrocystoscopy, are inconspicuous and the patient spontaneously recovers, there is no urgent need for further testing. However, if a gross haematuria does not spontaneously resolve, the possibility of a urethral injury from implantation should be ruled out through contrast imaging of the urethra or repeat diagnostic urethrocystoscopy. Unlike in the initial reports in the literature [1, 2], we only considered severe postoperative pain measured as a VAS score greater than 3 that lasted longer than 4 weeks after ATOMS implantation to be a postoperative complication. Hence, only seven patients (3.9%) were observed to have prolonged pain. The continuation of or, if necessary, an increase in perioperative analgesics is recommended for treating prolonged perineal or scrotal pain, though if the pain persists for up to 6 months, the option of removing the ATOMS device should be discussed with the patient. The possible causes of prolonged pain include local irritation by the foreign body itself, periosteal irritation of the lower pubic bone as a result of the transobturator approach, which is similar to the transobturator tape used for female urinary incontinence surgery [18, 19], and painful scarring, though the origin of prolonged pain is difficult to determine for each patient. Nonetheless, an absolute recommendation for implantation is to tunnel the mesh arms not too close to the lower pubic bone to avoid local periosteal irritation.

In the literature, the AdVance sling is reported to have peri- and postoperative complication rates of 10–20%, with the minor complications usually involving transient perineal pain or hypercontinence requiring transurethral catheterization. Complications such as sling removal, wound infection or even persistent pain are rare (1% each) [20–22]. For the classical retropubic Argus and MRS Reemex, intraoperative bladder perforation (5–10%) has also been described [23, 24]. The Argus device is reported to have a postoperative complication rate of approximately 15–50%, depending on the definition, with complications including wound infection (< 5%), urethral lesion (< 5%), device removal (< 10%) and transient (< 50%) or permanent (1%) inguinal and perineal pain. Inguinal and perineal pain reportedly occurs more frequently with the transobturator approach [25, 26].

No studies thus far have reported data about the learning curve for placing an ATOMS device, though surgical treatment of male SUI is technically demanding because of the many factors to consider. In the present study, a learning curve of at least 25 patients was assumed, and the postoperative complication rate was higher for these first 25 than for the subsequent patients (44% vs. 21.1%, $p = 0.02$), especially in terms of grade IIIb complications and, in turn, for primary wound infections. Is this just a coincidence, or is there a real detrimental effect on patients? The ATOMS device was introduced in Europe in 2009 as an adjustable 'sling', and its application was always carried out to the best of our knowledge and belief. Nonetheless, we realize that this device is not simply an adjustable sling. The recommendation of hygiene may sound almost patronizing

to more experienced surgical colleagues, and yet it is so important for our patients. Thus, we changed our perioperative management strategy based on our initial findings. Our procedure involves shaving the urogenital hair of the patient exclusively in the operating room after the patient has been positioned; the area is then cleaned, and the remaining hair is removed. A 10-min disinfection period for placing an artificial sphincter is not required for this procedure. The usual skin disinfection routine is performed, including applying Betadine and securely covering the anus to prevent bacterial contamination of the surgical perineal area. Postoperatively, the patient should be instructed to engage in hygienic measures. Overall, as with any other artificial implants, special care should be taken to ensure that the wound is clean and that appropriate wound management is being implemented. These measures prevent complications of primary wound infection and are generally recommended.

Furthermore, diabetes mellitus and hyperglycaemia correlate significantly with impaired wound healing [27], suggesting that poor hyperglycaemia control is directly associated with complications from the operation. This correlation has been insufficiently studied with regard to the surgical treatment of male SUI. In accordance with the few existing studies [13, 28], our data showed no significant correlation between complications and the presence of diabetes mellitus or comorbidities in general ($p = 0.280$ and $p = 0.460$, respectively). The ATOMS device has been further developed over the last few years to optimize the position and shape of the port, which has also led to a reduction in the postoperative complication rate [4] because of the use of a smaller and completely silicone-coated scrotal port. In this way, complications such as long-term cutaneous erosions with consecutive infection and the need for device removal are prevented. In addition to the learning curve and surgical expertise, these new developments have influenced and minimized the occurrence of major complications. Moreover, in accordance with the literature [4], our data revealed fewer port-associated complications for SSP than for IP and SP ($p = 0.0219$, $p = 0.0235$ and $p = 0.0180$), especially for Clavien grade IIIb complications, which were 17.3% for IP, 36.4% for SP and 5.6% for SSP.

Limitations of the study

The limitations of this study include the lack of a control group as well as the heterogeneous patient sample, which ultimately corresponds to daily practice. Such heterogeneity may have influenced both the patient outcomes and complication rate. Further and larger investigations are needed.

Conclusions

Implantation of an ATOMS device is an established and effective surgical procedure for treating persistent male SUI. The most severe postoperative complications of ATOMS are primary wound infection and cutaneous erosion, which may occur more easily if the patient received previous radiotherapy. Furthermore, high surgical expertise and new developments of the ATOMS device are less frequently associated with major complications. These factors should be included in the consultation process prior to surgery. Regardless, a special focus on ensuring hygienic and accurate implantation techniques is recommended.

Author contributions SM: protocol development, data collection and analysis, and manuscript writing, JCA: data collection and analysis, and manuscript writing. NM: manuscript editing. AS: manuscript editing. PF: protocol development and manuscript editing.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflicts of interest.

Ethical approval Ethical approval was obtained.

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