



# An overview of the ATOMS generations: port types, functionality and risk factors

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## Abstract

**Background** We report the multicentre comparison of the different port types of the adjustable transobturator male incontinence system (ATOMS, A.M.I., Austria).

**Methods** Between 10/09 and 10/16, 383 patients received an ATOMS. Of these, 63% received the inguinal port (IP, 2009–2013), 23% the intraoperative manually connectable scrotal port (SP, 2013–2015), and 14% the pre-connected fully silicone-covered scrotal port (SSP, 2014–2016). During the follow-up period, continence parameters, pain and quality of life ratings and postoperative port-associated complications were evaluated and compared. Statistical analysis was performed with GraphPad Prism 7<sup>®</sup>,  $p < 0.05$  considered as significant.

**Results** Regarding preoperative parameters (BMI, ASA score, previous radiotherapy/incontinence surgery, and preoperative 24-h pad count/24-h pad test), no significant differences were found. Regarding perioperative parameters, the mean operative time was significantly shorter for the SP and SSP (IP vs. SP  $p < 0.0001$ , IP vs. SSP  $p = 0.0048$ , SP vs. SSP  $p = 0.697$ ). Comparison of the postoperative 24-h pad count, 24-h pad test and uroflowmetry data revealed no significant differences. However, the postoperative ICIQ-SF score was significantly better for the SSP ( $p = 0.0232$ ) than the SP. A significant difference was also observed in postoperative port-associated complications. According to the Clavien–Dindo classification, we identified one grade I and 29 grade IIIb complications for the IP, 1 grade I and 6 grade IIIb complications for the SP, but only 2 grade IIIb complications for the SSP (IP vs. SP  $p = 0.0231$ , IP vs. SSP  $p = 0.0189$  and SP vs. SSP  $p = 0.0453$ ).

**Conclusion** The SSP shows fewer complications while retaining comparable efficacy.

**Keywords** Male stress urinary incontinence · Artificial implants · ATOMS · Port types · Functionality

## Background

Male stress urinary incontinence (SUI) is very embarrassing for the affected patients. The surgical treatment options for male SUI range from the implantation of bulbourethral slings (e.g., AdVance, Boston Scientific, Massachusetts,

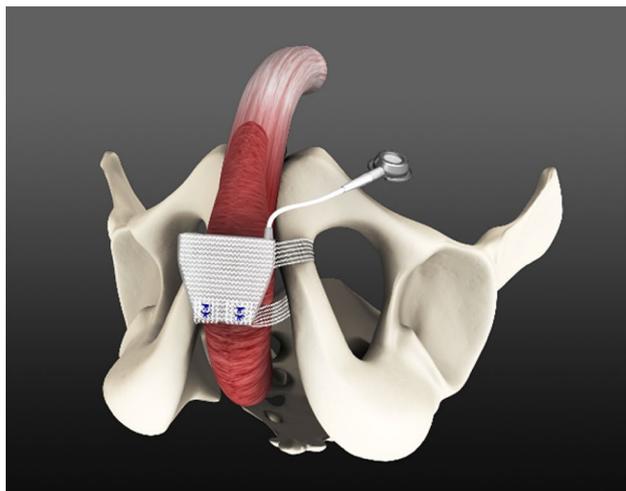
USA; Surgimesh M-SLING, Dipro Medical Device, San Mauro Torinese, Italy) to adjustable systems (e.g., Argus, Promedon SA, Cordoba, Argentina; ATOMS, Agency for Medical Innovations, Feldkirch, Austria) and artificial urinary sphincters (e.g., AMS 800, Boston Scientific, Massachusetts, USA). Ultimately, with the correct diagnosis and indications, all devices achieve reasonable results in the medium and long term [1–10]. However, over time, almost all of these incontinence devices have evolved to become easier to implant and, therefore, more efficient. With regard to the adjustable transobturator male incontinence system (ATOMS, Agency for Medical Innovations, Feldkirch, Austria), the titanium port has changed in terms of the size and location of the implantation from the initial inguinal port (1st ATOMS generation, IP, 2009–2013; Fig. 1) to a precursor, intraoperative manually connectable, but relatively large scrotal port (2nd ATOMS generation, SP, 2013–2015;

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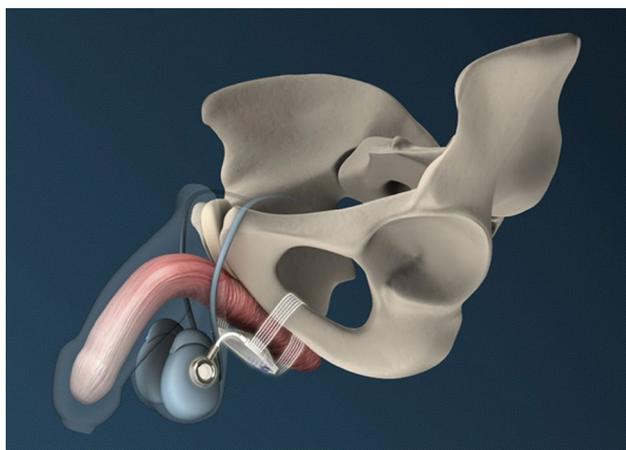


**Fig. 1** ATOMS® Inguinal port (IP, 2009–2013); With courtesy of A.M.I., Agency for Medical Innovation, Feldkirch, Austria

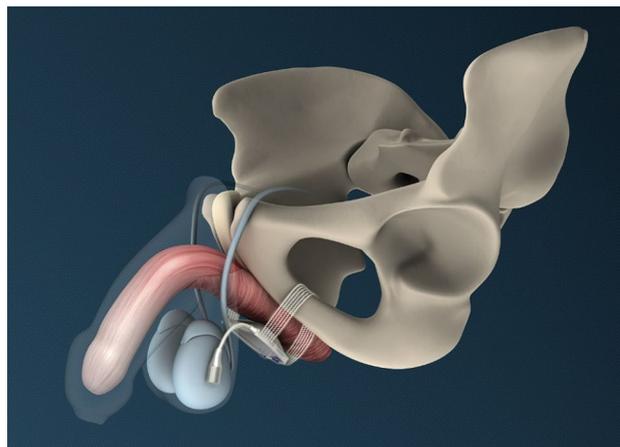
Fig. 2) to a pre-connected, smaller and fully silicone-covered scrotal port (3rd ATOMS generation, SSP, application since 2014; Fig. 3). Therefore, the question of the precise benefits of this evolution remains. In the literature, only Friedl et al. [8] and Angulo et al. [9] have discussed the three different ATOMS port generations. Therefore, we report our multicentre comparison of the different port generations of the ATOMS.

## Methods

In the present international multicentre prospective observational study (Vienna, Austria; Prague, Czech Republic; Halle (Saale), Germany), we evaluated the data of



**Fig. 2** ATOMS® Simple scrotal port (SP, 2013–2015); With courtesy of A.M.I., Agency for Medical Innovation, Feldkirch, Austria



**Fig. 3** ATOMS® Pre-connected fully silicone-covered scrotal port (SSP, since 2014); With courtesy of A.M.I., Agency for Medical Innovation, Feldkirch, Austria

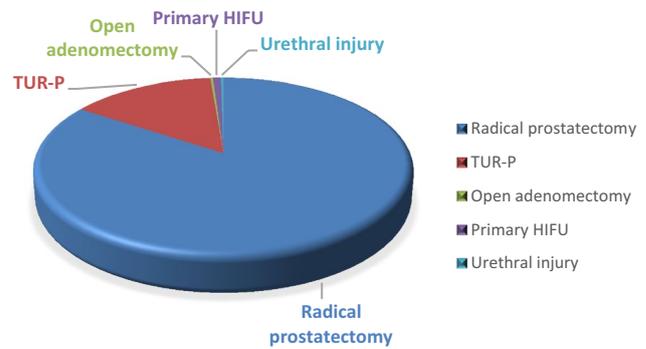
383 patients with SUI who received an ATOMS between October 2009 and 2016. Of these patients, 63% received the IP, 23% received the former manually connectable SP, and 14% received the pre-connected SSP. The aim of the present multicentre study was to compare the three different port generations of the ATOMS. 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 the 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 evaluated differentiated also the indication for other devices for the treatment of urinary incontinence. In the present study, however, only patients who received an ATOMS incontinence system were included. The preoperative investigation contained 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 urodynamic and diagnostic cystoscopy. An untreated anastomotic stricture or detrusor overactivity was considered a contraindication for surgical treatment. The classification of SUI was carried out in accordance with 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 [11, 12]. The procedures were carried out by five surgeons (AF, RZ, SM, NM, and PF). The average follow-up period of the study was  $40 \pm 27.8$  months, with a minimum of 12 months. For IP, SP and SSP, the mean follow-up was  $51 \pm 34.3$  months,  $29.6 \pm 22.4$  months and  $21 \pm 17.6$  months, respectively. During the follow-up period, continence parameters (24-h pad

count and 24-h pad test), urodynamic parameters (uroflowmetry and post-void residual volume), pain and quality of life (QoL) ratings [visual analog scale (VAS) and International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF)], as well as postoperative complications, especially port-associated complications, were evaluated. The first follow-up examination took place 4 weeks after the implantation in an ambulant setting. Adjustments of the implant fill volume were carried out in accordance with the individual requirements of the patient at intervals of approximately 4 weeks. After achieving the required continence results, further follow-up examinations were carried out every 12 months. The 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 with  $p < 0.05$ . Time-dependent changes among the groups [IP vs. SP (IP/SP), IP vs. SSP (IP/SSP) and SP vs. SSP (SP/SSP)] were evaluated by the Kruskal–Wallis test.

### Results

The baseline characteristics of the overall population are shown in Table 1. Our population included patients after radical prostatectomy ( $n = 323$ , 84.3%), primary high-intensity focused ultrasound ( $n = 3$ , 0.8%), transurethral resection of the prostate ( $n = 55$ , 14.4%) and even one patient after open adenomectomy (0.26%) and urethral injury (0.26%)

(Fig. 4). Comparison of the three port generations preoperatively revealed no significant differences regarding the BMI, ASA score, previous radiotherapy and incontinence surgery or 24-h pad count and pad test (each  $p > 0.05$ ). Only patient age, comorbidities measured by the Charlson comorbidity index (CCI), and the preoperative ICIQ-SF score showed significant differences. Herein, the patients who received an SSP were significantly older ( $p$  values for patient age: IP/SP  $p = 0.0451$ , IP/SSP  $p = 0.0064$ , SP/SSP  $p \geq 0.9999$ ), had significantly more comorbidities ( $p$  values for CCI score: IP/SP  $p = 0.6001$ , IP/SSP  $p = 0.0011$ , SP/SSP  $p = 0.0606$ ) and were significantly more impaired due to their incontinence ( $p$  values for preoperative ICIQ-SF score: IP/SP  $p > 0.9999$ ,



**Fig. 4** Genesis of urinary incontinence of the overall population ( $n = 383$  patients)

**Table 1** Baseline characteristics of the patient population (overall population  $n = 383$  patients)

Category	Overall, $n = 383$	IP, $n = 240$	SP, $n = 89$	SSP, $n = 54$	$p$ value* IP/SP, IP/SSP, SP/SSP
Patient age [years] (range)	69.4 ± 6.8 (49–94)	68.5 ± 7.0 (49–88)	70.8 ± 6.6 (55–94)	71.6 ± 5.4 (59–85)	<b>0.0451, 0.0064</b> , > 0.9999
BMI [kg/m <sup>2</sup> ] (range)	28.1 ± 3.7 (20–47)	28 ± 3.6 (21–47)	27.9 ± 3.4 (20–38)	29 ± 4.4 (21–40)	> 0.9999, 0.4279, 0.5269
ASA score (range)	2.2 ± 0.6 (1–4)	2.2 ± 0.7 (1–4)	2.1 ± 0.6 (1–4)	2.3 ± 0.7 (1–4)	> 0.9999, 0.1336, 0.2368
CCI score (range)	7.2 ± 1.8 (0–16)	7.1 ± 2.0 (0–16)	7.3 ± 0.9 (5–9)	8 ± 1.6 (5–15)	0.6001, <b>0.0011</b> , 0.0606
Primary/secondary radiation (%)	95/383 (24.8)	58/240 (24.2)	22/89 (24.7)	15/54 (27.8)	> 0.9999, > 0.9999, > 0.9999
Previous surgery due to SUI (%)	92/383 (24)	58/240 (24.2)	27/89 (30.3)	7/54 (13)	0.7609, 0.2391, 0.0559
Preoperative 24-h pad count (range)	5.0 ± 2.8 (2–18)	5.1 ± 3.1 (2–18)	4.6 ± 2.4 (1–18)	4.8 ± 2.3 (2–10)	0.5552, > 0.9999, > 0.9999
Preoperative 24-h pad test [ml] (range)	588 ± 427 (40–2500)	603 ± 417 (40–2500)	522 ± 447 (70–2500)	634 ± 428 (150–2000)	0.0562, > 0.9999, 0.0679
Preoperative ICIQ-SF score (range)	17 ± 2.1 (12–21)	16.7 ± 2.1 (12–21)	16.9 ± 2.0 (13–21)	18.2 ± 1.8 (15–21)	> 0.9999, <b>0.0001, 0.0035</b>
Preoperative VAS score (range)	0.04 ± 0.27 (0–3)	0.1 ± 0.3 (0–3)	0.03 ± 0.24 (0–2)	0.04 ± 0.19 (0–1)	> 0.9999, > 0.9999, > 0.9999

Bold values indicate significant differences

Mean ± standard deviation (range) or percentage

\*Kruskal–Wallis test ( $\alpha = 0.05$ )

IP/SSP  $p=0.0001$ , SP/SSP  $p=0.0035$ ) than the patients who received an IP or SP.

The peri- and postoperative data are shown in Table 2. For the overall population, the mean operative time was  $50.7 \pm 20.5$  (11–148) min. Furthermore, considering the whole population, 50.1% of the patients became ‘dry’ (0 or a ‘safety pad’/day), while 32.4% achieved at least an improvement of more than 50% (with 1–2 pads/day), representing an overall success rate of 82.5%. The mean number of pads per day decreased from  $5.0 \pm 2.8$  (2–18) to  $1.3 \pm 1.4$  (0–6), in which the average number of adjustments was  $3.4 \pm 2.1$  (0–9). Because the ATOMS represents a system that achieves continence by sub-urethral pressure, we performed a uroflowmetry evaluation, which showed a flow of  $14.6 \pm 3.8$  (4–35) ml/s and a postoperative post-void residual volume of  $8 \pm 23$  (0–200) ml. Evaluation of the QoL 6 months after surgery revealed a significant improvement. Compared to baseline, the ICIQ-SF score dropped from  $17 \pm 2.1$  (12–21) to  $4.6 \pm 4.4$  (0–20) at 6 months postoperatively ( $p=0.0001$ ). We implemented a standardized postoperative analgesic regime with the use of non-steroidal anti-inflammatory drugs (NSAID) during the wound healing period within the first 4 weeks after implantation. Only severe, prolonged postoperative pain, measured with a VAS score of more than 3 and lasting longer than 4 weeks after implantation, was graded as a postoperative complication. The mean VAS score of the overall population 6 months after implantation was  $0.6 \pm 0.4$  (0–6). Comparing the three port generations, we found no significant differences peri- or postoperatively in relation to the 24-h pad count, 24-h pad test, uroflowmetry,

post-void residual volume or VAS score. A significant difference was observed in the operative time (Fig. 5), postoperative adjustments and postoperative ICIQ-SF score (Fig. 6). Significantly shorter operative times [IP  $56 \pm 19.1$  (28–148); SP  $42 \pm 18.7$  (19–117); SSP  $40 \pm 20.9$  (11–117);  $p$  values: IP/SP  $p < 0.0001$ , IP/SSP  $p = 0.0048$ , SP/SSP  $p = 0.697$ ] and fewer postoperative adjustments (IP  $4.1 \pm 2.0$  (0–9); SP:  $2.5 \pm 1.7$  (0–9); SSP:  $1.8 \pm 2.2$  (0–9);  $p$  values: IP/SP  $p < 0.0001$ , IP/SSP  $p < 0.0001$ , SP/SSP  $p = 0.0539$ ) were found for the SP and SSP than for the IP, while the postoperative ICIQ-SF score was significantly better for the SSP than the SP [IP  $4.5 \pm 4.3$  (0–19); SP  $5.4 \pm 4.6$  (0–20); SSP  $3.4 \pm 4.2$  (0–17);  $p$  values: IP/SP  $p = 0.4016$ , IP/SSP  $p = 0.2111$ , SP/SSP  $p = 0.0232$ ].

As expected, no intraoperative complications were observed. Postoperative complications were classified according to the Clavien–Dindo classification system [13], with a particular focus on serious port-associated events. The postoperative port-associated complications and their management are shown in Table 3. For the overall population, we observed two grade I (0.5%) and 37 grade IIIb complications (9.7%). Comparing the three port generations, we also observed a significant difference. Herein, we found 1 grade I (0.4%) and 29 grade IIIb (12.1%) complications, as well as 1 grade I (1.1%) and 6 grade IIIb (6.7%) complications for the IP and SP, respectively, but only 2 grade IIIb complications (3.7%) for the SSP (IP/SP  $p = 0.0231$ , IP/SSP  $p = 0.0189$  and SP/SSP  $p = 0.0453$ ). Regarding prolonged postoperative pain, only one patient with an SP (1/89, 1.1%) described a ‘generalized’, conservative therapy–refractory pain, with maximum pain in the perineal area but also in the

**Table 2** Peri- and postoperative parameters of the patient population (overall population  $n=383$  patients)

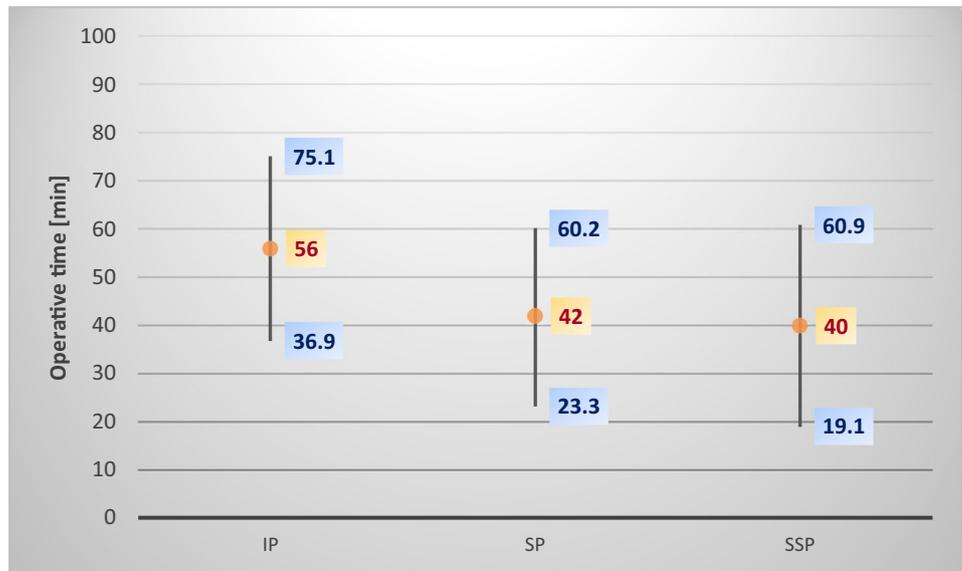
Category	Overall, $n=383$	IP, $n=240$	SP, $n=89$	SSP, $n=54$	$p$ value* IP/SP, IP/SSP, SP/SSP
Operative Time [min] (range)	$50.7 \pm 20.5$ (11–148)	$56 \pm 19.1$ (28–148)	$42 \pm 18.7$ (19–117)	$40 \pm 20.9$ (11–117)	<b>&lt;0.0001</b> , <b>0.0048</b> , 0.697
Postoperative adjustments (range)	$3.4 \pm 2.1$ (0–9)	$4.1 \pm 2.0$ (0–9)	$2.5 \pm 1.7$ (0–9)	$1.8 \pm 2.2$ (0–9)	<b>&lt;0.0001</b> , <b>&lt;0.0001</b> , 0.0539
Postoperative 24-h pad count (range)	$1.3 \pm 1.4$ (0–6)	$1.3 \pm 1.5$ (0–5)	$1.0 \pm 1.2$ (0–6)	$1.1 \pm 1.6$ (0–6)	0.2062, 0.2043, 0.1091
Postoperative 24-h pad test [ml] (range)	$80 \pm 156$ (0–1000)	$79 \pm 155$ (0–1000)	$86 \pm 131$ (0–1000)	$78 \pm 155$ (0–1000)	0.0891, 0.1051, 0.0912
Postoperative uroflowmetry [ml/s] (range)	$14.6 \pm 3.8$ (4–35)	$14.4 \pm 4.1$ (4–35)	$15.2 \pm 3.2$ (10–30)	$14.6 \pm 3$ (4–22)	0.1533, 0.9883, >0.9999
Postoperative residual volume [ml] (range)	$8 \pm 23$ (0–200)	$6 \pm 18$ (0–200)	$9 \pm 14$ (0–100)	$12 \pm 42$ (0–200)	0.0534, 0.9883, 0.0899
Postoperative ICIQ-SF score (range)	$4.6 \pm 4.4$ (0–20)	$4.5 \pm 4.3$ (0–19)	$5.4 \pm 4.6$ (0–20)	$3.4 \pm 4.2$ (0–17)	0.4016, 0.2111, <b>0.0232</b>
Postoperative VAS score (range)	$0.6 \pm 0.4$ (0–6)	$0.6 \pm 0.3$ (0–4)	$0.7 \pm 0.3$ (0–4)	$0.7 \pm 0.2$ (0–6)	>0.9999, 0.1336, 0.2368

Bold values indicate significant differences

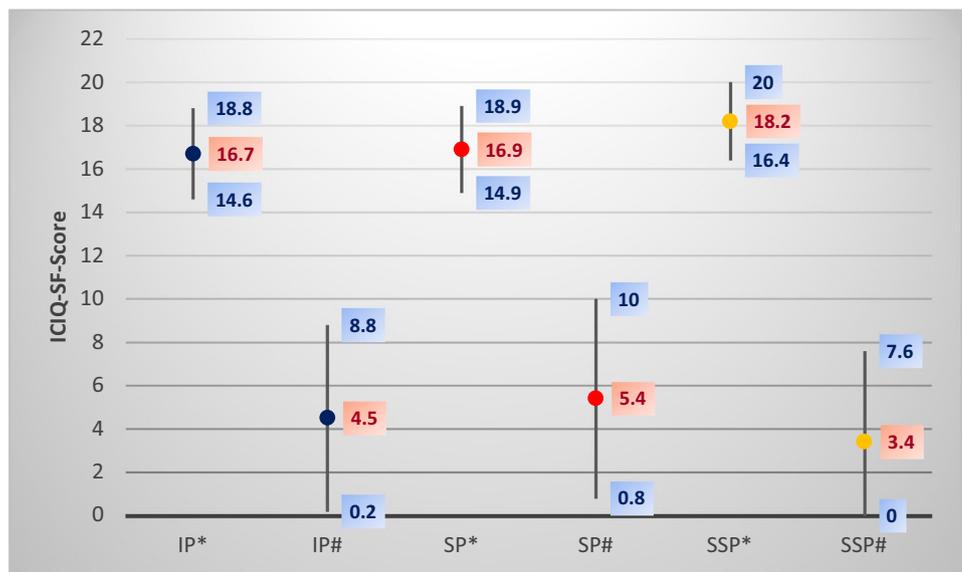
Mean  $\pm$  standard deviation (range) or percentage

\*Kruskal–Wallis test ( $\alpha=0.05$ )

**Fig. 5** Comparison of the three ATOMS® port generations regarding operative time (min); Mean ± standard deviation



**Fig. 6** Comparison of the three ATOMS® port generations regarding pre- and postoperative ICIQ-SF score; \*preoperative status, #postoperative status; Mean ± standard deviation



area of the SP. Ultimately, a removal of the ATOMS in this patient was necessary.

### Discussion

For affected patients, male SUI is very embarrassing. Currently, there are no solid epidemiological data regarding male SUI [14, 15]. While urological surgical techniques, especially radical prostatectomy, are a common cause of male SUI, these techniques have developed over the past few years, and the feared side effect of urinary incontinence has become less frequent [16–20]. Nevertheless, male SUI

can still occur [21], and after exhausting all conservative treatment options, surgery is a valid option for many of these patients.

For multiple decades, the only surgical option for treating male SUI was the artificial urinary sphincter. Therefore, it became the gold standard. However, this gold standard has been challenged over the past 15 years by the development of further treatment options. Meanwhile, we have an armamentarium of different implants available. Their indication for implantation varies according to the degree of SUI, as well as the previous treatments and specific needs of the patient. All commonly used implants evolve over time, while there are hardly any publications in the literature that have

**Table 3** Port-associated postoperative complications of the patient population (overall population  $n=383$  patients)

Clavien grade—port-associated postoperative complications	Complication management	IP, $n=240$	SP, $n=89$	SSP, $n=54$	$p$ value* IP/SP, IP/SSP, SP/SSP
Clavien I					
Scrotal hematoma (< 30 days)	Conservative	1 (0.4%)	1 (1.1%)	0	<b>0.0231, 0.0189, 0.0453</b>
Clavien IIIb					
Pain with necessity for device removal (> 30 days)	Device removal	0	1 (1.1%)	0	
Wound infection port (< 30 days)	1 × device removal (SP), 1 × open wound management + secondary suture (IP)	1 (0.4%)	1 (1.1%)	0	
Incipient erosion of the port (> 30 days)	Re-placement of the port	2 (0.8%)	0	0	
Erosion and infection of the port capsule (> 30 days)	Device removal	24 (10%)	4 (4.5%)	2 (3.7%)	
Erosion and infection of the port catheter (> 30 days)	Device removal	2 (0.8%)	0	0	

Bold values indicate significant differences

According to Clavien–Dindo classification [13]

\*Kruskal–Wallis test ( $\alpha=0.05$ )

investigated these developments and evaluated the ‘promised improvements’; this line of inquiry is of eminent importance, as discovered in the context of female prolapse surgery [22, 23].

For the ATOMS incontinence system, these developments have concerned the localization and size of the port. The ATOMS evolved from a first generation with inguinal port (IP) to the second (SP) and third generation with a scrotal port (SSP), whereby these differ in size and coverage. To date, only Friedl et al. [8] and Angulo et al. [9] have published a series including the three different ATOMS port generations, with short- to mid-term follow-up periods. Thus, we report our multicentre comparison of the different port generations of the ATOMS, in terms of the benefit of the third ATOMS generation.

Regarding the baseline characteristics, we found no significant differences in previous radiation or incontinence surgery, or the 24-h pad count and pad test. Significant differences were found only in the patient age, CCI and ICIQ-SF score, wherein the patients who received the SSP were significantly older, with comorbidities and impaired due to their incontinence. However, these results are difficult to explain because significant differences in baseline characteristics were not expected; additionally, there was no specific selection for patient age or comorbidities. These findings could be coincidental or, more plausibly, older patients are more impaired due to their incontinence because of pronounced immobility, for example, as described in literature [24]. On the other hand, no significant differences in the ASA score were found among the three port generations. Perhaps differences between scoring systems could have led to this difference [25, 26].

Regarding peri- and postoperative data, a significant difference was found only in the operative time, postoperative adjustments and postoperative ICIQ-SF score, in which significantly shorter operative times and fewer adjustments were found for the SP and SSP than for the IP, respectively, while the ICIQ-SF score was significantly better for the SSP. For the operative time, this result was expected because of the absence of a second incision and the pre-connected port catheter of the SSP [8]. The smaller number of adjustments for the SSP is possibly due to the shorter follow-up time, while the better postoperative ICIQ-SF score is much harder to explain; perhaps it was influenced by patient counseling and hence the learning curve of the consulting physician. It could also be a true significance due to the better overall course of the patients. Regarding the further development of other incontinence devices (e.g., AdVance/AdVance XP, Argus/Argus T and AMS 800), unfortunately, there have been no comparisons of the ICIQ-SF score or the QoL [2, 5, 6, 27–29]. Therefore, there are no final conclusions regarding the improvement in the ICIQ-SF score of SSP patients.

Regarding postoperative complications, according to the Clavien–Dindo classification [13], we found 2 grade I (0.5%) and 37 grade IIIb (9.7%) complications for the overall population. Comparing the three port generations, we observed a significant difference, wherein we found significantly fewer port-associated complications for the SSP (IP/SP  $p=0.0231$ , IP/SSP  $p=0.0189$  and SP/SSP  $p=0.0453$ ). This result is most likely due to the significantly smaller wound area and inherent features of the SSP [8]. Additionally, for the other incontinence devices, individual developments have led to significant reductions in postoperative complications [28, 29]. Each of these individual developments on its own has,

therefore, led to increased therapeutic efficacy and improved patient comfort.

The aim of incontinence surgery is to achieve the maximum result, not only in terms of continence but also in terms of patient satisfaction. However, as with all other surgical implants, it is less likely to achieve high satisfaction for severely incontinent patients than for patients with mild or moderate degrees of urinary incontinence. Therefore, the personalized counseling of patients seems mandatory for selection of the best individual treatment. For patients with only slight urinary incontinence and good residual sphincter function, a bulbourethral sling may also be an option. In the case of complete incontinence without any residual sphincter function, an artificial urinary sphincter may be the best approach [30]. Finally, all urinary incontinence devices have evolved and proven effective for the correct indications. However, it is nearly impossible to compare the different devices because the patients represent a very heterogeneous collective due to different degrees of incontinence, different previous treatments and ultimately different levels of suffering. However, observational studies can be used to specify the indications of the different devices and identify the respective advantages and disadvantages of the devices and their developments [2, 28–30]. Thus, the development of the ATOMS into the smaller, pre-connected SSP not only saves time intraoperatively but is equally efficient, shows fewer complications and is, therefore, the correctly optimized device when utilizing an ATOMS implant.

The limitations of this study include the lack of a control group and the heterogeneous patient sample, which ultimately corresponds to daily practice. Furthermore, the procedures were performed in multiple centers by several surgeons (AF, RZ, SM, NM, and PF), rendering their individual learning curves a factor. Thus, the different surgical experiences and learning curves may have influenced the patient outcomes as well as the complication rate. Further investigations are needed.

## Conclusion for the practice

The treatment of male SUI using the ATOMS is an established and effective surgical therapy. Herein, the further development of the ATOMS into a system with the smaller, pre-connected fully silicone-covered scrotal port shows less port-associated complications and is, therefore, the correctly optimized device when utilizing an ATOMS implant.

**Author contributions** SM: protocol development, data collection and analysis, manuscript writing. AF: data collection and analysis, manuscript writing. RZ: data collection and analysis. NM: data collection, manuscript editing. AS: manuscript editing. GT: data analysis, manuscript editing. PF: protocol development, data collection, 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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