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ORIGINAL ARTICLE

Clinical results of a dorsally positioned hydraulic ID-sling in male patients with post-prostatectomy-incontinence

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Abstract

Purpose To prospectively evaluate the effectiveness and safety of and the long-term experience with a re-adjustable hydraulic sling (ID-sling) device positioned dorsally to the urethra for the treatment of male post-prostatectomy incontinence (PPI).

Materials and methods Between September 2007 and November 2009 13 patients with persisting SUI were treated consecutively with an ID-sling™ in two European tertiary centers by a single surgeon. Physical examinations and standardized questionnaires (ICIQ-SF + VAS), pad tests, and 24-h pad number counts were performed at baseline and during follow-up.

Results The implantation of the hydraulic cuff was uncomplicated in all cases. The ICIQ-SF score diminished from a preoperative mean value of 18 to a mean of five postoperatively. One patient remained completely dry with normal micturition. All patients demonstrated a mild improvement at primary filling but did not show any significant improvement after the second or any subsequent filling. In total, 1/13 (7.7%) patients were completely dry and 5/13 (38.4%) showed improved continence. In 6/13 (46.2%) patients, satisfactory continence results according to subjective criteria, were not achieved. Subsequently, artificial urinary sphincter (AUS) implantation was offered to one patient (7.7%) after 12 months and to ten patients (76,9%) after 24 months.

Conclusions The implantation of a dorsally placed hydraulic sling is a not yet standardized and complex procedure, even for the experienced surgeon. To date, this implantation method is not an alternative to other devices. An improved sling design is necessary to simplify the surgical procedure and to improve long-term stability.

Keywords Male stress urinary incontinence · Radical prostatectomy · Adjustable male hydraulic urethral sling

Introduction

Stress urinary incontinence (SUI) may occur in 1–40% of patients after radical prostatectomy and occasionally after transurethral resection of the prostate. This single surgical complication may have a significant negative impact on patient's quality of life [1, 2]. There are many treatment modalities for post-prostatectomy incontinence (PPI), ranging from conservative management such as pelvic floor exercise or biofeedback, to surgical methods including implantation of an artificial urinary sphincter (AUS) and more recently male urethral slings [3–5].

Worldwide more than 150,000 AUS devices, mainly the AMS 800™ device, have been implanted to date. Since 1987 [6], this device with its narrow back cuff design, has proven to be reliable and durable and therefore has not been altered significantly. The high overall success rate of 60–92% [7] even after long-term follow-up of over 10 years [8], has made AMS 800™ the gold-standard for severe to moderate PPI [9]. However, implantation of this device requires substantial surgical skill. The surgical revision rates range between 17 and 37% [10] even in high volume centers [11], mainly due to urethral erosion or more frequently atrophy. In addition, following implantation, this device is not adjustable if urinary continence is not fully achieved. Different

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types of male synthetic slings have thus been introduced [12]. In relation to regaining urinary continence two main therapeutic concepts were postulated; firstly InVance™ and Argus™ frequently cause urethral compression as the main continence parameter and ATOMS™ additionally causes some degree of repositioning of the bulbar and membraneous urethra. However, avoiding circular urethral compression which might jeopardize blood micro-circulation leading to urethral atrophy. Secondly, continence restoration may be achieved by repositioning the urethral bulb (AdVance™) [12]. However, simple compression will lead to obstructive voiding posing potential risk to the lower urinary tract and particularly significant urinary incontinence which cannot be treated fully. Moreover, the majority of slings are not adjustable postoperatively. To overcome this, adjustable slings such as REEMEX™ and Argus™ devices have been developed. However, the process of adjusting these devices postoperatively, is minimally invasive and complicated after the healing phase. Likewise, continence rates were only moderate in most cases [13]. The only easily re-adjustable hydraulic sling is the ATOMS™ system; however, this device acts mainly by urethral compression. Moreover, all implanted devices are positioned ventrally, which differs from the natural sphincter mechanisms which are dorsally positioned to allow natural and unobstructed voiding.

This study reports a re-adjustable hydraulic sling device (ID-sling), that is positioned dorsally to the urethra in attempt to reposition the posterior urethra and mimic normal anatomic properties. The aim of this study is to evaluate the effectiveness and safety of a dorsally positioned hydraulic sling in male patients suffering from SUI, and to report on long-term experience with this device.

Patients and methods

A retrospective analysis of a consecutive case series was performed on 13 patients suffering from grade 2–3 SUI, who were recruited between September 2007 and November 2009. After approval from the local ethics committee, patients were enrolled into two European tertiary centers by a single surgeon. All patients had at least a 12-month history of persisting SUI. Two patients had a previous history of TUR/P due to benign disease and 11 patients suffered from post-prostatectomy incontinence. Prior to implantation, medical and specific urological history was obtained from all patients and standardized questionnaires (KHQ, ICIQ-SF + VAS) were completed by each patient. All patients underwent flexible cystoscopy to rule out urethral stricture or any other pathology at the implantation site. In addition, SUI was quantified by a 20 min pad test and 24-h pad number count. In nine patients an additional 24-h pad test was performed. Exclusion criteria were urethral stricture, anatomical malformation, an untreated overactive bladder, and previous history of radiation or incontinence surgery.

Preoperatively, all patients underwent a local AUS placement protocol

A urine culture was obtained 1 week prior to sling implantation and local perineal-anal skin disinfection was initiated 2 days prior to surgery. This was performed twice daily utilizing a betadine solution in all cases. A pre-surgery antibiotic regimen was initiated the day before surgery either concordant to urinary culture findings or alternatively using amoxicillin and clavulan acid.

Surgical technique

The ID-sling™ (Braun Aesculap, Tuttlingen, Germany) consists of an inflatable cuff (12 × 50 mm), attached to two 10 mm macroporuous monofilament tapes and a port system for further inflation (Figs. 1, 2). Prior to surgery the sling was assembled and checked for leakage by filling with a diluted contrast dye (aqua destillata and Jopamiro™ 300/diluted 60:56 ml). Air bubbles were removed and the balloon completely emptied. Surgery was performed either under spinal or general anesthesia in a slight head down lithotomy position. A 12F Foley catheter was inserted intraoperatively and removed postoperatively on day 2. A median perineal skin incision was performed with bulbar urethral exposure and then the urethra was dorsally mobilized as with AUS implantation. The deflated cuff was positioned dorsally, mainly proximally onto the urethra, approximately at the junction of both crura of the cavernous body (Fig. 3). The sling tape was then shortened and the loose ends were used

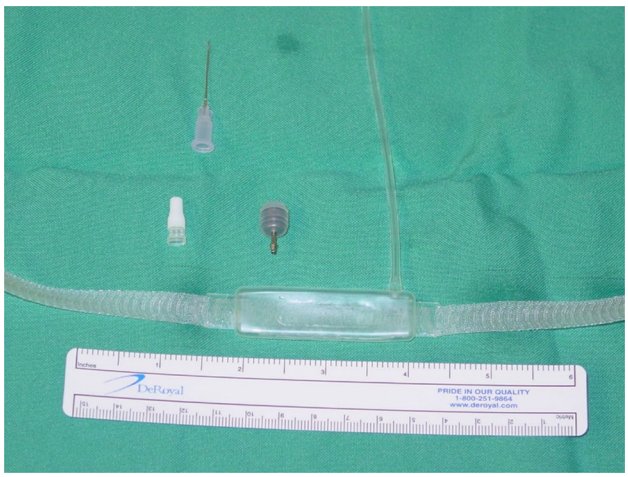

Fig. 1 ID-sling™ assemble kit containing the non-filled hydraulic sling with attached macroporous mesh, access port, connector, and filling needle

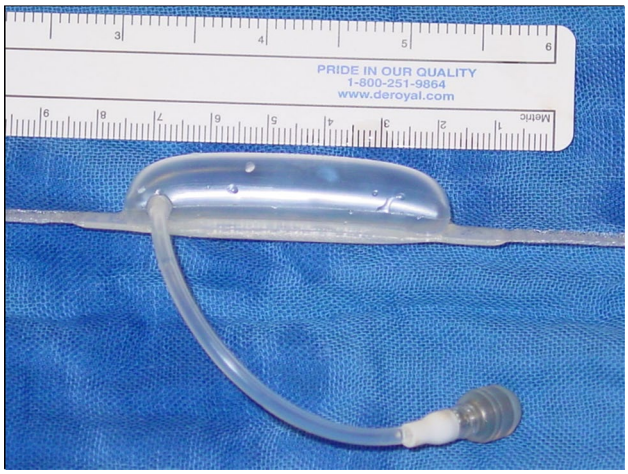

Fig. 2 Close-up of the assembled and filled ID-sling™ prior to implantation to demonstrate water tightness of the device 5

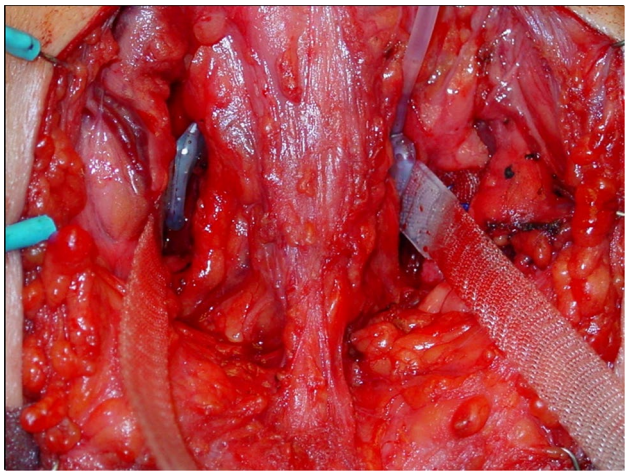

Fig. 3 Intraoperative setting—the ID-sling™ in a dorsal position at the bulbar urethra (at the junction of the corpora cavernosa). The left obturatoric tape in position and ready to be attached to the sling with sutures

for ring fixation in the obturatoric foramen. A specially curved needle was used to access the obturatoric fossa on both sides and the free tape ends were wrapped around the pubic rami in duplicate. Thereafter, the loop was placed under tension and the tape was fixed with non-absorbable sutures. The wound was rinsed with a gentamycin solution. The access port was positioned subcutaneously at the right scrotal skin region. Median wound closure was performed with subcutaneous sutures using Vicryl 3–0 and skin sutures using Monocryl 4–0. A local compressive dressing was applied and left for 2 days after surgery. The catheter was removed on day 2 after surgery, and post-void residual urine was recorded by ultrasonography. Antibiotic treatment was maintained for 7 days. Patients were followed-up after 2 and 4 weeks. After 4 weeks, cuff inflation was initiated. This was performed after local skin disinfection via port puncture, using a special 20 mm 19G needle and aqua destillata/contrast medium solution for filling as described above.

Outcome

The primary endpoints were objective and subjective treatment success. Urinary function was evaluated using the International Consultation on Incontinence Questionnaire—Short-Form (ICIQ-SF), daily pad use and results obtained from the pad test. Patients were classified as dry if they did not use any regular pads and had no further incontinence symptoms according to questionnaire findings. Postoperative complications were assessed using records from the prospective centralized database that included follow-ups at 3, 6, 12 and 24 months. Furthermore, patients were questioned about any long-term complications during the subsequent annual follow-up visits. At the first follow-up, a urethrogram and voiding cystography was performed. The longest follow-up was 8 years in one patient. In addition, secondary endpoints were ease of implantation and intraoperative handling of the sling, which were assessed and rated based on scale ranging from one (very easy) to five (very difficult).

Results

In two European tertiary centers, 13 patients with a mean age of 64 years underwent implantation of the hydraulic ID-sling™. Preoperative patients' characteristics are listed in Table 1.

Operative data

Mean operating time was 96 min (range 55–140 min). There were no significant intraoperative or postoperative complications. In particular, no erosion of the urethra or local infection occurred. In two patients, slight perineal paresthesia was observed in the region supplied by the pudendal nerve (mean VAS score 2.2, range 1–3). In all cases, perineal paresthesia

Table 1 Preoperative patients' characteristics of 13 patients with stress incontinence, treated with dorsally positioned hydraulic sling

Characteristics	Value
Age (years)	
Mean (range)	64 (52–79)
Daily pad usage	
Mean (range)	4.4 (2–8)
Nightly pad usage	
Mean (range)	1 (0–2)
ICIQ-SF score	
Mean (range)	18 (12–21)

regressed completely within a few weeks, without further therapy.

The implantation of the hydraulic cuff was uncomplicated in all cases (score 2.0). However, positioning of the sling loops with the existing Dechamps type needle was rated 4.0–5.0 in 7/13 (53.8%) patients. The Dechamps-type needles were insufficiently curved and helically oriented and so a more curved and helical shaped needle was utilized in these patients. The implantation was subsequently easier, but the needle type and shape was still regarded as insufficient. Particularly, in very obese patients ($n=5$), immobile patients ($n=1$) and/or if a very narrow obturatoric foramen ($n=2$) was present, obtaining the correct proximal positioning and stable fixation at the bulbar urethra proved to be impossible.

In one patient, the cuff was accidentally punctured during sling suturing and a new sling was implanted during the same surgical procedure.

Mechanical failure or dysfunction of the sling or refill port was not observed. All slings could be easily refilled as planned after the healing period. In one patient, a single 2 ml filling was sufficient, whereas the remaining patients required multiple refills up to a maximum of 15 ml cuff volume. A mean of 3.9 (range 1–7) re-fillings were required. The handling of the access port for refilling was feasible and easy (score 1.0–2.0) in all cases. There were no complications associated with the slings and the port systems.

No patient presented with subjective or objective obstructed voiding symptoms, increased post-void residual volume (mean 12 ml, range 0–40 ml) or urinary retention postoperatively. The ICIQ-SF score diminished from a mean value of 18 preoperatively to a mean of five postoperatively. The usage of nightly pads showed no improvement after a follow-up of 24 months. The average number of pads needed per day reduced after a follow-up of 24 months (Table 2).

Table 2 Functional outcome of 13 male patients, treated with dorsally positioned hydraulic sling

Timepoint	ICIQ-SF score	Daily pad usage	Nightly pad usage
3 months FU			
Mean	15	3	1
Range	4–21	0–6	0–1
6 months FU			
Mean	15	4	1
Range	3–21	0–6	0–2
12 months FU			
Mean	14	3	1
Range	1–21	0–6	0–1
24 months FU			
Mean	16	4	1
Range	8–21	2–7	0–1

One patient remained completely dry with normal micturition. As seen in the urethrogram and voiding cystography, the cuff placement site was optimal (Fig. 4a, b). In six patients with cuff positioning regarded as sub-optimal, continence results were acceptable. They displayed a significant improvement between 50 and 70% based on questionnaire findings and required a mean of only 2.2 (range 2–3) pads instead of 6.6 (range 6–7) pads within a 24 h period. In all other patients, the cuff was positioned too distally on X-ray, and subsequent refilling in attempt to improve continence tended to cause the cuff to rotate and flatten (Fig. 5). All these patients demonstrated a mild improvement at the primary filling, but did not show any significant improvement after the second or any subsequent filling. Subsequently AUS implantation was offered to one patient after 12 months, and to ten patients after 24 months. Implantation of the artificial sphincter was not hampered by the pre-intervention and no complications were apparent. One patient received a FlowSecure™ AUS and remaining patients received an AMS 800™ AUS. All patients were dry

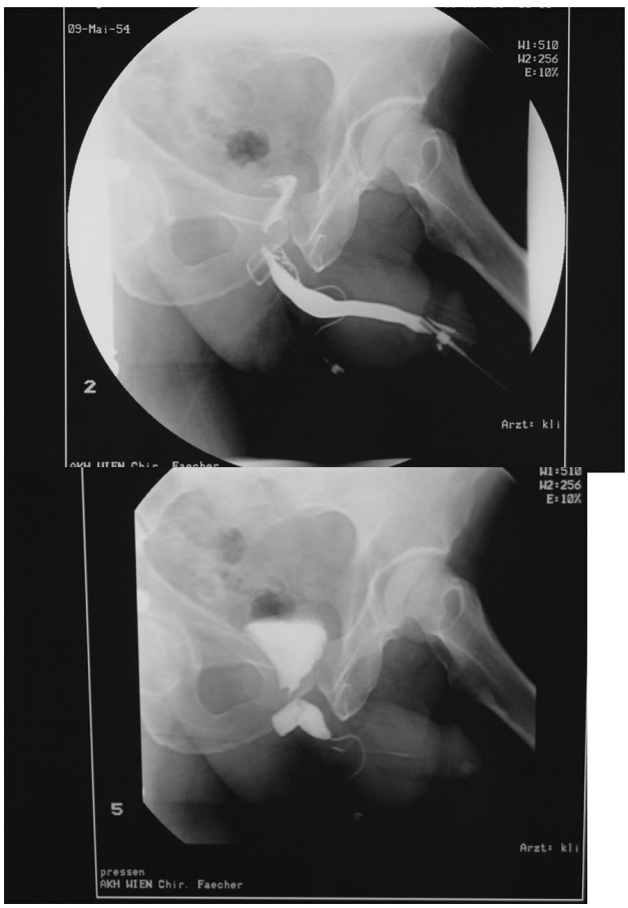

Fig. 4 **a**,**b** Optimal positioning of the ID sling™ at first postoperative filling with 2 cc of diluted contrast medium. The patient was completely dry after one single filling

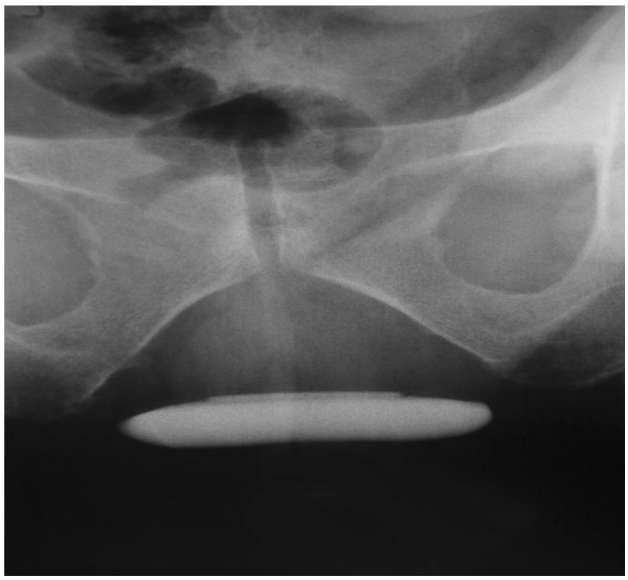

Fig. 5 Insufficient continence achieved due to flattening and slight rotation of the ID-sling™, caused by distal sling positioning

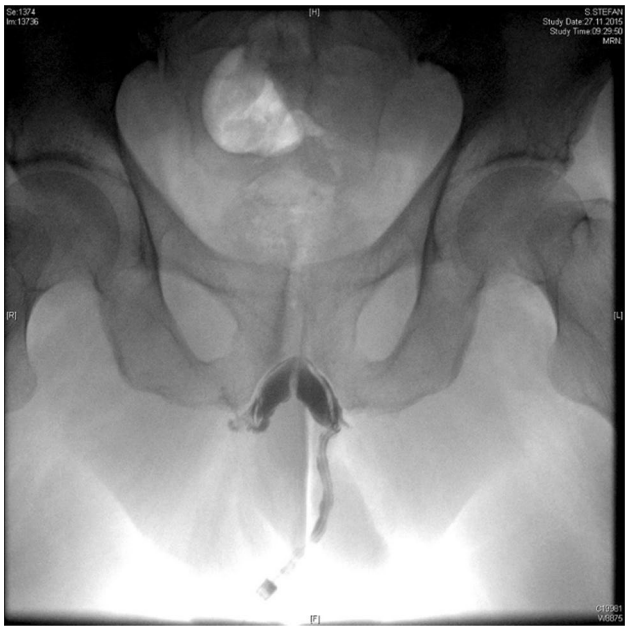

Fig. 6 Contrast filling of an ID-sling after a 6-year follow-up period due to recurrent incontinence. This demonstrates leakage on the right sling cuff-side

after AUS implantation (0–1 safety pad). Unfortunately, the FlowSecure™ required explanting after 12 months due to cuff leakage. Another AMS 800 was successfully implanted after 3 months and again full continence was achieved. One AMS 800 was lost 8 weeks postoperatively due to local infection. This patient refused any further surgical intervention due to his deteriorating general health condition. The completely dry patient with the ID-sling™ presented after 8 years with recurrent mild SUI (1–2 pads/24 h, 39 ml in the 24-h pad test). The sling cuff could not be identified with perineal ultrasonography and cuff leakage was seen on X-ray (Fig. 6). As no infection was present, the level of incontinence was mild and because the patient was not overly concerned, the decision was made to leave the sling in situ and assess for any further continence deterioration.

Discussion

The implantation of a dorsally positioned hydraulic sling is complex and requires an accurate technique. Performed by an experienced surgeon, this procedure is safe and can be performed without major complications. At least in this small cohort no significant peri- and postoperative complications occurred. It must be mentioned, however, that the surgeon's expertise was at a very high level having previously performed 170 AUS implantations. Also, the pre-operative setting and the ID-sling™ implant procedure closely resembled that of the AUS.

Several potential pitfalls influencing the surgical procedure and subsequent outcomes were observed. Fixation of the slings at the lower pubic ramus was much more difficult in comparison to other standard slings and compared to AUS implantation. ID sling™ implantation was problematic due to insufficient numbers of application needles and the concept of using duplicate wrapping of tape in the obturatoric foramen for fixation. A self-anchoring system and a "ready-to-use" closing system would have eased the entire implantation process dramatically, however, this was unavailable at this time. In addition, fixating the sling tapes to the obturatoric fixation ring and using circular needles near the cuff promoted accidental perforation on one occasion. This incidence however, would have been much higher with an unexperienced surgeon. Likewise, final cuff positioning was largely dependent on correct ring placement. The aim of attaining very proximal positioning was hindered by the Dechamps-type needles being insufficiently curved and helically oriented. Based on experience, the Dechamps-type needles used initially are not well suited for positioning during this procedure. The use of new needles such as those which are more helical and circular in design, will aid implantation as they are better suited for the narrow intraoperative situs of the male pelvis. Nowadays, suitable application needles like in the AdVance™ system are readily available. Consequently, it was not possible to access the entire length of the pubic ramus. In cases where the patient was very obese ($n=5$), immobile ($n=1$) and/or those with a very narrow obturatoric foramen ($n=2$), it was not possible to attain correct proximal positioning and stable fixation at the bulbar urethra.

Consequently, the effectiveness of this technique was only moderate. In total, 1/13 (7.7%) patients were completely dry and 5/13 (38.4%) showed clearly improved continence. In 6/13 (46.2%) patients, satisfactory measures of continence according to subjective criteria were not achieved. Unsurprisingly, one patient (1/13) already requested AUS implantation at the 12-month visit and the remaining patients (12/13) after the final 24-month visit. Seven patients from Hungary had no local access to AUS reimbursement at that point. However, after 3–4 years, all then received AUS. Subsequent AUS implantation resulted in a substantially improved continence outcomes in all of these patients, demonstrating an effectiveness significantly exceeding standard AUS results. The AMS sphincter is considered the gold standard for the management of moderate and severe incontinence with a continence rate of 75–92% [14]. An even higher continence rate was achieved as a result of the introduction of a narrow back cuff, yielding a continence rate of up to 92% [15]. After a follow-up of between 6 and 8 years, a total and social continence rate of 27 and 52% were achieved, respectively [16]. In summary, it was not possible to match these data in most patients. Excellent and durable results could be obtained only if the cuff position was regarded as optimal (= very proximal bulbar urethra, Fig. 4a, b). Again, the implantation technique for loop positioning was not well elaborated and is believed to be the main reason for insufficient results. Likewise, the cuff shape and the cuff width of only 12 mm warrants further research and basic experimental refinement. This small cuff size is similar to AUS, but means that the slings tend to rotate with increased filling. A broader cuff would help to stabilize the hydraulic sling. In addition, the sling movement causes less urethral compression. In this case, despite reloading the sling, continence outcome was poor. In addition, the cuff pressure would work out better a longer urethral area. This finding has been well demonstrated in the ATOMS™ sling. Unfortunately, their ventral positioning will still work with simple obstruction.

AUS implant is an expensive procedure that requires manual dexterity and is associated with various complications such as erosion and mechanical dysfunction leading to re-operation or explantation. As an alternative, male slings are recommended by European Guidelines for moderate incontinence. Kumar et al. have shown that about 75% of patients with moderate post-prostatectomy incontinence prefer a sling over an AMS sphincter [17]. Recent data regarding adjustable male slings have shown an improvement in incontinence rate and cure rate by 72–79 and 40–66%, respectively [18]. Despite the long-term data regarding the efficacy and safety of male slings, the cure rate remains low. To our knowledge, we describe a new technique for the treatment of male male post-prostatectomy incontinence using a re-adjustable device with a dorsally positioned hydraulic sling. There was an improvement in ICIQ-SF score, and daily use of pads in a significant proportion of patients. However, the use of nightly pads did not differ postoperatively. The most important finding was, that obstructive voiding did not occur in this study, supporting the concept of positioning the cuff dorsally. Due to the high number of AUS sphincter implantations, it may also be concluded, that the implantation of a single-step AUS after an unsuccessful ID-sling™ implantation, is easier compared to other slings that were used.

This present study has limitations that must be mentioned. This is a retrospective case analysis study, involving a limited number of patients. To date, the method of using a dorsally placed hydraulic sling for male male post-prostatectomy incontinence is still under investigation. Also, sling procedures performed by two experienced surgeons were selected and so experience-related procedural outcomes could not be demonstrated.

Conclusions

To conclude, implantation of a dorsally placed hydraulic sling is a feasible surgical procedure. This surgical method is not yet standardized and the implantation technique is too complex even for an experienced surgeon and is not an alternative to other devices at this moment. In particular, the sling fixation technique led to a negative outcome and so requires improvement. Further technical development of the sling is needed to improve surgical implantation and long-term stability.

References

1. Olsson LE, Salomon L, Nadu A et al (2001) Prospective patient-reported continence after laparoscopic radical prostatectomy. Urology 58:570–572
2. Cooperberg MR, Master VA, Carroll PR (2003) Health related quality of life significance of single pad urinary incontinence following radical prostatectomy. J Urol 170:512–515
3. Caremel R, Corcos J (2014) Incontinence after radical prostatectomy: anything new in its management? Can Urol Assoc J 8:202–212
4. Trigo Rocha F, Gomes CM, Mitre AI, Arap S, Srougi M (2008) A prospective study evaluating the efficacy of the artificial sphincter AMS 800 for the treatment of postradical prostatectomy urinary incontinence and the correlation between preoperative urodynamic and surgical outcomes. Urology 71:85–89
5. Wilson LC, Gilling PJ (2011) Post-prostatectomy urinary incontinence: a review of surgical treatment options. BJU Int 107(Suppl 3):7–10
6. Scott FB, Bradley WE, Timm GW (1974) Treatment of urinary incontinence by an implantable prosthetic urinary sphincter. J Urol 112:75–80

7. Bauer RM, Gozzi C, Hubner W, Nitti VW, Novara G (2011) Contemporary management of postprostatectomy incontinence. Eur Urol 59:985–996
8. Kretschmer A, Hübner W, Sandhu JS, Bauer RM (2016) Evaluation and management of postprostatectomy incontinence: a systematic review of current literature. Eur Urol Focus 2(3):245–259
9. Kretschmer A, Nitti V (2017) Surgical treatment of male postprostatectomy incontinence: current concepts. Eur Urol Focus 3(4–5):364–376
10. Bauer RM, Bastian PJ, Gozzi C, Stief CG (2009) Postprostatectomy incontinence: all about diagnosis and management. Eur Urol 55:322–333
11. Margreiter M, Farr A, Sharma V, Schauer I, Klingler HC (2013) Urethral buttressing in patients undergoing artificial urinary sphincter surgery. J Urol 189:1777–1781
12. Lucas MG, Bosch RJ, Burkhard FC, Cruz F, Madden TB (2012) European Association of Urology, EAU guidelines on surgical treatment of urinary incontinence. Eur Urol 62:1118–1129
13. Hubner WA, Gallistl H, Rutkowski M, Huber ER (2011) Adjustable bulbourethral male sling: experience after 101 cases of moderate-to-severe male stress urinary incontinence. BJU Int 107:777–782
14. James MH, McCammon KA (2014) Artificial urinary sphincter for post-prostatectomy incontinence: a review. Int J Urol 21:536–543
15. Elliott DS, Barrett DM (1998) Mayo clinic long-term analysis of the functional durability of the AMS 800 artificial urinary sphincter: a review of 323 cases. J Urol 159:1206–1208
16. Kim SP, Sarmast Z, Daignault S, Faerber GJ, McGuire EJ (2008) Long-term durability and functional outcomes among patients with artificial urinary sphincters: a 10-year retrospective review from the University of Michigan. J Urol 179:1912–1916
17. Kumar A, Litt ER, Ballert KN, Nitti VW (2009) Artificial urinary sphincter versus male sling for post-prostatectomy incontinence—what do patients choose? J Urol 181:1231–1235
18. Welk BK, Herschorn S (2012) The male sling for post-prostatectomy urinary incontinence: a review of contemporary sling designs and outcomes. BJU Int 109:328–344