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ORIGINAL ARTICLE

Long-term results of ProACT primary and repeat implantation for treatment of stress urinary incontinence in men

Sebastian Nestler[1] · C. Thomas[2] · A. Neisius[2] · P. Rubenwolf[2] · F. Roos[2] · C. Hampel[2] · J. W. Thüroff[2]

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Abstract

Introduction Urinary incontinence in men after radical prostatectomy affects strongly quality of life. If conservative treatment fails, surgical treatment consists of implantable devices. If the requirement of manual dexterity in the artificial sphincter is to be avoided, the ProACT system offers a readjustable system, which shows good continence, but also high revision rates. Aim of our single-centre, single-surgeon study was to evaluate the success and revision rates of ProACT over long-term follow-up and if repeat ProACT implantation after failure would be a reasonable strategy.

Materials and methods In May 2017, follow-up of all patients who underwent ProACT implantation between 2003 and 2013 was obtained. Parameters were numbers of pads used, filling volume of balloons, and patient-reported satisfaction. Furthermore, revisions were noted.

Results Between 2003 and 2013, 134 patients were implanted a ProACT system. Median age was 71 years; median follow-up was 118 months. 112 implantations were successful (82.6%) and the number of pads used decreased significantly ($p < 0.005$). 63 patients were revised and 49 were successful (77.8%). No differences in success rate, pads used, or filling volume were seen (all $p > 0.8$). In a second revision, again, no differences in success rate or pads used were noted (all $p > 0.7$). Patients' personal satisfaction was high despite the high revision rate.

Conclusion In the hands of an experienced surgeon, ProACT is a safe and effective therapy for post-prostatectomy incontinence especially if mayor surgery is to be avoided. Revision rates are high, but the results of ProACT reimplantation are comparable to the results after the first implantation.

Keywords Stress urinary incontinence · Artificial urinary sphincter · ProACT system

Introduction

Urinary incontinence is a common issue in men with a prevalence of up to 39% [1]. The most common cause is radical prostatectomy (RP), the surgical standard therapy for localised prostate cancer [2]. In the literature, stress urinary incontinence (SUI) after RP is reported in up to 87% of men [3]. Moreover, SUI is reported in 1% of men after TUR-P [4]. Regardless of the cause, urinary incontinence is for patients the most cumbersome handicap with a strong impact on quality of life. Symptoms of overactive bladder (OAB), which may be experienced in addition, are mostly self-limiting after 1 year [5], but SUI requires special attention and treatment. Therapeutic options are primarily conservative such as pelvic floor muscle training; however, if no satisfactory continence is achieved, surgery is required.

For surgical treatment of SUI, several implantable devices are available. The AMS 800 artificial urinary sphincter (AUS) is considered the gold standard [1] because of continence rates of up to 90% in short- and also long-term follow-up [6, 7]. However, despite excellent success rates, the AUS also carries a risk of complications such as erosion, infection, and mechanical failure. Related revision rates are reported in 8–45% due to urethral atrophy and infections may occur in up to 17% of cases [8]. Furthermore, a distinct manual dexterity is required for opening the sphincter for voiding.

To avoid the difficulties for the patient to actively operate the artificial urinary sphincter, several passive devices have

✉ Sebastian Nestler
sebastian-nestler@web.de

[1] Urogate Bad Vilbel, Bad Vilbel, Germany

[2] Department of Urology, University of Mainz, Mainz, Germany

been developed for patients who do not have the confidence to handle the AUS. One concept comprises suburethral slings. According to the principle of the fascial sling operation for males [9], several alloplastic suburethral male slings have been developed, some with the feature of postoperative readjustment possibilities. Continence rates of up to 80% are reported on short-term follow-up [10] throughout the variety of synthetic slings [11] with low complication rates and short operation times [10, 11].

The ProACT system is based on the concept of proximal urethral compression. It consists of two inflatable balloons, which are placed on either side of the bladder neck and continence is achieved by lateral urethral compression. Two scrotal ports permit easy postoperative adjustment of the filling volume of the balloons [12]. Reported continence rates after 6 months are up to 71% [13] and up to 67% after a median follow-up of 56 months [14]. However, surgical revision rates of up to 30% due to balloon deflation or migration are reported [14]. With increasing experience of the surgeon with the system, revision rates seem to decline [10].

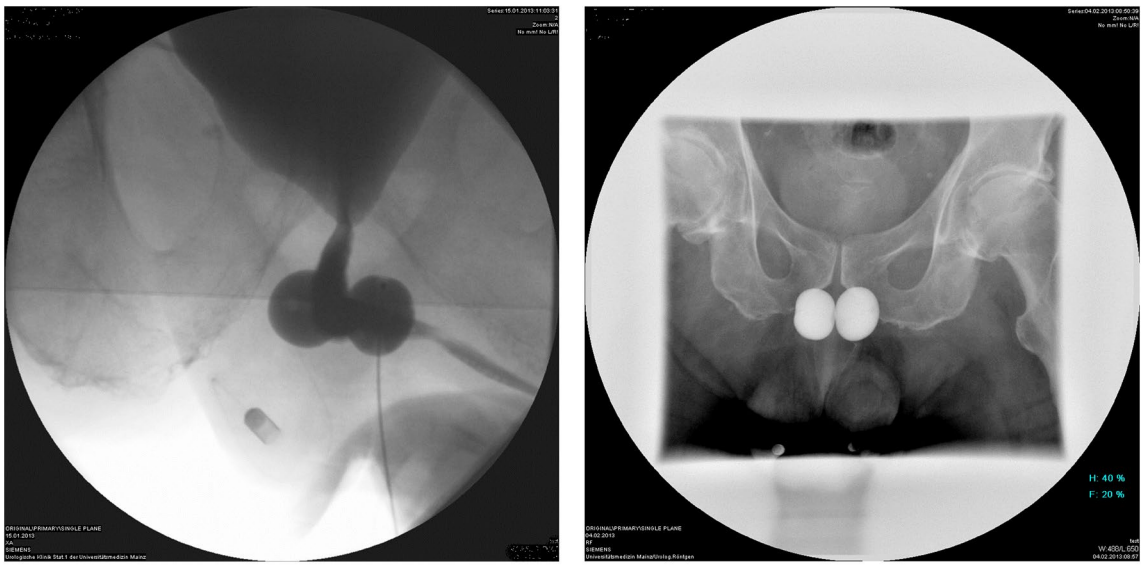
Aim of our study was to evaluate, from a prospectively collected single-centre single-surgeon database, the success and revision rates of ProACT over long-term follow-up with special attention to the question, if a repeat ProACT implantation after an initially successful but secondary failed implantation would be a reasonable strategy.

Materials and methods

In this retrospective study, we obtained a recent follow-up of all patients, who underwent an implantation of a ProACT system between 2003 and 2013 by a single surgeon (C.H.) in our institution. Informed consent was obtained from all individual participants included in the study and institutional permission was obtained by our internal review board. Only patients with a complete data set were included.

Before ProACT implantation, all patients had undergone urine tests including culture, cystoscopy to exclude urethral or anastomosis stricture, and urodynamic studies to exclude an overactive detrusor muscle. Urinary tract infections and strictures were treated before implantation; an overactive detrusor muscle was an exclusion criterion. The same criteria were used for revisions.

Implantation was performed in the OR under general anaesthesia. Cystoscopy was performed first; the balloons were placed under radiologic imaging with the cystoscope shaft in the urethra for guidance. The balloons were placed lateral of the urethra under the bladder neck and 2 ml of isotonic contrast dye solution were insufflated during surgery (see Fig. 1). Two weeks later, filling was continued by 1 ml per ballon per week until patients were satisfied with radiological control of the position of the balloons every 2 weeks and weekly bladder ultrasound to check for residual urine. Filling of balloons was continued until continence was achieved or the maximum of 8 ml on each side was reached. In general, success was defined as a > 50% reduction of pads used with a maximum of a total of two pads per day and satisfaction with the result of the surgery. Patients were seen



a b

Fig. 1 **a** Pelvis a.p., intraoperatively: retrograde urethrogram with cystogram: correctly positioned ProACT balloons. **b** Pelvis a.p.: correct position of ProACT balloons during follow-up

Table 1 Patient`s characteristics

		IQR
Median age (years)	71	67–75
Conservative treatment (months)	35	19–63
Median follow-up (months)	118	87–139
	n	%
Overall	134	100
Retropubic radical prostatectomy	83	61.9
Perineal radical prostatectomy	12	8.9
Minimal-invasive prostatectomy	7	5.2
TUR-P	28	20.6

in the hospital on a yearly basis for radiological controls and ultrasound for residual urine or whenever they experienced a change in continence.

Primary surgery and interval between primary ProACT implantation and revisional surgery were noted. Parameters of outcome of surgery were number of pads used before and after surgery, whereas the number of pads was taken as the average of 3 consecutive days.

Furthermore, filling volume of balloons and patient-reported personal satisfaction scores were evaluated. Satisfaction scores measured using the quality of life question of the validated IPSS questionnaire ["How would you feel, if you had to live with your urinary condition the way it is now, no better, no worse, for the rest of your life?"; score 0 (best)–5 (worst)].

Over the follow-up period, reason for and number of revisions and the above-mentioned parameters of outcome of surgical revision were noted. To all patients with a poor outcome immediately after the first implantation and to all patients with failure during follow-up, a new set of ProACT balloons was offered or a change to another implant (ATOMS or AMS 800-AUS). Preparation for repeat surgery was the same as for the first implantation. ProACT was offered up to three times; thereafter, a change of device was strongly recommended.

In May 2017, all patients were interviewed via telephone for their current status and to record any additional therapy elsewhere. Only patients with a follow-up of at least 14 months were included.

All intraoperative complications and adverse events during follow-up were noted according to the Clavien–Dindo classification.

Statistical analyses were performed using the *t* test for independent samples and logistic regression analysis in SPSS 22.0. Interquartile range was used to document the range and was defined as 25–75%.

Results

Between 2003 and 2013, 134 patients had a ProACT system implanted for urinary incontinence in our institution. For patient's characteristics, see Table 1.

Primary implantation of ProACT system

112 of 134 implantations of a ProACT system (82.6%) were primarily successful according to our definition. All patients provided complete data sets including pad use per day. The number of pads used was preoperatively 6 (IQR 4–7) and declined postoperatively to 1 (IQR 1–2; $p < 0.005$). The median balloon filling volume was 8 ml (IQR 7–9) and median operation time was 27 min (IQR 19–44 min). Personal satisfaction scores improved from preoperatively median 4 (IQR 4–5) to postoperatively median 1 (IQR 0–2).

Perioperative complications occurred in 11 cases, mainly Clavien–Dindo I. In three cases, the transurethral catheter was postoperatively left indwelling for 7 days because of a minor injury of the bladder during implantation; five patients developed a minor hematoma. Three complications were Clavien–Dindo IIIb: two patients had to be explanted because of an infected hematoma and one patient because of symphysitis.

First revision of ProACT system

59 of 112 primarily successful implants of a ProACT system (52.7%) had to be revised after a median of 26 months (IQR 9–59) due to rupture ($n = 35$) or dislocation/migration ($n = 24$) of at least one of the balloons (see Fig. 2). Dislocation or rupture was diagnosed radiologically after patients presented with increasing incontinence and pad use. No cases of infection or fistula occurred. In addition, four patients, who had failed at the primary implantation, received a second ProACT implant, as well. The dislocated or ruptured balloons were explanted by a small incision at the scrotal port during reimplantation. The probability of dislocation did not change with increasing experience of the surgeon.

Of these 63 patients, 49 were successful (77.8%). There were no statistical significant differences between primary and repeat implants concerning success rates ($p = 0.82$), filling volumes of the balloons ($p = 0.81$), and postoperative number of pads used ($p = 0.92$; see also Table 2). Operation time was longer for the repeat implant (median 34 min, IQR 20–59 min) than for the first implant. However, operation for the repeat implant includes explantation of the primary implant. Three minor complications occurred (all Clavien–Dindo I).

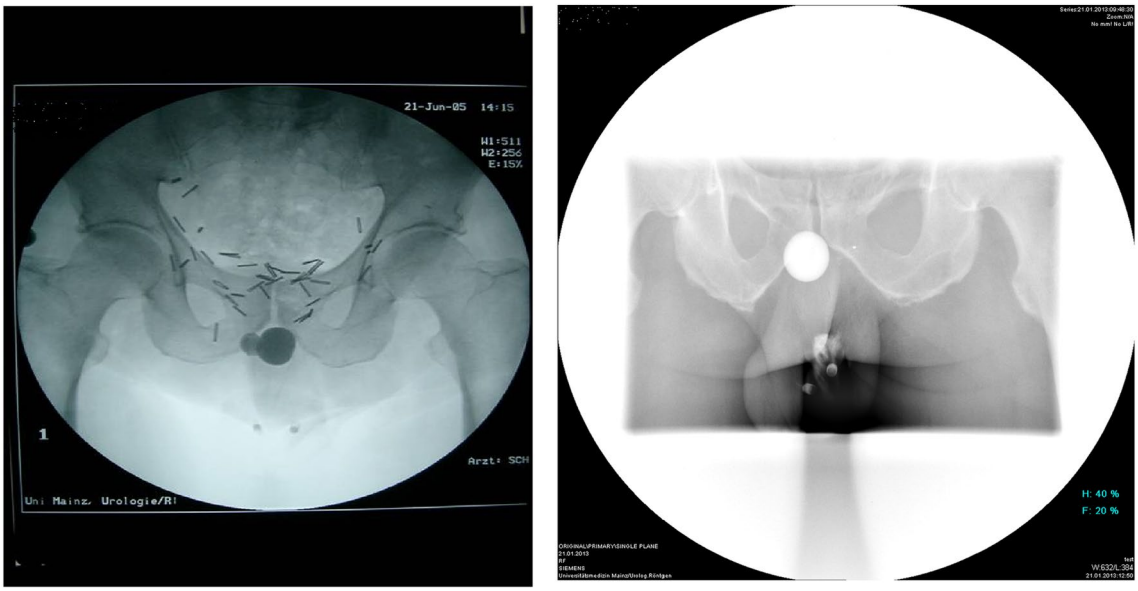


Fig. 2 **a** Pelvis a.p.: leakage of the right ProACT balloon, probably caused by contact with a metallic clip used in radical prostatectomy. **b** Pelvis a.p.: rupture and dislocation of the left ProACT balloon

Personal satisfaction scores worsened after failure to median 4 (IQR 4–5) and improved again after implantation to 1 (IQR 1–2, $p < 0.005$).

Second revision of ProACT system

10 of 59 successfully revised patients (20.4%) underwent a second revision after a median of 39 months (IQR 22–65) due to rupture ($n = 6$) or dislocation ($n = 4$) of at least one of the balloons. Eight of ten patients were successfully reimplanted (80%). Again, no significant differences between primary implant and first or second repeat implant were detected concerning filling volumes of balloons (median 6 ml, $p = 0.73$) and postoperative number of pads (median 1, IQR 1–2, $p = 0.88$). Operation time was comparable to that of the first revision (median 32 min, IQR 22–56 min; see also Table 2).

Similar to the first revision, personal satisfaction scores worsened after failure to median 4 (IQR 3–5) and improved again after implantation to 1 (IQR 1–2, $p < 0.005$).

Patient satisfaction and change of device

Of the initially successfully implanted patients, three patients (4.5%) elected implantation of a different device after rupture or dislocation of at least one of the balloons; all other patients did receive another ProACT implant after failure of the first one. After the second failure, four patients (28.5%) elected implantation of a different device and ten elected to receive a third ProACT implant. Patient satisfaction was generally high, switching to a different device was at least after the first failure for most patients not an option.

Impact of the cause of incontinence (type of surgery), age, and operation time of ProACT on the outcomes of ProACT implantation

The type of prostate surgery had no impact on postoperative continence rates or revision rates. The revision rate for the different subgroups (types of prostate surgery) was not significantly different from the overall revision rate (Table 3). Logistic regression analysis showed no significant

Table 2 Outcome parameters

	First implantation ($n = 134$)	First revision ($n = 63$)	Second revision ($n = 10$)	p value
Success rate	112 (82.6%)	49 (77.8%)	8 (80%)	0.82
Filling volume (ml)	8 (IQR 7–9)	8 (IQR 6–9)	6 (IQR 5–8)	0.73
Pad use (no.)	1 (IQR 1–2)	1 (IQR 1–2)	1 (IQR 1–2)	0.88
Operation time (min)	27 (IQR 19–44)	34 (IQR 20–59)	32 (IQR 22–56)	0.17

differences between patients being treated for prostate cancer by radical prostatectomy and patients treated for BPH by TUR-P (odds ratio 0.71 for continence and 1.00 for revision rate). Similar results could be shown for age (older than 68 years vs younger than 68 years; odds ratio 0.48 for continence and 0.84 for revision rate) and operation time for implantation (> 34 min vs > 34 min; odds ratio 1.44 for continence and 0.76 for revision rate).

Impact of optical internal urethrotomy prior to ProACT implantation on the outcome of ProACT implantation

Eleven patients of our cohort had undergone optical internal urethrotomy for a urethral stricture prior to the ProACT implantation. Before ProACT implantation, a recurrent stricture was excluded by cystoscopy. Nine of these eleven patients were implanted successfully (81.8%, $p = 0.93$). Between these patients and the total cohort, no significant differences were detected concerning filling volume (7 ml, IQR 7–8, $p = 0.73$) and number of pads (1, IQR 1–2, $p = 0.82$). However, the revision rate was higher than in the total group. Seven of nine patients (77.8%) had to be revised after median 35 months (IQR 18–61); four of whom were successful (57.1%). Nevertheless, logistic regression showed no significant differences in the outcomes concerning revision rates (odds ratio 3.68, $p = 0.23$) and continence rates (odds ratio 5.6, $p = 0.15$).

Impact of bulking agents prior to ProACT implantation on the outcome of ProACT implantation

Fifteen patients had undergone the injection of periurethral bulking agents (mostly Teflon) before being implanted with ProACT. Eleven of fifteen implantations were successful; there were no significant differences whether the initial operation was a radical prostatectomy (8/11 successful, 72.7%) or TUR-P (3/4 successful, 75%). Similar to patients after optical internal urethrotomy, revision rates were higher compared to the total cohort. After a median of 6 months (IQR 4–9), seven patients were revised (63.4%) and four of them successfully (57.1%). However, logistic regression revealed no significant differences concerning revision rates (odds ratio 1.6, $p = 0.51$) or continence rates (odds ratio 0.34, $p = 0.17$).

At the end of our follow-up of a median of 95 months, 85 of 134 initially implanted patients (63.4%) were still successful on the ProACT implant and satisfied with the results.

Discussion

For treatment of post-prostatectomy incontinence, different surgical options are available. Depending on the severity of incontinence, patient`s age, general health and the expertise of the surgeon, and different surgical principles and approaches are applicable. Even in the EAU guidelines, no explicit recommendations are made in respect to which patient is preferably treated by which implantable device [1]. However, the AMS 800-AUS is still considered gold standard [1] but may not be suitable for every patient. Therefore, passive urethral compression systems have been established. Especially, the ProACT system seems to be suitable for elderly patients, who cannot undergo major surgery or try to avoid an active system. However, the literature on ProACT reports high revision rates, and consequently, the usefulness of ProACT implantations remains controversial [1].

Whereas several studies have demonstrated efficacy and safety of ProACT [13, 14], the incidence of revisions cannot be denied. Up to now, only a few cases were reported, in whom at surgical revision after primary ProACT, a repeat implantation of a ProACT system was performed [13]. These cases were successful, but are too few for drawing any conclusions. Yiou and colleagues have shown successful revisions after primary sling implantation with implantation of a ProACT system [15]. To our knowledge, our study is the first using ProACT for revisional surgery after a primarily successful operation with failure over time.

Furthermore, our study is the first to investigate the relationship between transurethral surgery before ProACT implantation and the outcomes of ProACT implantation.

Our revision rate after primary ProACT implantation is in agreement with the literature [1]. After the initial implantation, 52.7% of the successfully implanted patients had to be revised over time for rupture or dislocation of at least

Table 3 Number and percentage of all patients (total implants) and patients with revision (revision implants), grouped by the cause of their incontinence

	Total ProACT implants (%)	Revision implants (%)	*p* value
Open retropubic prostatectomy	83 (61.9%)	49 (55%)	0.81
Laparoscopic/robotic radical prostatectomy	7 (5.2%)	5 (5.6%)	0.44
Perineal radical prostatectomy	12 (8.8%)	5 (5.6%)	0.42
TUR-P	28 (20.6%)	18 (20.2%)	0.9
Total	130 (100%)	77 (100%)	–

one balloon. No infections or other causes for explantation were encountered. Nevertheless, all patients elected a repeat ProACT implantation, even though other devices such as the AMS 800-AUS or ATOMS were offered. Even after a second failure, all patients but one elected a third ProACT implantation. Therefore, our data support the statement in the literature, that patient satisfaction is associated with continence achieved, not with the number of revisions [6].

The reason for dislocation and rupture remains unclear. A contact with metal clips used in radical prostatectomy (see Fig. 2a) could be a cause of balloon rupture. An increased physical activity after regaining urinary continence could result in balloon dislocation; however, neither of these causes is proven and remains open for speculation.

Continence for all implantations was satisfactory, about 80% of all patients achieved continence with one pad per day or less, and over 90% of all patients had a > 50% reduction of pads per day or two pads per day or less. We used for this definition of success in accordance with the success criteria used for neuromodulation [16], since they have demonstrated a good correlation with realistic patient's expectations before the first implantation. We found no differences in continence rates after the first, second, or third implantation. To our knowledge, no data with a sufficient case number are available for other passive compression devices, mostly because the AMS–AUS is used in revisions.

Furthermore, we were able to show that optical internal urethrotomy or implantation of bulking agents prior to ProACT implantation does not compromise the success of primary ProACT implantation; no significant difference was seen in success of primary ProACT comparing patients with or without bulking agents or optical internal urethrotomy before implantation.

Continence rates were comparable to patients without these prior procedures and no significant differences could be detected in revision and continence rates. However, ProACT failed earlier during follow-up in patients after bulking agents and success rates of revisions were significantly lower compared to the primary implantation. In contrast, we did not detect earlier failures in follow-up after internal urethrotomy and time to revision was comparable to patients without internal urethrotomy. In consequence, ProACT can be an option for patients with post-prostatectomy incontinence after optical internal urethrotomy but may not be first choice after therapy with bulking agents. Nevertheless, a number of cases of these subgroups are too small for a final statement.

The limitations of this study are the retrospective design with all well-known flaws and the self-assessment of patient`s satisfaction. We used a validated questionnaire, but satisfaction is a very individual criterium. Data could be obtained from all ProACT patients in our institution, but subgroups of the second revision, patients with bulking agents and internal urethrotomy were too small to draw final conclusions.

In summary, ProACT offers a minimal-invasive alternative to other implantable devices for surgical therapy of post-prostatectomy incontinence.

Conclusion

In the hands of an experienced surgeon, ProACT is a safe and effective therapy for male urinary stress incontinence and a minimal-invasive alternative to other implantable devices for surgical therapy of post-prostatectomy incontinence. Revision rates are high, but the results of ProACT reimplantation are comparable to the results after primary implantation. Patients are mostly very satisfied with the outcome and like to continue with the device in spite of revisions. ProACT can be recommended especially if major surgery is to be avoided.

Author contribution S Nestler: project development, data collection, data analysis, and manuscript writing. C Thomas: data analysis and manuscript editing. A Neisius: data analysis and manuscript editing. P Rubenwolf: manuscript editing. FC Roos: manuscript editing. C Hampel: manuscript editing. JW Thüroff: manuscript writing and manuscript editing.

Compliance with ethical standards

Conflict of interest The authors were not compensated and retained the control over the content of the manuscript.

Research involving human participants The study was performed in accordance with the ethical standards of the institutional research committee.

Informed consent Informed consent was obtained from all patients at time of follow-up.

References

1. Bauer RM, Gozzi C, Hübner W, Nitti VW, Novara G, Peterson A, Sandhu JS, Stief CG (2011) Contemporary management of postprostatectomy incontinence. Eur Urol 59(6):985–996
2. Shamliyan TA, Wyman JF, Ping R, Wilt TJ, Kane RL (2009) Male urinary incontinence: prevalence, risk factors, and preventive interventions. Rev Urol 11(3):145–165
3. Bauer RM, Bastian PJ, Gozzi C, Stief CG (2009) Postprostatectomy incontinence: all about diagnosis and management. Eur Urol 55(2):322–333
4. Rassweiler J (2009) Editorial comment on: four-year outcome of a prospective randomised trial comparing bipolar plasmakinetic and monopolar transurethral resection of the prostate. Eur Urol 55(4):929–930

5. Porena M, Mearini E, Mearini L, Vianello A, Giannantoni A (2007) Voiding dysfunction after radical retropubic prostatectomy: more than external urethral sphincter deficiency. Eur Urol 52(1):38–45
6. Gousse AE, Madjar S, Lambert MM, Fishman IJ (2001) Artificial urinary sphincter for post-radical prostatectomy urinary incontinence: long-term subjective results. J Urol 166(5):1755–1758
7. Kim SP, Sarmast Z, Daignault S, Faerber GJ, McGuire EJ, Latini JM (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(5):1912–1916
8. 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(4):1206–1208
9. Thüroff JW, Hohenfellner M, Schultz-Lampel D (1992) Die Harninkontinenz des Mannes. Faszienzügelplastik zur Therapie der Stressinkontinenz (german). Aktuelle Urol 23:149–157
10. Hübner 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(5):777–782
11. Sousa-Escandón A, Cabrera J, Mantovani F, Moretti M, Ioanidis E, Kondelidis N, Neymeyer J, Noguera R (2007) Adjustable suburethral sling (male remeex system) in the treatment of male stress urinary incontinence: a multicentric European study. Eur Urol 52(5):1473–1479
12. Trigo-Rocha F, Gomes CM, Pompeo AC, Lucon AM, Arap S (2006) Prospective study evaluating efficacy and safety of Adjustable Continence Therapy (ProACT) for post radical prostatectomy urinary incontinence. Urology 67(5):965–969
13. Lebret T, Cour F, Benchetrit J, Grise P, Bernstein J, Delaporte V, Chartier-Kastler E, Botto H, Costa P (2008) Treatment of post-prostatectomy stress urinary incontinence using a minimally invasive adjustable continence balloon device, ProACT: results of a preliminary, multicenter, pilot study. Urology 71(2):256–260
14. Rouprêt M, Misraï V, Gosseine PN, Bart S, Cour F, Chartier-Kastler E (2011) Management of stress urinary incontinence following prostate surgery with minimally invasive adjustable continence balloon implants: functional results from a single center prospective study. J Urol 186(1):198–203
15. Yiou R, Butow Z, Baron T, Salomon L, Audureau E (2015) Adjustable continence therapy (ProACT™) after male sling failure for patients with post-radical prostatectomy urinary incontinence: a prospective study with one-year follow-up. World J Urol 33(9):1331–1336
16. Kessler TM, La Framboise D, Trelle S, Fowler CJ, Kiss G, Pannek J, Schurch B, Sievert KD, Engeler DS (2010) Sacral neuromodulation for neurogenic lower urinary tract dysfunction: systematic review and meta-analysis. Eur Urol 58(6):865–874