



A transobturator adjustable system for male incontinence: 30-month follow-up of a multicenter study

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ABSTRACT

Purpose: To report long-term results of the Argus T adjustable system for treatment of post-prostatectomy urinary incontinence (PPI).

Materials and Methods: From October 2007 to August 2008, 37 patients with PPI were included in a prospective, single-arm, multicenter trial of treatment with the Argus T adjustable system (Promedon, Argentina). Preoperative evaluation included urine culture, urethrocystoscopy, urodynamic testing, 24-h pad weight test (PWT) and quality of life questionnaires. Patients were stratified according to baseline degree of incontinence (mild-moderate or severe). Postoperative evaluation included immediate PWT, quality of life questionnaires and daily use of pads at 1, 12 and 30 months.

Results and Conclusions: One patient was lost to follow-up. At the 30-month follow-up, 24/31 patients (77%) were dry, 3/31 (10%) improved and 4/31 (13%) were failures. In particular, in the mild-moderate group, 8/8 (100%) patients were dry. In the severe group, 20/28 patients (71%) were dry, 3/28 (11%) improved and 5/28 (18%) were failures. Median visual analogue scale (VAS) scores dropped from 9 (4-10) to 0.5 (0-10) and International Consultation on Incontinence Questionnaire Short Form scores from (ICIQ-SF) 19 (12-21) to 1 (0-10). Retrograde leak point pressure increased from 18 (5-29) to 35 (22-45) cm H₂O after intraoperative adjustment. Complications included immediate postoperative infection in 2/36 patients (6%) and transient inguinal and/or perineal pain in 22/36 patients (61%). Argus T has a long-term high success rate (86% cure + improvement at the 30-month follow-up). Good outcomes were achieved even in severe incontinence cases and maintained for over 30 months.

ARTICLE INFO

Key words:

Suburethral Slings; Prostatectomy; Urinary Incontinence; Urodynamics

Int Braz J Urol. 2014; 40: 781-9

Submitted for publication:
October 19, 2013

Accepted after revision:
March 03, 2014

INTRODUCTION

Although rare, stress urinary incontinence secondary to prostate surgery, whether for prostate cancer or benign prostatic hyperplasia (BPH), causes significant deterioration of patients' quality of life. Persistent urinary incontinence occurs in 5-10% of post radical prostatectomy patients and

in 0.5-3% of post BPH surgery patients. In both situations, incontinence can be severe enough to require surgical management.

Conservative management is generally recommended during the first 6-12 months after prostatectomy. Behavioral modifications, pelvic floor muscle training and drug therapy have been the most frequently recommended options.

Surgical interventions are the next treatment option for persistent UI. Peri-urethral injection for temporary relief, minimally invasive compression devices, fixed and adjustable slings and artificial urinary sphincters (AUS) are the current recommended forms of surgical treatment (1-3).

Suprapubic slings had seldom been used prior to Schaeffer et al. report in the late 1990s of a success rate of 75% (cure + improvement) for a bulbourethral device in a group of 64 patients with a 2-year follow-up (4). After this initial report, several other researchers assessed this procedure and added modifications to the original design. Romano et al. (2) reported a success rate of 83% (73% cure + 10% improved) for an adjustable bulbourethral device inserted via a suprapubic approach in a group of 48 patients with a mean follow-up of 7.5 months. The same group later reported long-term stability with a 78.8% success rate (66.0% cure + 12.8% improved) after a mean follow-up of 45 months (5).

To find a simpler and safer approach for implantation, we evaluated a transobturator approach in 2003 (6). After proving its feasibility in 2007, we began a multicenter trial. Data from this study are reported in this paper.

MATERIALS AND METHODS

Potential subjects were screened for a prospective, single-arm, multicenter trial from October 2007 to August 2008. The study protocol was approved by the corresponding independent ethics committees and written informed consents were obtained before patients' inclusion. A group of 37 patients who met the eligibility criteria were finally selected. Inclusion criteria were 1 year or more of PPI (of any degree of severity) that had altered quality of life to the extent that the patient agreed to a surgical procedure and urodynamic confirmation of stress incontinence. Exclusion criteria included untreated urinary infection, urethral stricture, low bladder capacity (less than 200mL) and bladder stone unable to be resolved during a sling procedure.

Preoperative evaluation included a complete urologic exam, urine culture, urethrocystoscopy, 24-h PWT and quality of life questionnaires

(ICIQ-SF and VAS). Urodynamic testing was also performed to assess the filling variables of sensitivity, capacity, compliance, detrusor overactivity and to confirm the stress nature of the UI as well as the retrograde leak point pressure (RLPP) (7, 8). The emptying variables of free flow and voluntary detrusor contractility were also recorded. The baseline characteristics of the enrolled patients are shown in Table-1.

Patients were grouped according to their degree of incontinence into mild-moderate and severe categories. This stratification was based on 24-h PWT preoperative measurements. The patient was assessed as having mild-moderate incontinence if the leakage was less than or equal to 400g and severe incontinence if it was greater than 400g (9) (Table-1).

An amendment was made to the protocol in four of the five initial centers to include a follow-up at 30 months. For this reason, 31 patients were followed at 1, 12 and 30 months and the remaining five patients only at 1 and 12 months postoperatively.

Argus T adjustable systems (Promedon, Argentina) were surgically implanted in the patients. This system consists of two cone columns that serve as fixation arms and a central pad made of radiopaque silicone foam. The system is completed by placing two rings (washers) on each fixation arm to provide safe anchoring and positioning of the device against the fibro muscular tissue of the obturator foramen.

The surgical procedure is as follows. The patient is placed in the lithotomy position, under spinal or general anesthesia. As has previously been described (2, 5, 10), a perineal incision is performed in the same way as for suprapubic or transobturator devices to dissect the bulbar urethra at the level of the inter bulbospongiosus and ischiocavernosus muscles area. The bulbospongiosus muscles are left in situ and the urethra is not mobilized from the central tendon. A helical needle is then introduced via the inguinal fold, 2cm below the insertion of the adductor magnus muscle, using an outside-in approach such that the needle tip appears in the dissected area of the perineum. The fixation arm is pulled out along the needle path and the procedure repeated on the other

Table 1 - Patients' baseline characteristics.

Characteristic	N (%)	Median (range)
Age (years)		70 (58–81)
RLPP (cmH ₂ O)		18 (5–29)
Underlying pathology		
Post-prostate cancer	30 (81)	
Post-adenectomy	7 (19)	
Adjuvant Radiotherapy	2 (5)	
Prior incontinence surgery	6 (16)	
Argus (retropubic)	1 (3)	
ProACT™ (parurethral balloon)	3 (8)	
Macroplastique™ (injectable bulking agent)	2 (5)	
Degree of incontinence		24-h PWT (g)
Mild–moderate	8 (22)	215 (100–350)
Severe	29 (78)	1200 (500–2880)
Total	37 (100)	1100 (100–2880)

side. After placing the rings on the fixation arms and checking that the foam pad is centered, symmetrical adjustment is performed one cone at a time until an RLPP of 30 to 40cmH₂O is achieved. The ruler (included in the kit) must be positioned with the 0 (zero) at the level of the patient's pubis (Figures 1-4).

The urethral catheter is left in place for 24 to 48 h. Patients are given intraoperative cephalosporin 1g and gentamicin 80mg every 12h until the catheter

has been removed, after which oral ciprofloxacin (500mg every 12h) is prescribed for 7–10 days.

The follow-up plan included evaluations at 1, 12 and 30 months. Quality of life was assessed by the ICIQ-SF questionnaire and a VAS scale (from 0 [no discomfort] to 10 [very uncomfortable]). The degree of incontinence was objectively assessed on the basis of 24-h PWT at the first postoperative follow-up visit (1 month) and by daily pad use on the other visits.

Figure 1 - ARGUS T adjustable system – Promedon SA.

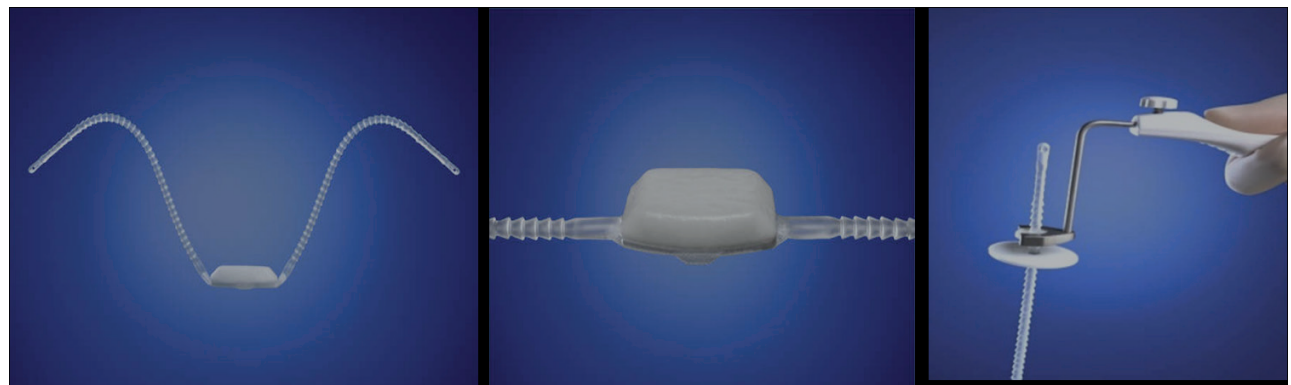


Figure 2 - Left - tip of left needle in the perineal wound. Right – Implant: Pad, Rings and hidden fixation arms, in final position after the RLPP measure.

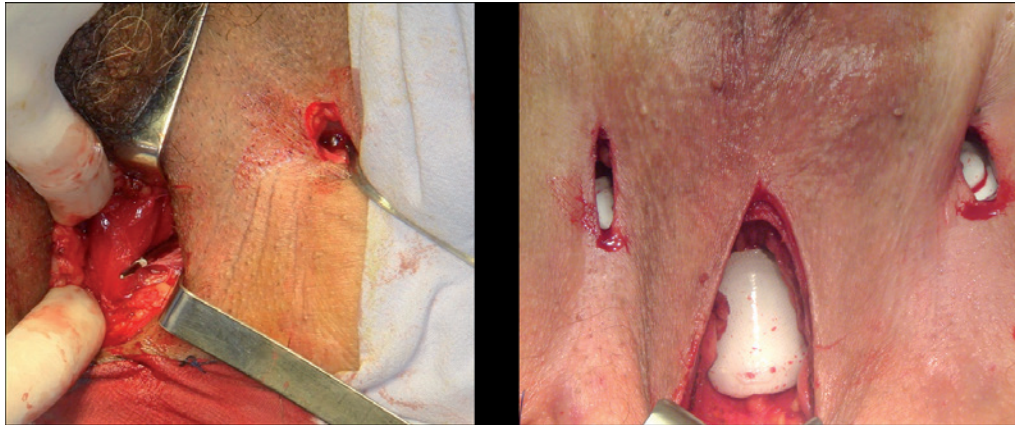


Figure 3 - Left – urethral lumen before the procedure. Right – urethral lumen after RLPP adjust.

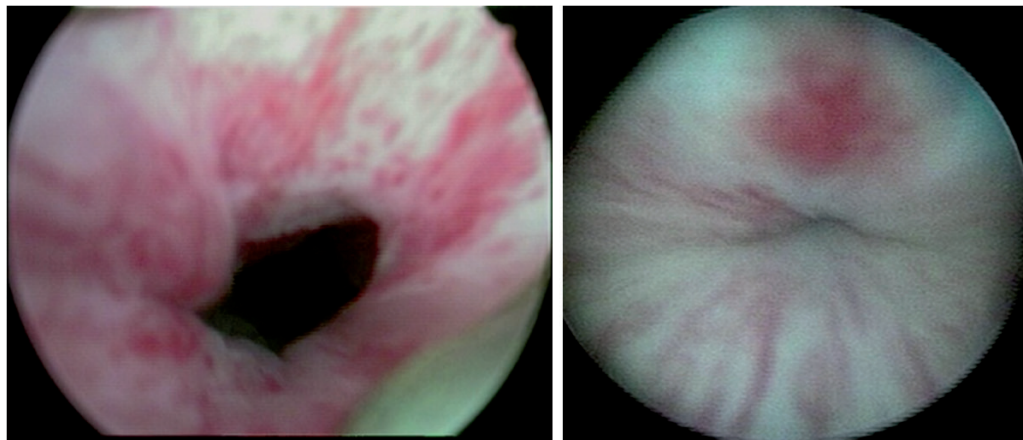


Figure 4 - Left – final position of the implant in a plain x-ray. Right – final position of the implant in a MRI 3D reconstruction.



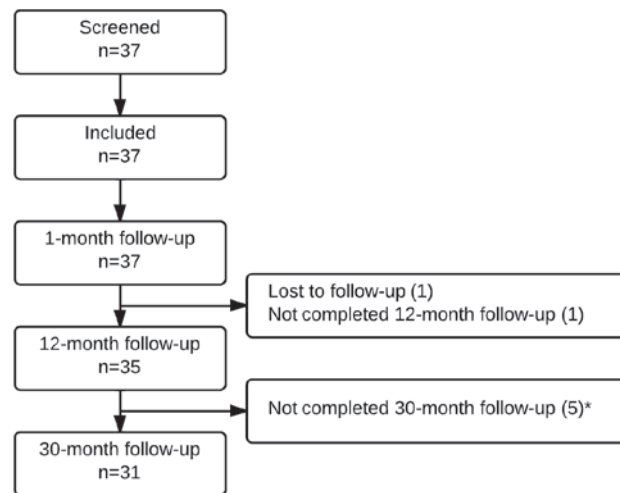
The patients' statuses were classified according to the daily use of pads as dry (no pads or one for protection), improved (one wet pad a day) or failure (two or more wet pads daily or implant removal).

During follow-up, adverse events were also recorded and the Clavien–Dindo Classification of Surgical Complications was used to report them (11, 12).

RESULTS

One of the 37 study patients was lost to follow-up after the first postoperative visit. As has already been stated, five patients were only followed up for 12-months. The study subject distribution tree is shown in Figure-5.

Figure 5 - Study subjects' distribution tree.



*The five patients who did not complete the 30-month follow-up were from the center that did not amend the protocol to extend the duration of follow-up.

In the short term, at the 1-month follow-up the median 24-h PWT had improved from 1100g (100–2880g) overall to 0g (0–35g) in dry patients and 50g (50–72g) in improved patients. The RLPP measured during the process of surgical adjustment of the implant increased from 17 (5–29) to 35 (22–45)cmH₂O.

All quality of life indicators changed favorably: the median VAS score from 9 (4–10) to 0.5 (0–10) and the ICIQ-SF from 19 (12–21) to 1 (0–10) (Table-2).

In the mild–moderate group, all eight patients achieved continence. In the severe group 20/28 patients achieved continence and 3/28 patients improved, requiring only one pad per day (Table-3).

No one in the mild–moderate group needed postoperative readjustment because they all achieved continence postoperatively. In the severe group, seven patients (25%) who remained incontinent after surgery gave their consent to readjustment. The median time from the initial surgery to readjustment was 14 (7–25) months. Results of readjustment are reported in Table-4.

Immediate infection occurred in 2/36 patients (5.6%). One of them required implant removal (Grade III-a). This patient had previously had a ProACT™ (Uromedica, USA) implanted; this had also required removal because of infection. The other patient with immediate infection was treated with local wound care and antibiotics and required no further intervention after 3 months (Grade II). Upon catheter removal, postoperative urinary retention occurred in 2/36 patients (5.6%). In one of these patients, the retention was overcome by postoperative readjustment (loosening) of

Table 2 - Postoperative results.

		Pre-op	1 month	12 months	30 months
Daily pad use N (%)	Dry		26 (70)	28 (80)	24 (77)
	Improved		6 (16)	3 (9)	3 (10)
	Failed		5 (14)	4 (11)	4 (13)
ICIQ-SF score median (range)		19 (12–21)	2 (0–20)	2 (0–20)	1 (0–10)
VAS score median (range)		9 (4–10)	1 (0–10)	0 (0–10)	0.5 (0–10)

Table 3 - Results segregated by baseline degree of incontinence, according to each patient's last follow-up.

Baseline degree of incontinence	Postoperative outcome	
Mild-moderate	Dry	8/8 (100%)
	Improved	0/8 (0%)
	Failed	0/8 (0%)
Severe	Dry	20/28 (71%)
	Improved	3/28 (11%)
	Failed	5/28 (18%)

Table 4 - Readjustment of the Argus T device postoperatively.

Patient group	Number of readjustments	Outcome after readjustment	
Mild-moderate	0/8 (0%)	NA	
Severe	7/28 (25%)	Dry	5/7 (72%)
		Improved	1/7 (14%)
		Failed	1/7 (14%)

the implant, thus decreasing the RLPP (Grade III-a). The other patient had impaired bladder contractions (hypocontractility) postoperatively: after 6 months of intermittent catheterization, he regained spontaneous bladder evacuation with no post-voiding residual urine (Grade II).

Transient inguinal and/or perineal pain was reported immediately after surgery by 22/37 patients (61%). The pain resolved within 3–4 weeks after treatment with analgesics, nonsteroidal anti-inflammatory drugs (Grade I) and/or corticosteroids (Grade II). In one patient (2.8%), pain persisted for 2 months before resolution.

DISCUSSION

As recently as 10 years ago, the only reliable surgical treatment for PPI was the AUS (13, 14). Although it has been associated with significant complications such as infection, erosion and mechanical failure, including urethral atrophy with recurrent incontinence, and a revision rate of greater than 50% (15, 16), this procedure continues to play a predominant role.

During the last decade, a series of adjustable and non-adjustable devices have been developed for treating PPI. All of them attempt to achieve continence by urethral coaptation, rather than by closing the urethral lumen as the AUS does. The latter works as a hydraulically operated open-close valve that produces either complete obstruction of the urethral lumen or complete opening, whereas the coaptation devices aim to increase the baseline RLPP to reinforce the sphincteric mechanism. Therefore, with coaptation devices continence and micturition are ruled by the normal physiological balance between intravesical pressure and urethral resistance. Adjustable devices offer a great advantage over the non-adjustable ones: their ability to be adapted to changes in patients' conditions. Examples of adaptable devices are the Argus (Promedon, Argentina), Remeex (Neomedic, Spain), ATOMS (A.M.I., Austria) and ProACT™ (Uromedica, USA) devices (5, 17–20).

Among the non-adjustable devices are various models of autologous fascial slings or polypropylene tapes such as Invance™ (bone anchored sling), Advance™ and other devices (21–27).

The AdVance™, one of the most commonly used non-adjustable devices, reportedly has very good results (around 80%) in selected cases of mild to moderate PPI (3). It is claimed that this retro-urethral transobturatory sling works by repositioning the residual sphincter to an intra-abdominal location by mobilizing the urethra from the perineal central tendon, thus avoiding the urethral hypermobility that can be caused by surgery. At the same time, the urethra is occluded by the sling, which should be implanted under tensioning, as is recommended (25, 26).

The main advantage of adjustable systems is that they allow postoperative increasing or decreasing of sling tension to improve or correct initial outcomes. Sling tension can be increased to augment urethral resistance in patients whose incontinence persists. In addition, sling tension can be decreased by loosening the sling, thus decreasing the RLPP, in patients with urinary retention or obstruction. In this study, five patients who remained incontinent after surgery benefited from this advantage. They achieved continence (dry patients) after postoperative sling adjustments. Furthermore, by loosening the urethral coaptation postoperatively, it was possible to reverse the urinary retention of the patient who had not been able to reverse it naturally. Argus T's adjustment rings provide reliable fixation, which helps to maintain the coaptation achieved during surgery. These rings also offer a point of reference for postoperative tension adjustments.

Soljanik et al. (28) highlighted the need for reducing sling slippage and failure at short-term follow-up in patients with the AdVance™ device. They improved the surgical technique by tunneling the sling arms subcutaneously and using at least four non-absorbable sutures instead of an absorbable one.

It is important to note that, in most patients, the ability to adjust the Argus T to an intraoperative RLPP of 30 to 40cmH₂O, combined with the reliable anchoring supported by the rings, resulted in sustained positive outcomes without the need to perform subsequent adjustments. The recommended RLPP range has been established over more than 10 years of experience, with the aim of applying the minimum pressure in the urethra

necessary to achieve continence while minimizing pain, erosion and obstruction (2, 5, 29).

In the mild-moderate incontinence patients, who comprised 22% of study patients, the results obtained were excellent (100% continence). In addition, the patients with severe incontinence (78% of study patients) achieved a success rate of 82% (71% cure + 11% improvement). These figures are encouraging in terms of efficacy and, remarkably, the results are good regardless of the severity of incontinence preoperatively. Some devices that have shown promising results in patients with mild to moderate incontinence, such as the AdVance™, are relatively ineffective in, and therefore not indicated for, patients with severe incontinence (3, 30). Consequently, in severe cases for which options for effective surgical treatment are limited, the Argus T is an attractive alternative, as evidenced by the results presented in this paper.

Infections occurred in our series only during the immediate postoperative period and are therefore seemingly related to intraoperative contamination. However, our infection rates are similar to or even lower than those reported for other implants used for management of male incontinence, such as the AUS and Argus devices, both of which are also made from silicone (5, 16).

In summary, historically bulbourethral compression devices have been a prominent component of the armamentarium for treatment of PPI and have achieved very satisfactory results in 65 to 90% of patients (3, 5, 10, 17, 21, 22, 24, 26, 27). Based on examination of data from medium and long-term follow-up, we believe that the common goal of all these devices is to create mild bulbourethral pressure that allows coaptation of the mucosa, thus controlling incontinence. Indeed, it appears that the lower the passive resistance required to achieve continence, the greater the likelihood of avoiding dysuria, urinary retention, pain and erosion (29).

CONCLUSIONS

We found that the Argus T adjustable system can be easily and safely implanted through a transobturator approach, providing a high success rate (86% cure + improvement). We achieved good

outcomes even in patients with severe incontinence and these were sustained during 30 months of follow-up. This device is a valuable treatment option for most patients with PPI.

CONFLICT OF INTEREST

None declared.

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