

Romano S¹, Hubner W², Trigo Rocha F³, Vaz F⁴, Muller V⁴, Nakamura F⁵

1. Hospital Durand, 2. Dept. of Urology, Humanis Clinic, Korneuburg, Lower Austria, Austria, 3. Hospital das clinicas, São Paulo, Brasil, 4. Hospital Dos Servidores Do Estado, Rio De Janeiro, Brasil, 5. Centro Medico Ultralitho, Florianopolis, Brazil

POST PROSTATECTOMY URINARY INCONTINENCE TREATED WITH ARGUS T MALE SLING- ENDURANCE OF THE RESULTS OF A MULTICENTRE TRIAL.

Hypothesis / aims of study:

To report an update of the results of post prostatectomy urinary incontinence (PPI) patients (pts) treated with an adjustable male sling, Argus T™ included in a multicentre trial.

Study design, materials and methods:

From November 2007 and August 2008, 37 PPI patients (30 post-radical prostatectomy and 7 post adenomectomy) were included in a multicentre trial to be treated with an adjustable male sling (Argus T™ - Promedon SA). The implantation technique was previously described^{1,2}.

The silicone soft pad of the sling was located against the bulbar urethra. The needles that entered outside-in transobutratory, pulled out the cone columns, and the desired tension was adjusted with the washers at a medium of 35.6 cm water (22-45), measured by retrograde urethral pressure (RUP). (Fig 1) The Foley catheter remains for 24 to 48 hs.

Before and after surgery all pts completed a full urologic evaluation, a validated International Consultation on Incontinence Questionnaire (ICIQ – SF), 24h pad test, Visual Analogue Scale, urethrocistoscropy, urodynamics, and a global impression (GI) expressed as Dry (D): no pads or one for protection, Improved (I): 1 pad a day, and Failure (F): 2 or more pads daily or sling removal.

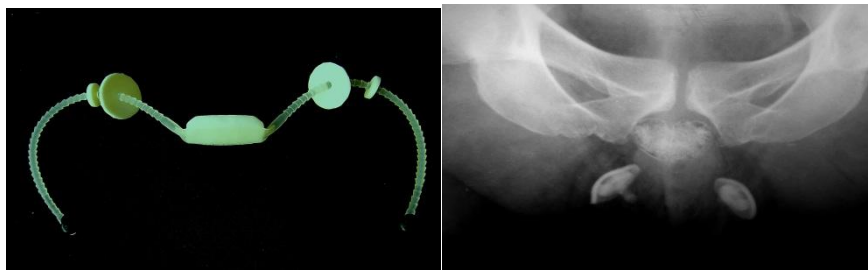


Fig 1 : Argus T and a plain XR of the patient implanted transobutratory

Results: At November 2010, 36 pts were evaluated (one patient was lost for follow-up) with a mean F- up of 29.6 month (15 - 37.4). All pts had a minimum of 24 months; At Inclusion, 29 of the 37 pts had severe incontinence, moderate in 6 and mild in 1, according with the pad test

classification. The Pad test and the ALPP were 1182gr (100-2880) and 46.2 cm of water

(4-92) (Table 1). From operation or readjustment, the ICIQ-SF changed from 18.8 (12-21) to 4 (0-21), the VAS and RUP changed from 8.9 to 2 and from 16.9 to 33 cm of water, respectively.

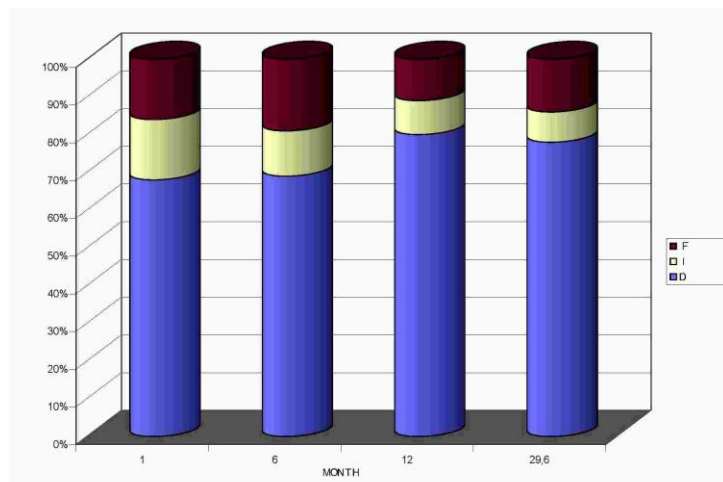
Postoperative readjustment was necessary in 7 patients (20%) The GI was Dry, Improved and Failed in 28 (78%), 3 (8.3%), and 5 (14%) respectively (Table 2) and (Graphic 1)

N 37	Mean	Max	Min
ICIQ	18,8	21	12
VAS	8,9	10	4
VLPP	46,2	92	4
RUP	16,9	29	5
Pad T (gr)	1182,6	2880	100

Table 1: Preoperative evaluation (At inclusion)

N 36			
	Mean	Max	Min
ICIQ	4	10	0
VAS	2	10	0
RUP	33	45	15
Pad test (gr) Dry	6	38	0
Pad test (gr) Improve	25	60	10
GI	D: 28 (78%) - I: 3 (8.3%) - F: 5 (14%)		

Table 2: Follow-up: mean 29.6 moths (15- 37.4) minimum of 24 month



Graph.1: Results at 29.6mths, Blue (Dry), Yellow (Improve), Red (Fail)

Complications: 1 patient became incontinent (previous Improve) after TUR of the prostate cancer progression and obstruction 2 pts became infected immediately in the postoperative; one of them needed sling removal, the other cured after local and general antibiotics treatment. 2 patients had acute urinary retention; both are dry and regained spontaneous bladder evacuation; one after sling loosening and the other (with impaired bladder contraction) after a long term (6 month) of self clean intermittent catheterization. Most pts complained of mild or moderate inguinal and or perineal pain lasting less than 30 days postoperatively except one that took more than 2 months to disappear.

Interpretation of results

Our results show that the transobturator adjustable male sling, Argus Ttm, maintained its good initial results even after more than 2 years (29.6 months).The test of the time is a very important condition for any new device used in the treatment of post prostatectomy urinary incontinence.

Concluding message

The Argus male sling has demonstrated the durability of its efficiency and safety to treat the patients with PPI when implanted transobturatorily, with the advantage of the less invasiveness and harmfulness of this approach.

References

1. "The Transobturator Approach for Treating Postprostatectomy Urinary Incontinence with Argus T, the adjustable male sling. Early results of a multicenter trial". Poster N° 869 Romano SV, Hubner W, Trigo Rocha F, Vaz F, Muller V, Nakamura F. Poster Session of Male urinary incontinence. In the European Association of Urology, Stockholm Sweden, March 20, 2009. DOI EAU POSTER VIRTUAL: 10.3252/pso.eu.24eau.2009.
2. Argus T for post prostatectomy urinary incontinence. Romano SV, Hubner W, Trigo Rocha F, Vaz F, Muller V, Nakamura F. NeuroUrol Urodyn (2010) 29: 918-919

Specify source of funding or grant	Prof Romano S. is a Principal Investigator and Spicker of Promedon SA that funding in part this multicentre trial.
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
Is this a Randomised Controlled Trial (RCT)?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Independent Ethic Committee
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes