

# An adjustable male sling for treating urinary incontinence after prostatectomy: a phase III multicentre trial

SALOMON V. ROMANO, SERGIO E. METREBIAN\*, FERNANDO VAZ†, VALTER MULLER‡, CARLOS A. D'ANCONA‡, EUGENIO A. COSTA DE SOUZA¶ and FABIO NAKAMURAS

*Urology Departments, Hospital Durand, Buenos Aires, and\*Hospital Privado, Cordoba, Argentina, †Hospital Dos Servidores Do Estado, Rio De Janeiro, ‡Universidade De Unicamp, Campinas, ¶Fundação Felice Rosso, Belo Horizonte, and §Centro Medico Ultralitho, Florianopolis, Brazil*

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## OBJECTIVE

To evaluate the efficacy and safety of a new adjustable bulbourethral sling (Argus®, Promedon SA, Cordoba, Argentina) in the treatment of male stress urinary incontinence (SUI) after prostate surgery.

## PATIENTS AND METHODS

In all, 48 patients with SUI because of prostatic surgery for prostate cancer (39) or benign prostatic hyperplasia (nine) had a new sling implanted in a multicentre trial at six institutions between April 2003 and September 2004. All patients were fully evaluated, including a questionnaire (International Consultation on Incontinence Questionnaire-Short Form, ICIQ-SF, range 0–21), endoscopy, and urodynamic evaluation. The Argus system comprises a 4.2 × 2.6 × 0.9 cm thick silicone foam pad for soft bulbar urethral compression. The pad is

attached to the silicone cone columns that, after being passed with needles from the perineum to the abdominal wall, are adjusted with silicone washers to regulate and keep the desired tension against the urethra. The pad and washers are radio-opaque, which allows their position to be assessed during follow-up. The surgical technique was one described previously, with some modifications.

## RESULTS

At a mean (range) follow-up of 7.5 (1–17.5) months, 35 (73%) of the 48 patients were dry, five (10%) were improved, and eight (17%) were incontinent, including four (8%) who needed sling adjustment. The mean (range) ICIQ-SF improved from 19.2 (12–21) to 4 (0–21). There were three (6%) urethral perforations during surgery that were resolved by re-passing the needle. The sling was removed in three men (6%) due to erosion and in two (4%) due to infection.

Seven (15%) cases of acute urinary retention resolved spontaneously, except for one that needed the sling loosening. No cases of chronic retention were reported. There was perineal discomfort and mild dysuria soon after surgery that resolved spontaneously after a few weeks.

## CONCLUSION

This new adjustable male sling safely and effectively controls sphincter incontinence in men after prostate surgery, with an acceptably low complication rate. The early results are encouraging; the Argus is a valid alternative to the artificial urinary sphincter, the standard therapy for this condition.

## KEYWORDS

prostatectomy, urinary incontinence, male sling, urodynamics, incontinence, quality of life

## INTRODUCTION

Sphincter urinary incontinence in men can be an unfortunate complication of prostatic surgery. Although infrequent when treating prostate cancer, and even more uncommon after TURP or open surgery for BPH, it can have devastating effects on the patient's quality of life and be very difficult to treat. The reported incidence of incontinence after radical prostatectomy varies widely at 5–65% [1–3]. This variation can be explained by different definitions of continence and methods of assessment. Another group of incontinent patients due to intrinsic sphincter deficiency (ISD) are those of neurological origin, e.g. post-traumatic or myelomeningocele.

The treatment options include fluid restriction, pelvic floor exercises, biofeedback, an indwelling catheter, condom catheter, penile clamp and pads, which may benefit some selected patients or those with mild incontinence, but more severe cases usually require surgical treatment that includes an artificial urinary sphincter (AUS, considered the standard treatment), periurethral bulking agents, and more recently, the sling techniques, both perineal mesh with bone anchors [4,5] and the suprapubic suspension of the bulbous urethra, extensively reported by Shaeffer *et al.* [6]

A recent option offered by a new sling procedure is very encouraging; we evaluated the efficacy and safety of a new adjustable bulbourethral sling (Argus®, Promedon SA,

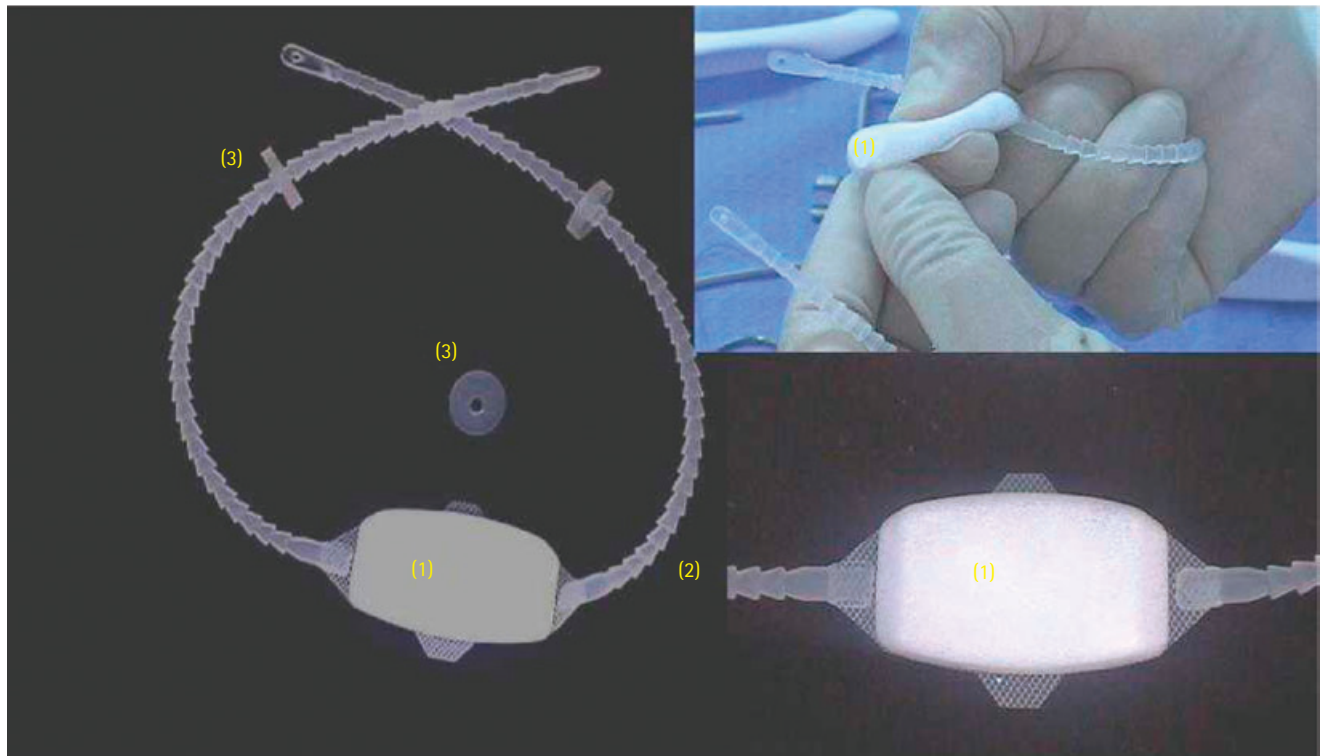
Cordoba, Argentina) for male stress urinary incontinence (SUI) after prostate surgery.

## PATIENTS AND METHODS

In all, 48 men (mean age 67.7 years, range 52–77) had a bulbourethral sling procedure for SUI between April 2003 and September 2004. All patients reported moderate-to-severe (most) SUI for >1 year after radical prostatectomy (39) or after adenectomy (nine). None of the patients had had radiotherapy, or had untreated urethral stenosis or UTI.

The evaluation before implanting the sling included a history, and a validated questionnaire for SUI, the International

FIG. 1. The Argus sling components: (1) foam pad; (2) cone columns; and (3) the washers.



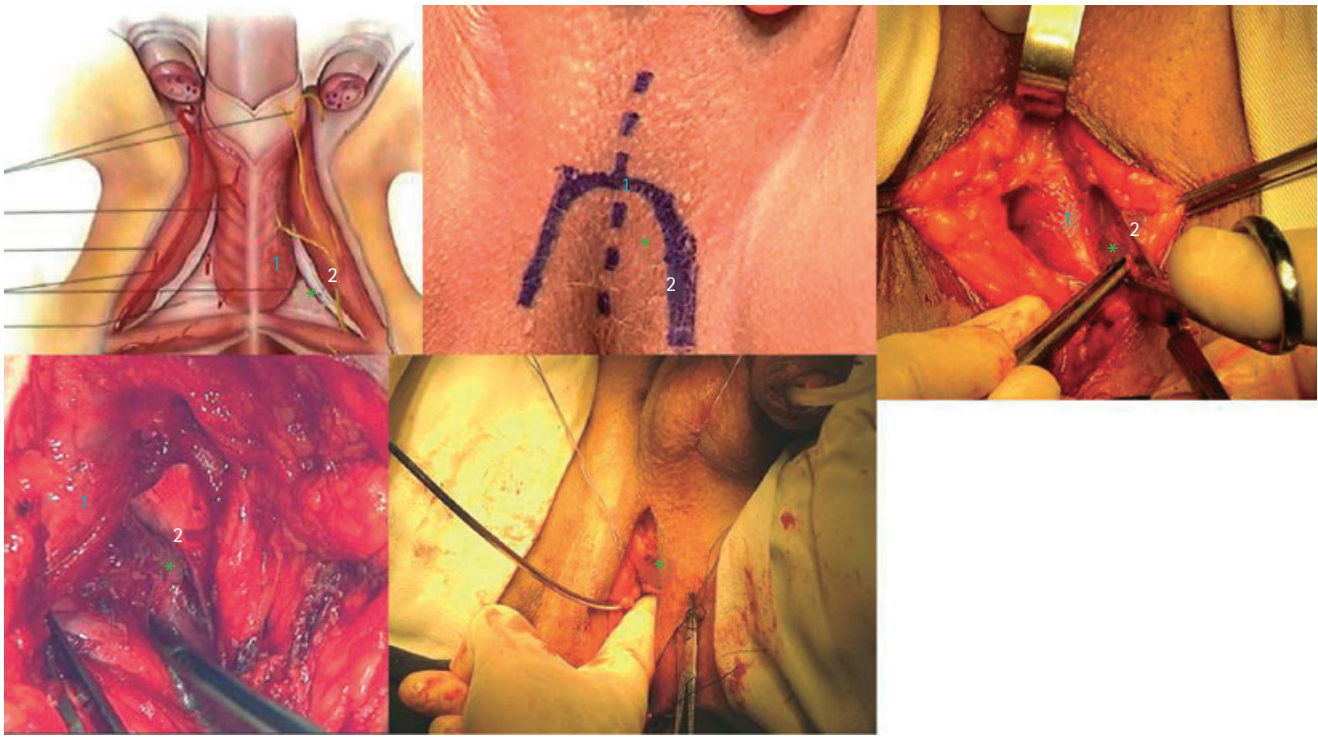
Consultation on Incontinence Questionnaire, Short-Form (ICIQ-SF, range 0–21, minimal to maximum symptoms) to assess the severity of incontinence symptoms and the impact on quality of life. In addition, a physical examination, cystoscopy, and urodynamic evaluation were used to determine bladder and sphincter function. The sphincter function was evaluated by assessing the retrograde leak-point pressure (LPP) [7]. The slings were implanted surgically at six different institutions in a multicentre trial directed by one of the authors (S.V.R.) using a standardized technique and the Argus system. The sling has three components (Fig. 1): (i) the pad, a  $4.2 \times 2.6 \times 0.9$  cm thick silicone foam cushion, designed to provide soft compression of the bulbar urethra while decreasing the erosion rate. Importantly, the pad thickness decreases by almost half after the first 15 days; (ii) the silicone columns attached to both ends of the pad are made of multiple cone-like sections that allow it to be fixed against the abdominal rectus fascia with; (iii) the silicone washers. All components are radio-opaque so that the position of the sling can be assessed after implantation. With this device, pressure and soft compression against the bulbous urethra can be applied.

The device can be regulated by moving the washers up and down to keep the desired tension.

The operation was as described by Shaeffer *et al.* [6] with minor modifications, as follows: after spinal or general anaesthesia, a 16 F Foley catheter is passed transurethraly. With the patient in the position for a standard TURP, the shaved surgical area is scrubbed with povidone-iodine soap. Drapes are placed making sure that the anus area is clear. A 5-cm transverse suprapubic blunt incision is made to reach the abdominal rectus fascia, avoiding its perforation. A 7-cm median perineal incision, centred in the inferior border of the pubic bone, is progressed until the bulbocavernosus muscle is seen, and kept in place. The inter-bulbocavernosus muscle and ischiocavernosus muscle space is sharply developed until the surface of the superficial perineal aponeurosis is clearly visible (Fig. 2). At this point the urethra can easily be palpated (with the catheter inside), with the ischiopubic ramus of the pubic bone as the outer limit and the inferior border of the symphysis pubis as the superior limit of the surgical field. With the aid of the specially designed 90° crochet needle with a removable

handle (Fig. 3), the perineal membrane is perforated between the bulbous urethra and the ischiopubic bone. The urethra is protected and displaced contralaterally using the index finger of one hand, while the needle is introduced with the other hand, 'shaving' the ischiopubic ramus, parallel to the operating table and the membranous urethra. After the perineal membrane is perforated, the needle handle is moved downwards so that the tip goes up into the abdomen, behind the pubic bone. It is then pushed up to perforate the rectal fascia at a point that can be selected by palpating the tip inside the previous suprapubic incision. The procedure is repeated on the other side. With the needles in place, the Foley catheter is replaced with the cystoscope to confirm the integrity of the urethra and the bladder. If necessary, the needle is repositioned, usually more laterally. After endoscopic evaluation, the handles are changed at the suprapubic tip, freeing the crochet tip in the perineum, where the columns are snapped and moved up into the abdominal area. The needles are loaded with a #1 polyglycolic acid suture in case the columns become disconnected, to provide a second opportunity to move them with no need to pass the needles again. At this point,

FIG. 2. The perineal surgical field (sharp dissection): 1, bulbar urethra; 2, left crura and descending ramus of the pubis bone; \*, the selected point in the perineal aponeurosis to be perforated with the needle.



the washers are transferred and positioned against the aponeurosis, but still not tightened. The pad must remain in the middle of the bulbous urethra.

The cystoscope is then reinserted and, with the water level at 45 cm from the pubic bone (level 0), adjustment starts by moving the washers with a specially designed 'pusher', up to loosen or down to tighten (Fig. 4). The objective is to achieve urethral wall coaptation and stop the drip, indicating that a retrograde LPP of 45 cmH<sub>2</sub>O has been achieved. An indwelling 16 F Foley catheter is placed and, after generous irrigation with saline and gentamicin, the wound is closed in several layers. The patient is given 1 g of parenteral cephalothin in the operating theatre and 80 mg gentamicin until the Foley catheter is removed, which is then replaced by ciprofloxacin orally for 7–10 more days. The catheter is removed 24–48 h after surgery, but could be re-placed for a few more days if voiding is not possible. Before hospital discharge, a plain X-ray of the pelvis is taken to assess the final position of the sling and, if necessary, to use for comparison during the follow-up (Fig. 5). The follow-up included the history of the patient, a physical examination

and completing the ICIQ-SF questionnaire after 1 and 3 months, and then every 3 months.

## RESULTS

Incontinence had been a serious problem for all the men for  $\geq 1$  year and was refractory to pharmacological therapy, perineal exercises and other conservative treatments. Of the 48 patients, 19 wore pads, using a mean (range) of 5 (3–8) pads/day, with weights of 83 (17–198) g; 29 used a penile clamp or a condom catheter. The mean (range) follow-up was 7.5 (1–17.5) months, and in 30 (63%) men it was  $>6$  months. The patients' bladder capacity and compliance were within the normal range.

Before and after surgery, the mean (range) retrograde LPP was 23.5 (5–66) and 47.5 (35–55) cmH<sub>2</sub>O, respectively, and the ICIQ-SF score was 19.2 (12–21) and 4 (0–21). Overall, SUI was cured (dry, no pads) in 35 (73%) patients, and improved in five (10%; mild, sporadic incontinence, one or fewer pads/day). The treatment failed in eight patients (17%, more than two pads a day), despite readjustment in three (6%) and loosening in

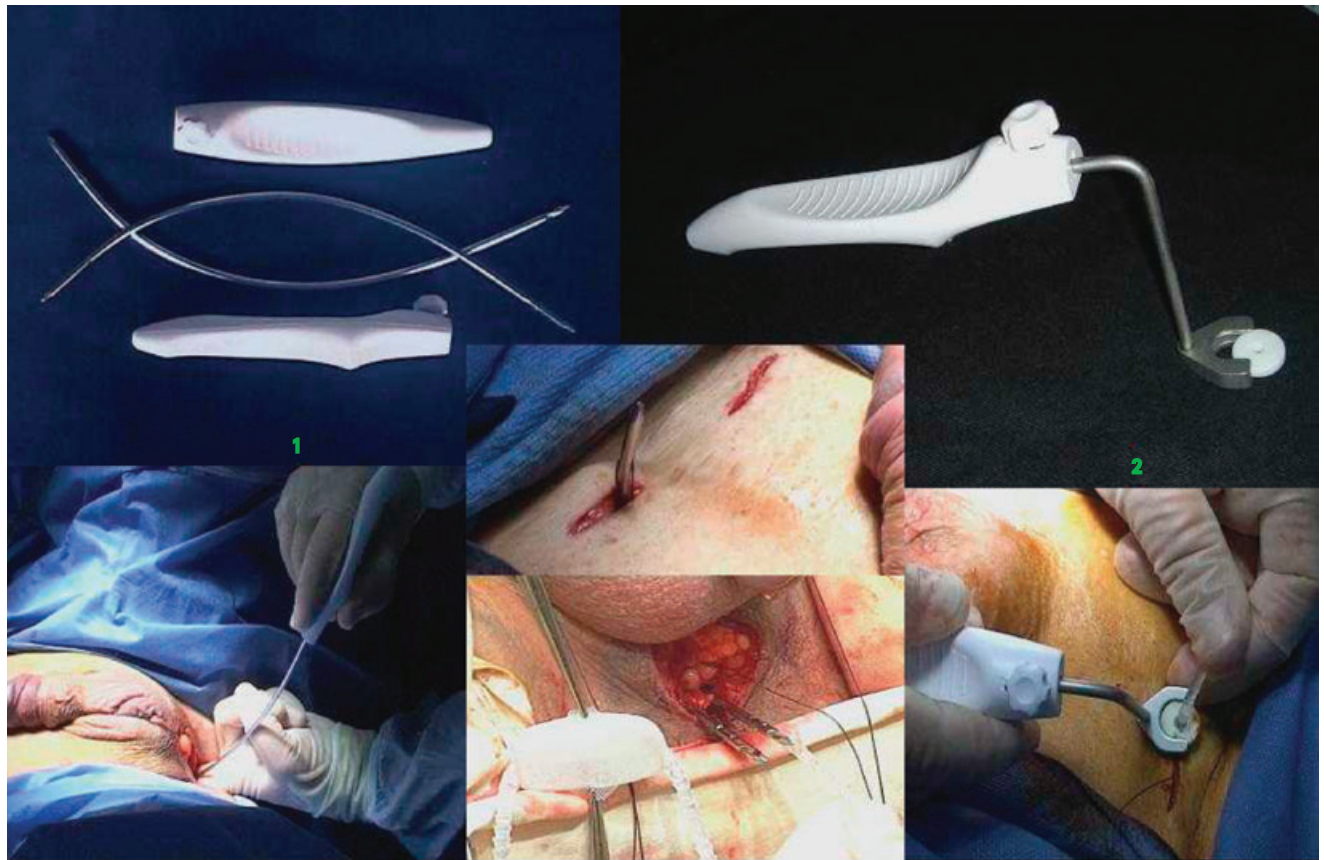
one (2%). In all, 41 (86%) patients could void at the first attempt after removing the Foley catheter; thus, seven (15%) patients with acute urinary retention were cured spontaneously after a short period of catheter replacement, except for one where the sling had to be loosened and the washer moved upwards 15 days after surgery, leading to comfortable voiding and continence. The sling was removed in three patients (6%) due to urethral erosion and in two (4%) due to infection, restoring their previous incontinence. There was a potential urethral perforation in three (6%) men during surgery and repositioning the needle solved the problem with no further complications. Ten men (21%) had dysuria, which was associated with perineal discomfort or moderate pain, temporary problems that resolved or became very mild and tolerable after 1 or 2 months of analgesic and NSAIDs.

## DISCUSSION

SUI after prostate surgery, either radical prostatectomy or adenectomy, is mainly due to ISD and usually associated with some degree of bladder dysfunction [8–10]. Moderate-to-severe SUI has a major impact



FIG. 3. 1, The needles with removable handles; and 2, the 'pusher'.



on the patient's quality of life and in such cases, surgical treatment is indicated, the options including periurethral injection of bulking substances, the AUS and slings. Although periurethral injection is a minimally invasive procedure, it does not give good long-term results [11,12].

The AUS has become the standard treatment for this serious condition; a review [13] reported a high rate of 70–90% cure/improvement in the long-term follow-up, with 90% of patients satisfied. However, considerable revision is still needed; there have been cases where removal was necessary due to malfunction, erosion or infection; the AUS requires manual dexterity and it is an expensive device [6,14].

Compressing the bulbar urethra in an attempt to provide urinary continence was suggested by Marshall *et al.* in 1946 [15]; they proposed that with compression and elevation of the perineal area, sphincter support could be provided, thus improving its function. This allowed continence and voiding for patients

who had an abdominoperineal excision of the rectum and became incontinent after TURP.

The use of bulbourethral sling procedures in which the sling is transferred to the abdomen using needles was seldom reported [16–20] until Shaeffer *et al.* [6] published their series of 64 patients, with 64% cure/improvement, and a 75% success rate after adjustment in 27% of the patients. After their reports, many centres reconsidered this encouraging treatment as an option for SUI after prostatectomy, especially as the technique was confirmed to be easy, allowed spontaneous voiding, and had a low complication rate. In addition, the sling is much less expensive than the AUS.

The slings previously used included various models handmade from synthetic and autologous materials. A different model inspired by Kaufman's operations [21–23], which compresses the bulbous urethra in the perineum without entering the abdomen, was described by Madjar *et al.* [4] and

subsequently by Comiter [5] using bone anchors to fix a polypropylene mesh for urethral compression, with excellent results (90% cure/improvement) in a mean follow-up of 1 year. Another interesting model available commercially is the Remex® male sling (Zeppelin Medical Instruments GmbH, Dornbirn, Austria) [24]. The initial results were encouraging for the authors, who in six operations cured five patients, while the sixth improved over the 18-month follow-up. With its ingenious mechanism, called 'varitensor', the sling can be adjusted on the day after surgery to provide the necessary bulbar urethral compression. The surgical technique, which entails retropubic and perineal dissection, makes the procedure complicated, and the thin and short polypropylene mesh sling, when applied with tension against the bulbar urethra, seems to increase the possibility of erosion. Nevertheless, more cases and more time are needed to confirm the encouraging initial results.

The Argus bulbourethral sling efficiently solves some of the problems of the earlier

FIG. 4. Adjustment under simultaneous control: urethral coaptation at the desire pressure (45 cmH<sub>2</sub>O).

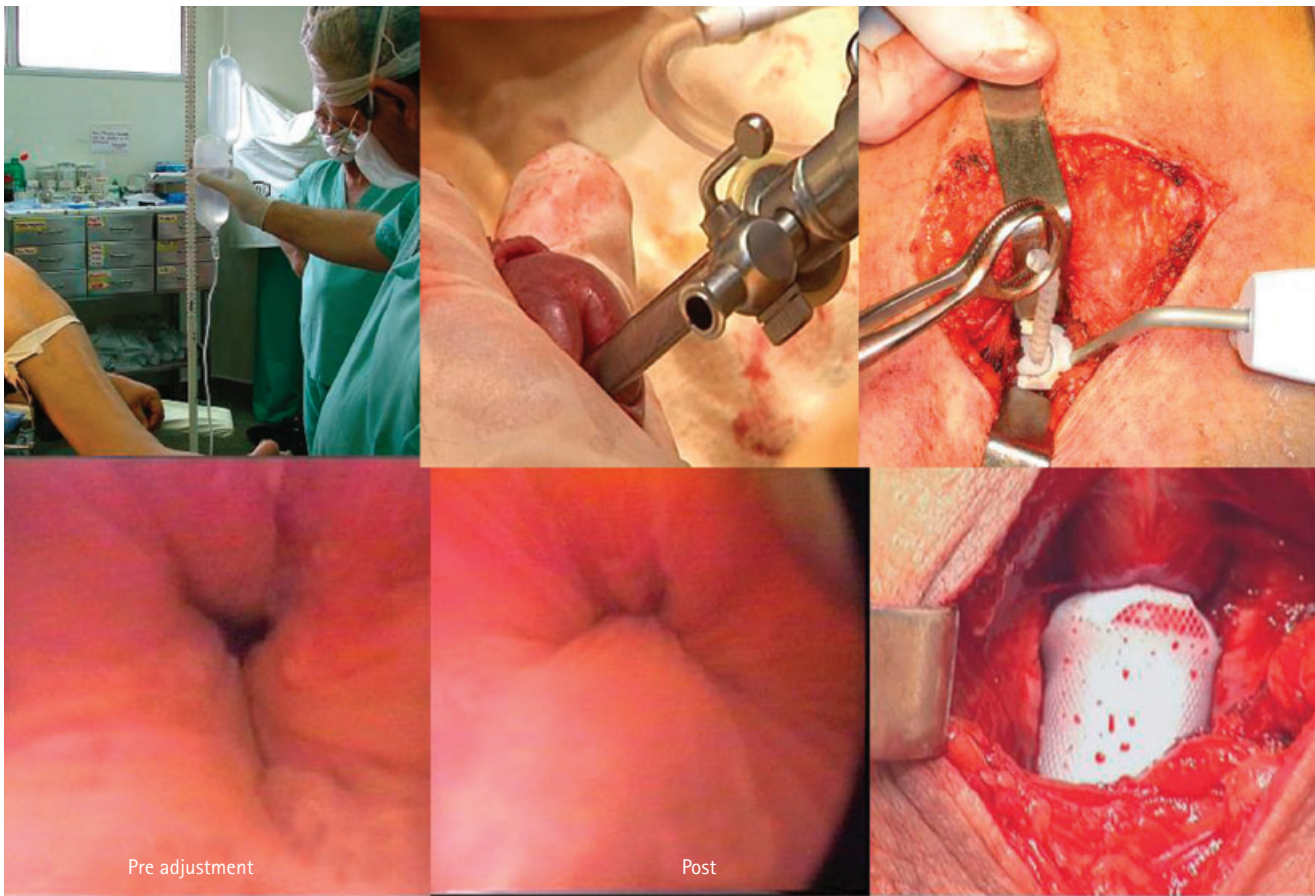
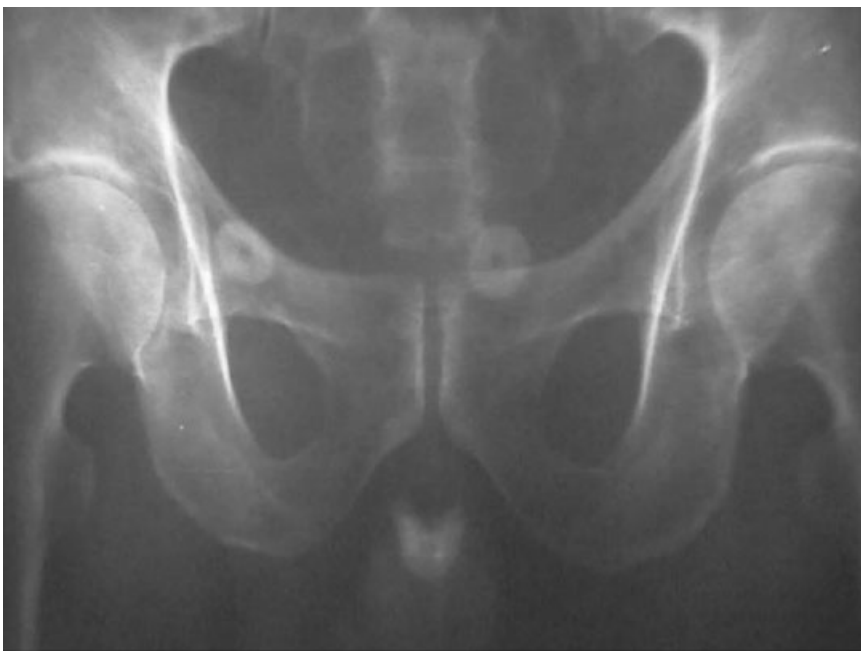


FIG. 5. A plain film of the Argus after implantation.



devices. One of the present authors (S.V.R.) began work on the bulbourethral male sling in 2001, following Schaeffer's recommendations, replacing the bolsters with a silicone foam pad to provide soft urethral compression. This pad had been used in a sling for female SUI (SMART®, Promedon) [25]; unfortunately, this sling had to be discontinued due to early and unacceptable extrusion in 56% of 69 cases.

In the initial use of the male sling, a retrograde LPP of 100 cmH<sub>2</sub>O was used for intraoperative adjustment in the first two of six cases, but resulted in severe perineal pain that could only be eased by cutting the suture in the suprapubic area at 7 and 25 days after surgery. Nevertheless, the early results were satisfactory in four of six patients, one of whom needed sling readjustment [26,27].

The present model incorporates many changes, including column reinforcement due

to spontaneous breakage in seven early cases a few days after implantation. The sling was successfully replaced in six patients and one is waiting to be re-implanted. The day of re-implantation was taken as the starting point for the follow-up. No broken slings were reported after reinforcement. After surgery, local anaesthesia can be used if readjustment is needed. The adjustment pressure was decreased to 45 cmH<sub>2</sub>O to avoid pain, dysuria and erosion. This value was selected considering the abdominal pressure when standing, which is usually lower. However, once the sling is in place many changes occur in the anatomical and functional structures providing continence, so the final explanation as to why continence is achieved remains poorly understood. The minimum tension required is unknown, but it could probably be decreased to  $\approx 35$  cmH<sub>2</sub>O to reduce adverse events but maintain the efficacy. Given the possibility of easily adjusting the tension after surgery, a future trial with a lower pressure seems reasonable. The situation is different for female SLI, where the sling works with no tension, while in men, tensioning the sling is mandatory.

Our technique of regulating tension using the retrograde LPP under visual control, assessing how and where the urethra is coapted, makes the procedure more accurate. Passing the needles from the perineum to the abdomen instead of vice versa seems to be useful in preventing urethral lesions. Sharp dissection avoids trapping the pudendal nerve ramus with the sling, preventing perineal pain. The surgical technique using the Argus device has been reproduced by eight urologists in the present multicentre trial, who have performed at least three sling procedures each and have obtained very similar results.

The present study has some limitations; the short-term follow-up does not allow any prediction of the durability of the effect, and we cannot assess possible changes in the urinary tract as a consequence of the fixed resistance to urinary flow. The consistency of the erosion rate could not be affirmed. It will also be necessary to confirm the feasibility of further adjustments to the sling after many years of implantation.

In conclusion, this new sling is effective in the short term for treating SLI after prostatectomy (83% cured/improved) with an acceptable complication rate. The sling

provides a standardized technique that allows comparison with future Argus procedures. Finally, if the present results are confirmed by other urologists in more patients and remain durable, it will be a good treatment option for male SLI.

## ACKNOWLEDGEMENTS

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## CONFLICT OF INTEREST

Salomon V. Romano is a study investigator funded by sponsor. Source of funding: Promedon SA.

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**Correspondence:** Salomón V. Romano, Urology Department, Hospital Durand, Buenos Aires, Argentina.  
e-mail: sromano1@arnet.com.ar

**Abbreviations:** **ISD**, intrinsic sphincter deficiency; **AUS**, artificial urinary sphincter; **SUI**, stress urinary incontinence; **LPP**, leak-point pressure; **ICIQ-SF**, International Consultation on Incontinence Questionnaire, Short-Form.