

IMPLANTATION TECHNIQUE OF THE ARTIFICIAL URINARY SPHINCTER "FLOWSECURE™" IN THE BULBAR URETHRA

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Summary.- *OBJECTIVES:* Artificial urinary sphincter "FlowSecure™" is a prosthesis designed for stress urinary incontinence that has achieved excellent results. Although implantation is easy, some urologist used to other prosthesis may find difficult the change to this new technique. This article shows how easily and quickly this new sphincter can be implanted and discuss the differences with the artificial sphincter AMS-800™.

METHODS: Following the case of a patient who was implanted artificial urinary sphincter "FlowSecure™" in our center we describe with pictures the technique of implantation and give some advices to make this quicker and easier.

RESULTS: Surgical time was 90 minutes. Patient presented uneventful recovery, urethral catheter was removed 24 hours after surgery and discharge was done 72 hours after surgery. Three months after implantation patient describes complete resolution of his stress urinary incontinence.

CONCLUSIONS: Artificial urinary sphincter "FlowSecure™" is easy and quick to implant, and as its use is extended we would compare if results are better than those of the AMS-800™ model.

Keywords: Artificial urinary sphincter. Urinary Stress Incontinence. Surgical Technique.

Resumen.- *OBJETIVO:* El esfínter urinario FlowSecure™ es una prótesis para la incontinencia urinaria de esfuerzo que ha proporcionado unos excelentes resultados hasta el día de hoy. Si bien su colocación es sencilla, los urólogos acostumbrados a la colocación de otros tipos de prótesis pueden encontrar inconveniente el cambio a esta nueva técnica. Este artículo pretende demostrar que este nuevo esfínter se puede colocar de forma rápida y sencilla, así como discutir las diferencias respecto del modelo AMS-800™.

MÉTODOS: A raíz de un paciente al que se colocó el esfínter urinario FlowSecure™ en nuestro centro se describe mediante dibujos la técnica de colocación y se apuntan ciertos consejos prácticos que hacen más fácil y rápida su colocación.

RESULTADO: El tiempo quirúrgico fue de 90 minutos. El paciente presentó un postoperatorio correcto, retirándose la sonda vesical a las 24 horas y siendo dado de



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alta a las 72 horas. A los 3 meses de la intervención el paciente refiere resolución completa de su incontinencia urinaria de esfuerzo.

CONCLUSIONES: El esfínter urinario FlowSecure™ resulta una prótesis de colocación rápida y sencilla, y a medida que su utilización se vaya extendiendo podremos valorar si sus resultados a largo plazo son mejores que los del modelo AMS-800™.

Palabras clave: Esfínter urinario artificial. Incontinencia urinaria de esfuerzo. Técnica quirúrgica.

INTRODUCTION

Artificial urinary sphincter "FlowSecure™" is a prosthesis for stress urinary incontinence designed by M.D. Cragg and A.R. Mundy in the Institute of Urology and Nephrology in London. Their aim was to improve deficiencies observed in previous models without compromising comfort and continence for the patient (1). Its implantation is easy and quick, but urologist used to the only model disposable for the last 23 years (American Medical System's AMS-800™) may find difficult learning the implantation technique of "FlowSecure™".

We have had the chance of using FlowSecure™ in a 71 years old patient presenting urinary incontinence to minimal stress 2 years after laparoscopic radical prostatectomy performed in our center. Here we show using pictures and in an easy way which are the steps to implant this new urinary sphincter.

MATERIAL AND METHODS

Parts of the Prosthesis

Urinary prosthesis FlowSecure™ consists on 4 parts which are: an adjustable pressure-regulating balloon, a stress relief reservoir, a control pump and valve assembly unit with self-sealing port and a urethral cuff. It's recommended to pump the prosthesis before its implantation because it may block due to the sterilization process.

The valve assembly unit allows free flow of liquid in direction to the stuff but prevents its return. When patient press the pump passage of the liquid is momentary altered, lowering pressure in the cuff. Originaly direction of flow is recovered when compression on the pump stops.

FlowSecure™ is accompanied by a plastic trocar and its obturator, which allows transposal of urethral cuff between Retzius space and perineum, and a tube of glue for temporary fixation of the belt over the cuff when adjusting it (2).

Additional elements

Additional material needed for prosthesis implantation are: 16 Ch silicon urethral catheter, bokwalter retractor, 2 rubber-shod mosquito forceps (to occlude connection tubes), 2 sterile syringes, one (a 10 mL syringe) for decompressing the sphincter and the other (a 2 mL syringe) to apply the glue, a 25G insulin needle with a length of 15 mm (to extract liquid from the prosthesis through its self-sealing port), a Penrose drainage and a 4-0 prolene suture(3).

Prosthesis implantation

See pictures 1 to 10.

Postoperative

Urethral catheter may be removed 24 hours after surgery. Prosthesis is left deactivated and patient presents null or slight improvement of his incontinence. If continence is referred, he must be encouraged to press the pump to urinate when scrotal edema begins to diminish.

At the first visit 4 weeks after surgery patient will be examined and, if incontinence is still present,

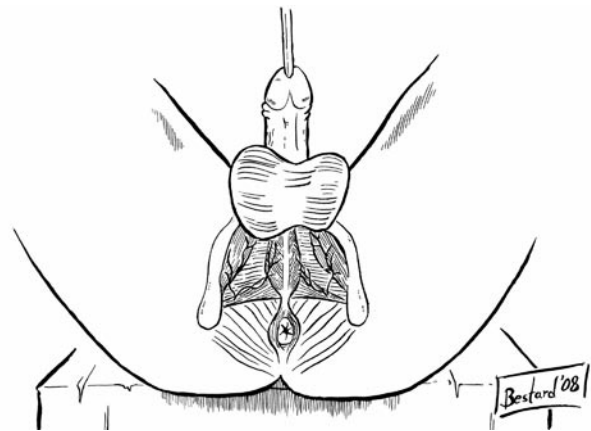


FIGURE 1. Patient disposed in lithotomy position and preparation of the operation area. Perineal and suprapubic access will be needed. Urethral catheterism with a silicon-foley catheter.

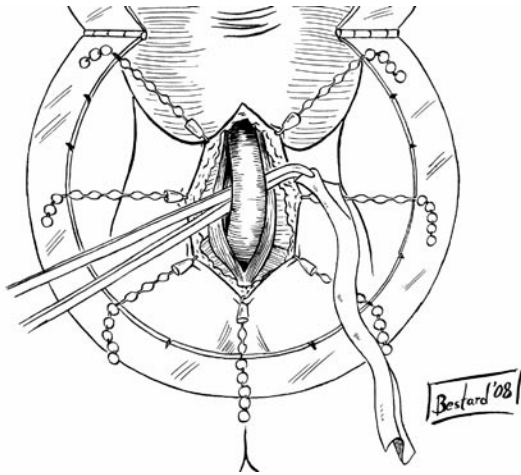


FIGURE 2. Longitudinal perineal incision and dissection of 4 cm of bulbar urethra, which is identified with a penrose drainage. Accurate dissection of the urethra is achieved by opening bulbocavernosus muscle, as cuff is designed to transmit direct pressure over the urethra with no risk of erosion.

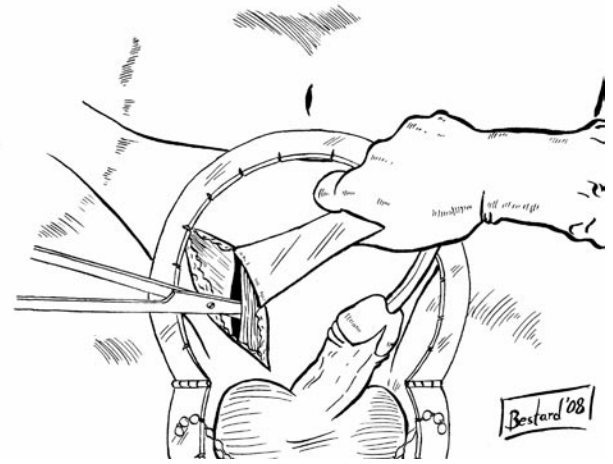


FIGURE 3. Right inguinal incision with opening of oblique major fascia and blunt dissection of musculature. A cavity in Retzius space is developed where pressure-regulating balloon and stress relief reservoir will be lodged.

we will inject percutaneously 4 to 6 mL of saline serum through its self-sealing port. With this maneuver pressure in the system will be between 40 and 60 cm H₂O, which is usually enough to maintain continence at rest with no tissular damage.

If incontinence persists at following visits, new doses of saline serum should be injected, not exceeding 2 mL at each visit (3).

RESULTS

Surgical time was of 90 minutes. Prothesis was submerged in a solution of 200 cc of saline serum with 240 mg of gentamicine for antibiotic prophylaxis. Moreover, 1 gram of amoxicillin/clavulanic acid was administered parenterally before intervention. Postoperatively, 500 mg of Amoxicillin/clavulanic acid was administered orally every 8 hours for 7 days. Patient presented uneventful postoperative, removing urethral catheter 24 hours after surgery and discharging patient 72 hours after surgery.

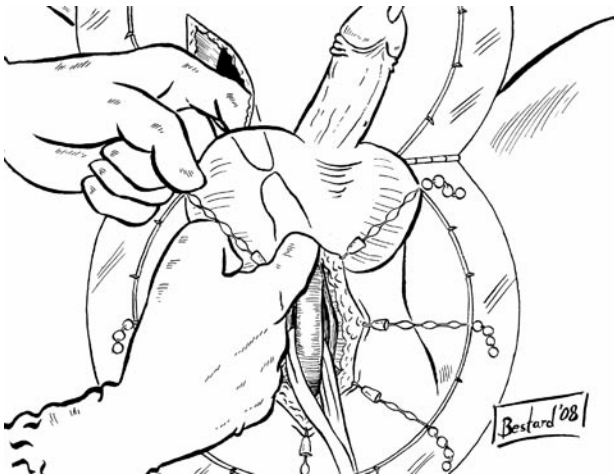


FIGURE 4. With both fingers we dissectate a paracordal space communicating both incisions, as well as a subcutaneous space in scrotum where control pump will be lodged.

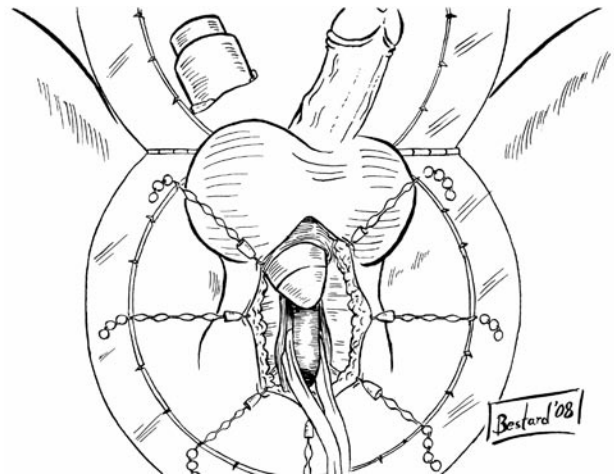


FIGURE 5. Trocar with its obturator is introduced through paracordal space. Trocar should be removed quickly to prevent haematomas at this level.

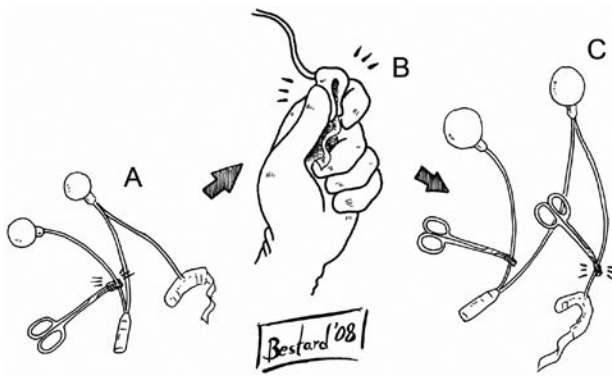


FIGURE 6. Protection tube of the pressure-regulating balloon must be occluded with rubber-shod mosquito forceps slightly pressed (A). Then the cuff should be pressed until complete emptying and pass of all its content to the stress relief reservoir (B). A second mosquito forceps is placed occluding the tube that joins stress reservoir and cuff (C).

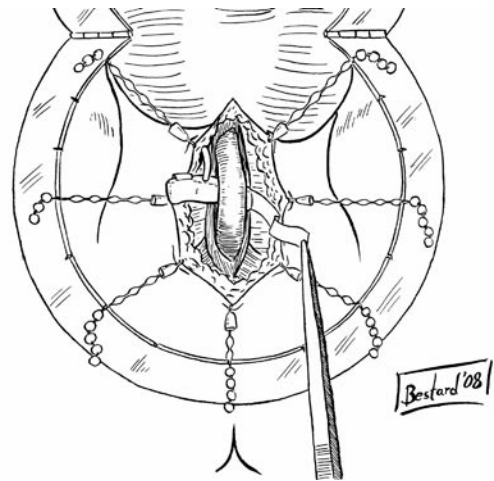


FIGURE 7. Oburator will be removed and we will transpose the cuff through the trocar pulling from the belt with long forceps and leaving the rest of the prosthesis sterilely wrapped over the abdomen.

DISCUSSION

Since last eighties, diffusion of radical prostatectomy for treatment of localized prostate cancer has increased then number of patients presenting

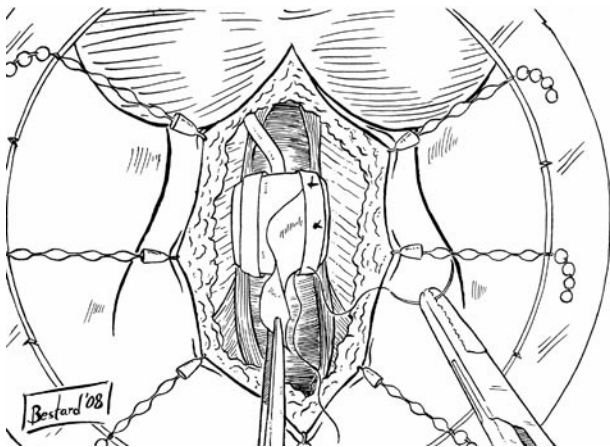


FIGURE 8. Belt is passed through the two buckles a couple of times. Prosthesis must be firmly attached, but movements of rotation and along the urethra should be possible. Every time we pass the belt through the buckles glue should be applied with the 2 mL syringe to maintain it momentary fixed. When passed two times, belt should be secured to the buckles with 3 single knots of 4/0 prolene, being aware of not damaging the prosthesis with the needle. If possible, prosthesis should be manipulated with fingers to prevent silicon damaging. Remaining belt should be cut and perineal incision closed.

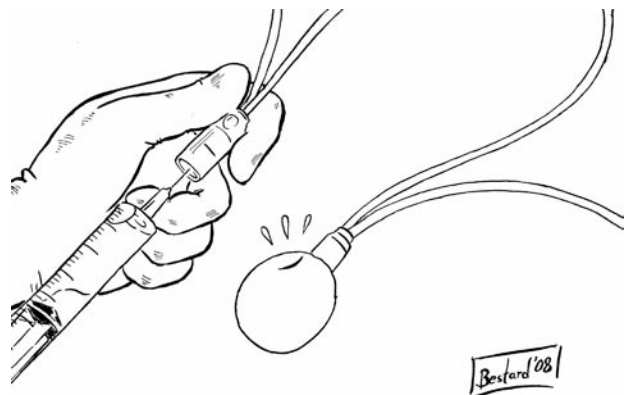


FIGURE 9. Prosthesis depressurithation: Mosquito forceps from the cuff tube will be removed and this will completely refilled. With a 25G/a5 mm needle we will extract enough volume through its self-sealing port to produce a notch in the pressure reservoir (about 10 mL). At this moment prosthesis is at zero atmospherical pressure and we will remove the second mosquito forceps.

stress incontinence after surgery. Therapeutic options offered to this patients are pelvic floor rehabilitation, pharmacological treatment with duloxetine, intraurethral injections of expansive substances, implantation of suburethral slings and implantation of an artificial sphincter. This last option is the one achieving best results in patients with severe stress incontinence (4). In 1947 Foley reported the first artificial sphincter,

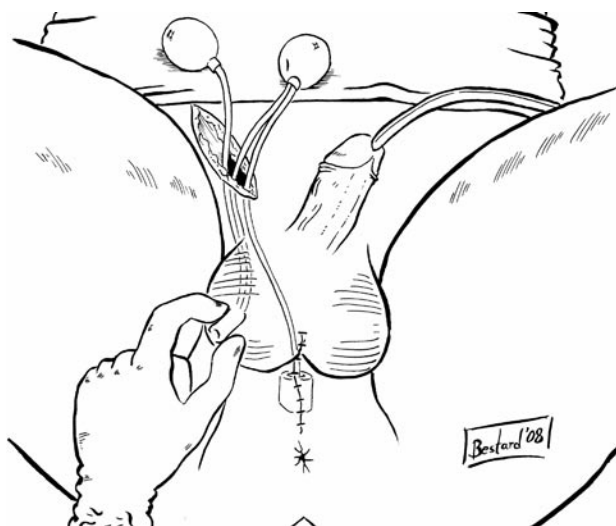


FIGURE 10. We will lodge pressure-regulating balloon and stress relief reservoir in Retzius space and control pump in scrotum, and suprapubic incision will be closed.

consisting on a cuff that achieved continence by inflating around the penis, but provoking erection at the same time (5).

Nowadays, indications for implantation of urethral sphincter are, in decrescent order, post-surgical urinary incontinence (after radical prostatectomy or transurethral resection of the prostate), incontinence due to congenital abnormalities (like spina bifada), incontinence after spinal injuries, neurogenic bladder and, at last, stress incontinence in women when other reconstructive surgical techniques have failed.

Urinary sphincter AMS-800™ has been the only model disposable for many years. It was patented by American Medical Systems in 1983 and, in spite of its excellent results, presented a serie of disadvantages that have been improved in the FlowSecure model (6).

FlowSecure is a single-piece prothesis while AMS-800™ consists of 3 pieces. This theoretically diminish the risk of mechanical failure as there are is no need of connection between its elements (3).

AMS-800™ prothesis presented 3 different reservoirs which transferred different pressure to the cuff. A cuff with pressures between 71-80 cm H₂O was recommended when implantation had to be performed on the bladder neck, and a cuff with pressure between 61-70 cm H₂O when implantation had to be performed on bulbar urethra. Incontinence resolution was observed only postoperatively and, if it was

no resolved, a new intervention was required to implant a higher pressure reservoir. On the other hand, when an insufficient 61-70 cm H₂O pressure reservoir had to be changed for a 71-80 cm H₂O pressure reservoir, difference of pressure could be between 1 and 19 cm H₂O, with no knowledge of which pressure supported the urethra at each moment and which would be the minimal pressure increase necessary for continence (6).

Self-sealing port of FlowSecure™ allows percutaneous manipulation and individual adjustment to each patient, just by injecting or extracting saline serum.

AMS-800™ makes constant pressure over the urethra the same in valsalva as when patient rests. FlowSecure™ increases pressure in the cuff just if intraabdominal pressure increases, transmitting pressure from the stress reservoir immediatly to the cuff. When pressure increase stops cuff turns back to the initial pressure (conditional occlusion system). With this system rest pressure doesn't exceed 40 cm H₂O, minimizing damage over the urethra.

FlowSecure™ cuff is also different from cuff of AMS-800™. This last model presented 3 pillows concentrating pressure over 3 different points of the urethra. Instead, FlowSecure™ presents a circular cuff that adapts to the urethra of each patient and transmits equal pressure all over its surface. This prevents damage over the urethra and cracks on the cuff (3).

AMS-800™ was originally designed to be implanted on the bladder neck, as erosions are less frequent in this zone. But when vascularization of this area is compromised (like happens after prostatic surgery), bulbar urethra is the only possible place (6). FlowSecure™ has been originally designed to be implanted over bulbar urethra with no risk of erosions. Its length of 7 cm makes it suitable to be adapted to most of bladder necks, including women (3).

CONCLUSIONS

FlowSecure™, is a prothesis that adopts advantages from AMS-800™ but offering changes to minimize mechanical failure and reduce harm over the urethra. Its implantation is easy and quick, and as their use is extended we would compare if its theoretical advantages from its antecessor are reflexed in better results and better quality of life for the patient.

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