MRI evaluation of the Flow-Secure™ artificial urinary sphincter.

Poster No.: C-0793
Congress: ECR 2012
Type: Educational Exhibit
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Keywords: Urinary Tract / Bladder, MR, Technical aspects, Structured reporting, Complications, Prostheses
DOI: 10.1594/ecr2012/C-0793

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Learning objectives

1. To review the state of the art in the evaluation of Artificial Urinary Sphincter (AUS) Flow Secure™ by MRI.

2. To describe the normal findings of this device and what the urologist wants to know.

3. The surgery procedure and potential complications will be also briefly reviewed.

Background

In 1947, Foley designed the first artificial urinary sphincter consisting of a ring that was placed around the penis and inflated or deflated by a pump control hidden in the pocket of the patient. Aside from the aesthetic, the main problem was the erection that was inevitably produced when the ring was inflated. To avoid this problem, Foley developed a surgical technique that allowed the ring around the urethra not to include the cavernosa bodies and thus restore continence in incontinent patients without producing erection at all.

The second important milestone in the history of artificial urinary sphincter occurs in 1972, when Scott Bradley and Timm introduce AS-721 model, a prototype whose components were fully implemented within the body and could be manipulated from the exterior. However, due to the complexity of the prosthesis implantation was laborious and often some components failed. In subsequent years there were multiple changes (AS-761, AS-742, AS-791 and AS-792) to facilitate surgery and reduce mechanical failure rate. The process culminating in 1983 with the appearance of the sphincter AMS-800 (Fig. 1), the only commercially available over the past 23 years. Although the results published were successful, rate of complications exceeded 30% and range from the reappearance of urethral atrophy and incontinence to removal of the prosthesis due to infection, erosion or mecanic failure.

Since 1986, teachers Mundy and Craggs, devised a series of modifications to the AMS-800 model that included a pump a self-sealing port control to modify the volume of the prosthesis without intervention, a more adaptable to the cuff urethra with less likelihood of erosion or perforation and the introduction of an additional reservoir sensitive to increased intraabdominal pressure. A prototype one-piece which facilitated the surgical technique and decreased the incidence of mechanical failures while protecting the
urethra from excessive continuous pressure exerted by the AMS-800. The result was the FlowSecure™ artificial sphincter (Fig. 2).

Images for this section:

Fig. 1: AMS 800, urinary artificial sphincter.
Fig. 2: Diagram of Craggs artificial urinary sphincter. 1: urethral cuff; 2: primary reservoir/balloon; 3: additional reservoir (stress-relief balloon); 4: scrotal pump. The design allows a temporarily increased intra-abdominal pressure (caused by a stress such as coughing) to be transmitted from 3 into 1. This prevents stress incontinence, as well as urethral erosion that could be caused by a constant high pressure on the urethra even during rest when a conventional artificial sphincter was used.
THE DEVICE

The FlowSecure™ artificial urinary sphincter is a one-piece silicone device filled with about 30 ml of 0.9% saline solution and consists of (Figs. 2, 3):

1) A ballon which regulates the pressure of the prosthesis and provides basal occlusion pressure.

2) A second ballon placed in series with the first, called stress relief reservoir, which allows conditional occlusion cuff reversibly depending on the intra-abdominal pressure.

3) A cuff adapted to the urethra.

4) A pump with a valve, a self-sealing port and a fast filling accessory mechanism.

1) Primary Reservoir/Ballon. The pressure regulator reservoir.

It is the system component that determines the basal occlusion pressure exerted by the cuff. This occlusion pressure is adjustable between 0 and 80 cmH₂O and can be modified by injection or extraction through the self-sealing port of the pump depending on patient’s clinical needs. This reservoir transmits pressure to the cuff through the pump and through the additional ballon. The pump presents a control valve that allows fluid to flow into the sleeve but prevents their return. Only when the patient squeezes the bulb of the pump to urinate, the valve temporarily reverts the urine direction until the compression of the pump control has ceased (Figs. 4, 5).

2) Additional reservoir/ballon: Stress relief reservoir

The stress relief ballon is identical to the first one and it is located in series. It is also connected directly with the cuff, so the fluid flow doesn’t pass through the pump control. It transmits changes in intraabdominal pressure, increasing urethral occlusion pressure immediately when there is an increase of intraabdominal pressure and viceversa. This mechanism is called conditional occlusion and allows occlusion pressure to increase only when necessary (when the intraabdominal pressure is increased), protecting ischemia of the urethral wall resulting from the permanent occlusion of the cuff. The association in series of the first and the second ballon allows either low urethral occlusion pressures (reservoir pressure regulator) or a conditional occlusion pressure (stress relief ballon) which increases only during the time that there is high intraabdominal pressure.
It has been estimated that the stress relief balloon transmits almost 100% of intraabdominal pressure and takes 200 milliseconds to transmit increased pressure to the cuff (Figs. 4, 5).

3) The cuff

The first balloon pressure and also the extra pressure from the second balloon is transmitted to the sleeve. It is designed in such a way that is adaptable to the urethral wall like a belt. Presents a tape allowing to fit the urethral circumference to a maximum of 7 cm. Although this measure could be used in the majority of the female bladder necks, this sleeve is designed specifically for the male urethra and has not been used in women. To adjust the urethra, the sleeve is provided with two buckles where the tape passes through. The manufacturer provides a special adhesive but the lack of security of sealing leads many surgeons to suture the tape to one of the buckles once it has been adapted to the urethra. The inner surface the cuff is circular, so that there is an homogeneous transmission of the pressure (decreasing the likelihood of atrophy and erosion) and minimizes the creation of cracks in the silicone (decreasing the possibility of perforation) (Figs. 6, 7, 8).

4) The pump control

The pump contains: 1) the bulb to empty the cuff; 2) an accessory mechanism of fast emptying and 3) a self-sealing port for injecting or removing saline volume depending on clinical needs. It presents a resistance valve that in normal conditions, allows only the fluid to flow from the reservoir pressure regulator to the cuff. Only when you compress the bulb pump the resistance is switched off, allowing the flow to the opposite direction. Every time the bulb is compressed fluid is transferred from the cuff to the reservoir and the patient must continue pressing until a good flow of urine is obtained. After draining, the cuff automatically refills itself, although there is an accessory mechanism that the patient can use if a fast refilling is required (Figs 9, 10).

HOW IT WORKS

The hydraulic operation of the system

The system is the epitome of the hydraulic laws applied to urology. The prosthesis only works when is filled with liquid, which passes from the first balloon to the second one (through the pump control) and from here directly to the cuff. When the system is working, the movement of liquid always occurs from the first balloon to the cuff, which progressively inflates decreasing the lumen; thus, the hydraulic pressure wave becomes an occlusive force (Fig. 11). In basal conditions the first balloon has a constant pressure on the urethra that usually does not exceed 40 cm H2O, which is sufficient to maintain continence at rest without damage tissue. With increasing intra-abdominal pressure, for example when
you cough, the pressure is transmitted to the second ballon and right to the cuff in a second, thereby avoiding incontinence (Fig. 12). As the intraabdominal pressure yields, the cuff is deflated to basal pressure dictated by the first ballon. When the patient wishes to urinate pushes the pump bulb repeatedly until there is a good flow. The compression of the pump aspirates the fluid of the cuff and transfers it to the first ballon. Subsequently, the cuff refills spontaneously due to excess of pressure in the first ballon; on the other hand, the resistance of the pump control slows the filling of the cuff, allowing the patient to empty his bladder (Fig. 13). After a few minutes the cuff will be completely full thanks to the basal pressure and the continence will be restored. In those cases in which the filling time is excessive and the patient leaks urine once the voiding is completed, they can manipulate the attachment mechanism of rapid filling.

THE SURGERY

Combined perineal and abdominal incisions are required for exposure of bulbar urethra, creation of a cavity in the para-vesical space and dissection of a pocket under de scrotal wall. A trocar with a stylet is routed from the abdominal incision to the perineal incision to pass the deflated cuff to the perineal site. The cuff is placed around the urethra and secured with Prolene sutures. After refilling the cuff, fluid is removed from the system until the stress relief balloon becomes just indented (atmospheric pressure 0) (Fig. 14). The pump is placed in the scrotum and the balloons in the paravesical space. The design of the whole one-piece system makes the surgery easy, and can be done in about 30 minutes, it prevents possible entry of air or blood particles and fat during the intervention (as it is not need any connection process) and minimizes the incidence of mechanical failure. Although it is designed for the adult male urethra and sleeve length is 7 cm, it could be possible to be placed in most of the necks of female bladders.

IMAGING

The follow-up of the FlowSecure™ sphincter, unlike the usual devices cannot be identified by plain X-ray because it is filled with normal saline and no contrast. For this reason the study of routine is performed by ultrasonography and flowmetry, although the best method of evaluation is the MRI since it allows to visualize the precise position of all components of the sphincter as well as their integrity.

Besides, postoperative imaging is important for assessing the position, configuration and function of an implanted AUS. Being the whole implant made from silicone rubber and containing normal saline, lends itself to MRI, a modality using no ionizing radiation. MRI, unlike ultrasound, can cover a large body volume without any particular imaging window and with no need of direct contact with the body parts being examined. This is necessary for visualizing the FlowSecure™ AUS because it occupies both intrapelvic and
perineal spaces, and its cuff is implanted around the delicate urethral tissue that should not be deformed for functional assessment.

Conventional two-dimensional (2D) imaging requires expertise to compose a mental three-dimensional (3D) picture from a series of 2D images. Moreover, a 2D images could be very confusing when we are evaluating some of the components such as the balloons, very similar to each other, with connections to others parts of the device that are not well identified unless a 3D algorithm image is performed (Fig. 15). Studies have demonstrated that 3D MRI improve comprehension of the spatially complex morphology in the pelvis. Deng et al. described a method in which thanks to the "inversion-fusion" technique they were able to display in 3D both low and high intensity structures of interest.

However, at our institution we used a standard 3D MRCP-like sequence, performing a heavily T2-weighted 3D TSE restore sequence. Due to the extremely long TE (TR(msec)/TE (msec)/flip angle = 1300/680/180°), fluid is the main signal source. The 3D MRCP images were reconstructed with a volume rendered algorithm allowing us to check the different parts of the device (Figs. 3, 14).

There are some specific points that we should communicate to the urologist in our report:

1) Are the different parts of the device correctly placed within the body? The balloons in the iliac fossa (either right or left), the cuff around the urethra and the pump within the scrotum.

2) Are all the components connected to each other? The Volume rendered images will be very useful evaluating this point (Fig. 3).

3) Have the balloons enough fluid? There should be an indentation on the surface of the second balloon but they should never be totally collapsed (Fig. 14).

COMPLICATIONS

Some patients never achieved satisfactory continence despite pressurisation injections in the device. This might be due to the cuff fixation that has come undone and therefore no pressure is being applied to the urethra.

If the patient complaints of sudden return of incontinence after lifting of heavy weight it is probable to find a fracture at the joint between the tubes and the cuff.

Other complications such as infections, urethral erosions and urethral atrophy are said to be much less frequent than the previous artificial urinary sphincters.
**Fig. 2:** Diagram of Craggs artificial urinary sphincter. 1: urethral cuff; 2: primary reservoir/balloon; 3: additional reservoir (stress-relief balloon); 4: scrotal pump. The design allows a temporarily increased intra-abdominal pressure (caused by a stress such as coughing).
to be transmitted from 3 into 1. This prevents stress incontinence, as well as urethral erosion that could be caused by a constant high pressure on the urethra even during rest when a conventional artificial sphincter was used.

**Fig. 3:** Volume Rendered MR image showing the components of Craggs artificial urinary sphincter and their relationships. 1: urethral cuff; 2: primary reservoir/balloon; 3: additional reservoir (stress-relief balloon); 4: scrotal pump.
**Fig. 4:** Axial T2WI MR shows two rounded hyperintense components in the left iliac fossa corresponding to the ballons (arrow). Other planes and postprocessing techniques are required in order to distinguish between the two ballons.
Fig. 5: Coronal T2WI MR shows two rounded hyperintense components in the left iliac fossa corresponding to the ballons (arrows). These ballons are identical in one image, so other planes and postprocessing techniques are required in order to distinguish between the two.
**Fig. 6:** This sagittal T2WI MR shows the cuff (arrow) surrounding the bulbar part of the urethra (arrowhead).
Fig. 7: Axial T2WI Mr shows the longitudinal axis of the cuff (arrow). The short axis of the pump is also noted in this image (arrowhead)
**Fig. 8:** Coronal T2WI MR shows the short axis of the cuff (arrow). This is a good plane to see the relationships of this part of the device with the cavernous bodies (dashed arrows). One of the balloons is also noted in this image (arrowhead)
**Fig. 9:** Coronal T2WI shows the long axis of the pump within the scrotum.
**Fig. 10:** This sagittal T2WI also shows the long axis of the pump (arrow) within the scrotum.
**Fig. 11:** In basa conditions, the first ballon transmits its pressure to the cuff through the pump and the second ballon (basal occlusion pressure)
Fig. 12: During elevation of abdominal pressure the second balloon transmits the pressure directly to the cuff. When intraabdominal pressure decreases, the cuff comes back to the previous state (conditional occlusion pressure).
Fig. 13: When the patient squeezes the pump, the fluid from the cuff flows to the first ballon through the second ballon and the pump itself. The cuff empties and the patient can eliminate the urine. Some minutes later the pressure from the first balloon inflates the cuff again leading to the basal occlusion pressure.
**Fig. 14**: Volume Rendered MR image shows nicely an indentation of the surface of the second balloon which correlates with a 0 atmosphere pressure (arrow).
Fig. 15: Sagittal T2WI MR shows one of the balloons (arrow). It is almost impossible to determine whether it is the first or second component of the device.
Conclusion

The FlowSecure™ artificial urinary sphincter is a new concept for the treatment of effort incontinence. The introduction of a stress relief reservoir with conditional occlusion allows establish low basal occlusion pressures preserving the urethral irrigation and therefore reducing the risk of complications. Besides, it is easy to modify the pressure of the system without intervention by injecting or removing fluid the system. Innovations in the cuff not only allow better adaptation to the urethra, reducing the possibility of mechanical failure. We will have to wait longer to get results for establishing which place this prosthesis can occupy in the treatment of incontinence, although the preliminary results are very encouraging.

We have to understand the device because the MR is the best method of evaluation, and only when we get familiar with this new AUS we could tell the urologists the specific findings that they are wanting to know.

Personal Information

References


